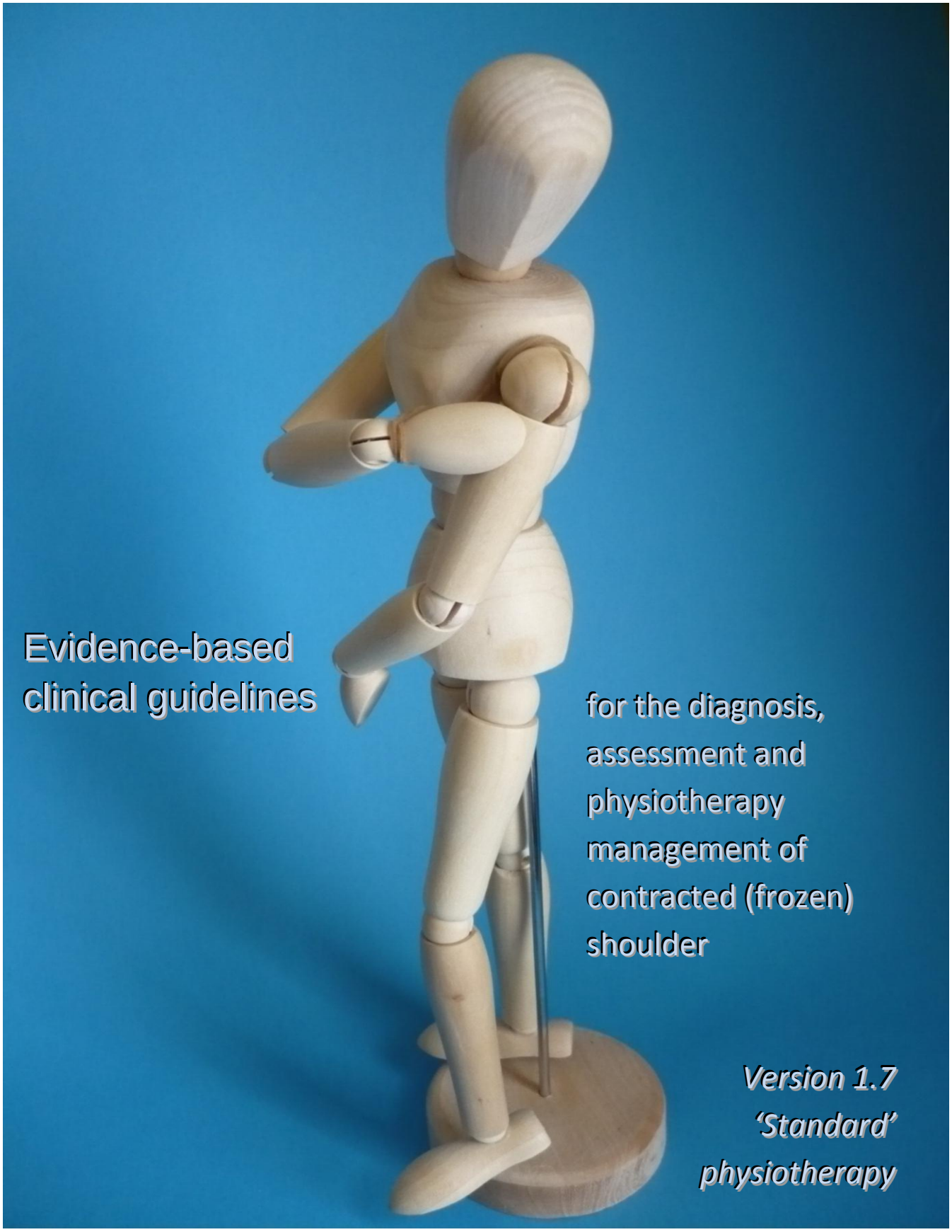

Evidence-based clinical guidelines

for the diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder

Version 1.7

'Standard' physiotherapy

skipp
SUPPORTING KNOWLEDGE IN PHYSIOTHERAPY PRACTICE

Endorsed by THE CHARTERED SOCIETY OF PHYSIOTHERAPY

Evidence-based clinical guidelines for the diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder

Version 1.7, 'Standard' physiotherapy

Endorsed by the Chartered Society of Physiotherapy

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Part 5: APPENDICES

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These clinical guidelines were endorsed by the Good Practice Panel of the Chartered Society of Physiotherapy in December 2010. The endorsement process has included review by relevant external experts as well as peer review. The rigour of the appraisal process can assure users of the guidelines that the recommendations for practice are based on a systematic process of identifying the best available evidence at the time of endorsement.

Minor revisions history

See Appendix J

Major update of the 'standard physiotherapy' treatment guidelines due: 2015.

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Competing interests: None known.

Introduction

Please start here!

These guidelines are meant to be accessible to a broad spectrum of readers (*see* Scope, below). So, as far as possible, we have written them in non-technical language; but in some places, technical language and concepts have been unavoidable. We have differentiated between non-technical and technical sections by using the following symbols:

 **= Non-technical**

 **= Technical**

Preamble 

An estimated 50–80% of people with shoulder pain don't seek medical attention for it. Despite this, shoulder pain is the third most common musculoskeletal reason for people to visit their GPs, and around 15% of these people are referred for physiotherapy in the three years following their initial consultations (reviewed by Linsell et al 2006). Others will consult a physiotherapist in the first instance. For physiotherapists, therefore, as well as sufferers and GPs among others, shoulder pain is a significant problem.

Contracted (frozen) shoulder is an important type of shoulder pain. More specifically, it is a combination of shoulder pain and stiffness that causes sleep disturbance and marked disability, and which runs a prolonged course. In some cases, it does not resolve completely (Bunker 2009). Its prevalence appears to vary by setting. For example, Walker-Bone et al (2004) conducted a large, UK-based primary care[1] study, comprising a questionnaire survey and subsequent physical examination of respondents who reported shoulder pain, and found that contracted (frozen) shoulder affected 8.2% of men and 10.1% of women of working age. In contrast, based on his extensive tertiary care[1] experience as a specialist shoulder surgeon, Bunker (2009) estimates that contracted (frozen) shoulder affects only 0.75% of the population. A plausible explanation for this discrepancy is that, by definition, only the most resistant cases are seen in the tertiary (and to a lesser extent, the secondary[1]) care settings. Since physiotherapy spans all three care settings, individual physiotherapists might encounter contracted (frozen) shoulder often; this, added to the unpleasant nature of the condition, makes it important to identify the most effective ways for physiotherapists to diagnose it, evaluate it and manage it. But no detailed physiotherapy guidelines for contracted (frozen) shoulder have hitherto been published either in the UK or abroad.

[1] Primary care refers to community-based healthcare. Secondary care is hospital-based, whereas tertiary care—also hospital-based—is specialised consultative care.

In the UK in particular, this leaves a vacuum of accessible information at a critical time. Widespread freezing of physiotherapist posts in the NHS has had profound implications for physiotherapy graduate employment, student recruitment and academic staff retention, and thus for patient care. Looking to the coming decade, the Chief Executive of the Chartered Society of Physiotherapy (CSP), summarising the implications of the Darzi report (Department of Health 2008), has observed that 'CSP members will have to … make both the business case and the clinical case for physiotherapy at a local level' (Gray 2008). Meeting these unprecedented challenges requires physiotherapists to be effective, to evidence their effectiveness, and to make healthcare commissioners aware of this evidence. Unfortunately, despite dramatic increases in the quality and quantity of physiotherapy research over recent decades, implementation of the findings by clinical physiotherapists and commissioners has been scant.

'Priorities for physiotherapy research in the UK' reports six consistent barriers to evidence-based practice (Chartered Society of Physiotherapy 2002). Four of these:

- shortage of time;
- the need to develop skills in critical appraisal and the understanding of statistics;
- difficulty translating findings into local clinical practice; and
- problems accessing the evidence

may potentially be addressed or circumvented by guidelines. Furthermore, by highlighting areas where future research is required, guidelines may indirectly address the fifth consistent barrier,

- a lack of high quality research.

Guidelines can also make a case for the provision of specific treatments, as well as influencing commissioning. Both factors may help physiotherapists better to meet their patients' identified needs.

The development of these evidence-based clinical guidelines on the physiotherapy diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder is therefore timely.

Scope 

These guidelines are about contracted (frozen) shoulder in people aged 18 and over. Based on the best available research evidence, they focus on physiotherapy but set it in context, giving an overview of the diagnosis and management possibilities for this condition, from initial consultation (e.g. by a GP) to, if necessary, operative care. The guidelines target professionals who are directly or indirectly involved in caring for people with contracted (frozen) shoulder—physiotherapy teachers and practitioners foremost, but also commissioners/providers of healthcare, GPs, orthopaedic surgeons, radiologists (doctors who specialise in X-rays and other types of medical imaging) and rheumatologists (doctors whose specialty includes the non-operative management of joint problems) and others. Not least, they were written in plain English, because we intended them to be accessible to patients and their representative organisations. To help us in achieving

this aim, we involved a Delphi expert panel, which included patients and patient representatives among others (*see* footnote[2]).

Exclusions 

We specifically do not intend the guidelines to apply to:

- pain from causes other than contracted (frozen) shoulder; or shoulder pain or stiffness secondary to:
    - stroke;
    - significant trauma (e.g. fracture or dislocation);
    - surgery (except in relation to operations undertaken to treat contracted (frozen) shoulder, such as manipulation under anaesthetic); or
    - systemic inflammatory conditions (e.g. rheumatoid arthritis).

Aims and objectives 

Through the development of the guidelines we have aimed to improve patient care by:

- addressing the clinical question, 'what is best practice in the diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder?'; and
- facilitating best practice in physiotherapists' diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder.

These aims have taken account of pain, movement and patient-reported outcome measures (PROMs).

Our objectives have been to:

- identify and critically appraise the best available evidence relating to the diagnosis and assessment of contracted (frozen) shoulder;
- systematically review the best available evidence relating to the physiotherapy management of contracted (frozen) shoulder;
- make *general* recommendations, derived by transparent processes from the best available evidence, for the diagnosis and assessment of contracted (frozen) shoulder;
- make graded recommendations, again derived by transparent processes from the best available evidence, for the physiotherapy management of contracted (frozen) shoulder;
- highlight areas where further research is required;
- help implement evidence, as a basis both for optimising practice and influencing healthcare commissioning;
- enable people to take a more active role in their treatment if they wish to do so; and
- develop guidelines that are user-friendly and practical.

[2] We intended the guidelines as a resource for patients as well as healthcare professionals. However we were advised by our Delphi panellists to produce a separate patient information leaflet.

Protocol 

As a measure against introducing bias into the guidelines, we developed a protocol in advance, and adhered to this throughout the development process. Any deviations from the protocol have been explicitly justified.

Key research concepts and methods in brief 

This section introduces some key concepts and briefly explains how we developed the guidelines. For the full methods, *see* APPENDICES A and A2. We aimed for accessibility, such that a clinician with only a limited grounding in research should be able to understand the judgements made.

Clinical trials

The guidelines' recommendations for management are based on evidence from clinical trials. There are several types of clinical trials. All investigate a study 'sample': a group of patients meant to be representative of the population of people with the same condition. Randomised controlled trials (RCTs) are considered the best clinical trials because they are least prone to bias. In RCTs, each patient in the sample is randomly allocated to either a treatment group or a 'control' group, resulting in a fair distribution of condition severity and other key characteristics across the groups. The groups are tested on a chosen measure (called an 'outcome measure') at the start and at the end of the trial. If the randomisation was effective, one would expect the outcomes to be comparable at the start of the trial. Furthermore, if the treatment made a difference, one would expect the outcomes to be different at the end of the trial. Based on the results in their study sample, researchers use statistical tests to make inferences about how the population would respond to the same treatment. Valid inferences depend on the sample really being representative of the population, a property called 'external validity'. Quasi-RCTs differ from RCTs in that people are not allotted to groups in a truly random fashion, but by some other means e.g. according to whether their birth date is odd or even. Quasi-RCTs are considered inferior to RCTs because they are more prone to bias, but better than non-randomised controlled trials, in which patients are allocated to groups without any randomisation.

Systematic reviews and meta-analyses

Individual controlled trials may not include enough patients to detect moderate to small differences between the treatment and control groups, even though the differences may be clinically important. A solution to this would be to have much larger trials, but these are often prevented by practical constraints. An alternative is to find, collate and evaluate all the trials that have investigated the condition of interest, ideally using a transparent, systematic process (a 'systematic review'); then, if a number of the trials are sufficiently similar, to perform a special statistical test called a meta-analysis. Meta-analyses combine the results of two or more similar studies and increase our ability to detect differences between groups. Systematic reviews that include a meta-analysis (if this is appropriate) are now regarded as the highest level of research evidence where trials are concerned; but, in fact, not all such reviews are good. Inappropriate meta-analyses, for example, may give meaningless or misleading results.

Cochrane Collaboration and Cochrane reviews

The Cochrane Collaboration (http://cochrane.co.uk/en/collaboration.html) is an international, not-for-profit and independent organisation dedicated to producing systematic reviews (including meta-analyses, as appropriate) of high methodological quality: Cochrane reviews are generally regarded as the 'gold standard' of systematic reviews.

Search for Cochrane reviews

We searched in the on-line Cochrane Library (http://www.cochrane.org/) for Cochrane reviews on treatments that physiotherapists might use for shoulder pain. We found four, respectively covering 'standard physiotherapy' (Green, Buchbinder & Hetrick 2003), acupuncture (Green, Buchbinder & Hetrick 2005), corticosteroid injections (Buchbinder, Green & Youd 2003) and distension therapy, which involves injecting a large volume of fluid to stretch out the joint (Buchbinder et al 2008). For this version of the guidelines (*version 1.X*) our focus was 'standard physiotherapy' treatments, corresponding to those modalities which a newly graduated physiotherapist in the UK would have at his or her disposal, although this has involved comparison with other interventions. The relevant Cochrane review (Green, Buchbinder & Hetrick 2003) had considered for inclusion RCTs and quasi-RCTs up to June 2002.

Systematic review

We noted the trials included in the above Cochrane reviews, obtained the trials' original reports and filtered out those that were not applicable to the present guidelines. We then derived our search strategy from the Cochrane reviews, increasing its specificity to contracted (frozen) shoulder and limiting it to reports in the English language, and ran searches on the Ovid MEDLINE, AMED, CINAHL and EMBASE databases from 2001 to 09 July 2008, using the OvidSP platform. Thus our search period overlapped with that of the earliest of the four Cochrane reviews (Green, Buchbinder & Hetrick 2003), whose cut-off for inclusion of trials was June 2002. Using methodology based on Verhagen et al (1998) and the Cochrane Handbook (2009) we then evaluated the trials and, with special focus on results' clinical importance, conducted analyses or, if appropriate, meta-analyses.

Questionnaire survey of CSP members

We conducted a survey of Chartered Society of Physiotherapy (CSP) members in order to:

- obtain a snapshot of physiotherapists' approaches to diagnosing and treating contracted (frozen) shoulder at the present time, enabling us to:
    - identify the treatments currently in use and focus on these in our overview of interventions (section 1.6);
    - set the overview of interventions in context;
    - establish a baseline against which the guidelines' impact might be evaluated; and
- identify discrepancies between practice and research.

We posted notices on eight special interest networks of the interactive CSP (iCSP) website, to whose subscribers contracted (frozen) shoulder might be of interest. The notices invited subscribers to follow a link to a self-administered, on-line questionnaire. The questionnaire

required respondents to state whether or not they had a 'special interest' in contracted (frozen) shoulder, because we were interested to see whether this distinction affected the diagnostic and management strategies they used; and to differentiate according to whether pain or stiffness was the primary problem. A full version of the survey report is available in full elsewhere (Hanchard et al 2011).

GRADE system

Finally, we graded the quality of the evidence and derived our recommendations using the GRADE system, which is recommended by the Cochrane Collaboration, transparent, and increasingly in standard use. Specifically, we graded the quality of the evidence using GRADEprofiler *version* 3.2.2 software, which was developed by the GRADE Working Group. Aspects of quality include:

- design and limitations (risk of bias);
- inconsistency (which occurs when trials' results do not agree);
- indirectness (which occurs when the trials' results are inapplicable to the population of interest);
- imprecision (which occurs when the estimates of effect are wide); and
- publication bias (underestimation or overestimation of effects due to selective publication of trials).

The resulting tables—GRADE evidence profile tables—are in APPENDIX E.

Our recommendations for management have taken the quality of the evidence into account. When evidence is graded 'high', it means that further research is unlikely to change our confidence in the estimated effect; when it is 'moderate', further research is likely to influence our confidence in the estimated effect, and may change the estimate; when it is 'low', further research is very likely to seriously influence our confidence in the estimated effect, and is likely to change the estimate; and when it is 'very low', any estimate of effect is very uncertain. With the quality of the evidence taken into account, potential benefits were weighed against potential harms and, if feasible, a recommendation for management made. As recommended by the GRADE Working Group, we used four classifications of recommendation: 'do it', 'probably do it', 'probably don't do it' and 'don't do it'. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that a majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004).

> 'A recommendation to use or withhold an intervention does not mean that all patients should be treated identically. Nor does it mean that clinicians should not involve patients in the decision, or explain the merits of the alternatives. However, because most well informed patients will make the same choice, the explanation of the merits of the alternatives may be relatively brief. A recommendation is intended to facilitate an appropriate decision for an individual patient or a population. It should therefore reflect what people would likely choose, based on the evidence and their own values or preferences in relation to the expected outcomes. A recommendation to "probably do something" indicates a need for clinicians to more fully and carefully consider patients' values and preferences when offering them the intervention.' (GRADE Working Group 2004)

In instances where the evidence was insufficient to make a recommendation for practice, we reserved judgement.

We have not considered economic data in this iteration of the guidelines.

Feedback from target audience

We engaged representative members of our diverse target audience (a Delphi expert panel) to feed back to us during the development process, thus ensuring the guidelines' 'fitness for purpose' (APPENDICES F, G).

Endorsement

On the guidelines' completion, CSP endorsement was contingent upon a successful twofold peer-review process, by the GPP and five anonymous, independent expert reviewers using the AGREE instrument.

Future versions

Future versions of these guidelines will incorporate acupuncture, corticosteroid injections and capsular distension, thus encompassing other interventions that might be used by physiotherapists. The guidelines' electronic format will facilitate this staged process.

Structure 

The guidelines are presented in three parts, as follows.

This is a systematic review of treatment interventions which, in this first version (*version 1.X*), is restricted to 'standard physiotherapy'. We have defined 'standard physiotherapy' as any intervention(s) that might be undertaken by a graduate physiotherapist without additional training, namely: advice; exercise therapy; manual therapy; electrotherapy; heat or cold treatments; ultrasound; or any combination of these.

Recommendations for management are derived from the systematic review using the GRADE system.

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1. Background, diagnosis, assessment and overview of strategies for managing contracted (frozen) shoulder

1.1. Anatomy of the shoulder 

The shoulder joint is a ball and socket joint between between the head of humerus (the upper arm bone) and the scapula (shoulder blade). A membrane (synovial membrane) lining the non-articulating surfaces constantly secretes and reabsorb a slippery lubricant, synovial fluid; the articulating surfaces are covered with smooth cartilage; and the whole is enclosed in a flexible fibrous capsule, which is attached to bone at the margins of the articulating surfaces, but not to the articulating surfaces themselves. In some other joints, the capsule has an important stabilising function—for example at the knee, where, at the sides, the capsule is condensed into the tough collateral ligaments that prevent side-to-side movement. But this is less so at the shoulder, where the capsule must be relatively lax to allow for mobility in all directions. This laxity, which gives the joint a surprisingly large capacity—a normal shoulder joint holds 10–30 ml of fluid (Lee et al 2002)—is greatest underneath the joint in the axilla (armpit), where it forms the redundant axillary fold. The other aspects of the joint capsule blend with the tendons of the rotator cuff, the shoulder's deep stabilising and controlling muscles. Specifically, the tendons of teres minor and infraspinatus lie behind (posteriorly) and merge with the rear of the capsule; the tendon of supraspinatus lies above (superiorly) and merges with the top of the capsule; and the tendon of subscapularis lies in front (anteriorly) and merges with the front of the capsule. There is no clear demarcation between the tendons, which merge with each other as well as the capsule, except anteriorly, between supraspinatus and subscapularis, where there is a deficiency in the rotator cuff called the rotator interval. At the shoulder joint, stability is a dynamic affair, brought about by interplay between the rotator cuff components and other muscles.

The rotator cuff is separated from the bone, ligament and muscle overlying it by a bursa (a sac lined with synovial membrane which, like synovial membrane inside the joint, secretes slippery synovial fluid). This bursa which, at about the size of the palm of the hand, is the largest in the body, prevents friction between the rotator cuff and its adjacent structures. In some circumstances (discussed by Hanchard, Cummins & Jeffries 2004) the bursa is unable to fulfil this role, and allows painful pinching of the soft tissues between bony protuberances on the humerus (the humeral tuberosities) and the arch of bone and ligament above them (the acromion process and the coraco-acromial ligament) which extends from the scapula. This is subacromial or outlet impingement, which can lead to erosion of the rotator cuff. Other types of impingements can occur inside the shoulder joint, especially in sportspeople who forcibly move their shoulders to the extremes of range, menacing the deep surface of the rotator cuff tendons among other structures (Edelson & Teitz 2000, Gold et al 2003, Halbrecht, Tirman & Atkin 1999, Jobe 1996, 1997, Pappas et al 2006, Valadie et al 2000). The various impingements are the main intrinsic causes of shoulder pain, and therefore important differential diagnoses from contracted (frozen) shoulder. Neck problems are a common extrinsic cause of shoulder pain, which is why neck movements should be screened as part of a shoulder assessment.

Movements at the shoulder joint are defined in standard anatomical terms (FIGURES 1.1a–h). All of the movements, especially elevation, are augmented by movements of the scapula relative to the chest wall.

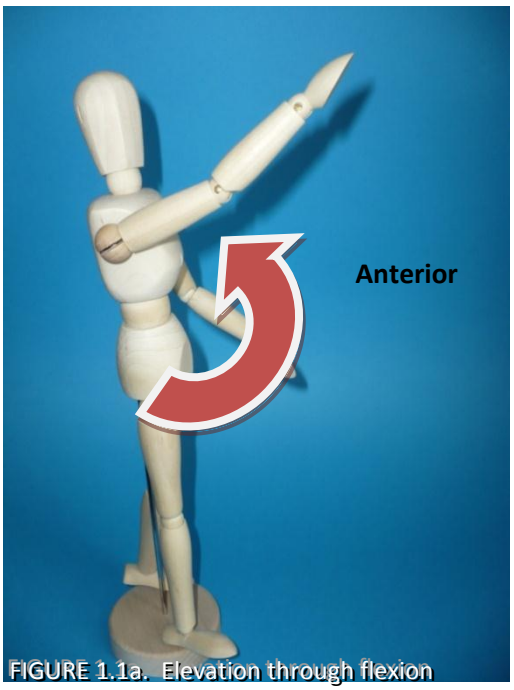

FIGURE 1.1a. Elevation through flexion

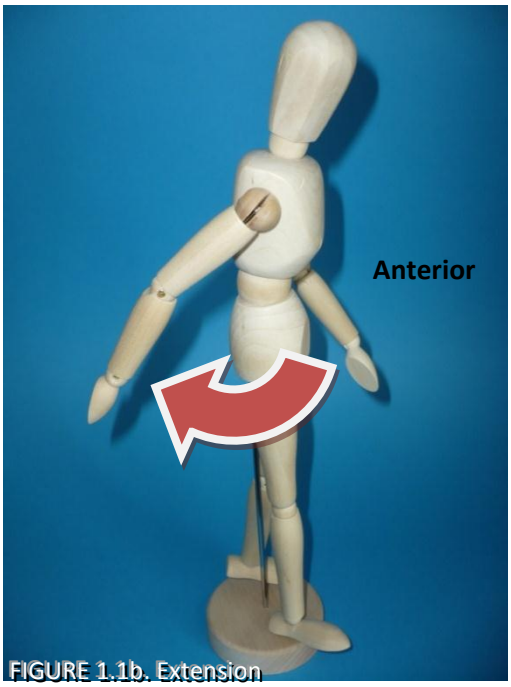

FIGURE 1.1b. Extension

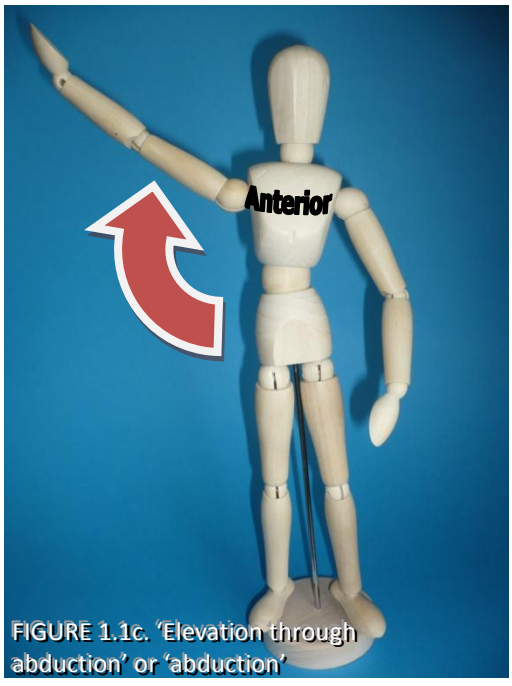

FIGURE 1.1c. 'Elevation through abduction' or 'abduction'

FIGURE 1.1d. Adduction

FIGURE 1.1e. External (or lateral) rotation with elbow at side

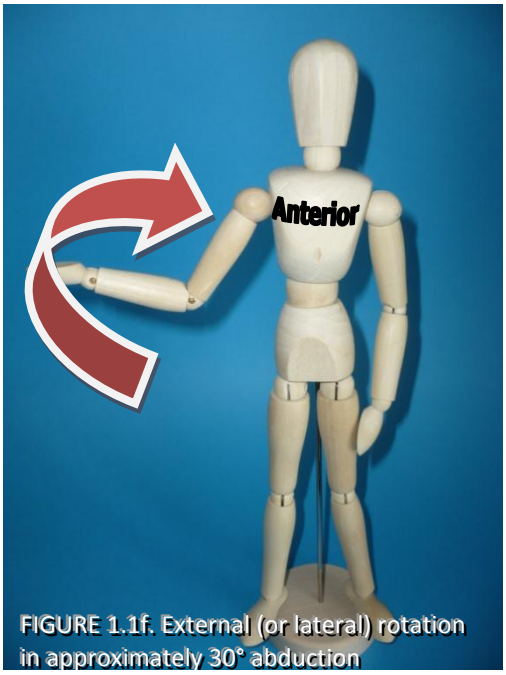

FIGURE 1.1f. External (or lateral) rotation in approximately 30° abduction

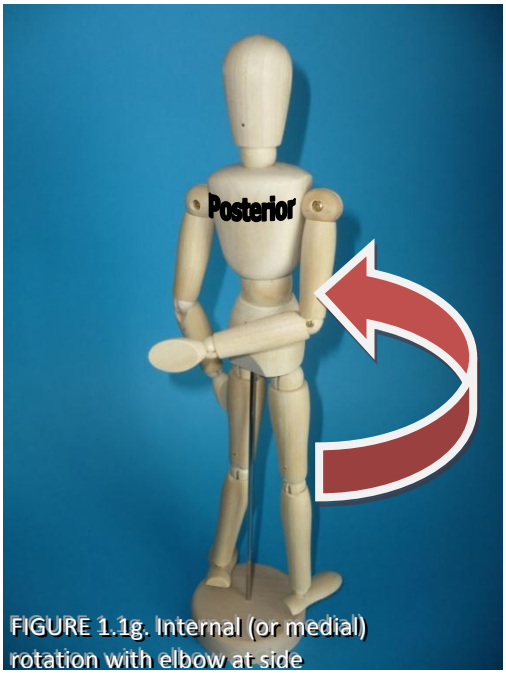

FIGURE 1.1g. Internal (or medial) rotation with elbow at side

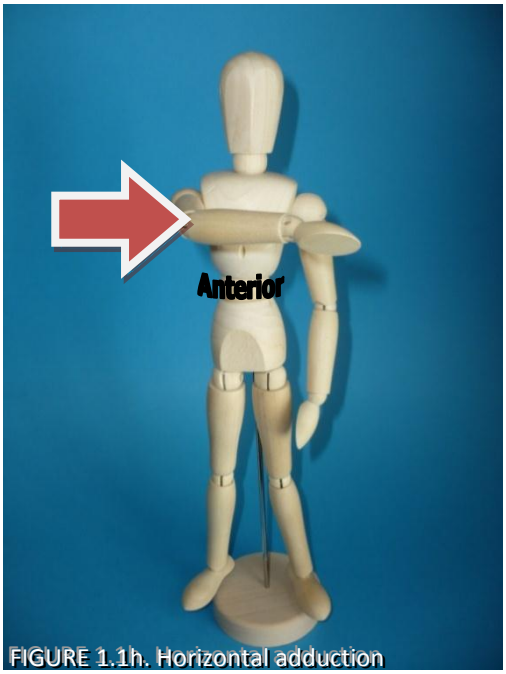

FIGURE 1.1h. Horizontal adduction

1.2. From '50s shoulder' to 'contracted (frozen) shoulder': a tour of terminology and pathology

The terminology surrounding contracted (frozen) shoulder has been reviewed extensively by Nobuhara (2003). In Japan, the condition has long been known as 50s shoulder. Nobuhara reports a reference to this term in an eighteenth-century source, *Rigenshuran*, which offers, as an alternative

descriptor, ‘long-life disease’. It seems that to survive beyond 50 was noteworthy, then. Perhaps a painful shoulder was a small price to pay. According to Nobuhara (2003), *Rigenshuran* defines 50s shoulder as ‘pain in the arm and joints which develops at about age 50 at times, but improves after a while without the administration of drugs’. This catches some of the essence of contracted (frozen) shoulder, although it omits to mention stiffness, which is a key feature. Recognition of the condition took rather longer in the West. It was not until 1867 that the French surgeon E.S. Duplay reported the results of his surgical explorations, initially of post-traumatic stiff shoulders, and dignified these with the name ‘periarthritis scapulohumerale’. Later, he realised that this condition also occurred in the absence of trauma. He achieved the double distinction of having the condition named both by him (‘periarthritis scapulohumerale’) and for him (maladie de Duplay).

Mistakenly, Duplay and most of his contemporaries believed that the condition was primarily due to pathology in the subacromial–subdeltoid bursa (Lee et al 1973, Nobuhara 2003). Considering this, periarthritis (*peri* = around; *arthr* = joint; *itis* = inflammation) seems rather a vague term, since it could legitimately refer to inflammation of any tissue around a joint; but it may be this very vagueness that has accounted for its lasting appeal. In fact, ‘periarthritis’, and its variant ‘periarticular shoulder pain’, have remained in use to the present day (Lee et al 1973, Shehab & Adnam 2000, Nobuhara 2003). No more precise anatomically, and less so pathologically, is ‘frozen shoulder’, a label originated by the American surgeon E.A. Codman in his seminal book (1934). But this term has also stuck: so much so that we felt obliged to keep it in the title of these guidelines, albeit in brackets. Codman admitted that he was perplexed by the pathology of frozen shoulder. At first he, like Duplay, believed that the bursa played the primary role. Later, he implicated the tendons. This too was a false scent. However, his clinical description of patients with contracted (frozen) shoulder has hardly been bettered.

> It comes on ‘slowly; [with] pain usually felt near the insertion of the deltoid[3]; inability to sleep on the affected side; painful and incomplete elevation and external rotation; restriction of both spasmodic and mildly adherent type; atrophy of the spinati[4]; little local tenderness; [and] X-rays negative except for bone atrophy’ (Codman 1934).

Attention turned to the shoulder joint capsule as the source of problems with a series of surgical explorations in 10 patients by J.S. Neviaser, which he reported in 1945. Neviaser found that the capsules were thicker than normal and contracted: they gaped apart when he incised them with his scalpel. Additionally, he reported that in each case the capsule was abnormally adherent to the humerus, in the same way that sticky plasters are adherent to skin, but could be peeled off by repetitive rotational movements of the joint. In nine of the cases, he said, the capsule was also adherent to itself in the redundant axillary fold. Neviaser asserted that the primary pathology was not a periarthritis, and proposed the term ‘“adhesive capsulitis” … as descriptive of the pathology of “frozen shoulder”’ (Neviaser 1945). The term is widely used, especially in the USA. Meanwhile, the orthopaedic physician J.H. Cyriax had incriminated the joint capsule by deduction, and considered that Neviaser’s findings bore out his views (Cyriax 1982). The significance—indeed the

[3] The deltoid is the muscle that gives the shoulder its rounded contour. Its ‘insertion’ is where it attaches to the humerus, about half way down the bone.
[4] i.e. wasting of the supraspinatus and infraspinatus muscles.

existence—of adhesions has since been challenged (Bunker 1997, Bunker 2009, Omari & Bunker 2001), but Neviaser and Cyriax were right to incriminate the joint capsule.

Since Neviaser's study, the advent of arthroscopic (keyhole) techniques has made surgical exploration of shoulder joints commonplace. As reviewed by Bunker (2009), one of the most striking features on arthroscoping a contracted (frozen) shoulder is capsular contracture: the capsule becomes tough and thickened, and its volume may shrink to as little as 3–4 ml. (This loss of capacity is also obvious when attempting to inject moderate volumes of fluid into affected shoulders.) Another striking feature is the formation of new blood vessels in the synovial membrane, especially in the rotator interval area, but also in the superior capsule, the posterior capsule and the redundant axillary fold. In cases where the pain is giving way to stiffness, these new blood vessels become embedded in thick scar (Bunker 2009, Omari and Bunker 2001).

But the underlying pathology has been elusive. Some have argued that the fundamental process is inflammation; others that it is scarring; yet others that it is scarring produced in reaction to inflammation (Hand et al 2007). The last of these is logically appealing for a number of reasons: because frozen shoulder causes both pain and stiffness, but the stiffness outlasts the pain; because of the changes seen in relation to blood circulation; and also because painful contracted (frozen) shoulder may respond to injections of corticosteroid (Buchbinder, Green & Youd 2003), a potent suppressor of inflammation. Hand et al (2007) microscopically examined tissues from the rotator interval of 22 patients with frozen shoulder. This examination, combined with novel staining techniques, revealed large numbers of fibroblasts (cells that, among other things, produce scar); cells associated with chronic inflammation (Hand et al 2007); and an increase in blood vessels. On this basis, Hand et al (2007) have proposed that frozen shoulder does indeed represent a process in which inflammation leads to scarring. They have tentatively implicated mast cells in this link. Mast cells, which are among the inflammation-related cells they found, are known to control the proliferation of fibroblasts. Myofibroblasts, another cell type—a cross between fibroblasts and muscle cells, which cause scar to contract—may also be implicated in the pathology of frozen shoulder. Bunker (1997) and Omari and Bunker (2001) resorted to open surgery in patients with frozen shoulder that had responded to neither conservative measures nor manipulation under anaesthesia, and found abundant myofibroblasts in tissue taken from the rotator interval. Clearly, on a large scale, myofibroblasts could contribute to capsular contracture; and that Hand et al (2007) did not find significant numbers of these cells may reflect the fact that their patient population was less chronic. Another finding in capsular tissue from patients with frozen shoulder is the absence of certain enzymes that would normally be involved in the remodelling of scar tissue (Bunker 2009).

Regardless of the mechanism by which it comes about, contracture is such a striking feature of frozen shoulder that Bunker (2009) has suggested a further redesignation, 'contracted (frozen) shoulder', which we have adopted.

The subtypes of contracted (frozen) shoulder have also been inconsistently classified. Codman (1934)—and indeed Duplay—noted that the condition could be insidious or secondary to trauma. Cyriax called the former monarticular infective [*sic*] arthritis (Cyriax & Troisier 1953, Cyriax 1954)

then monarticular rheumatoid arthritis (Cyriax 1957), subsequently changing this, in deference to objections from the rheumatology community, to 'steroid-sensitive arthritis'. (He found it responsive to intra-articular injections of the corticosteroid hydrocortisone.) He called the latter traumatic arthritis (Cyriax & Troisier 1953, Cyriax 1954, 1957), though he later reported that these cases, too, were responsive to intra-articular injection of corticosteroid: not hydrocortisone, but triamcinilone, which became available to him in 1970 (Cyriax 1982). Lundberg's 1969 classification was into primary (of unknown cause) and secondary (to trauma). Others have since expanded Lundberg's secondary category to include any association with another event or condition (reviewed by Kelley, McClure & Leggin 2009). In this connection, 'another event' would include trauma or cardiac- or neuro-surgery; while 'another condition' would include diabetes[5], Dupuytren's disease[6], thyroid disease, Parkinson's disease, osteoporosis, cardiorespiratory disease, stroke, high cholesterol or adrenocorticotrophic hormone (ACTH) deficiency (reviewed by Hand et al 2008, Kelley, McClure & Leggin 2009). This expanded classification is helpful, and will be adhered to here, but it is not universally recognised. For example, some writers, following Lundberg's original classification system, would categorise contracted (frozen) shoulder in a person with diabetes as primary, providing it was non-traumatic in origin.

1.3. Diagnosing contracted (frozen) shoulder 

Formal diagnostic test accuracy studies (of sensitivity and specificity) for contracted (frozen) shoulder are impracticable because there is no agreed diagnostic reference standard (Harryman & Lazarus 2004). However, this section describes the options for clinically diagnosing contracted (frozen) shoulder (establishing that the condition is present); presents the evidence there is[6]; examines some of the strategies in use, based on the questionnaire survey of CSP members (Hanchard et al 2011); and offers suggestions.

Trials of treatments for shoulder pain vary in their inclusivity. Some evaluate treatments in samples incorporating different types of shoulder pain. Others represent an attempt to target specific types of shoulder pain. Green, Hetrick and Buchbinder (2003) note that trials of the second type are appealing to clinicians because they reflect the way in which clinicians work: clinicians treat different types of shoulder pain in different ways. As might be expected, contracted (frozen) shoulder and its subtypes go by many names in such trials. Also, the precise diagnostic criteria vary—often reflecting imprecise reporting—but, typically, they remain compatible with the clinical features described by Codman (1934).

There is a gradual onset of arm pain; the patient is unable to lie on the affected side; there is restriction of movements notably including elevation and external rotation; and all this in the face of negative X-rays. The condition runs a distinct course, divided into different phases by different authorities, though we recommend a simple 'pain-predominant' or 'stiffness-predominant' classification, which respondents to our survey (Hanchard et al 2011) found clinically meaningful.

[5] Among people with diabetes or severe Dupuytren's disease, contracted (frozen) shoulder is not only prevalent, but also potentially slower to resolve and more resistant to treatment (Bunker 2009).
[6] For search strategy and results *see* APPENDIX A2.

Over 90% of patients notice pain before stiffness (Boyle-Walker et al 1997). There is then a phase of increasing pain and increasing stiffness, during which pain is the predominant complaint: at its height, pain is present even at rest, may extend down the arm past the elbow, disturbs sleep and prevents lying on the affected side (Cyriax 1982). Sleep disturbance, often the patient's main reason for seeking help, is not especially helpful diagnostically, because the same symptom occurs with rotator cuff tears (reviewed by Hanchard, Cummins & Jeffries 2004). The pain abates leaving stiffness as the predominant complaint; then the condition ends—more or less—in resolution. Codman (1934) wrote that resolution was the rule within about two years, an assertion echoed by other authorities (e.g. Cyriax 1982); but a recent study of 223 patients referred to tertiary care with contracted (frozen) shoulder revealed that 38% had persistent mild symptoms at a mean follow-up time of 4.4 years from onset of symptoms (range 2–20 years), mostly pain; and that 3% had persistent severe symptoms with pain and loss of function. Those with the worst symptoms at the outset had the worst prognosis (Hand et al 2008).

Cyriax (1982) established that restriction of *passive* movement[7] was necessary to make the diagnosis of contracted (frozen) shoulder, and this is now a generally accepted principle. He also introduced the concept of the capsular pattern, a pattern of limitation of passive movements which is unique to each joint and which, theoretically, always denotes 'capsulitis' (literally *capsule inflammation*). Cyriax defined the capsular pattern of the shoulder as the ratio between three passive movements, whereby external rotation is most restricted, abduction less, and internal rotation less still, with the rotations being tested in the elbow-at-side position (Cyriax 1982). In theory, a capsular pattern would be expected in contracted (frozen) shoulder, since some degree of capsulitis is likely to be present. Rundquist et al (2003) tested this hypothesis in 10 patients with stiffness predominant primary contracted (frozen) shoulder, using electromagnetic sensors to track the 3-dimensional positions of the trunk, scapula and humerus during external rotation, abduction and internal rotation—although these movements were active, not passive—and found a classical capsular pattern in seven. External rotation was the most restricted movement in eight, and the most or second most restricted in nine. In a subsequent study of 23 patients, Rundquist and Ludewig (2004) found that external rotation was most restricted, jointly most restricted, or second most restricted in 92%. The other prospective studies with a primary focus on range of motion in contracted (frozen) shoulder have also reported proportionately predominant involvement of passive external rotation, with the arm in 0° abduction (Kerimoglu et al 2007), 45° abduction (Mitsch et al 2004) and 90° abduction (Binder et al 1984, Bulgen et al 1984). Furthermore in a study by Wolf and Cox (2010), pain on passive external rotation at 0° abduction—irrespective of restriction—was found to be indicative of glenohumeral osteoarthritis (identifiable on subsequent X-ray, n = 23/379) or, by exclusion, contracted (frozen) shoulder (n = 68/379 of whom 58 were available for follow-up). In the latter subgroup, treated by corticosteroid injection(s) and, in five cases, manipulation, satisfaction was high (85%) and of the nine who were dissatisfied, six had been improved and reported insufficient symptoms to warrant further intervention. Based on these results, Wolf and Cox (2010) argue that, in the absence of glenohumeral arthritis or a history

[7] Passive movements are those which are performed for the patient, while his or her muscles are relaxed. These are distinct from active movements, which the patient produces of his or her own volition.

of trauma, pain on passive external rotation should be considered sufficient to diagnose contracted (frozen) shoulder, even if range of movement is not (yet) restricted.

Setting the details of the capsular pattern aside, this involvement of external rotation is not surprising. Contracted (frozen) shoulder is known to centre on the rotator interval (Bunker 1997, 2009), and in experiments on eight cadaveric shoulders, Harryman et al (1992) found that shortening the rotator interval capsule by approximately 1 cm reduced external rotation by a mean value of 37.7° (± standard deviation 20.8°). In contrast, abduction and internal rotation were hardly affected. At 60° of flexion, the reduction in external rotation dwindled to a relatively modest 17.8° (± 6.3°): a persuasive argument, too, for testing external rotation in the elbow-at-side position.

In our survey of UK physiotherapists, we found the capsular pattern concept popular, but often misinterpreted. Many other respondents—more among those with a special interest—placed more emphasis on restriction of passive external rotation than its place in a multi-component pattern in diagnosing contracted (frozen) shoulder (Hanchard et al 2011). This approach contrasts with the consensus of 70 healthcare professionals from Australia and New Zealand, who favoured global loss of active and passive range of movement as a diagnostic criterion (Walmsely, Rivett and Osmotherly 2009); but focus on passive external rotation is better evidenced, simple, memorable, and unlikely to lead to confusion.

Differential diagnosis between contracted (frozen) shoulder and the impingement-type disorders does cause some confusion in practice, however. Specifically, standard tests for impingement are positive in the pain-predominant phase of contracted (frozen) shoulder, because they involve stretching the joint capsule. This applies to Neer's sign (Neer & Welsh 1977, Neer 1983), among others. Neer recognised this problem, and it was for this reason that he described Neer's test, which involves injecting local anaesthetic under the acromial arch. Neer argued that in subacromial impingement, this would render his sign negative (Neer & Welsh 1977, Neer 1983). A simpler approach is to regard signs of contracted (frozen) shoulder as taking primacy over signs of impingement.

Whether palpation has a place in the diagnosis of contracted (frozen) shoulder is unclear. One study (Carbone et al 2010) evaluated digital pressure over the coracoid process against an unclearly defined, composite 'reference' standard. Although the authors reported high accuracy, this must be considered in the light of the biases to which the study is prone (test review bias, differential verification bias, and possibly—though the reporting is too imprecise to be sure—diagnostic review bias) as well as technical uncertainties. By contrast, Bulgen et al (1984) reported tenderness, mainly over the humeral tuberosities, in only 21% (9/42) of their cohort.

Finally, Codman's (1934) observation, since amplified by Bunker (1997, 2009) and the findings of Wolf and Cox (2010), that a normal X-ray is prerequisite to a definitive diagnosis of contracted (frozen) shoulder, warrants restating. Restricted passive external rotation and the capsular pattern are not unique to contracted (frozen) shoulder: locked dislocations restrict passive external rotation; arthritis may cause painful passive external rotation, presumably with or without restriction (Wolf & Cox 2010); and arthritis and joint fractures would each theoretically cause a

capsular pattern (Cyriax 1982). All are visible on X-ray, though orthogonal views[8] (views taken at right angles) are recommended in order that abnormalities are not overlooked. It is perhaps unrealistic to expect that all patients presenting with the clinical features of contracted (frozen) shoulder will routinely be referred for X-ray, but it should be remembered that in the absence of this procedure the diagnosis is tentative. Care should therefore be taken during the history to rule out substantial trauma, systemic (body-wide) disease and general ill-health; specific examination should be made for crepitus (gross creaking or grating) on passive movement; and a poor response to treatment should promptly trigger further investigation.

1.4. Reproducibility of physical tests for contracted (frozen) shoulder, and general guidance on applying the physical tests

Is the capsular pattern a reproducible finding? One aspect of reproducibility concerns whether different testers agree on whether a capsular pattern is present. Nominal agreement of this type is necessary for the diagnosis is to be reproducible. Hanchard, Howe and Gilbert (2004), conducted a standardised history and physical examination of 53 patients with different types of shoulder pain. Patients were typically examined in standing, and universal goniometers (protractors for measuring joint angles) were made available to testers, although their use was optional. Agreements between testers (one expert and three non-expert) on diagnoses of contracted (frozen) shoulder were found to be respectively 'good', 'very good' and 'very good' (for those with a statistical turn of mind, κ = 0.63, 0.81 and 0.82).

Another aspect of reproducibility goes beyond agreement on whether passive movements are 'positive' or 'negative' and concerns the extent to which there is agreement on the *amount* of available movement, measured in degrees. Quantitative agreement of this type is necessary for estimations of the condition's severity to be reproducible. There are within-tester and between-testers elements. Specifically, the extent to which a single tester obtains similar values (in degrees) on successive measurements or estimates is termed within-tester agreement. The extent to which different testers obtain similar values is termed between-testers agreement. If its quantitative within-tester agreement is good (and it is otherwise valid), a test is useful for assessing a condition's severity (and its progress and outcome), providing the same person takes the measurements. If its between-tester reliability is good (and it is otherwise valid), a test is useful for such assessment even if different people take the measurements.

With respect to within-tester agreement, Tveita et al (2008a) took measurements a week apart in 32 patients with contracted (frozen) shoulder of three months' to two years' duration, using a digital, gravity-dependent measuring device (digital inclinometer). For measurements of rotation, their patients lay supine with 45^{o} of shoulder abduction. Based on their results, they estimated that, 95 times out of 100, a change in passive external rotation of $\geq$ 13^{o} would reflect real change; but that any smaller change would be indistinguishable from measurement error.

[8] A-P and axillary lateral views are normally taken

Regarding between-testers agreement, de Winter et al (2004) conducted a study in which two physiotherapists, again using a digital inclinometer, independently measured passive external rotation in 155 patients with different types of shoulder pain. Rotation was measured with patients lying supine, and their elbows at their sides. In this sample, $\geq 23^{o}$ change in passive external rotation was necessary to reflect real change 95 times out of 100. Terwee et al (2005) evaluated the agreement between two independent physiotherapists' visual estimates of joint angles in a sample of 201 patients with different types of shoulder pain. Patients were seated for the test movements, passive external rotation being tested with the elbow at the side. Visual estimation is standard practice for many—probably most—clinicians, who work within tight time constraints, and testing is very often done in an upright (sitting or standing) position, making the study particularly apposite. In their sample, changes in passive external rotation had to equal or exceed 35^{o} in order to reflect true change 95 times out of 100, and Terwee et al observed that agreement was particularly low for patients in severe pain and with major disability. Furthermore, Croft et al (1994), who evaluated agreement on visual estimated ranges of shoulder movement between primary care physicians, concluded 'external rotation is poorly reproducible because of systematic variation in examination technique and random variation in visual assessment'.

Included for completeness is Mullaney et al (2010), who compared agreement between goniometric and digital inclinometric measurements of active-assisted external rotation, within- and between-testers, in a sample with different types of shoulder pain. But because the measurements were conducted at 90° of shoulder abduction—and availability of this range was prerequisite to recruitment—the results have little relevance to contracted (frozen) shoulder populations.

In individual clinical instances, agreement may be better or worse that demonstrated in the foregoing studies' samples. The key messages here are that passive external rotation is fundamental to the diagnosis of contracted (frozen) shoulder, but an inexact tool for assessing the condition's severity, progress and outcome; and that, in so far as it is used in these capacities, repeated measurements are more meaningful when taken by one tester than by several. Also, it would be expected that standardised technique would probably enhance both within-tester and between-testers reproducibility. Prerequisite to standardised technique are clear operational definitions, such as whether the end point of movement is considered to be the maximum attainable range or (more likely) the point at which pain occurs, increases or becomes intolerable; and these definitions should be made explicit on patients' records. Stabilisation of the scapula or trunk is another important consideration and, especially if the test is performed in standing, great care should be taken to prevent trunk rotation. We suggest that external rotation be tested with the patient's elbow at his or her side for optimal 'sensitivity' to contracted (frozen) shoulder (Harryman et al 1992, Kerimoglu et al 2007, Rundquist et al 2003, Rundquist & Ludewig 2004, Wolf & Cox 2010). In this position (FIGURE 1.2a), the tester can limit trunk rotation and, with his or her shoulder behind the patient's scapula, is well placed to detect scapular retraction. Even so, the tester should be realistic about the likely reproducibility of his or her estimations of range, perhaps thinking in terms of 30^{o} increments rather than discrete degrees (FIGURE 1.2b). Where an estimate falls between two increments, the smaller (i.e. the more conservative) could be taken.

FIGURE 1.2a. A method for estimating passive external rotation (the key physical diagnostic test) in standing. The tester's trunk hand stabilises the patient's trunk; his trunk blocks scapular retraction and stabilises the patient's elbow.

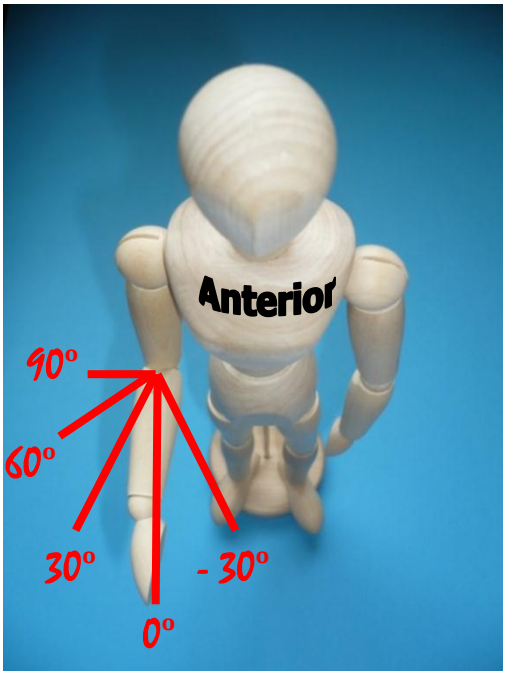

FIGURE 1.2b. Estimation of external rotation in 30° increments. Where an estimate falls between two values, the smaller can be taken.

1.5. Other 'tools' for assessment

It is essential to reliably measure and document the effectiveness of our interventions, and to do this in a way that is meaningful for our patients. Both generic and specific outcome measures exist. A key advantage of generic measures is that they allow for comparison of people with different conditions, or for comparison against normative values. Their main disadvantages are that, compared to specific outcome measures, they may be insensitive; that they may be prone to 'floor' or 'ceiling' effects; and that they may lack face validity. Region/joint-specific outcome measures are of restricted use for comparisons, but on the other hand, they tend to be sensitive and to have face validity (Finch et al 2002).

Some region/joint-specific outcome measures are for completion by the patient, and the additional advantage of these is that they cost the clinician no time. There are numerous outcome measures of this type which have been validated, usually in samples incorporating different types of shoulder pain. An indicative (by no means comprehensive) selection is shown in TABLE 1.1. An obvious question when using an outcome measure in practice is, 'how much change must there be before I know my patient's status has altered?' The statistic of interest here is the Minimum Clinically Important Difference (MCID). MCIDs have been reported for a number of outcome measures. Some are duplicated here (TABLE 1.1), but note that these values are specific to the populations, conditions and settings in relation to which they have been obtained.

Combined pain–function outcome measures	Abbrev.	MCID	Reference for MCID
Flexi-level Scale of Shoulder Function	FLEX-SF	3.02/50	Cook et al 2003[1]
Shoulder Disability Questionnaire - Netherlands	SDQ – NL	2–3/16 (14.0%)	Paul et al 2004[2]
Shoulder Disability Questionnaire – UK	SDQ-UK	1–2/23 (4–8.0%)	Paul et al 2004[2]
Shoulder Pain and Disability Index	SPADI	8.0%[3]	Paul et al 2004[2]
Shoulder Rating Questionnaire	SRQ	13.0%	Paul et al 2004[2]
American Shoulder and Elbow Surgeons' patient self-evaluation form	ASES	6.4%	Michener, McClure and Sennett 2002[4]
Pain outcome measures			
100 mm Visual Analogue Scale	100 mm VAS	1.4 cm	Tashjian et al 2009[5]
11-point Numeric pain rating Scale	11-point NPRS	2.0 (or 33%)	Salaffi et al 2004[6]

TABLE 1.1. Examples of combined pain–function and pain outcome measures, with Minimum Clinically Important Differences (MCIDs) and references. [1]Patients with different types of shoulder pain (the care setting was unclear); [2]Patients with first episode of shoulder pain in UK primary care; [3]But Tveita et al (2008b) reported a Smallest Detectable Difference (SDD) of 17% in individual patients with contracted (frozen) shoulder in Norwegian secondary care; [4]Patients with different types of shoulder pain at various outpatient clinics [5]Patients undergoing non-operative treatment in secondary care for rotator cuff disease; [6]Chronic musculoskeletal pain in secondary care.

1.6. Summary of key points in diagnosis and assessment

- The principal diagnostic test is passive external rotation, which is restricted in contracted (frozen) shoulder (but also in other conditions).
- A finding of restricted passive external rotation should be corroborated by history (screening for substantial trauma/serious disease), X-ray examination (which can exclude the other causes of restriction) and palpation (screening for gross crepitus).
- Measuring the range of passive external rotation reliably is difficult, and this should be recognised. We suggest a method in standing which involves estimating range to the nearest 30°. (Where an estimate falls between two values, the smaller can be taken.) We also suggest that operational definitions are made explicit.
- We recommend the terminology 'pain-predominant' and 'stiffness-predominant' to classify the stage of the condition. Where there is doubt, pain should take precedence.
- A validated region/joint-specific measure should be used to evaluate patients' status, progress and outcome.

An overview of treatment options 

This section gives an overview of treatment options, from advice and education to operative intervention, briefly discussing those options' intended effects and the means by which they are supposed to achieve their effects. Emphasis is placed on the more common interventions as determined by a questionnaire survey of CSP members with 289 valid respondents (Hanchard et al 2011) and the focus of recent trials. We have organised the treatment options from more to less conservative, but the order is not meant to be prescriptive. It should not be supposed that any individual would, or should, receive all of the treatments listed. Nor are the treatments necessarily mutually exclusive.

The information for each option is arranged under *Background* and, to provide clinical context, *Results of CSP survey* (Hanchard et al 2011). The popularity or otherwise of an intervention should not be taken as evidence of efficacy.

1.7.1. Conservative management

Advice and education

Background: Advice and education from physiotherapists may be tailored to individuals or given in more generic form, possibly as a patient information leaflet.

Patients may be frightened by the severity of their symptoms, and may compare their experience unfavourably with that of relatives or friends who have had 'shoulder pain', especially if improvement seems slow. Reassurance is therefore a key factor: specifically, reassurance that serious causes of shoulder pain are rare; that the patient has been screened for potential red flags; and that the condition is usually self-limiting. Simply acknowledging the severity of symptoms may help provide peace of mind, as may education on the potential spectrum and variability of symptoms in contracted (frozen) shoulder.

Advice includes activity modification in the home, at work and in sporting and leisure activities. Physiotherapists may be able to suggest alternative ways of completing tasks that do not aggravate symptoms. For example, patients may find dressing easier if they wear loose and front-fastening tops, and if they place the affected arm into the arm-hole first. In bed, and during activities that require sustained positions of the affected arm, support is important: this may be achieved by use of pillows or towels in bed, or, during activities, by building the elbow's or forearm's platform of support up to the level required. Advice on pacing activities, avoiding aggravating factors and managing symptoms may help to prevent disruption of social activities and/or minimise the condition's potential impact on the patient's quality of life.

Self-management may be enhanced by an understanding of pain mechanisms, and face to face education or recommendation of textbooks may be used to achieve this.

Results of CSP survey: Ninety-six percent of respondents said that they might use or recommend advice and education for pain-predominant contracted (frozen) shoulder; 88% said that they might use or recommend advice and education in the stiffness-predominant stage.

Supervised neglect

Background: Diercks et al (2004) describe supervised neglect as supportive therapy and pendular and active exercise within the limits of pain, and the resumption of tolerable activities, with use of anti-inflammatory or analgesic medication as required.

Results of CSP survey: Supervised neglect was not given as an option.

Superficial heat or cold

Background: Superficial heat and cold are widely used to promote repair and healing processes.

Typically, heat therapy involves the application of dry or moist hot pack to the skin through some intervening protective layer (to minimise the risk of heat damage or burns). Heat therapy is believed to reduce pain by mechanisms involving the release of endorphins. Additionally, the local warming effect may reduce stiffness in joints and spasm in muscles; and heat is thought to reduce oedema (swelling) by increasing fluid absorption from the tissues. The associated increase in blood flow is believed to improve transport of oxygen and nutrients to the tissues, while aiding the removal of waste products.

Cold may be applied in many ways and works on the principle of heat exchange. Placing a cold pack on warm skin will cause heat to be drawn away from underlying inflamed tissues, while swelling is limited by constriction (narrowing) of the capillaries. Other effects are muscle relaxation, local anaesthesia, analgesia and increased pain threshold. All these effects are usually achieved within 20–30 minutes of application, depending on body type. Applying cold packs for longer than 30 minutes risks damaging the skin or deeper tissues.

Results of CSP survey: Sixty-nine percent of respondents said that they might use or recommend superficial heat or cold for pain-predominant contracted (frozen) shoulder. Over 40% said they might use or recommend one or the other of these modalities in the stiffness-predominant stage.

Exercise therapy

Background: Exercise therapy is regularly used in the management of shoulder complaints. In the context of pain-predominant contracted (frozen) shoulder, gentle rhythmic active exercises (e.g. Codman's pendular exercises) may help to reduce pain (pain modulation) and maintain the health of tissues within and around the joint. In the stiffness-predominant stage, function-based exercises may be used to maintain/restore the range or quality (co-ordination and/or control) of movement or both.

Results of CSP survey: Seventy-nine percent of respondents said that they might use or recommend gentle active exercise in the management of pain-predominant contracted (frozen) shoulder. Seventy-five percent said that they might use or recommend function-based exercises for stiffness-predominant contracted (frozen) shoulder.

Manual mobilisations

Background: Manual mobilisations (normally abbreviated to 'mobilisations') are therapist-applied passive movements of joints or other structures performed in such a way that they are always within the control of the patient. They may be performed by various techniques and may be combined with active movement on the part of the patient. The main aim in pain-predominant contracted (frozen) shoulder is pain relief, for which rhythmic mobilisations within comfortable range are used. It is speculated that these cause interactions between different types of nerve fibres, 'blocking' the transmission of pain signals to the brain. The same theory underpins the use of several electrotherapies in pain-predominant contracted (frozen) shoulder (*see* further). In the stiffness-predominant stage, the main aim is to restore range of movement, so mobilisations will stretch the joint into resistance.

Results of CSP survey: Thirty-five percent of respondents said they might use or recommend joint mobilisations for pain-predominant contracted (frozen) shoulder. Eighty-seven percent said they might use or recommend mobilisations in the stiffness-predominant stage.

Electrotherapy

General

Background: Electrotherapy includes trans-cutaneous electrical nerve stimulation (TENS), a low cost pain-control device; interferential (IF), a therapist-applied type of nerve stimulation; and shortwave diathermy (SWD) and pulsed shortwave diathermy (PSWD), which are both forms of radio-frequency electromagnetic field. We have also included therapeutic ultrasound in this category. Ultrasound does not involve applying any currents or fields to the patient's tissues and, in that sense, is not, strictly speaking, 'electrotherapy'. But it is included among electrotherapy modalities by popular usage among physiotherapists and in many textbooks. (For an up to date list of electrotherapy books, *see* Professor Tim Watson's website at http://www.electrotherapy.org/index.htm).

Results of CSP survey: Electrotherapy ranked as only the tenth most preferred treatment for pain-predominant contracted (frozen) shoulder. Only 30% of all respondents chose this option: *see* under the individual modalities for a further breakdown. An interesting observation was that electrotherapy was substantially less popular among physiotherapists with a special interest in contracted (frozen) shoulder (22%) than those without (38%).This difference was statistically significant (Chi-square 7.780, $p = 0.0053$) and highly unlikely to be due to chance alone. For stiffness-predominant contracted (frozen) shoulder, fewer than 4% of respondents chose electrotherapy of any sort as an option.

Trans-cutaneous electrical nerve stimulation (TENS)

Background: TENS consists of low frequency electrical pulses (generated by a small, portable unit) transmitted to the tissues through electrodes on the skin. The pulses stimulate peripheral nerves in such a way as to suppress the perception of pain. Different pulse patterns are believed to achieve

analgesia by different mechanisms: by causing interactions between types of nerve fibres, resulting in a 'block' on the transmission of pain signals to the brain; or by releasing hormones that block pain receptors in the central nervous system.

Results of CSP survey: Sixteen percent of respondents said that they might use or recommend TENS at some stage in the management of contracted (frozen) shoulder.

Interferential

Background: Low frequency electrical currents are known to have analgesic effects in the tissues (*see* TENS above for postulated mechanisms), but a low frequency current sufficiently strong to reach deeper tissues would be painful on the skin. Medium frequency currents are more comfortable on the skin, but lack analgesic effects in the deeper tissues. Interferential aims to circumvent this problem. In classical ('four polar' or 'quadripolar') interferential, which uses four electrodes, two medium-frequency currents are applied to the skin surface in such a way that they interact in the deeper tissues, generating a low-frequency stimulus and the desired therapeutic response. Another type of interferential exists, called bipolar interferential. This differs from the traditional type in that the medium frequency currents interact within the machine, rather than the patient's tissues. As far as is known, the two types of interferential are interchangeable in terms of their physiological effects (reviewed by Watson, 2009).

Results of CSP survey: Six percent of respondents said that they might use or recommend interferential at some stage in the management of contracted (frozen) shoulder.

Shortwave diathermy (SWD) and pulsed shortwave diathermy (PSWD)

Background: SWD is radio-frequency energy which generates heat in the tissues. The heating effect is thought to be deeper than that obtainable using, for example, hot packs or a heat lamp. However, there is still disagreement over which tissues are preferentially heated by SWD. In recent years, PSWD has become relatively more prevalent than SWD. In this mode, SWD is applied in pulses, between which heat is able to dissipate to a greater or lesser extent (depending on the intensity, the length of the pulses, and the interval between them). In general, the therapeutic effects of heating include analgesia, reduced muscle spasm, reduced joint stiffness, increased metabolism and increased blood flow, all of which could, theoretically, be beneficial at some stage or other of contracted (frozen) shoulder.

Results of CSP survey: Eight percent of respondents said that they might use or recommend SWD or PSWD at some stage in the management of contracted (frozen) shoulder.

Therapeutic ultrasound

Background: Sound is mechanical vibration and ultrasound is mechanical vibration at very high frequencies—well above the audible range. Ultrasound does have a heating effect, although, as with PSWD (*see* above) it may be pulsed to allow heat to dissipate, and it is uncertain whether any effects are due to thermal or non-thermal mechanisms. Theoretical benefits include those

attributed to SWD and PSWD (*see* above) as well as increased rate of healing and improved quality of tissue repair.

Results of CSP survey: Six percent of respondents said that they might use or recommend therapeutic ultrasound at some stage in the management of contracted (frozen) shoulder.

Medication

Non-opioid analgesics

Background: Non-opioid analgesics include aspirin and the other non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol, and are suitable for pain of musculoskeletal origin. Paracetamol differs from the NSAIDs in having no anti-inflammatory activity but being less irritating to the gastric system.

Results of survey: Not applicable.

Opioid analgesics

Background: The opioid analgesics, e.g. codeine, are one of the main classes of pain relieving drugs, and act on the central nervous system to increase tolerance to pain. Semi-synthetic variants include Tramadol.

Results of survey: Not applicable.

Corticosteroids

Background: Corticosteroids (for which the generic term 'steroids' is usually used) strongly suppress all stages of acute and chronic inflammation. In relation to contracted (frozen) shoulder, they may be injected intra-articularly (directly into the joint) or taken orally (in tablet form), though the latter is unusual in the UK.

Results of CSP survey: Twenty-four percent of respondents reported practising injection therapy, and the proportion was significantly greater among those with a special interest in shoulders (Chi-square 33.803, $p < 0.0001$). Eighty percent of respondents said they would consider using or recommending an intra-articular steroid injection in the pain-predominant stage of contracted (frozen) shoulder. This fell to approximately 15% in the stiffness-predominant stage.

1.7.2. Minimally invasive treatments

Acupuncture

Background: Acupuncture can be used to treat the pain of contracted (frozen) shoulder. It involves inserting needles into the skin at sites which vary from case to case and also depend on the practitioners' school of thought. Typically some needles will be placed near the shoulder and others distant from it. Once the patient feels some sensation at the needling sites, the needles may simply be left in place for the treatment session; in other circumstances they may be stimulated, either by manual manipulation or by small electric pulses. According to traditional theory,

acupuncture restores health by removing blockages in energy force. Western explanations lean towards nerve interactions and hormonal mechanisms (*see* TENS and interferential).

Results of CSP survey: The majority of respondents (61%) reported practising acupuncture, and 68% of respondents said that they might use or recommend acupuncture for pain-predominant contracted (frozen) shoulder. Only 10% said that they might use or recommend acupuncture for stiffness-predominant contracted (frozen) shoulder.

Injections

Corticosteroids

See above

Distension therapy (hydrodilation)

Background: Distension therapy involves injecting large volumes of fluid (saline or local anaesthetic, with or without steroid) into the shoulder joint, with the aim of distending or even rupturing the joint capsule.

Results of CSP survey: Not applicable.

Sodium hyaluronate

Background: Sodium hyaluronate (hyaluronic acid) can be injected into the shoulder joint to treat the pain of contracted (frozen) shoulder. It has less known potential for adverse effects than steroids, and some prefer it on these grounds.

Results of CSP survey: Not applicable (information on use of sodium hyaluronate was not sought).

1.7.3. Operative treatments

Arthroscopic capsular release and manipulation under anaesthetic (MUA)

Background: Arthroscopic capsular release is usually reserved for patients with contracted (frozen) shoulder whose symptoms do not improve with an adequate course of physiotherapy. The procedure is normally performed in conjunction with an MUA, and may reduce the potential harms of that procedure by allowing it to be done less forcefully. Using a 'keyhole' technique, the surgeon divides the capsule at the front and lower part of the joint. If the patient continues to lack external rotation in abduction, the capsule can also be released at the back of the joint. In addition to a general anaesthetic, it is normal for a regional nerve block to be given. This causes post-operative numbness and enables the patient to get moving at the earliest possible stage. Intensive physiotherapy is regarded as essential to a good outcome.

Results of CSP survey: Not applicable.

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2. Systematic review and meta-analysis of treatment interventions (comparisons involving standard physiotherapy)

This section gives an overview of the systematic review and meta-analysis of treatment interventions (comparisons involving standard physiotherapy) and concludes by enumerating the responses to the questionnaire survey. We have kept it as light and readable as possible, but it is unavoidably complex because it is derived from methodologically stringent processes which underpin our recommendations for management.

- **If you are not at all interested in the methods, you may choose to skip straight to the recommendations (starting on page 66 for text, and 78 for summary table)**.
- Conversely, if you would like more information on the methods than is given here, you can read pages 1 to 6 for a light general background or, for greater depth, APPENDICES A and A2. Also, there are signposts throughout this section to detailed supporting information in the APPENDICES.

2.1 Results of search and filtering processes 

After de-duplication our search, which addressed both standard and more specialised physiotherapy interventions, retrieved 749 citations, most with abstracts. Primary filtering left 84 citations. The secondary filtering process excluded 66 of these (APPENDIX C: Table of excluded studies; APPENDIX D: References to table of excluded studies). Thus 18 trials remained, 14 of which included standard physiotherapy, the focus of the first version (*version 1.X)* of the guidelines. (*See* Table 2.1).

Intervention (or comparison)	Number of reports
Standard physiotherapy	14
Acupuncture	1
Steroid injection	5
Hyaluronate injection	2
Capsular distension	5
Manipulation under anaesthetic	2
Supervised neglect	1

TABLE 2.1. Included trials by intervention (or comparison). Some reports are included in more than one category.

To the 14 trials including standard physiotherapy, which we had derived from our own search, we added five trials on contracted (frozen) shoulder identified in Green, Buchbinder and Hetrick

(2003), the Cochrane review on standard physiotherapy. This gave a total of 19 trials including standard physiotherapy (Table 2.2). These involved various comparisons (34 in all) encompassing other standard physiotherapy interventions (home exercises, supervised physiotherapy) and pharmacological interventions.

Intervention	Number of reports
Standard physiotherapy	19
Acupuncture	1
Steroid injection	9
Hyaluronate injection	2
Capsular distension	5
Manipulation under anaesthetic	2
Supervised neglect	1

TABLE 2.2. Included trials by intervention (or comparison). Some reports are included in more than one category. This table incorporates trials identified in Green, Hetrick and Buchbinder (2003), the Cochrane review on standard physiotherapy interventions.

Detailed descriptions of these trials are given in (APPENDIX B: Table of included trials).

2.2. Methodological quality of trials considered for inclusion 

The methodological quality of trials considered for inclusion is summarised in TABLE 2.3.

Trial	Eligibility criteria specified	Random allocation	Concealed allocation	Groups similar at baseline	Blinding of subjects	Blinding of therapists	Blinding of assessors	Intention-to-treat	Point measures and measures of variability
Buchbinder et al (2007)	✓	✓	✓	✓	✓		✓	✓	✓
Bulgen et al (1984)	✓	✓					✓		
Calis et al (2006)	✓	✓		✓				✓	✓
Carette et al (2003)	✓	✓	✓	✓*	✓	✓	✓	✓	✓
Cheing, So and Chao (2008)	✓	✓		✓			✓		✓
Dacre, Beeney and Scott (1989)	✓	✓		✓			✓		
Ginn and Cohen (2005)	✓	✓	✓	✓			✓	✓	✓
Guler-Uysal and Kozanoglu (2004)	✓			✓			✓		✓
Johnson et al (2007)	✓	✓	✓	✓					✓
Khan et al (2005)	✓	✓		✓					
Kivimäki et al (2007)	✓	✓	✓	✓			✓	✓	✓
Lee et al (1973)	✓	✓	✓				✓		
Leung and Cheing (2008)	✓	✓	✓	✓			✓	✓	✓
Nicholson (1985)	✓	✓		✓			✓		✓
Pajareya et al (2004)	✓	✓	✓	✓			✓	✓†	✓
Ryans et al (2005)	✓	✓	✓	✓		✓	✓		✓
Van der Windt et al (1998)	✓	✓	✓	✓			✓	✓	✓
Vermeulen et al (2006)	✓	✓	✓	✓	✓		✓	✓	✓
Yang et al (2007)	✓	✓	✓	✓			✓	✓	✓

TABLE 2.3. Methodological quality of trials considered for inclusion. *Analyses were adjusted for unequal distribution of gender. †Reportedly yes, but not done in analysis. (Verhagen et al 1998, http://www.pedro.fhs.usyd.edu.au/)

The median sample size was 80 (range 18–149; interquartile range 41–104), and about half of the trials (9/19) were of good methodological quality (low risk of bias). In the remainder there were deficiencies in random allocation (Guler-Uysal & Kosanoglu 2004), allocation concealment (Bulgen et al 1984, Calis et al 2006, Cheing, So & Chao 2008, Dacre, Beeney & Scott 1989, Guler-Uysal & Kosanoglu 2004, Khan et al 2005, Nicholson 1985); or blinding of assessors (Calis et al 2006, Johnson et al 2007, Khan et al 2005). Each of these methodological deficiencies has been

empirically linked to overestimation of treatment effects. Trials with inadequate allocation concealment have been found to exaggerate treatment effects by around 40% on average (Moher et al 1998, Schulz et al 1995). Schulz et al (1995) have additionally shown that trials with unclear concealment methods exaggerate treatment effects by an average of 30%. Furthermore, Jüni et al (1999) found that trials with non-blinded outcome assessment exaggerate treatment effects by 35%.

Nine trials (Bulgen et al 1984, Cheing, So & Chao, 2008, Dacre, Beeney & Scott 1989, Guler-Uysal & Kozanoglu 2004, Khan et al 2005, Lee et al 1973, Nicholson 1985, Pajareya et al 2004, Ryans et al 2005) did not conduct analyses by intention-to-treat. In trials with drop-outs or other exclusions after randomisation, absence of intention-to-treat analysis might theoretically bias estimates of treatment effects (Cochrane Handbook 2009, Strauss et al 2005). Of the nine trials, Pajareya et al (2004) and Ryans et al (2005) were free of the three key methodological deficiencies empirically linked to bias (*see* above) and were included in the review. In Pajareya et al (2004) the drop-outs were very few (3%) and unlikely to be influential and there were no other exclusions after randomisation. In Ryans et al (2005) drop-outs/exclusions were 10% at 6 weeks and 29% at 16 weeks. Mindful of possible bias in this latter study, especially at 16 weeks, special note was made of drop-outs'/exclusions' distribution across groups relative to the probable direction and magnitude of bias; and of concordance between its results and those of Carette et al (2003), which was similar in terms of comparisons and follow-up points. These measures provided reassurance as to the results' validity.

2.3. Results of analyses 

Our protocol did not anticipate that there would be so many comparisons in so many trials with a moderate-to-high risk of bias (TABLE 2.3). Faced with this contingency, we limited further analyses to comparisons in those trials with a low risk of bias (TABLE 2.4). These comparisons could be grouped under six main headings:

1. Physiotherapy versus other physiotherapy
2. Physiotherapy versus other treatments
3. Physiotherapy versus combinations of physiotherapy and other treatments
4. Adding physiotherapy to other treatments
5. Adding physiotherapy elements to combinations of physiotherapy and other treatments
6. Adding other treatments to physiotherapy

The trials concerned used a range of outcome measures. For dichotomous outcomes (e.g. 'improved'/'not improved') we calculated the Relative Risk (RR) and its 95% confidence interval (95% CI). For outcomes measured on continuous scales we calculated the Mean Difference (MD) and its 95% CI.

Trial	Eligibility criteria specified	Random allocation	Concealed allocation	Groups similar at baseline	Blinding of subjects	Blinding of therapists	Blinding of assessors	Intention-to-treat	Point measures and measures of variability
Buchbinder et al (2007)	✓	✓	✓	✓	✓		✓	✓	✓
Bulgen et al (1984)	✓	✓					✓		
Calis et al (2006)	✓	✓		✓				✓	✓
Carette et al (2003)	✓	✓	✓	✓*	✓	✓	✓	✓	✓
Cheing, So and Chao (2008)	✓	✓		✓			✓		✓
Dacre, Beeney and Scott (1989)	✓	✓		✓			✓		
Ginn and Cohen (2005)	✓	✓	✓	✓			✓	✓	✓
Guler-Uysal and Kozanoglu (2004)	✓			✓			✓		✓
Johnson et al (2007)	✓	✓	✓	✓					✓
Khan et al (2005)	✓	✓		✓					
Kivimäki et al (2007)	✓	✓	✓	✓			✓	✓	✓
Lee et al (1973)	✓	✓	✓				✓		
Leung and Cheing (2008)	✓	✓	✓	✓			✓	✓	✓
Nicholson (1985)	✓	✓		✓			✓		✓
Pajareya et al (2004)	✓	✓	✓	✓			✓	✓†	✓
Ryans et al (2005)	✓	✓	✓	✓		✓	✓		✓
Van der Windt et al (1998)	✓	✓	✓	✓			✓	✓	✓
Vermeulen et al (2006)	✓	✓	✓	✓	✓		✓	✓	✓
Yang et al (2007)	✓	✓	✓	✓			✓	✓	✓

TABLE 2.3a. Methodological quality trials considered for inclusion: trials with moderate to high risk of bias excluded (shaded). *Analyses were adjusted for unequal distribution of gender. †Reportedly yes, but not done in analysis. (Verhagen et al 1998, http://www.pedro.fhs.usyd.edu.au/)

To pool trials which measured the same outcome but with different tools, e.g. SPADI and SRQ, we calculated the Standardised Mean Difference (SMD) and its 95% CI. We then converted the SMD and its 95% CIs back into the units of one of the original outcomes, since these are more meaningful clinically than the SMD (Cochrane Handbook 2009). To further enhance clinical relevance, we reported the Minimal Clinically Important Difference (MCID), if known, for all outcomes. We derived within-subject MCIDs from the research literature, but multiplied these by 0.4. We applied this adjustment because between-groups MCID (i.e. an important difference between groups, as in a controlled trial) is thought to approximate to 40% of that within individuals (Finch et al 2002). These processes allowed us to see whether the 95% CI for a given outcome (a) overlapped zero and (b) overlapped the adjusted threshold for MCID on either side of zero. If the 95% CI did not overlap zero it could be stated, with 95% confidence, that there would be a

directional effect in the population from which the sample was drawn. (Whether this effect favoured the intervention or the control would depend upon the direction.) Furthermore, a 95% CI that lay entirely beyond the adjusted threshold for a MCID could be said, with 95% confidence, to represent a clinically important effect. (Again, whether this effect favoured the intervention or the control would depend upon the direction.) We also considered smaller effects with directional implications. Specifically, a 95% CI which crossed the adjusted threshold for MCID on only one side was interpreted as unidirectional potential for a clinically important effect: in this way, an outcome might have unidirectional potential for a clinically important effect even if its 95% CI crossed zero.

The comparisons are considered below.

2.3.1. Physiotherapy versus other physiotherapy

2.3.1.1. Adding outpatient physiotherapy (with passive mobilisations) to home exercises for both stages of contracted (frozen) shoulder

We pooled the results of two trials (Carette et al 2003, Ryans et al 2005), with a combined sample size of 86 for the relevant subgroups, which evaluated the addition of outpatient physiotherapy (with passive mobilisations) to home exercises for mixed-stage contracted (frozen) shoulder in primary and secondary care. The combined pain-function outcome in Carette et al (2003) was the Shoulder Pain and Disability Index (SPADI) and that in Ryans et al (2005) was the 22-point Shoulder Disability Questionnaire (SDQ). In addition, Carette et al (2003) separately reported the SPADI score for pain (a 100 mm VAS), and Ryans et al (2005) scored pain at rest on a 100 mm VAS. Both trials evaluated passive external rotation. Neither reported adverse effects/events as an outcome.

Assessment time points included 6 weeks (short term), 4–6 months (medium term) and, for Carette et al (2003) only, 12 months (long term).

Summary: One outcome (pain, short term) had unidirectional potential for a clinically important effect in the population, in the direction favouring the addition of outpatient physiotherapy. This was corroborated by passive external rotation, short term, for which an effect favouring the addition of outpatient physiotherapy could be attributed to the population with 95% confidence; though the stand-alone clinical importance of this latter effect (<13°) is uncertain. The trial reports did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Combined pain-function outcome, short term (6 weeks)
Result: P = 0.59, SMD = 0.11 [-0.30, 0.53] and *see* FIGURE 2.1.
Result re-expressed as SPADI: Mean Difference (MD) = 1.85 [-5.03, 8.99].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. The pooled 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

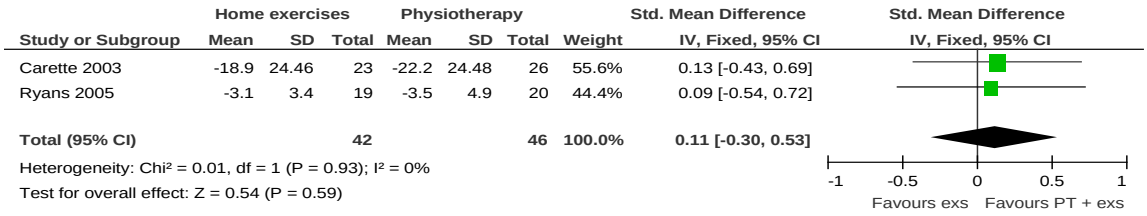

FIGURE 2.1

Combined pain-function outcome, medium term (4–6 months)

Result: P = 0.80, SMD = 0.06 [-0.39, 0.51] and *see* FIGURE 2.2.

Result re-expressed as SPADI: 1.01 [-6.54, 8.56].

*Adjusted threshold for MCID (calculated from data in Paul et al 2004):*3.2.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. The pooled 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

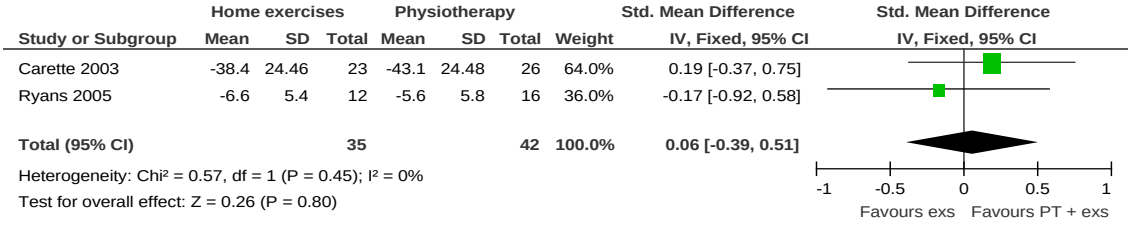

FIGURE 2.2

Combined pain-function outcome (SPADI), long term (12 months)

Result: P = 0.82, MD = -1.70 [-15.47, 12.07].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the home exercises only group in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We pooled the short term and medium term results for the SPADI pain score (a 100 mm VAS) in Carette et al (2003) with those for the 100 mm VAS for pain at rest in Ryans et al (2005). No long term results were reported by Ryans et al (2005).

Pain (100 mm VAS), short term (6 weeks)

Result: P =0.26, MD = 7.09 mm [-5.22, 19.40] and *see* FIGURE 2.3.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was clinically important but not statistically significant

favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but only the only potential for a clinically important effect was in the direction favouring the addition of outpatient physiotherapy.

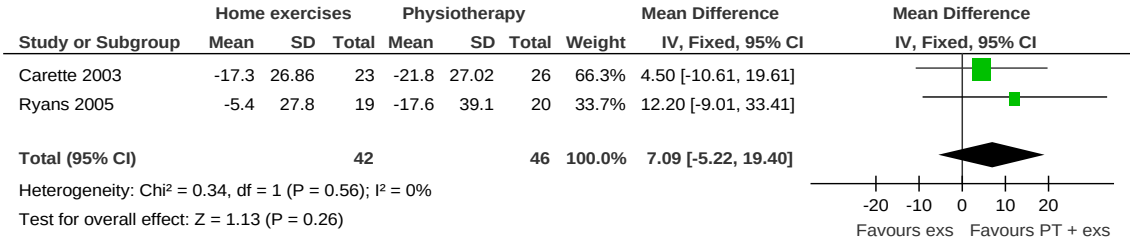

FIGURE 2.3

Pain (100 mm VAS), medium term (4–6 months)

Result: P = 0.31, MD = 6.72 mm [-6.27, 19.71] and *see* FIGURE 2.4.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was clinically important but not statistically significant favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. The pooled 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

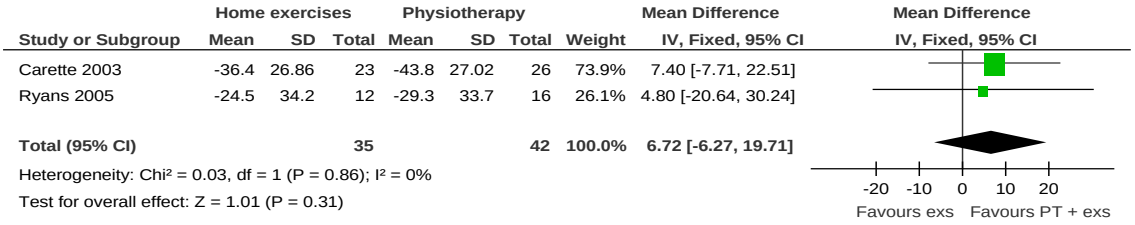

FIGURE 2.4

Pain (100 mm VAS), long term (12 months)

Result: P = 0.99, MD = 0.10 mm [-15.01, 15.21]

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: There was no substantive mean difference between groups in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We also pooled the short term and medium term results for improvement in passive external rotation (degrees) in Carette et al (2003) and Ryans et al (2005). No long term results were reported by Ryans et al (2005).

Passive external rotation (degrees), short term (6 weeks)

Result: P = 0.03, MD = 6.68° [0.53, 12.82] and *see* FIGURE 2.5.

Adjusted threshold for MCID: MCID not known.

Interpretation: A mean effect which was statistically significant favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. Based on the pooled 95% CI, a similarly directional effect would be anticipated in the population. The clinical importance of such an effect (< 13°) is uncertain.

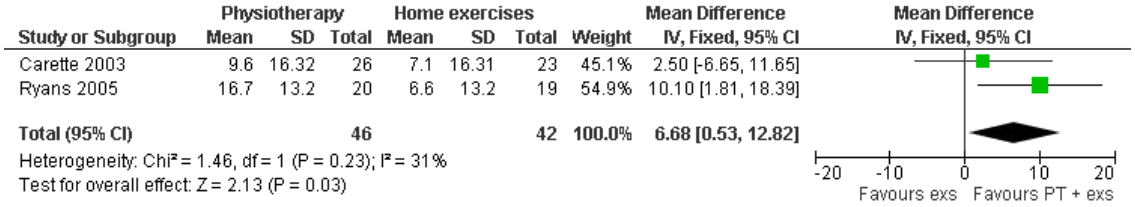

FIGURE 2.5

Passive external rotation (degrees), medium term (4–6 months)

Result: P = 0.79, MD = 1.44° [-6.59, 9.48] and *see* FIGURE 2.6.

Adjusted threshold for MCID: MCID not known.

Interpretation: A trivial mean effect which was not statistically significant favoured the addition of outpatient physiotherapy to home exercises in the pooled study sample. The pooled 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 10°) is also uncertain.

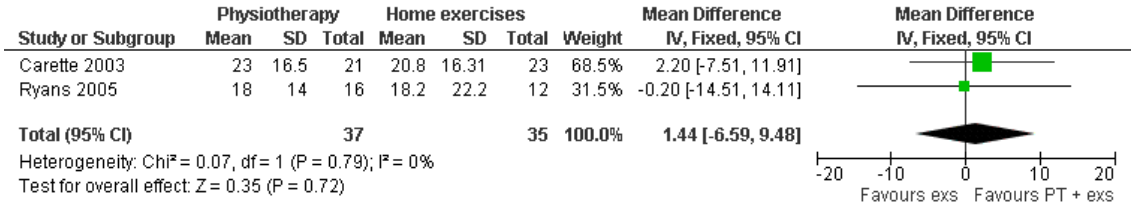

FIGURE 2.6

Passive external rotation (degrees), long term (12 months)

Result: P = 0.80, MD = 1.20° [-7.95, 10.35].

Adjusted threshold for MCID: MCID not known.

Interpretation: A trivial mean effect which was not statistically significant favoured the addition of outpatient physiotherapy to home exercises in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 11°) is also uncertain.

2.3.1.2. Home 'muscle function retraining programme' versus outpatient physiotherapy (with passive mobilisations) and standard home exercises for both stages of contracted (frozen) shoulder

In a subgroup of 50 patients with mixed-stage contracted (frozen) shoulder in secondary care, Ginn and Cohen (2005) compared an individualised programme of home exercises (a 'muscle function retraining programme') to a combination of outpatient physiotherapy (with passive mobilisations) and standardised home exercises. Outcomes were assessed at 5 weeks (short term) only and included patients' global perceptions of change: 'improved', 'stable' or 'deteriorated'. No subgroup-specific results were reported for pain, and passive external rotation was not among the outcome measures. Adverse effects were reported.

Summary: It is uncertain in which direction (if any) an effect would occur in the population. Adverse effects/events were equally distributed across groups. *See* below for detailed analysis.

Patients' global perception of change, short term (5 weeks)

We pooled the 'stable' and 'deteriorated' categories, and compared these to the 'improved' category for analysis.

Result: P = 0.37, RR = 0.87 [0.65, 1.17]).

Adjusted threshold for MCID: Not applicable (dichotomous outcome).

Interpretation: A small mean effect, which was not statistically significant, favoured outpatient physiotherapy and standard home exercises in the study sample. The 95% CI crossed one. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Adverse effects, short term (5 weeks)

Result: One subject in the muscle function retraining programme group (1/23 = 4.3%) and one in the outpatient physiotherapy and standardised home exercise group (1/26 = 3.8%) experienced 'deterioration' over the 5 week study period. No further details were given.

2.3.1.3. High grade mobilisations versus low grade mobilisations for stiffness-predominant contracted (frozen) shoulder

In a trial of 100 patients with stiffness-predominant contracted (frozen) shoulder in secondary care, Vermeulen et al (2006) compared a package of physiotherapy including high grade mobilisations to a similar package containing low grade mobilisations. Outcomes were assessed at 3 months (short term), 6 months (medium term) and 12 months (long term). Outcomes included the SRQ; pain during movement, at rest and at night, recorded on a 100 mm VAS; and passive external rotation measured using a goniometer. Also recorded was patient-reported, global assessment of change relative to baseline ('much better', 'better', 'no change', 'worse', 'much worse'). However, the 'worse' and 'much worse' categories were pooled with 'no change', so the proportion of adverse effects cannot be ascertained from the trial report.

Summary: For five outcomes the results indicated unidirectional potential for clinically important effects in the population. For four of these outcomes (SRQ, medium and long term; 100 VAS for night pain, long term; and 100 mm VAS for pain on use, long term) the potential was in the direction favouring high grade mobilisations. Also, for passive external rotation (long term), a treatment effect favouring high grade mobilisations could be attributed to the population with 95% confidence, though the stand-alone clinical importance of this (< 13°) is uncertain. For one outcome (pain at rest, short term) the potential for a clinically important effect was in the other direction, favouring low grade mobilisations. The manner of reporting precludes ascertainment of adverse effects. *See* below for detailed analysis.

SRQ, short term (3 months)
Result: P = 0.75, MD = 2.00 [-10.07, 14.07].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.2.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

SRQ, medium term (6 months)
Result: P = 0.20, MD = 4.50 [-2.40, 11.40].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.2.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring high grade mobilisations.

SRQ, long term (12 months)
Result: P = 0.07, MD = 6.60 [-0.61, 13.81].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.2.
Interpretation: A mean effect which was clinically important but fell short of statistical significance favoured high grade mobilisations in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring high grade mobilisations.

Night pain (100 mm VAS), 3 months (short term)
Result: P =0.58, MD = 3.80 mm [-9.75, 17.35]
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Night pain (100 mm VAS), 6 months (medium term)
Result: P = 0.58, MD = 7.10 mm [-7.10, 21.30].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important but not statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Night pain (100 mm VAS), 12 months (long term)
Result: P = 0.23, MD = 7.80 mm [-4.91, 20.51].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important but not statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring high grade mobilisations.

Pain at rest (100 mm VAS), 3 months (short term)
Result: P = 0.2, MD = -7.10 mm [-17.90, 3.70].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important but not statistically significant favoured low grade mobilisations in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring low grade mobilisations.

Pain at rest (100 mm VAS), 6 months (medium term)
Result: P = 0.74, MD = -2.00 [-13.74, 9.74]
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured low grade mobilisation in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Pain at rest (100 mm VAS), 12 months (long term)
Result: P = 0.87, MD -0.90 mm [-11.68, 9.88].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured low grade mobilisation in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Pain on use (100 mm VAS), 3 months (short term)
Result: P = 0.65, MD = 2.60 mm [-8.46, 13.66]
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured high grade mobilisation in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Pain on use (100 mm VAS), 6 months (medium term)
Result: P = 0.93, MD = 0.50 mm [-10.19, 11.19].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured high grade mobilisation in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Pain on use (100 mm VAS), 12 months (long term)
Result: P = 0.26, MD = 6.60 mm [-4.99, 18.19].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important but not statistically significant favoured high grade mobilisations in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring high grade mobilisations.

Passive external rotation (degrees), short term (3 months)
Result: P = 0.58, MD 1.40° [-3.50, 6.30].
Adjusted threshold for MCID: MCID not known.
Interpretation: A trivial mean effect favoured high grade mobilisations in the study sample. This effect was not statistically significant. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (<7°) is also uncertain.

Passive external rotation (degrees), medium term (6 months)
Result: P = 0.12, MD 4.10° [-1.03, 9.23].
Adjusted threshold for MCID: MCID not known.
Interpretation: A trivial mean effect favoured high grade mobilisations in the study sample. This effect was not statistically significant. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (<10°) is also uncertain.

Passive external rotation (degrees), long term (12 months)
Result: P = 0.04, MD 6.50° [0.27, 12.73].
Adjusted threshold for MCID: MCID not known.
Interpretation: A small mean effect favoured high grade mobilisations in the study sample. This effect was statistically significant and, based on the 95% CI, a similarly directional effect would be anticipated in the population. The clinical importance of such an effect (< 13°) is uncertain.

2.3.1.4. MWMs and home exercises versus high grade mobilisations and home exercises for both stages of contracted (frozen) shoulder

In a secondary or tertiary care setting, Yang et al (2007) divided 27 patients with mixed-stage contracted (frozen) shoulder between A-B-A-C and A-C-A-B groups, where A was mid-range mobilisation, B end-range mobilisation and C mobilisations with movement (MWMs). We considered that only the second phases (B versus C) constituted a randomised controlled trial, since phases 1 and 3 were unrandomised and allocation in phase 4 was predictable. The outcome was the Flexi-level Scale of Shoulder Function (FLEX-SF), which was assessed at baseline and after each 3-week phase of the trial. Of relevance here was the measurement at 6 weeks (short term), comparing end-range mobilisations and home exercises with MWMs and home exercises.

Summary: It is uncertain in which direction (if any) an effect would occur in the population and whether such an effect would be clinically important. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Flexi-level Scale of Shoulder Function (FLEX-SF), short term (6 weeks)
Result: P = 0.5, MD 1.90 [-3.61, 7.41].
Adjusted threshold for MCID (calculated from data in Cook et al 2003): 1.21.
Interpretation: A mean effect which was clinically important but not statistically significant favoured MWMs in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

2.3.1.5. Adding SWD to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder

One trial of stiffness-predominant contracted (frozen) shoulder, with 10 patients per subgroup, (Leung & Cheing 2008) added shortwave diathermy (SWD) to a combination of outpatient physiotherapy (supervised stretching exercises without passive mobilisations) and home stretching exercises. Outcome measures were assessed at 8 weeks (short term) and included the patient-completed section of the ASES, which is intended to measure pain and functional limitation. (The physician-completed section of the ASES was also used. This involves measuring range of movement, and data for external rotation were separately reported; but it is unclear whether these measurements related to passive or active range.)

Summary: A clinically significant effect favouring the addition of SWD could be attributed to the population with approaching 95% confidence. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Patient-completed section of ASES, short term (8 weeks)
Result: P = 0.03, MD = 17.50 [1.76, 33.24].
Adjusted threshold for MCID (calculated from data in Michener, McClure & Sennett 2002): 2.56.
Interpretation: A mean effect which was clinically important and statistically significant

favoured the addition of SWD in the study sample. The 95% CI lay on the side of zero that favoured SWD, so an effect in this direction would be expected in the population. Moreover, almost all of the 95% CI exceeded the adjusted threshold for MCID, so a clinically important effect favouring SWD might be attributed to the population with approaching 95% confidence.

2.3.1.6. Adding hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder

In the same trial, Leung and Cheing (2008) added hot packs to a combination of outpatient physiotherapy (supervised stretching exercises without passive mobilisations) and home stretching exercises.

Summary: It is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Patient-completed section of ASES, short term (8 weeks)
Result: P = 0.59, MD = 4.00 [-10.38, 18.38].
Adjusted threshold for MCID (calculated from data in Michener, McClure & Sennett 2002): 2.56.
Interpretation: A mean effect which was clinically important but not statistically significant favoured the addition of hot packs in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

2.3.1.7. Outpatient physiotherapy (SWD and exercises) and home exercises versus outpatient physiotherapy (hot pack and exercises) and home exercises for stiffness-predominant contracted (frozen) shoulder

The study considered above (Leung & Cheing 2008) also conducted a head-to-head comparison of outpatient physiotherapy (SWD and exercises) and home exercises versus outpatient physiotherapy (heat pack and exercises) and home exercises.

Summary: The results indicated unidirectional potential for a clinically important effect in the population favouring SWD and exercises over heat pack and exercises. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Patient-completed section of ASES, short term (8 weeks)
Result: P = 0.09, MD = 13.50 [-2.16, 29.16].
Adjusted threshold for MCID (calculated from data in Michener, McClure & Sennett 2002): 2.56.
Interpretation: A mean effect which was clinically important but not statistically significant

favoured SWD over hot packs in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring SWD.

2.3.2. Physiotherapy versus other treatments

2.3.2.1. Intra-articular steroid injections versus outpatient physiotherapy (with mobilisations) for both stages of contracted (frozen) shoulder

One primary care-based trial of 109 patients, probably with mixed-stage contracted (frozen) shoulder, compared intra-articular steroid injections to outpatient physiotherapy (with mobilisations) (van der Windt et al 1998). Outcome measures included the 16-item SDQ; 100-point VAS for day and night pain and improvement in passive range of external rotation, with assessment time-points including 7 weeks (short term), 6½ months (medium term) and 12 months (long term). Adverse effects/events were recorded by the clinician and by patients on their own forms.

Summary: For one outcome (16-item SDQ, short term) a clinically important effect favouring intra-articular steroid injections could be attributed to the population with 95% confidence. For another outcome (passive external rotation, short term) an effect favouring intra-articular steroid injections could be attributed to the population with 95% confidence, though the stand-alone clinical importance of such an effect (< 21°) is uncertain. For two further short term outcomes (100 mm VAS for night pain; 100 mm VAS for day pain) a clinically important effect favouring intra-articular steroid injections could be attributed to the population with approaching 95% confidence. Additionally, the results of two medium term outcomes (16-item SDQ; passive external rotation) indicated unilateral potential for clinically important effects in the population, both in the direction favouring intra-articular steroid injections. Adverse effects/events were minor and equally distributed across groups.

Improvement in 16-item SDQ, short term (7 weeks)
Result: P = 0.00001, MD = 25.00 [14.81, 35.19].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.6.
Interpretation: A mean effect which was clinically important and highly statistically significant favoured intra-articular steroid injections in the study sample. Based on the 95% CI, a similarly directional, and clinically important, effect would be anticipated in the population.

Improvement in 16-item SDQ, medium term (6½ months)
Result: P = 0.1, MD = 10.00 [-1.88, 21.88].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.6.
Interpretation: A mean effect which was clinically important but not statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring intra-articular steroid injections.

Improvement in 16-item SDQ, long term (12 months)
Result: P = 0.54, MD = 4.00 [-8.64, 16.64].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 5.6.
Interpretation: A mean effect which was clinically important but not statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether any such an effect would be clinically important.

Night pain (100 mm VAS), short term (7 weeks)
Result: P = 0.01, MD = 14.00 mm [3.06, 24.94].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important and statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI lay on the side of zero that favoured intra-articular steroid injections, so an effect in this direction would be expected in the population. Moreover, almost all of the 95% CI exceeded the adjusted threshold for MCID, so a clinically important effect might be attributed to the population with approaching 95% confidence.

Night pain (100 mm VAS), medium term (6½ months)
Result: P = 0.89, MD = 1.00 mm [-13.53, 15.53].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: There was no substantive mean effect in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Night pain (100 mm VAS), long term (12 months)
Result: P = 0.77, MD = 2.00 mm [-11.59, 15.59].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Day pain (100 mm VAS), short term (7 weeks)
Result: P = 0.005, MD = 12.00 mm [3.69, 20.31].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was clinically important and highly statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI lay on the side of zero that favoured intra-articular steroid injections, so an effect in this direction would be expected in the population. Moreover, almost all of the 95% CI exceeded the adjusted threshold for MCID, so a clinically important effect might be attributed to the population with approaching 95% confidence.

Day pain (100 mm VAS), medium term (6½ months)
Result: P = 1.0, MD = 0.00 [-10.00, 10.00].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: There was no mean difference between groups in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Day pain (100 mm VAS), long term (12 months)
Result: P = 0.52, MD = 3.00 mm [-6.24, 12.24].
Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured intra-articular steroid injections in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Improvement in passive external rotation (degrees), short term (5 weeks)
Result: P < 0.00001, MD = 15.00° [9.31, 20.69]
Adjusted threshold for MCID: MCID not known.
Interpretation: The mean effect was highly statistically significant and favoured intra-articular steroid injections in the study sample. Based on the 95% CI, a similarly directional effect would be expected in the population. The clinical importance of such an effect (< 21°) is uncertain.

Improvement in passive external rotation (degrees), medium term (6½ months)
Result: P = 0.02, MD = 9.00° [1.64, 16.36]
Adjusted threshold for MCID: MCID not known.
Interpretation: The mean effect was statistically significant and favoured intra-articular steroid injections in the study sample. Based on the 95% CI, a similarly directional effect would be expected in the population. The clinical importance of such an effect (< 16°) is uncertain.

Adverse events
Fifty-three percent of the injection group and 56% of the physiotherapy group reported adverse effects/events. (Note that, in a deviation from protocol, 5 patients were treated with both interventions.) These adverse effects/events were minor, and included: pain lasting a day or less after treatment (9 patients in the intra-articular steroid injections group; 17 patients in the physiotherapy group); pain lasting 2 days or more after treatment (16 patients in the intra-articular steroid injections group; 13 patients in the physiotherapy group); facial flushing (9 patients in the intra-articular steroid injections group; 1 patient in the physiotherapy group); irregular menstruation (2 patients in the intra-articular steroid injections group); self-diagnosed fever (2 patients in the intra-articular steroid injections group; 1 patient in the physiotherapy group); skin irritation (1 patient in the intra-articular steroid injections group; 2 patients in the physiotherapy group); and other events, including

sweating, fatigue, dry mouth, dizziness and headache (6 patients in the intra-articular steroid injections group), and slight swelling, tingling and radiating pain (4 patients in the physiotherapy group).

2.3.2.2. Home muscle function retraining programme versus a subacromial steroid injection for both stages of contracted (frozen) shoulder

In a subgroup of 45 patients with mixed-stage contracted (frozen) shoulder in secondary care, Ginn and Cohen (2005) compared an individualised programme of home exercises (a 'muscle function retraining programme') to a subacromial steroid injection. Outcomes were assessed at 5 weeks (short term) and included patients' global perceptions of change: 'improved', 'stable' or 'deteriorated'. No subgroup-specific results were reported for pain, and passive external rotation was not among the outcome measures. Adverse effects were reported.

Summary: There was no substantive difference between groups in terms of the proportions 'improved', and none would be inferred to the population. Adverse effects/events were equally distributed across groups. *See* below for detailed analysis.

Patients' global perception of change, short term (5 weeks)

We pooled the 'stable' and 'deteriorated' categories, and compared these to the 'improved' category for analysis.

Result: P = 0.79, RR = 0.96 [0.69, 1.33].

Adjusted threshold for MCID: MCID not known.

Interpretation: There was no substantive difference between groups and none would be inferred to the population.

Adverse events, short term (5 weeks)

One patient in the muscle function retraining programme group (1/24 = 4%) and one in the subacromial injection group (1/22 = 5%) experienced deterioration. No further details were given.

2.3.2.3. Subacromial steroid injection versus outpatient physiotherapy (with passive mobilisations) and home exercises versus a for both stages of contracted (frozen) shoulder

Ginn and Cohen (2005) compared a subacromial steroid injection to a combination of outpatient physiotherapy (with passive mobilisations) and standard home exercises in a subgroup of 48 patients with mixed-stage contracted (frozen) shoulder in secondary care. Outcomes were assessed at 5 weeks (short term) and included patients' global perceptions of change: 'improved', 'stable' or 'deteriorated'. No subgroup-specific results were reported for pain, and passive external rotation was not among the outcome measures. Adverse effects were reported.

Summary: There was no substantive difference between groups in terms of the proportions 'improved', and none would be inferred to the population. Adverse effects/events were equally distributed across groups. *See* below for detailed analysis.

Patients' global perception of change, short term (5 weeks)

We pooled the 'stable' and 'deteriorated' categories, and compared these to the 'improved' category for analysis.

Result: P = 0.52, RR = 0.91 [0.69, 1.21]

Adjusted threshold for MCID: MCID not known.

Interpretation: There was no substantive difference between groups, and none would be inferred to the population.

Adverse effects/events, short term (5 weeks)

Result: One patient in the outpatient physiotherapy and home exercises group (1/26 = 4%) and one in the subacromial injection group (1/22 = 5%) experienced deterioration. No further details were given.

2.3.3. Physiotherapy versus combinations of physiotherapy and other treatments

2.3.3.1. Outpatient physiotherapy (with passive mobilisations) and home exercises versus an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder

We pooled the results of two trials (Carette et al 2003, Ryans et al 2005), with a combined sample size of 88 for the relevant subgroups, which compared outpatient physiotherapy (with passive mobilisations) and home exercises to an intra-articular steroid injection and home exercises for mixed-stage contracted (frozen) shoulder in primary and secondary care. The combined pain-function outcome in Carette et al (2003) was the Shoulder Pain and Disability Index (SPADI) and that in Ryans et al (2005) was the 22-point Shoulder Disability Questionnaire (SDQ). In addition, Carette et al (2003) separately reported the SPADI score for pain (a 100 mm VAS), and Ryans et al (2005) scored pain at rest on a 100 mm VAS. Both trials evaluated passive external rotation. Neither reported adverse effects/events as an outcome.

Assessment time points included 6 weeks (short term), 4–6 months (medium term) and, for Carette et al (2003) only, 12 months (long term).

Summary: For one outcome (combined pain-function, short term) a clinically important effect favouring an intra-articular steroid injection could be attributed to the population with approaching 95% confidence. For two other outcomes (combined pain-function, medium term; pain, short term) the results indicated unidirectional potential for clinically important effects favouring an intra-articular steroid injection in the population. The trial reports did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Combined pain-function outcome, short term (6 weeks)

Result: P = 0.02, SMD = 0.52 [0.10, 0.95] and *see* FIGURE 2.7.

Result re-expressed as SPADI: MD = 8.73 [1.68, 15.94].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was clinically important and statistically significant favoured an intra-articular steroid injection in the pooled study sample. The pooled 95% CI lay on the side of zero that favoured an intra-articular steroid injection, so an effect in this direction would be expected in the population. Moreover, almost all of the 95% CI exceeded the adjusted threshold for MCID, so a clinically important effect favouring an intra-articular steroid injection might be attributed to the population with approaching 95% confidence.

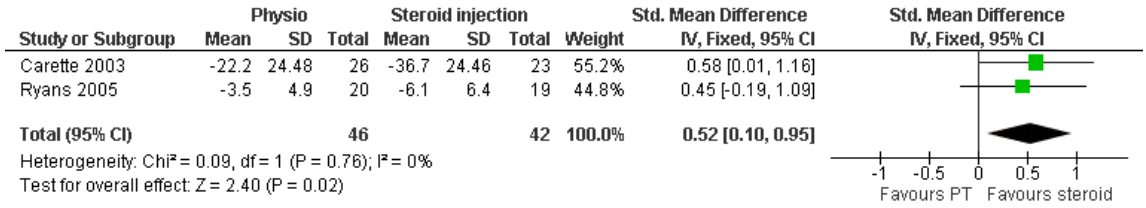

FIGURE 2.7

Combined pain-function outcome, medium term (4–6 months)

Result: P = 0.13, SMD = 0.34 [-0.11, 0.79].

Result re-expressed as SPADI: 5.71 [-1.85, 13.26].

Adjusted threshold for MCID (calculated from data in Paul et al. 2004): 3.2.

Interpretation: A mean effect which was clinically important but not statistically significant favoured an intra-articular steroid injection in the pooled study sample. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring an intra-articular steroid injection.

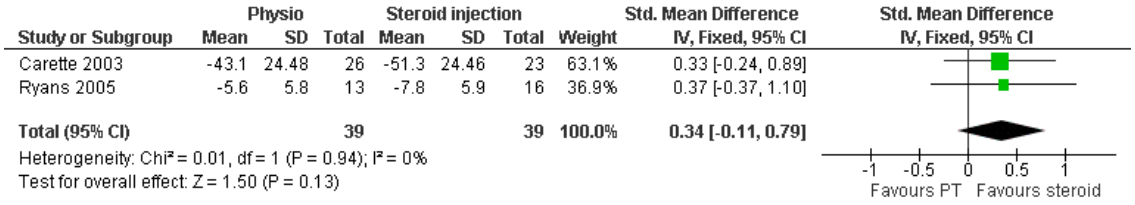

FIGURE 2.8

Combined pain-function outcome (SPADI), long term (12 months)

Result: P = 0.51, MD = 4.60 [-9.13, 18.33].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was clinically important but not statistically significant favoured an intra-articular steroid injection in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We pooled the short term and medium term results for the SPADI pain score (a 100 mm VAS) in Carette et al (2003) with those for the 100 mm VAS for pain at rest in Ryans et al (2005). No long term results were reported by Ryans et al (2005).

Pain (100 mm VAS), short term (6 weeks)

Result: P =0.17, MD = 8.42 mm [-3.73, 20.57] and *see* FIGURE 2.9.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: The results were heterogeneous, but a clinical explanation may tentatively be offered.[9] In the pooled study sample, a mean effect which was clinically important but not statistically significant favoured an intra-articular steroid injection. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring an intra-articular steroid injection.

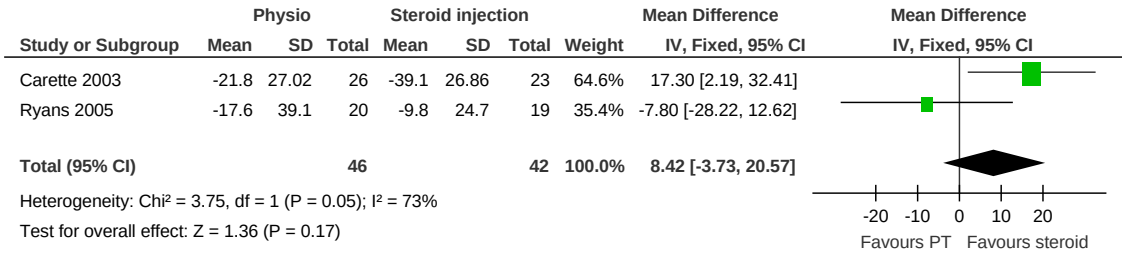

FIGURE 2.9

Pain (100 mm VAS), medium term (4–6 months)

Result: P = 0.83, MD = -3.24 mm [-33.17, 26.68] and *see* FIGURE 2.10.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: The results were heterogeneous. Although the explanation may be clinical,[9] such an attribution cannot be made with any confidence because of the susceptibility to bias of Ryans et al (2005) at this time point. Consequently the quality of the evidence is reduced. In the pooled study sample, a very small mean effect which was neither clinically important nor statistically significant favoured outpatient physiotherapy. The pooled 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero, so it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

[9] The heterogeneity is consistent with differences in injection accuracy—fluoroscopic guidance was used in Carette et al (2003), whereas the injections in Ryans et al (2005) were administered blindly—and a dose-response gradient.

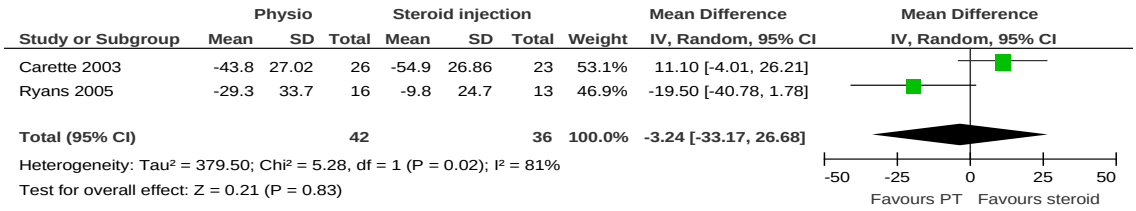

FIGURE 2.10

Pain (100 mm VAS), long term (12 months)

Result: P = 0.40, MD = 6.50 [-8.61, 21.61]

Adjusted threshold for MCID: (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was clinically important but not statistically significant favoured an intra-articular steroid injection in the study sample. The 95% CI crossed zero and the adjusted MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We also pooled the results for improvement in passive external rotation in the short term and medium term. No long term results were reported by Ryans et al (2005).

Passive external rotation (degrees), short term (6 weeks)

Result: P = 0.35, MD = 3.03° [-3.37, 9.43] and *see* FIGURE 2.11.

Adjusted threshold for MCID: MCID not known.

Interpretation: The results were marginally heterogeneous, but a clinical explanation may tentatively be offered.[10] In the pooled study sample, a mean effect which was not statistically significant favoured an intra-articular steroid injection. The pooled 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 10°) is also uncertain.

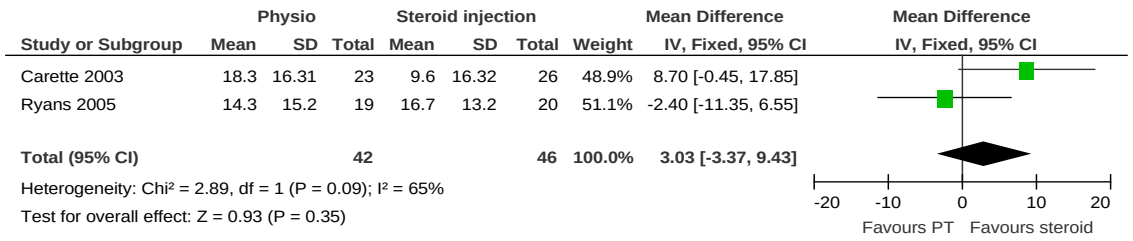

FIGURE 2.11

[10] The heterogeneity is consistent with differences in injection accuracy—fluoroscopic guidance was used in Carette et al (2003), whereas the injections in Ryans et al (2005) were administered blindly—and a dose-response gradient.

Passive external rotation (degrees), medium term (4–6 months)

Result: P = 0.22, MD = 4.61 [-2.77, 12.00] and *see* FIGURE 2.12.

Adjusted threshold for MCID: MCID not known.

Interpretation: A mean effect which was not statistically significant favoured an intra-articular steroid injection in the pooled study sample. The pooled 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (≤ 12°) is also uncertain.

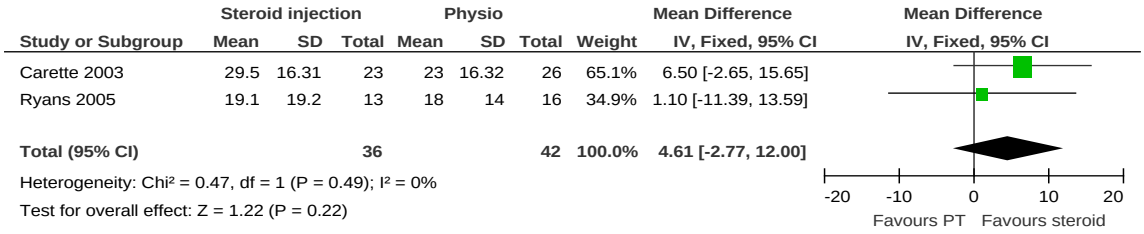

FIGURE 2.12

Passive external rotation (degrees), long term (12 months)

Result: P = 0.82, MD = -0.80 [-7.58, 5.98,]

Adjusted threshold for MCID: MCID not known.

Interpretation: There was no substantive mean difference between groups in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 8°) is also uncertain.

2.3.4. Adding physiotherapy to other treatments

2.3.4.1. Adding outpatient physiotherapy (with mobilisations) and home exercises to distension for both stages of contracted (frozen) shoulder

One trial of 149 patients with mixed-stage contracted (frozen) shoulder in primary and secondary care evaluated the effect of adding a package of outpatient physiotherapy (with passive mobilisations) and home exercises to arthrographic distension (Buchbinder et al 2007). Outcomes included SPADI; pain scores on a 10-point Likert scale, assessed globally, at night, at rest and on use; and adverse effects/events by open-ended questions. Assessment points included six weeks (short term) and six and a half months (medium term).

Summary: It is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

SPADI, short term (6 weeks)

Result: P = 0.89, MD = -0.50 [-7.60, 6.60].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: There was no substantive mean difference between groups in the study

sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

SPADI, medium term (6½ months)
Result: P = 0.52, MD = -2.40 [-9.69, 4.89]
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.
Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the distension-only group in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

Global pain, 10-point Likert scale, short term (6 weeks)
Result: P = 1.00, MD = 0.00 [-0.69, 0.69]
Adjusted threshold for MCID: MCID not known.
Interpretation: There was no mean difference between groups in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Global pain, 10-point Likert scale, medium term (6½ months)
Result: P = 0.81, MD = -0.10 [0.93, -0.73].
Adjusted threshold for MCID: MCID not known.
Interpretation: There was no substantive mean difference between groups in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Pain at night, at rest and on use, short term (6 weeks) and medium term (6½ months)
As in the preceding pain comparisons, mean differences between groups were either absent or trivial and the 95% CIs were equally uninformative.

2.3.4.2. Adding outpatient physiotherapy (with passive mobilisations) to NSAIDs for both stages of contracted (frozen) shoulder

One trial of 122 patients with mixed-stage contracted (frozen) shoulder in secondary care evaluated the addition of outpatient physiotherapy (with passive mobilisations) to NSAIDs (Pajareya et al 2004). Outcomes included the SPADI and range of external rotation (it was unclear whether this was passive or active), which were assessed at 3 weeks (short term), and adverse effects/events. Regarding the latter, the physiotherapy group were asked (a) whether or not they experienced pain for > 2 hours after treatment and (b) whether they had more disability next morning; and all patients were asked by a blinded rater 'Have the trial drugs and/or treatment programme upset you in any way?' and examined for signs of bruises or burns during evaluation of movement.

Summary: For SPADI, short term, a clinically important effect favouring the addition of outpatient physiotherapy could be attributed to the population with 95% confidence. Adverse effects/events ascribed to NSAIDs were more numerous and serious than those ascribed to physiotherapy. *See* below for detailed analysis.

SPADI, short term (3 weeks)
Result: P = 0.002, MD = 8.60 [3.28, 13.92].
Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.
Interpretation: A mean effect which was clinically important and statistically significant favoured the addition of physiotherapy in the study sample. Based on the 95% CI, a similarly directional, and clinically important, effect would be anticipated in the population.

Adverse effects, short term (3 weeks)
Result: Four patients (6.7%) reported, in total, 10 episodes of pain lasting > 2 hours after physiotherapy. Fifteen patients (12.5%) reported gastrointestinal side-effects of NSAIDs. Six of these had to stop taking NSAIDs due to severe dyspepsia. Two reported severe oedema (site not specified) and one a severe headache which quickly resolved when the drug treatment was discontinued.

2.3.5. Adding physiotherapy elements to combinations of physiotherapy and other treatments

2.3.5.1. Adding outpatient physiotherapy (with mobilisations) to an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder

We pooled the results of two trials (Carette et al 2003, Ryans et al 2005), with a combined sample size of 83 for the relevant subgroups, which evaluated the effect of adding outpatient physiotherapy (with mobilisations) to a package of an intra-articular steroid injection and home exercises for mixed-stage contracted (frozen) shoulder in primary and secondary care. The combined pain-function outcome in Carette et al (2003) was the Shoulder Pain and Disability Index (SPADI) and that in Ryans et al (2005) was the 22-point Shoulder Disability Questionnaire (SDQ). In addition, Carette et al (2003) separately reported the SPADI score for pain (a 100 mm VAS), and Ryans et al (2005) scored pain at rest on a 100 mm VAS. Both trials evaluated passive external rotation. Neither reported adverse effects/events as an outcome.

Assessment time points included 6 weeks (short term), 4–6 months (medium term) and, for Carette et al (2003) only, 12 months (long term).

Summary: For two short term outcomes (combined pain-function; pain) the results indicated unidirectional potential for clinically important effects in the population: in each case the potential was in the direction favouring the addition of outpatient physiotherapy. This was corroborated by passive external rotation, short term, for which an effect favouring the addition of outpatient physiotherapy could be attributed to the population with 95% confidence; though the stand-alone clinical importance of this effect (<15°) is uncertain. The trial reports did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Combined pain-function outcome, short term (6 weeks)

Result: P = 0.13, SMD = 0.34 [-0.10, 0.77] and *see* FIGURE 2.13.

Result re-expressed as SPADI: 5.71 [-1.68, 12.92].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the addition of outpatient physiotherapy in the pooled study sample. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring the addition of outpatient physiotherapy.

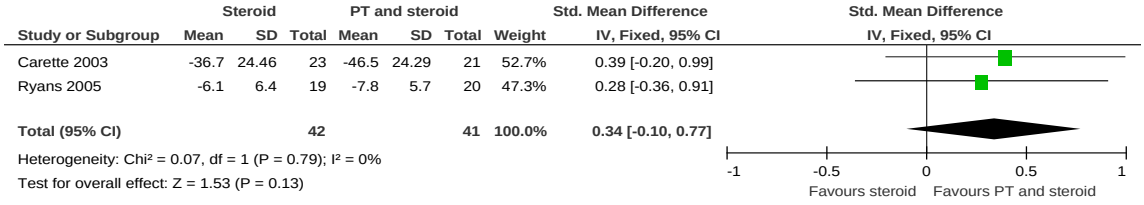

FIGURE 2.13

Combined pain-function outcome, medium term (4–6 months)

Result: P = 0.13, SMD = 0.02 [-0.44, 0.47] and *see* FIGURE 2.14.

Result re-expressed as SPADI: 0.34 [-7.38, 7.89].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: The mean effect for the pooled study sample was trivial. The pooled 95% CI crossed zero and the adjusted threshold for MCID in either direction. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

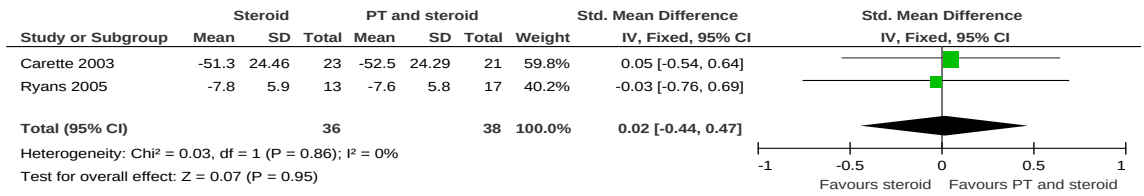

FIGURE 2.14

Combined pain-function outcome (SPADI), long term (12 months)

Result: P = 0.81, MD = 1.80 [-12.62, 16.22].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the addition of outpatient physiotherapy in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether any such an effect would be clinically important.

We pooled the short term and medium term results for the SPADI pain score (a 100 mm VAS) in Carette et al (2003) with those for the 100 mm VAS for pain at rest in Ryans et al (2005). No long term results were reported by Ryans et al (2005).

Pain, short term (6 weeks)

Result: P =0.14, MD = 7.93 mm [-2.69, 18.56] and *see* FIGURE 2.15.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was clinically important but not statistically significant favoured the addition of outpatient physiotherapy in the pooled study sample. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring the addition of outpatient physiotherapy.

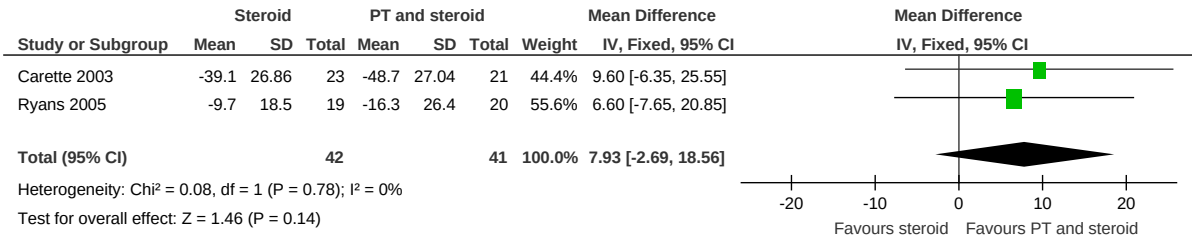

FIGURE 2.15

Pain (100 mm VAS), medium term (4–6 months)

Result: P =0.97, MD = 1.65 [-10.21, 13.51] and *see* FIGURE 2.16.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was clinically important but not statistically significant favoured the addition of outpatient physiotherapy in the pooled study sample. The pooled 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

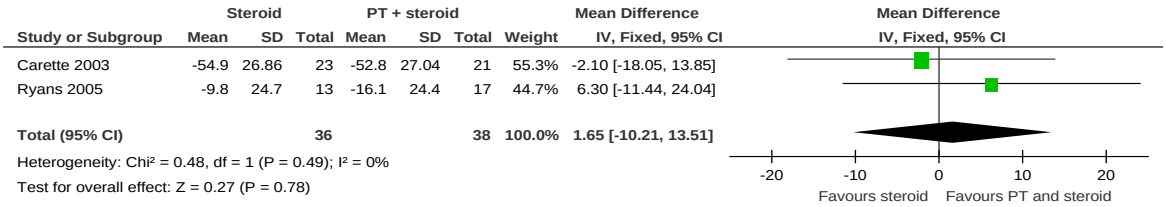

FIGURE 2.16

Pain (100 mm VAS), long term (12 months)

Result: P = 0.61, MD = -4.20 mm [-20.15, 11.75]

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009): 5.5 mm.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the intra-articular steroid injection and home exercises only group in the study sample. The 95% CI crossed zero and the 95% confidence interval for the adjusted MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We also pooled the results for improvement in passive external rotation in the short and medium term. No long term results were reported by Ryans et al (2005).

Passive external rotation (degrees), short term (6 weeks)

Result: P = 0.04, MD = 7.47° [0.52, 14.42] and *see* FIGURE 2.17.

Adjusted threshold for MCID: MCID not known.

Interpretation: A mean effect which was statistically significant favoured the addition of outpatient physiotherapy in the pooled study sample. Based on the pooled 95% CI, a similarly directional effect would be anticipated in the population. The clinical importance of such an effect (<15°) is uncertain.

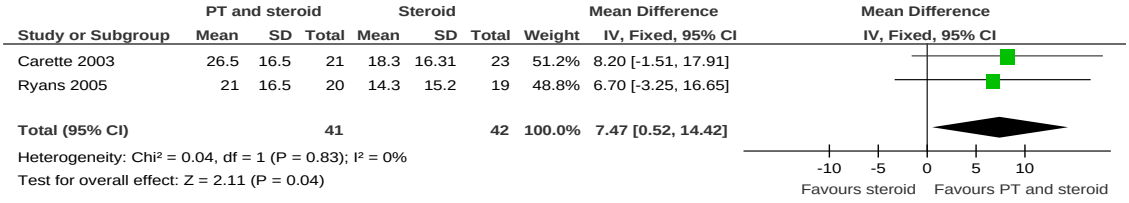

FIGURE 2.17

Passive external rotation (degrees), medium term (4–6 months)

Result: P = 0.42, MD = 3.30° [-4.68, 11.29] and *see* FIGURE 2.18.

Adjusted threshold for MCID: MCID not known.

Interpretation: A small mean effect, which was not statistically significant, favoured the addition of outpatient physiotherapy in the pooled study sample. The pooled 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 12°) is also uncertain.

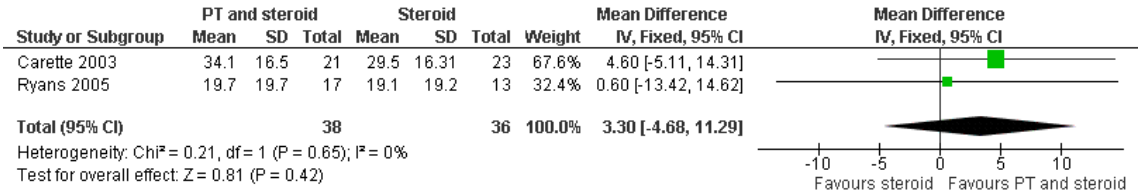

FIGURE 2.18

Passive external rotation (degrees), long term (12 months)

Result: P = 0.15, MD = 7.20° [-2.51, 16.91].

Adjusted threshold for MCID: MCID not known.

Interpretation: A small mean effect, which was not statistically significant, favoured the addition of outpatient physiotherapy in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of any such effect (< 17°) is also uncertain.

2.3.6. Adding other treatments to physiotherapy

2.3.6.1. Adding an intra-articular steroid injection to outpatient physiotherapy (with mobilisations) and home exercises for both stages of contracted (frozen) shoulder

We pooled the results of two trials (Carette et al 2003, Ryans et al 2005), with a combined sample size of 84 for the relevant subgroups, which evaluated the effect of adding an intra-articular steroid injection to a package of outpatient physiotherapy (with passive mobilisations) and home exercises for mixed-stage contracted (frozen) shoulder in primary and secondary care. The combined pain-function outcome in Carette et al (2003) was the Shoulder Pain and Disability Index (SPADI) and that in Ryans et al (2005) was the 22-point Shoulder Disability Questionnaire (SDQ). In addition, Carette et al (2003) separately reported the SPADI score for pain (a 100 mm VAS), and Ryans et al (2005) scored pain at rest on a 100 mm VAS. Both trials evaluated passive external rotation. Neither reported adverse effects/events as an outcome.

Assessment time points included 6 weeks (short term), 4–6 months (medium term) and, for Carette et al (2003) only, 12 months (long term).

Summary: For two short term outcomes (combined pain-function, pain) a clinically important effect favouring the addition of an intra-articular steroid injection could be attributed to the population with 95% confidence or approaching 95% confidence. This was corroborated by passive external rotation, short term and medium term, for each of which an effect favouring the addition of an intra-articular steroid injection could be attributed to the population with 95% confidence; though the stand-alone clinical importance of these latter effects (<18° and <16° respectively) is uncertain. The trial reports did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Combined pain-function outcome, short term (6 weeks)

Result: P = 0.0001, SMD = 0.89 [0.45, 1.34] and *see* FIGURE 2.19.

Result re-expressed as SPADI: 14.93 [7.56, 22.49].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was clinically important and highly statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. Based on the pooled 95% CI, a similarly directional, and clinically important, effect would be anticipated in the population.

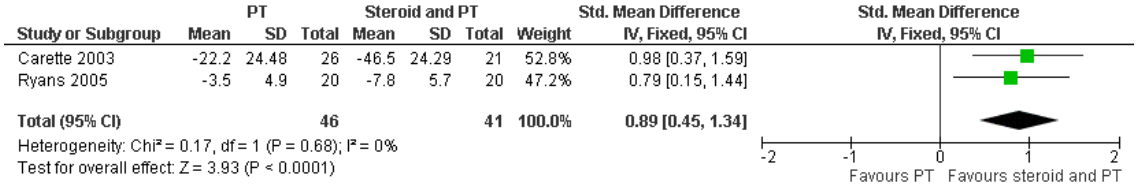

FIGURE 2.19

Combined pain-function outcome, medium term (4–6 months)

Result: P = 0.11, SMD = 0.36 [-0.08, 0.80] and *see* FIGURE 2.20.

Result re-expressed as SPADI: 6.04 [-1.34, 13.42].

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was clinically important but not statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. The pooled 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population, but the only potential for a clinically important effect was in the direction favouring the addition of an intra-articular steroid injection.

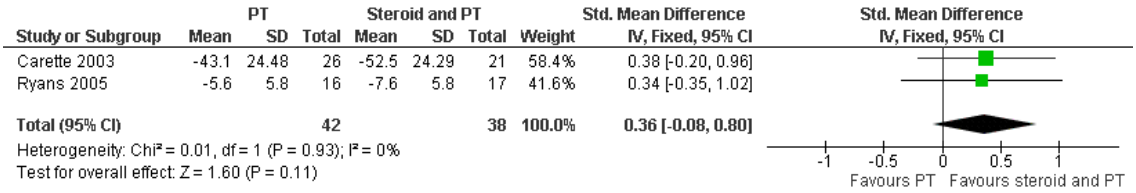

FIGURE 2.20

Combined pain-function outcome (SPADI), long term (12 months)

Result: P = 0.7, MD = 2.80 [-11.22, 16.82]

Adjusted threshold for MCID (calculated from data in Paul et al 2004): 3.2.

Interpretation: A mean effect which was neither clinically important nor statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We pooled the short term and medium term results for the SPADI pain score in Carette et al (2003) with those for the 100 mm VAS for global pain in Ryans (2005). No long term results were reported by Ryans et al (2005).

Pain (100 mm VAS), short term (6 weeks)

Result: P =0.008, MD = 16.72 [4.29, 29.14] and *see* FIGURE 2.21.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009)*:* 5.5 mm.

Interpretation: The results were heterogeneous, but a clinical explanation may tentatively be offered.[11] A mean effect which was clinically important and highly statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. Based on the pooled 95% CI, a similarly directional effect would be anticipated in the population. Almost all of the pooled 95% confidence interval exceeded the adjusted MCID in the direction favouring the addition of an intra-articular steroid injection, so a clinically important effect might be attributed to the population with approaching 95% confidence.

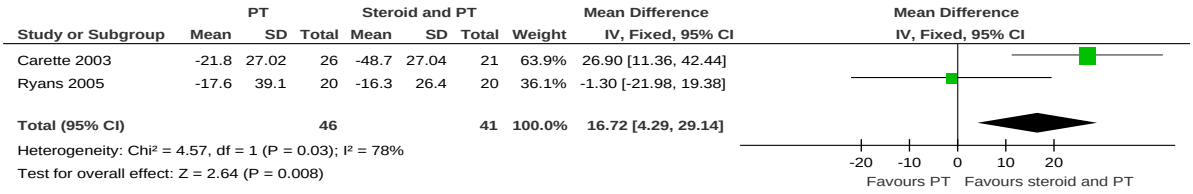

FIGURE 2.21

Pain (100 mm VAS), medium term (4–6 months)

Result: P = 0.92, MD = -1.17 mm [-22.85, 20.51] and *see* FIGURE 2.22.

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009)*:* 5.5 mm.

Interpretation: The results were marginally heterogeneous. Although the explanation may be clinical,[11] such an attribution cannot be made with any confidence because of the susceptibility to bias of Ryans et al (2005) at this time point. Consequently the quality of the evidence is reduced. In the pooled study sample, a mean effect which was neither clinically important nor statistically significant favoured outpatient physiotherapy alone. The pooled 95% CI crossed zero and the adjusted threshold for MCID in either direction. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

[11] The heterogeneity is consistent with differences in injection accuracy—fluoroscopic guidance was used in Carette et al (2003), whereas the injections in Ryans et al (2005) were administered blindly—and a dose-response gradient.

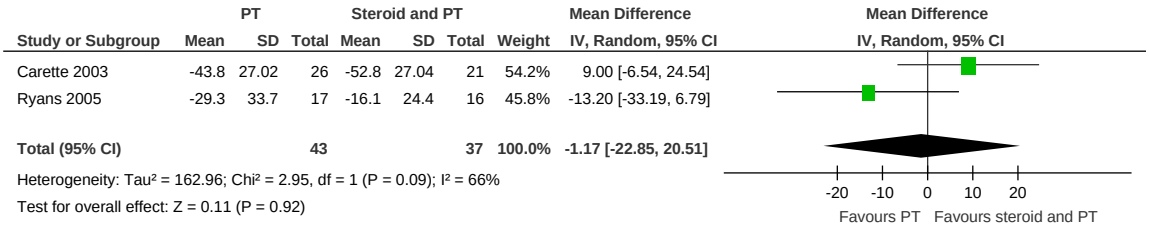

FIGURE 2.22

Pain (100 mm VAS), long term (12 months)

Result: P = 0.40, MD = 6.50 [-8.61, 21.61].

Adjusted threshold for MCID (calculated from data in Tashjian et al 2009)*:* 5.5 mm.

Interpretation: A mean effect which was not statistically significant favoured the addition of an intra-articular steroid injection in the study sample. The 95% CI crossed zero and the adjusted threshold for MCID on both sides of zero. Thus it is uncertain in which direction (if any) an effect would occur in the population, and whether such an effect would be clinically important.

We also pooled the results for improvement in passive external rotation in the short and medium term. No long term results were reported by Ryans et al (2005).

Passive external rotation, short term (6 weeks)

Result: P = 0.002, MD = 10.48 [-3.87, 17.09] and *see* FIGURE 2.23.

Adjusted threshold for MCID: MCID not known.

Interpretation: The results were heterogeneous, but a clinical explanation may tentatively be offered.[12] A mean effect which was statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. Based on the pooled 95% CI, a similarly directional effect would be anticipated in the population. The clinical importance of such an effect (< 18°) is uncertain.

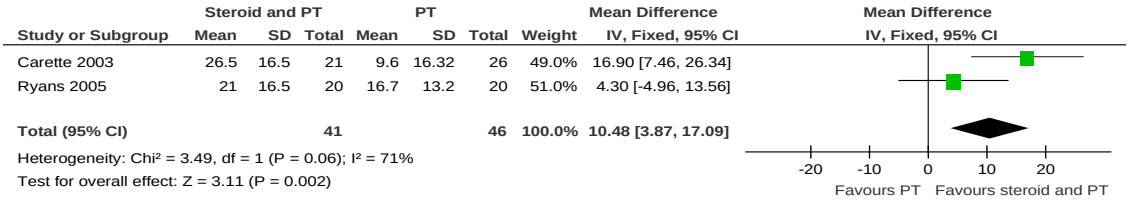

FIGURE 2.23

Passive external rotation, medium term (4–6 months)

Result: P = 0.05, MD = 7.40 [0.05, 14.76] and *see* FIGURE 2.24.

Adjusted threshold for MCID: MCID not known.

Interpretation: A mean effect which was statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. Based on the pooled 95% CI, a

[12] The heterogeneity is consistent with differences in injection accuracy—fluoroscopic guidance was used in Carette et al (2003), whereas the injections in Ryans et al (2005) were administered blindly—and a dose-response gradient.

similarly directional effect would be anticipated in the population. The clinical importance of such an effect (< 15°) is uncertain.

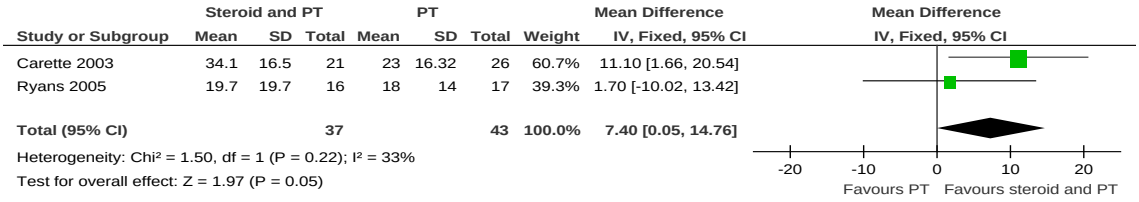

FIGURE 2.24

Passive external rotation (degrees), long term (12 months)

Result: P = 0.18, MD = 6.40° [-3.04, 15.84].

Adjusted threshold for MCID: MCID not known.

Interpretation: A mean effect which was not statistically significant favoured the addition of an intra-articular steroid injection in the pooled study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population. The clinical importance of such an effect (<16°) is also uncertain.

2.3.6.2. Adding MUA to home exercises for both stages of contracted (frozen) shoulder

One trial of 125 patients with mixed-stage contracted (frozen) shoulder in secondary care evaluated the addition of MUA to home exercises (Kivimäki et al 2007). Outcomes included a modified SDQ (2 questions were omitted from the standard 16-point questionnaire), pain intensity on an 11-point scale and passive external rotation. Adverse effects/events in individuals were not specified as outcomes. Assessments were undertaken in the short term (6 weeks), medium term (6 months) and long term (12 months).

Summary: It is uncertain in which direction (if any) a treatment effect would occur in the population. For three pain outcomes there was unilateral potential for clinically important effects, but this potential was very marginal and inconsistent in direction, favouring exercises only in the short term, and the addition of MUA in the medium and long term. The trial report did not specify adverse effects/events as an outcome. *See* below for detailed analysis.

Modified SDQ, short term (6 weeks)

Result (as reported): MD = 0.30 [-1.7, 2.3].

Adjusted threshold for MCID: MCID not known.

Interpretation: A small mean effect favoured the addition of MUA in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Modified SDQ, medium term (6 months)

Result (as reported): MD = -0.30 [-2.69, 2.75].

Adjusted threshold for MCID: MCID not known.

Interpretation: A small mean effect favoured the exercises-only group in the study sample.

The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Modified SDQ, medium term (6 months)
Result (as reported): MD = -0.30 [-2.75, 2.69].
Adjusted threshold for MCID: MCID not known.
Interpretation: A small mean effect favoured the exercises-only group in the study sample. The 95% CI crossed zero. Thus it is uncertain in which direction (if any) an effect would occur in the population.

Pain on 11-point NPRS, short term (6 weeks)
Result (as reported): MD = 0.20 [-0.64, 1.02].
Adjusted threshold for MCID (based on data from Salaffi et al 2004): 1.
Interpretation: There was no substantive mean effect in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population. The only potential for a clinically important effect (and this was only marginal) was in the direction favouring exercises-only.

Pain on 11-point NPRS, medium term (6 months)
Results (as reported): MD = 0.80 [-0.20, 1.80].
Adjusted threshold for MCID (based on data from Salaffi et al 2004): 1.
Interpretation: There was no substantive mean effect in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population. The only potential for a clinically important effect (and this was only marginal) was in the direction favouring the addition of MUA.

Pain on 11-point NPRS, long term (12 months)
Results (as reported): MD = 0.7 [-0.4, 1.80].
Adjusted threshold for MCID (based on data from Salaffi et al 2004): 1.
Interpretation: There was no substantive mean effect in the study sample. The 95% CI crossed zero, so it is uncertain in which direction (if any) an effect would occur in the population. The only potential for a clinically important effect (and this was only marginal) was in the direction favouring the addition of MUA.

Passive external rotation (degrees), short term
Results (as reported): MD = 5° [-2, 12].
Adjusted threshold for MCID: MCID not known.
Interpretation: A small mean effect, which was probably not clinically important, favoured the addition of MUA. The 95% CI was uninformative in respect of inferences to the population.

Passive external rotation (degrees), medium term
Results (as reported): MD = 6° [-2, 14].
Adjusted threshold for MCID: MCID not known.
Interpretation: A small mean effect, which was probably not clinically important, favoured the MUA group. The 95% CI was uninformative in respect of inferences to the population.

Passive external rotation (degrees), long term

Results (as reported): MD = 4° [-4.2, 12.2].

Adjusted threshold for MCID: MCID not known.

Interpretation: A small mean effect, which was probably not clinically important, favoured the addition of MUA. The 95% CI was uninformative in respect of inferences to the population.

2.4. Results of questionnaire survey of CSP members 

There were 289 valid responses. A full report is published elsewhere (Hanchard et al 2011).

2.5. References to Part 2 

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3. Recommendations for management of contracted (frozen) shoulder (comparisons involving standard physiotherapy)

Our recommendations for management of contracted (frozen) shoulder by 'standard physiotherapy' are set out and justified below. The process has, in some cases, involved comparison with other treatments (which will be the focus of future versions).

The justifications take account of the respective trials' results (*see* section 3), their risk of bias (we have only included RCTs and, moreover, only those RCTs judged to be at low risk of bias) and their GRADE quality assessments. Over and above risk of bias, GRADE quality assessments consider the following factors:

- inconsistency (which occurs when trials' results do not agree);
- indirectness (which occurs when the trials' results are inapplicable to the population of interest);
- imprecision (which occurs when the estimates of effect are wide); and
- publication bias (underestimation or overestimation of effects due to selective publication of studies).

An evidence quality grading ('high', 'moderate', 'low' or 'very low') is given accordingly, and influences the strength of the recommendation. The GRADE quality assessments are tabulated in APPENDIX E (GRADE evidence profile tables).

Our recommendations are summarised in TABLES 3a–e

3.1. Physiotherapy versus other physiotherapy

3.1.1. In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) to home exercises for both stages of contracted (frozen) shoulder?

References: Carette et al (2003), Ryans et al (2005).
Settings: Secondary care in Canada, primary care in Northern Ireland.

Synthesis: The median quality of the evidence was low for the critical outcomes (combined pain-function, pain) and moderate for the important but non-critical outcomes (passive external rotation).

In the short term, it was unclear in which direction (if any) an effect on combined pain-function would occur in the population, and whether any such effect would be clinically important (low quality evidence). Pain showed unidirectional potential for a clinically important effect in the population, favouring the addition of outpatient physiotherapy (moderate quality evidence). At this time point too, passive external rotation favoured the addition of outpatient physiotherapy, providing corroboration (moderate quality evidence).

In the medium and long term, it was unclear in which direction (if any) an effect on combined pain-function, pain (low quality evidence) or passive external rotation (moderate quality evidence) would occur in the population, and whether any such effect would be clinically important.

Potential harms of mechanical therapy include temporary aggravation of symptoms and would be expected to be common to both interventions, but adverse effects/events were neither quantified nor described in the trial reports.

Summary of evidence: In the short term, a combination of outpatient physiotherapy (including passive mobilisations, and modified according to the stage of the condition) and home exercises is potentially more beneficial for pain than home exercises alone (moderate quality evidence). Also at this time point, the results for passive external rotation favour the addition of outpatient physiotherapy (moderate quality evidence). Adverse effects/events are neither quantified nor described in the trial reports, but would be expected to be temporary, minor and common to both groups.

Recommendation: **Probably add outpatient physiotherapy (with passive mobilisations) to home exercises for both stages of contracted (frozen) shoulder in primary and secondary care.**

3.1.2. In secondary care, which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or outpatient physiotherapy (with passive mobilisations) and standard home exercises?

References: Ginn and Cohen (2005).
Settings: Secondary care in Australia.
Synthesis: The quality of the evidence was moderate for patients' global impression of change ('improved' versus 'not improved' or 'deteriorated') and adverse effects ('deteriorated'), both of which were critical outcomes and were only reported in the short term. The 95% CI for the absolute effect indicated that the home muscle function retraining programme would result in 296 fewer to 144 more 'improved' classifications per 1000 patients.

Potential harms of mechanical therapy include temporary aggravation of symptoms and would be expected to be common to both interventions. Adverse effects/events were not described in the trial report, but self-reports of 'deterioration' were quantified. The 95% CI for the absolute effect indicated that muscle function retraining would result in 36 fewer to 618 more 'deteriorated' classifications per 1000 patients.

Summary of evidence: The quality of the evidence is moderate but the estimates of effect relating to efficacy are imprecise and only short term outcomes are reported. Adverse effects/events would likely be minor, but there is potential for instances of 'deterioration' to be more numerous in patients treated with muscle function retraining.

Recommendation: **Probably use outpatient physiotherapy (with passive mobilisations) and standard home exercises in preference to a home muscle function retraining programme for both stages of contracted (frozen) shoulder in secondary care**.

3.1.3. In secondary care, which should we use for stiffness-predominant contracted (frozen) shoulder: high grade or low grade mobilisations?

References: Vermeulen et al (2006).
Settings: Secondary care in The Netherlands.
Synthesis: The median quality of the evidence was low for the critical outcomes (SRQ, pain) and moderate for the important but non-critical outcomes (passive external rotation).

Short term, pain at rest showed unidirectional potential for a clinically important effect in the population, and was alone in favouring low grade mobilisations (moderate quality evidence). For SRQ, night pain, and pain on use it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence); likewise for passive external rotation (moderate quality evidence).

In the medium term, SRQ showed unidirectional potential for a clinically important effect in the population, favouring high grade mobilisations (moderate quality evidence), and this was corroborated by passive external rotation, for which almost all of the 95% CI lay on the corresponding side of zero (moderate quality evidence). For the other outcomes (night pain, pain at rest, pain on use) it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

In the long term, SRQ, night pain and pain on use showed unidirectional potential for a clinically important effect in the population, favouring high grade mobilisations (moderate quality evidence), and were corroborated by passive external rotation, which showed a directional effect (moderate quality evidence). For pain at rest, it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

Adverse effects (self-reports of 'worse' or 'much worse') cannot be quantified, because these categories were pooled with 'no change' in the trial report.

Summary of evidence: Short term, low grade mobilisations are potentially more beneficial than high grade mobilisations for pain at rest (moderate quality evidence). Conversely, in the medium term, high grade mobilisations are potentially more beneficial than low grade mobilisations as judged by the SRQ (moderate quality evidence); and in the long term, high grade mobilisations are potentially more beneficial than low grade mobilisations as judged by the SRQ, and for night pain and pain on use (moderate quality evidence). Also, the results for passive external rotation favour high grade mobilisations in the medium term and especially the long term (moderate quality evidence). No specific data on adverse effects/events are provided in the trial report, though any such effects/events would likely be temporary and minor. On this basis, the potential benefits of high grade mobilisations are likely to outweigh the potential harms.

Recommendation: **Probably use high grade mobilisations (in preference to low grade mobilisations) for stiffness-predominant contracted (frozen) shoulder in secondary care.**

3.1.4. In secondary care, which should we add to home exercises for both stages of contracted (frozen) shoulder: high grade mobilisations or MWMs?

References: Yang et al (2007).
Settings: Secondary care in Taiwan.
Synthesis: The quality of the evidence was low. A single, critical, outcome—the FLEX-SF—was reported, and only in the short term. From the results, it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important.

Potential harms of mechanical therapy include temporary aggravation of symptoms and would be expected to be common to both interventions. Adverse effects/events were neither quantified nor described in the trial report, however.

Summary of evidence: The quality of the evidence is low, estimates of effect are imprecise and only a short term outcome (FLEX-SF) is reported. It is uncertain in which direction (if any) change would occur in the population, and whether any such change would be clinically important. Adverse effects/events would probably be minor and common to both interventions, although they are neither quantified nor described in the trial report; but uncertainty as to the interventions' relative benefits means that no recommendation for practice can be made.
Recommendation: **No recommendation**.

3.1.5. In secondary care, should we add SWD to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?

References: Leung and Cheing (2008).
Settings: Secondary care in Hong Kong.
Synthesis: The quality of the evidence was moderate. A single, critical, outcome—the patient-completed portion of the ASES—was reported, and only in the short term. From the results, a clinically important effect favouring the addition of SWD might cautiously be inferred to the population (approaching 95% confidence).

Potential harms of SWD include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events were neither quantified nor described in the trial report.

Summary of evidence: The quality of the evidence is moderate but only a short term outcome is reported. The patient-completed section of the ASES is suggestive of a clinically important effect favouring SWD in the population. Potential harms of SWD include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events are neither quantified nor described in the trial report.
Recommendation: **Probably add SWD to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder in secondary care**.

3.1.6. In secondary care, should we add hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?

References: Leung and Cheing (2008).
Settings: Secondary care in Hong Kong.
Synthesis: The quality of the evidence was low. A single, critical, outcome—the patient-completed portion of the ASES—was reported, and only in the short term. From the results, it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important.

Potential harms of hot packs include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events were neither quantified nor described in the trial report.

Summary of evidence: The quality of the evidence is low and only a short term outcome is reported. It is uncertain in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important. Potential harms of hot packs include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events are neither quantified nor described in the trial report.
Recommendation: **Probably don't add hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder in secondary care**.

3.1.7. In secondary care, which should we add to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder: SWD or hot packs?

References: Leung and Cheing (2008).
Settings: Secondary care in Hong Kong.
Synthesis: The quality of the evidence was moderate. A single, critical, outcome—the patient-completed portion of ASES—was reported, and only in the short term. The results showed unidirectional potential for a clinically important effect in the population, in the direction favouring the addition of SWD.

Potential harms of SWD and hot packs include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events were neither quantified nor described in the trial report.
Summary of evidence: The quality of the evidence is moderate but only a short term outcome is reported. Addition of SWD to home exercises is potentially more beneficial as judged by the patient-completed portion of ASES than the addition of hot packs. Potential harms of SWD and hot packs include burns, but there are well established protocols for minimising the risk of these occurring. Adverse effects/events are neither quantified nor described in the trial report.
Recommendation: **Probably add SWD (in preference to hot packs) to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder in secondary care.**

3.2. Physiotherapy versus other treatments 

3.2.1. In primary care, which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with mobilisations) or intra-articular steroid injections?

References: van der Windt et al (1998).
Settings: Primary care in The Netherlands.
Synthesis: The median quality of the evidence was moderate for the critical outcomes (SDQ, pain and adverse effects/events) and the important but non-critical outcomes (passive external rotation).

In the short term, a clinically important effect favouring intra-articular steroid injections could be inferred to the population for the SDQ (moderate quality evidence). A clinically important effect favouring intra-articular steroid injections could be cautiously inferred to the population (approaching 95% confidence) for two further outcomes: night pain and day pain (moderate quality evidence).

In the medium term, the only potential for a clinically important effect on the SDQ was in the direction favouring intra-articular steroid injections (moderate quality evidence). Other outcomes, at this time point and in the long term, were equivocal both in terms of the direction of their effects and their clinical importance.

Potential harms of physiotherapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary aggravation of symptoms and, possibly, diminished collagen density (Shibata et al 2001). Adverse effects/events were both quantified and described in the trial report (moderate quality evidence). Fifty-three percent of the injection group and 56% of the physiotherapy group reported adverse effects/events. (Note that, in a deviation from protocol, 5 patients were treated with both interventions.) These adverse effects/events were minor, and included: pain lasting a day or less after treatment (9 patients in the injection group; 17 patients in the physiotherapy group); pain lasting 2 days or more after treatment (16 patients in the injection group; 13 patients in the physiotherapy group); facial flushing (9 patients in the injection group; 1 patient in the physiotherapy group); irregular menstruation (2 patients in the injection group); self-diagnosed fever (2 patients in the injection group; 1 patient in the physiotherapy group); skin irritation (1 patient in the injection group; 2 patients in the physiotherapy group); and other events, including sweating, fatigue, dry mouth, dizziness and headache (6 patients in the injection group), and slight swelling, tingling and radiating pain (4 patients in the physiotherapy group). The 95% CI for absolute effect indicated that 185 fewer to 174 more patients per 1000 would suffer adverse effects/events with intra-articular steroid injections than with physiotherapy.
Summary of evidence: In the short term, intra-articular steroid injections are more beneficial as judged by the SDQ (moderate quality evidence), and probably more beneficial for day pain and night pain (moderate quality evidence), than outpatient physiotherapy. In the medium term, intra-articular steroid injections are potentially more beneficial as judged by the SDQ than outpatient physiotherapy (moderate quality evidence). For other efficacy-related outcomes, at this time point

and in the long term, the evidence is unclear both in terms of direction of effects and clinical importance.

The adverse effects/events reported were all minor. The 95% CI for relative risk indicate that 185 fewer to 174 more patients per 1000 would suffer adverse effects/events with intra-articular steroid injection than with physiotherapy. The possibility of longer term adverse effects of steroid injections (Shibata et al 2001) should be considered, however.

Recommendation: **Probably use intra-articular steroid injections rather than outpatient physiotherapy for both stages of contracted (frozen) shoulder in primary care.**

3.2.2. In secondary care, which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or a subacromial steroid injection?

References: Ginn and Cohen (2005).
Settings: Secondary care in Australia.
Synthesis: The quality of the evidence was moderate for patients' global impression of change ('improved' versus 'not improved' or 'deteriorated') and adverse effects/events ('deteriorated') , both of which were critical outcomes and were only reported in the short term. The 95% CI for the absolute effect indicated that the home muscle function retraining programme would result in 240 fewer to 255 more 'improved' classifications per 1000 patients.

Potential harms of mechanical therapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary aggravation of symptoms and, possibly, diminished collagen density (Shibata et al 2001). Adverse effects/events were not described in the trial report, but self-reports of 'deterioration' were quantified. The 95% CI for the absolute effect indicated that muscle function retraining would result in 43 fewer to 608 more 'deteriorated' classifications per 1000 patients.

Summary of evidence: The quality of the evidence is moderate but only short term outcomes are reported. There is no clear differential in terms of benefit. Muscle function retraining shows more potential for 'deterioration'.
Recommendation: **No recommendation for practice**.

3.2.3. In secondary care, which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) and home exercises or a subacromial steroid injection?

References: Ginn and Cohen (2005).
Settings: Secondary care in Australia.
Synthesis: The quality of the evidence was moderate for patients' global impression of change ('improved' versus 'not improved' or 'deteriorated') and adverse effects/events ('deteriorated'), both of which were critical outcomes and were only reported in the short term. The 95% CI for the absolute effect indicated that a subacromial steroid injection would result in 262 fewer to 178 more 'improved' classifications per 1000 patients.

Potential harms of mechanical therapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary aggravation of symptoms and, possibly,

diminished collagen density (Shibata et al 2001). Adverse effects/events were quantified but not described in the trial report. The 95% CI for the absolute effect indicated that a subacromial steroid injection would result in 35 fewer to 647 more 'deteriorated' classifications per 1000 patients.
Summary of evidence: The quality of the evidence is moderate but only short term outcomes are reported. The results show less potential for benefit with a subacromial steroid injection, and more potential for 'deterioration'.
Recommendation: **Probably use outpatient physiotherapy (with passive mobilisations) and home exercises in preference to a subacromial steroid injection for both stages of contracted (frozen) shoulder in secondary care**.

3.3. Physiotherapy versus combinations of physiotherapy and other treatments

3.3.1. In primary and secondary care, which should we add to home exercises for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) or an intra-articular steroid injection?

References: Carette et al (2003), Ryans et al (2005).
Settings: Secondary care in Canada, primary care in Northern Ireland.
Synthesis: The median quality of the evidence was low for the critical outcomes (combined pain-function, pain) and moderate for the important but non-critical outcomes (passive external rotation).

In the short term, a clinically important effect favouring an intra-articular steroid injection could be cautiously inferred to the population (approaching 95% confidence) for combined pain-function (moderate quality evidence). Pain showed unidirectional potential for a clinically important effect in the population, favouring an intra-articular steroid injection (moderate quality evidence).

In the medium term, combined pain-function showed unidirectional potential for a clinically important effect in the population, favouring an intra-articular steroid injection (low quality evidence). For the remaining outcomes, at this time point and in the long term, it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

Potential harms of mechanical therapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary worsening of symptoms and, possibly, diminished collagen density (Shibata et al 2001). Adverse effects/events were not quantified or described in the trial reports.

Summary of evidence: In the short term, addition of an intra-articular steroid injection to home exercises is probably more beneficial than addition of outpatient physiotherapy for combined pain-function, and potentially more beneficial for pain (moderate quality evidence). In the medium term, addition of an intra-articular steroid injection to home exercises is potentially more beneficial than addition of outpatient physiotherapy for pain (low quality evidence). Adverse effects/events are not quantified or described in the trial reports, but the results of another trial (van der Windt

1998) suggest that adverse effects/events would be fewer in the intra-articular steroid injection group. That trial did not investigate histology, however, and the possibility of adverse effects on collagen density should be borne in mind.

Recommendation: **Probably add an intra-articular steroid injection (rather than outpatient physiotherapy with passive mobilisations) to home exercises for both stages of contracted (frozen) shoulder in primary or secondary care.**

3.4. Adding physiotherapy to other treatments 

3.4.1. In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) and home exercises to distension for both stages of contracted (frozen) shoulder?

References: Buchbinder et al (2007).

Settings: Primary and secondary care in Australia.

Synthesis: The median quality of the evidence was moderate for SPADI, pain and adverse effects/events, all of which were critical outcomes and were reported in the short and medium term.

For all outcomes at both time points it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important. Adverse effects/events were more prevalent in the group that received distension and placebo physiotherapy: the 95% CI for the absolute effect was from 14 fewer to 94 more in the short term, and from 48 fewer to 118 more in the medium term.

Summary of evidence: The overall quality of the evidence is moderate. The estimates of relative benefits are too imprecise to enable a judgement. There is greater potential for adverse effects/events in the distension and placebo physiotherapy and distension group.

Recommendation: **No recommendation for practice.**

3.4.2. In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) to NSAIDs for both stages of contracted (frozen) shoulder?

References: Pajareya et al (2004).

Settings: Secondary care in Thailand.

Synthesis: The quality of the evidence was moderate. A single, critical, outcome—the SPADI—was reported, and only in the short term. A clinically important effect favouring the addition of outpatient physiotherapy could be inferred to the population (moderate quality evidence).

Potential harms of physiotherapy include temporary aggravation of symptoms; those of NSAIDs primarily gastro-intestinal (GI) disturbances. Adverse effects/events were quantified and described in the report of this trial. Four patients reported pain lasting > 2 hours after physiotherapy. Fifteen patients in the NSAIDs group reported GI disturbances, and six of these had to stop medication due to severe dyspepsia. Two reported severe oedema (the site was unspecified) and one a severe headache which resoled on discontinuation of NSAIDs.

Summary of evidence: The quality of the evidence was moderate. The results point to a clinically important effect favouring the addition of outpatient physiotherapy (with passive mobilisations) in the population.

Recommendation: **A combination of outpatient physiotherapy (with passive mobilisations) and NSAIDs is more beneficial than NSAIDs alone for both stages of contracted (frozen) shoulder in secondary care. (The potential harms of NSAIDs should be carefully considered, although such considerations fall outside the non-prescriber's remit.)**

3.5. Adding physiotherapy elements to combinations of physiotherapy and other treatments

3.5.1. In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) to an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder?

References: Carette et al (2003), Ryans et al (2005).
Settings: Secondary care in Canada and primary care in Northern Ireland.
Synthesis: The median quality of the evidence was low for the critical outcomes (combined pain-function, pain) and moderate for the important but non-critical outcomes (passive external rotation).

In the short term, combined pain-function and pain showed unidirectional potential for a clinically important effect favouring the addition of outpatient physiotherapy in the population (moderate quality evidence). This was corroborated by passive external rotation, for which there was a directional effect (moderate quality evidence).

In the medium term, pain-function showed unidirectional potential for a clinically important effect favouring the addition of outpatient physiotherapy (very low quality evidence). For pain and passive external rotation it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

In the long term, it was unclear for all outcomes in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

Potential harms of mechanical therapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary worsening of symptoms and, possibly, diminished collagen density (Shibata et al 2001). Adverse effects/events were not quantified or described in the trial reports.

Summary of evidence: In the short term, addition of outpatient physiotherapy to an intra-articular steroid injection and home exercises is potentially more beneficial than an intra-articular steroid injection and home exercises alone for pain-function and pain (moderate quality evidence). In the medium term, addition of physiotherapy to outpatient physiotherapy and an intra-articular steroid injection is potentially more beneficial than outpatient physiotherapy and an intra-articular steroid injection alone for pain-function (very low quality evidence). Adverse effects/events were not mentioned in the trial reports, but the results of another trial (van der Windt 1998) suggest that

adverse effects/events would be fewer in the intra-articular steroid injection group. That trial did not investigate histology, however, and the possibility of adverse effects on collagen density should be borne in mind.

Recommendation: **Probably add outpatient physiotherapy (with passive mobilisations) to an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder in primary or secondary care.**

3.6. Adding other treatments to physiotherapy 

3.6.1. In primary and secondary care, should we add an intra-articular steroid injection to outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder?

References: Carette et al (2003), Ryans et al (2005).

Settings: Secondary care in Canada and primary care in Northern Ireland.

Synthesis: The median quality of the evidence was low for the critical outcomes (combined pain-function, pain) and moderate for the important but non-critical outcomes (passive external rotation).

In the short term, a clinically important effect favouring the addition of an intra-articular steroid injection could be inferred to the population (95% confidence) for pain-function (moderate quality evidence). For pain, a clinically important effect favouring the addition of an intra-articular steroid injection could be cautiously inferred to the population with approaching 95% confidence (moderate quality evidence). Corroboration was provided by passive external rotation, for which there was a directional effect (moderate quality evidence).

In the medium term, combined pain-function showed unidirectional potential for a clinically important effect in the population, favouring the addition of an intra-articular steroid injection (low quality evidence). This was corroborated by passive external rotation, for which there was a directional effect (low quality evidence). For pain, it was unclear in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (very low quality evidence).

In the long term, it was unclear for all outcomes in which direction (if any) an effect would occur in the population, and whether any such effect would be clinically important (low quality evidence).

Potential harms of mechanical therapy include temporary aggravation of symptoms. Those of steroid injections include facial flushing, temporary worsening of symptoms and, possibly, diminished collagen density (Shibata et al 2001). Adverse effects/events were not quantified or described in the trial reports.

Summary of evidence: In the short term, addition of an intra-articular steroid injection to outpatient physiotherapy and home exercises benefits pain-function (moderate quality evidence) and probably benefits pain (moderate quality evidence). Also, the results for passive external rotation favour the addition of an intra-articular steroid injection (moderate quality evidence). In the medium term, addition of an intra-articular steroid injection to outpatient physiotherapy and home exercises potentially benefits combined pain-function (low quality evidence). This too is

corroborated by results for passive external rotation (low quality evidence). Adverse effects/events were not mentioned in the trial reports, but the results of another trial (van der Windt 1998) suggest that adverse effects/events would be fewer in the intra-articular steroid injection group. That trial did not investigate histology, however, and the possibility of adverse effects on collagen density should be borne in mind.

Recommendation: **Probably add an intra-articular steroid injection to outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder in primary or secondary care.**

3.6.2. In secondary care, should we add MUA to home exercises for both stages of contracted (frozen) shoulder?

References: Kivimaki et al (2007).

Settings: Secondary care in Finland.

Synthesis: The median quality of the evidence was (estimated as) moderate. The critical outcomes (a modified SDQ and the NPRS) and the important but non-critical outcomes (passive external rotation) were assessed in the short, medium and long term.

In the short term it was unclear in which direction (if any) effects would occur in the population. For the NPRS, the only potential for a clinically important effect (which was marginal) in the population was in the direction favouring home exercises only.

In the medium and long term it was unclear in which direction (if any) effects would occur in the population, though for the NPRS at each time point the only potential for a clinically important effect on the NPRS in the population was in the direction favouring the addition of MUA.

Potential harms of MUA include humeral fractures, rotator cuff ruptures, brachial plexus and vascular injuries; those of mechanical therapy include temporary aggravation of symptoms. Adverse effects/events were neither quantified nor described in the trial report.

Summary of evidence: The estimates of relative benefits show potential for added MUA to exert a clinically important beneficial effect over home exercises alone on pain in the medium and long term (quality of evidence not estimable). Adverse effects/events are neither quantified nor described in the trial report, but potential harms are known and may be serious. The balance of benefits and harms is unclear.

Recommendation: **No recommendation for practice.**

Physiotherapy versus other physiotherapy

Question		Recommendation for practice
3.1.1	In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) to home exercises for both stages of contracted (frozen) shoulder?	Probably add outpatient physiotherapy (with passive mobilisations) to home exercises.
3.1.2	In secondary care, which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or outpatient physiotherapy (with passive mobilisations) and standard home exercises?	Probably use outpatient physiotherapy (with passive mobilisations) and standard home exercises in preference to a home muscle function retraining programme.
3.1.3	In secondary care, which should we use for stiffness-predominant contracted (frozen) shoulder: high grade or low grade mobilisations?	Probably use high grade mobilisations in preference to low grade mobilisations.
3.1.4	In secondary care, which should we add to home exercises for both stages of contracted (frozen) shoulder: high grade mobilisations or MWMs?	No recommendation for practice.

TABLE 3a. Clinical questions and recommendations. The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Physiotherapy versus other physiotherapy (continued)

Question		Recommendation for practice
3.1.5	In secondary care, should we add SWD to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?	Probably add SWD to outpatient physiotherapy (without passive mobilisations) and home exercises.
3.1.6	In secondary care, should we add hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?	Probably don't add hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises.
3.1.7	In secondary care, which should we add to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder: SWD or hot packs?	Probably add SWD (in preference to hot packs) to outpatient physiotherapy (without passive mobilisations) and home exercises.

TABLE 3a (continued). Clinical questions and recommendations. The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Physiotherapy versus other treatments

Question		Recommendation for practice
3.2.1	In primary care, which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with mobilisations) or intra-articular steroid injections?	Probably use intra-articular steroid injections in preference to outpatient physiotherapy.
3.2.2	In secondary care, which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or a subacromial steroid injection?	No recommendation for practice.
3.2.3	In secondary care, which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) and home exercises or a subacromial steroid injection?	Probably use outpatient physiotherapy (with passive mobilisations) and home exercises in preference to a subacromial steroid injection.

TABLE 3b. Clinical questions and recommendations. The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Physiotherapy versus combinations of physiotherapy and other treatments

	Question		Recommendation for practice
3.3.1	In primary and secondary care, which should we add to home exercises for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) or an intra-articular steroid injection?	⇨	Probably add an intra-articular steroid injection (rather than outpatient physiotherapy with passive mobilisations) to home exercises.

TABLE 3c. Clinical questions and recommendations. The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Adding physiotherapy to other treatments

Question		Recommendation for practice
3.4.1	In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) and home exercises to distension for both stages of contracted (frozen) shoulder?	No recommendation for practice.
3.4.2	In secondary care, should we add outpatient physiotherapy (with passive mobilisations) to NSAIDs for both stages of contracted (frozen) shoulder?	A combination of outpatient physiotherapy (with passive mobilisations) and NSAIDs is preferable to NSAIDs alone. (The potential harms of NSAIDs should be carefully considered, although such considerations fall outside the non-prescriber's remit.)

TABLE 3d. Clinical questions and recommendations.  The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Adding physiotherapy elements to combinations of physiotherapy and other treatments

	Question		Recommendation for practice
3.5.1	In primary and secondary care, should we add outpatient physiotherapy (with passive mobilisations) to an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder?	⇨	Probably add outpatient physiotherapy (with passive mobilisations) to an intra-articular steroid injection and home exercises.

Adding other treatments to physiotherapy

	Question		Recommendation for practice
3.6.1	In primary and secondary care, should we add an intra-articular steroid injection to outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder?	⇨	Probably add an intra-articular steroid injection to outpatient physiotherapy (with passive mobilisations) and home exercises.
3.6.2	In secondary care, should we add MUA to home exercises for both stages of contracted (frozen) shoulder?	⇨	No recommendation for practice.

TABLE 3e. Clinical questions and recommendations.  The GRADE levels of recommendation are used. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004). For further explanation, *see* pages 6–7.

Facilitators	Barriers
CSP accreditation (assurance of quality)	Cost: addition of physiotherapy to home exercises has cost implications
Electronic-only format: easy accessibility for those with access to the internet	Cost: training (e.g. injection therapy, shortwave diathermy)
Cost: the guidelines are free	Cost: consumables and equipment
Advertising (CSP)	Availability of resources: e.g. prescriptions for injections
Presentations	Electronic-only format: requires internet access
Workshops	Attitudes and beliefs
Quick reference guide	Time
Patient Information sheet	
Audit tool	

TABLE 3f. Facilitators and barriers to implementation of the guidelines

3.7. References to Part 3 

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Yang J-I, Chang C-w, Chen S-y, Wang S-F, Lin J-j (2007) mobilization techniques in subjects with frozen shoulder syndrome: Randomized multiple-treatment trial, *Physical Therapy,* 87, 1307–1315.

4. Recommendations for research 

Approximately half (9/19) of our initially included trials were of low methodological quality and carried a moderate-to-high risk of bias. Of these, four were over 20 years old (Bulgen et al 1984, Dacre Beeney & Scott 1989; Lee et al 1973), but the remainder were published recently—between 2004 and 2008—postdating the CONSORT statement for reporting randomised trials (Altman et al 2001). It is disappointing that the CONSORT recommendations have yet to be generally implemented.

With respect to high quality trials, our survey of CSP members revealed a discrepancy between clinicians' and researchers' approaches. Clinicians differentiate between stages of contracted (frozen) shoulder and use this differentiation to guide their interventions, even though the stages have been inconsistently defined. We offered the terms 'pain-predominant' and 'stiffness-predominant' contracted (frozen) shoulder, for their clarity and non-ambiguity and, based on these terms, our respondents' choice of clinical interventions was clearly dichotomised. This dichotomy—or indeed any staged classification—is not usually evident in the research literature. In a number of trials in which the stage of the condition appears to have been mixed, and in which interventions, comparators or both were physiotherapy, there was no explicit adaptation of treatment according to stage. These trials included Ginn and Cohen (2005), among whose physiotherapy treatments were a muscle function retraining programme and a package of outpatient physiotherapy with passive mobilisations and standard home exercises; Yang et al (2007), who studied high grade mobilisations and MWMs; and Pajareya et al (2004), whose trial included physiotherapy with passive mobilisations. With all three trials, it is unclear whether the failure to report adaptation of treatment by the condition's stage represents an oversight or a true reflection of the method. In either case, the clinical applicability of these trials' findings is somewhat compromised. It would be helpful if, in future, researchers in this area were to report their interventions and comparators in sufficient detail to remove ambiguity; and either to focus on a specific stage of contracted (frozen) shoulder (we suggest 'pain-predominant' or 'stiffness-predominant', with pain taking primacy in ambiguous cases), or to subgroup their results by the condition's stage. The last two options might reveal therapeutic effects which are too dilute to detect in a generic sample.

We found a number of trials that used comparators in a way which does not mirror their application in practice. This applied particularly to intra-articular steroid injections (Carette et al 2003, Ryans et al 2005, van der Windt et al 1998), which were employed in studies of apparently mixed-stage contracted (frozen) shoulder. It would be interesting to know whether, as theoretical principles and clinical usage seem to suggest, such injections would be more efficacious in studies (or subgroups) confined to the pain-predominant stage. If so, the relative efficacy of physiotherapy, against which the injections were compared, would be reduced.

For many comparisons, the estimates of effect were too imprecise to allow firm conclusions to be drawn: often, the direction of the effect was unclear, as was its clinical importance (*see* Results). For those comparisons considered worth pursuing, the studies require replication with sample sizes sufficient to narrow the 95% CIs, render these less 'fragile' and facilitate more definitive

conclusions. However, implementing this suggestion and some of those made above—i.e. focusing on specific stages of contracted (frozen) shoulder or sub-grouping by those stages—would require relatively large samples, and we recognise that recruitment to research is problematic. There is a strong case for multi-centre trials.

To a greater or lesser extent, the evidence for the efficacy of interventions may be specific to the care settings in which those interventions have been studied. Early on in the guideline development, we spent much time arguing about the relative merits of tests and treatments. We eventually realised the source of our disagreements: our group had been (deliberately) drawn from different care settings, and we were each accustomed to managing different patient populations. It is important to bear in mind that, while translating results from one care setting to another will often give useful guidance, there is an element of uncertainty inherent in the process. In our recommendations for practice we have taken care to clearly state the setting(s) from which the evidence was derived. Clearly, many questions remain as to the efficacy of interventions in different care settings.

Lastly, a number of physiotherapy modalities have not been specifically evaluated in relation to contracted (frozen) shoulder in *any* care setting. These include pulsed shortwave diathermy, TENS, interferential and ultrasound, although ultrasound has been studied in populations incorporating different types of shoulder pain, and consistently found ineffective (Ainsworth et al 2007 and review by Hanchard, Cummins & Jeffries 2004). Whether much is to be gained from evaluating the remainder in stand-alone fashion is very doubtful, but these interventions may have roles as part of therapeutic packages.

4.1. References to Part 4 

Ainsworth R, Dziedzic K, Hiller L, Daniels J, Bruton A, Broadfield J (2007). A prospective double blind placebo-controlled randomized trial of ultrasound in the physiotherapy treatment of shoulder pain, *Rheumatology*, 46, 5, 815–820.

Altman DG, Schulz KF, Moher D et al (2001). The revised CONSORT statement for reporting randomized trials: Exploration and elaboration, *Annals of Internal Medicine*, 134, 663–694.

Bulgen DY, Binder AI, Hazleman BL, Dutton J, Roberts S (1984). Frozen shoulder: prospective clinical study with an evaluation of three treatment regimens. *Annals of the Rheumatic Diseases,* 43, 353–360.

Carette S, Moffet H, Tardif J, Bessette L, Morin F, Frémont P, Bykerk V, Thorne C, Bell M, Bensen W, Blanchette C (2003). Intraarticular corticosteroids, supervised physiotherapy,or a combination of the two in the treatment of adhesive capsulitis of the shoulder: A placebo-controlled trial, *Arthritis & Rheumatism*, 48, 3, 829–838.

Dacre JE, Beeney N, Scott DL (1989). Injections and physiotherapy for the painful stiff shoulder, *Annals of the Rheumatic Diseases,* 48, 322–325.

Ginn KA, Cohen ML (2005). Exercise therapy for shoulder pain aimed at restoring neuromuscular control: a randomized comparative clinical trial, *Journal of Rehabilitation Medicine*, 37, 115–122.

Hanchard N, Cummins J, Jeffries C (2004). *Evidence-based clinical guidelines for the diagnosis, assessment and physiotherapy management of shoulder impingement syndrome*, London, Chartered Society of Physiotherapy.

Lee M, Haq AMMM, Wright V, Longton EB (1973). Periarthritis of the shoulder: A controlled trial of physiotherapy, *Physiotherapy*, 59, 10, 312–315.

Pajareya K, Chadchavalpanichaya N, Painmanakit S, Kaidwan C, Puttaruksa P, Wongsaranuchit Y (2004). Effectiveness of physical therapy for patients with adhesive capsulitis: A randomized controlled trial, *Journal of the Medical Association of Thailand*, 87, 5, 473–80.

Ryans I, Montgomery A, Galway R, Kernohan WG, McKane R (2005). A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis, *Rheumatology*, 44, 529–535.

van der Windt DAWM, Koes BW, Devillé W, Boeke AJP, de Jong BA, Bouter LM (1998). Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial, *BMJ*, 317, 1292–1296.

Yang J-I, Chang C-w, Chen S-y, Wang S-F, Lin J-j (2007) mobilization techniques in subjects with frozen shoulder syndrome: Randomized multiple-treatment trial, *Physical Therapy,* 87, 1307–1315.

APPENDICES

APPENDIX A: Methods 

i. Types of studies

We considered for inclusion RCTs and quasi-RCTs, both in the form of full reports only. Abstracts, 'letters to the editor', responses to such letters, commentaries and leaders were not considered.

ii. Types of participants

We intended to include in our review a reasonably homogeneous group of patients with contracted (frozen) shoulder. To this end we required in each trial report:

a. a statement that the sample—or a subgroup with separately reported outcomes—had been diagnosed with 'adhesive capsulitis', 'capsulitis', 'contracted shoulder', 'frozen shoulder' or an equivalent term (but not 'periarthritis'[13]). No inclusion criteria were required in addition to this statement, but such criteria as were provided had to be consistent with a specific diagnosis of contracted (frozen) shoulder: thus inclusion of referred pain (from the neck), paraesthesia, painful arc, or pain or weakness on isometric actions were not acceptable.

Alternatively, we required:

b. that in relation to the sample—or a subgroup with separately reported outcomes—the report's inclusion criteria:

- should incorporate shoulder stiffness (ideally defining this as present on passive movement and affecting external rotation, with or without other movements); but
- should *not* incorporate any features of non-capsular causes of shoulder pain (referred pain from the neck or paraesthesia, combined neck-shoulder pain, painful arc, or pain or weakness on isometric actions).

iii. Types of interventions

For the 'standard physiotherapy' version of the guidelines, we considered the following interventions:

- advice;
- exercise therapy;
- manual therapy;

[13] 'Periarthritis' is an ambiguous term, considered by some to be synonymous with contracted (frozen) shoulder, but by others to include tendon and bursal disease (*see* Oxford Concise Colour Medical Dictionary). Therefore a diagnosis of 'periarthritis' was not an inclusion criterion *per se*.

- electrotherapy;
- heat or cold treatments; and
- ultrasound;

regardless of whether these have been used alone, in various combinations, or to supplement other interventions (e.g. corticosteroid injection, capsular distension, manipulation under anaesthetic).

iv. Types of comparisons

We considered comparison with any intervention or combination of interventions, with no intervention, or with placebo.

v. Types of outcome measures

Patients with frozen shoulder seek help for pain, functional difficulties or both. We therefore considered as our primary outcomes:

1. validated self-report instruments that included questions on shoulder pain and function (e.g. DASH, Oxford shoulder score); and
2. pain scores; whether at rest, at night or during activities; and whether stand-alone (e.g. 100 mm VAS, 11-point NPRS) or part of composite shoulder pain and function outcome instruments.

We also considered as primary outcomes:

3. passive or gravity-assisted range of passive external rotation, because restriction of this movement is thought to characterise the fact and severity of frozen shoulder more than any other single factor; and
4. adverse effects.

In the absence of 1, above, we considered the following secondary outcomes, in order of preference:

5. validated composite subjective/objective outcome measures (e.g. Constant Murley score);
6. other reportedly 'primary' subjective outcome measures (e.g. patients' global impression of improvement); and
7. other reportedly 'primary' objective outcome measures (e.g. independent assessor's global impression of improvement).

vi. Search methods for identification of studies

We designed our search strategy to cover all interventions that might be undertaken by a physiotherapist though, as detailed above, the guidelines will address these in stages, starting with 'standard physiotherapy' in the first version (*version 1.X*). Our first step was to identify in the Cochrane Library (http://www.cochrane.org/) the Cochrane reviews of interest. There were four: (1) Buchbinder, Green and Youd (2003) on corticosteroid injections for shoulder pain; (2) Buchbinder et al (2008) on arthrographic distension for adhesive capsulitis (frozen shoulder); (3) Green, Buchbinder and Hetrick (2003) on physiotherapy interventions for shoulder pain; and (4) Green, Buchbinder and Hetrick (2005) on acupuncture for shoulder pain.

We noted the trials included in these Cochrane reviews, obtained the original reports of these trials and, where necessary, filtered out those that were not applicable to the present guidelines. We then derived our search strategy from the Cochrane reviews, increasing its specificity to contracted (frozen) shoulder as indicated below (*see* Search strategy), and ran searches on the Ovid MEDLINE, AMED, CINAHL and EMBASE databases from 2001 to 09 July 2008, using the OvidSP platform. Thus our search period overlapped with that of the earliest of the four Cochrane reviews (Green, Buchbinder & Hetrick 2003), whose cut-off for inclusion of trials was June 2002.

Search strategy

(The numerals in superscript correspond to the Cochrane reviews listed above, and indicate the source of the search terms. Where the original terms were adapted, this is specified.) Note that truncation and wildcards were consistent across the OvidSP platform. For database-specific comments on the search strategy, *see* TABLE A1.1.

1. Shoulder Pain/[1–4]
2. Shoulder Impingement syndrome/[1,3–4]
3. Rotator Cuff/[1–4]
4. exp Bursitis/[1–4]
5. ((shoulder$ or rotator cuff) adj5 (bursitis or frozen or impinge$ or tendinitis or tendonitis or pain$)).mp. [1–4]
6. Rotator cuff.mp. [1–4]
7. adhesive capsulitis.mp. [1–4]
8. or/1–7
9. exp Rehabilitation/[3]
10. exp Physical Therapy Techniques/[3]
11. exp Physical Therapy/
12. exp Musculoskeletal Manipulations/[3]
13. exp Exercise Movement Techniques/[3]
14. exp Ultrasonography, Interventional/[3]
15. (rehabilitat$ or physiotherap$ or physical therap$ or manual therap$ or exercis$ or ultrasound or ultrasonograph$ or TNS or TENS or shockwave or electrotherap$ or mobili$).mp. [3]
16. exp Injections/[1]
17. ((an?esthe$ or bupivacaine or corticosteroid$ or hyaluron$ or li?ocaine or ropivacaine or steroid$ or sub?acromial) adj5 inject$).mp. [1 (adapted)]
18. exp Acupuncture/[4]
19. exp Acupuncture Therapy/[4]
20. exp Electroacupuncture/[4]

21. Acupuncture$.mp. [4 (adapted)]
22. Electro?acupuncture$.mp. [4 (adapted)]
23. (Dry adj needl$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
24. Dilatation/[2]
25. Arthrography/[2]
26. (Arthrographic adj5 distension).mp. [2]
27. Hydrodilat$.mp. [2]
28. or/9–27
29. Clinical trial.pt.[1,3–4]
30. Clinical trial.mp.
31. random$.mp. [1,3–4]
32. ((single or double) adj (blind$ or mask$)).mp. [1,3–4]
33. placebo$.mp. [1,3–4]
34. or/29–33
35. 8 and 28 and 34
36. limit 35 to english language
37. remove duplicates from 36

Line	Database			
	Ovid MEDLINE	AMED	CINAHL	EMBASE
9		Term invalid		
10			Term invalid, hence line 11 inserted	Term invalid, hence line 11 inserted
12			Term invalid	
13			Term invalid	
14			Term invalid	Term invalid
19			Term invalid	
24			Term invalid	
25		Term invalid		
26		Term valid, but test returned no results		
27		Term valid, but test returned no results		
29				Term invalid, hence line 30 inserted

TABLE A1.1. Database-specific comments on the search strategy

After de-duplication, this strategy retrieved 749 citations, most with abstracts.

Filtering

Filtering was independently conducted by two reviewers, who resolved any disagreements by consensus.

Preliminary filtering

In a preliminary filtering process (based on titles and—where these were available—abstracts), we included citations which:

- reported one or more conservative interventions (within the extended scope of physiotherapy practice) for intrinsic, musculoskeletal-type shoulder pain unrelated to significant trauma, stroke, or systemic inflammatory conditions.

We excluded those which:

- excluded from consideration contracted (frozen) shoulder;
- focused on peri-operative and post-operative procedures except where these explicitly related to the management of contracted (frozen) shoulder e.g. MUA; or
- were included in any of the four Cochrane reviews underpinning our own.

Secondary filtering

Secondary filtering was based on titles, abstracts and the full text of reports, as required. We included reports on:

- RCTs and quasi-RCTs.

We excluded reports:

- in which contracted (frozen) shoulder could not be identified as a distinct subgroup;
- no separate analysis was provided for the contracted (frozen) shoulder subgroup;
- of trials still in progress;
- of trials not directly relevant to physiotherapy; or
- which duplicated other, included, reports.

vii. Data collection and analysis

Data extraction was conducted in accordance with an *a priori* protocol. Data for each included trial were extracted on standardised forms by two independent reviewers. The independent reviewers also evaluated the risk of bias, using the criteria of Verhagen et al (1998). These Delphi-derived criteria are the basis of the PEDro scale (http://www.pedro.fhs.usyd.edu.au/) which is validated for RCTs of physiotherapy and was used in the 2003 Cochrane review on physiotherapy interventions (Green, Buchbinder & Hetrick 2003). A comparable approach was considered sensible in our own review for reasons of consistency. However, Green, Buchbinder and Hetrick (2003) did not present summary scores for methodological quality, and neither did we, since numerical methods scores have been criticised for their arbitrariness (Cochrane Handbook 2009).

Where it made sense to do so, we performed meta-analyses. We did not anticipate undertaking any sensitivity or subgroup analyses, and did not do so. We did anticipate that the included trials would use a range of outcome measures. For dichotomous outcomes (e.g. 'improved'/'not improved') we calculated the Relative Risk (RR) and its 95% confidence interval (95% CI). For outcomes measured on continuous scales we calculated the Mean Difference (MD) and its 95% CI. To pool trials which measured the same outcome but with different tools, e.g. SPADI and SRQ, we calculated the Standardised Mean Difference (SMD) and its 95% CI. We then converted the SMD and its 95% CIs back into the units of one of the original outcomes, since these are more meaningful clinically than the SMD (Cochrane Handbook 2009). To further enhance clinical relevance, we reported the Minimal Clinically Important Difference (MCID), if known, for all outcomes. We derived within-subject MCIDs from the research literature, but multiplied these by 0.4. We applied this adjustment because between-groups MCID (i.e. an important difference

between groups, as in a controlled trial) is thought to approximate to 40% of that within individuals (Finch et al 2002). These processes allowed us to see whether the outcome and its 95% CI (a) overlapped zero and (b) overlapped the adjusted threshold for MCID on either side of zero. If the 95% CI did not overlap zero it could be stated, with 95% confidence, that the intervention had a directional effect. Furthermore, a 95% CI that lay entirely beyond the adjusted threshold for a MCID could be said, with 95% confidence, to have a clinically important effect favouring that intervention.

If insufficient data were available to calculate these statistics, we reported the fact, but did not contact the authors for additional information.

viii. Questionnaire survey of CSP members

We conducted a survey of Chartered Society of Physiotherapy (CSP) members in order to:

- obtain a snapshot of physiotherapists' approaches to diagnosis and treating contracted (frozen) shoulder at the present time, enabling us to:
    - identify the treatment options currently in use and focus on these in our overview of interventions (section 1.6);
    - set the overview of interventions in context;
    - establish a baseline against which the guidelines' impact might be evaluated; and
- identify discrepancies between practice and research.

We posted notices on eight special interest networks of the interactive CSP (iCSP) website to whose subscribers contracted (frozen) shoulder might be of interest. The notices invited subscribers to follow a link to self-administered, on-line questionnaire. The questionnaire required respondents to state whether or not they had a 'special interest' in contracted (frozen) shoulder, because we were interested to see whether this distinction affected the diagnostic and management strategies they used; and to differentiate according to whether pain or stiffness was the primary problem.

ix. Grading the quality of evidence and strength of recommendations from supplementary systematic review of interventions

GRADE system

Finally, we graded the quality of the evidence and derived our recommendations using the GRADE system, which is recommended by the Cochrane Collaboration, transparent, and increasingly in standard use. Specifically, we graded the quality of the evidence using GRADEprofiler *version* 3.2.2 software, which was developed by the GRADE Working Group http://www.gradeworkinggroup.org/index.htm and is available at http://www.ims.cochrane.org/revman/gradepro/download. GRADEprofiler facilitates tabulation of the results for each outcome, and helps to make judgements on the quality of the available evidence transparent. Aspects of quality include:

- design and limitations (risk of bias);
- inconsistency (which occurs when trials' results do not agree);
- indirectness (which occurs when the trials' results are inapplicable to the population of interest);
- imprecision (which occurs when the estimates of effect are wide); and
- publication bias (underestimation or overestimation of effects due to selective publication of trials).

The resulting tables—GRADE evidence profile tables—are in APPENDIX E.

Our recommendations for management took the quality of the evidence into account. When evidence is graded 'high', it means that further research is unlikely to change our confidence in the estimated effect; when it is 'moderate', further research is likely to influence our confidence in the estimated effect, and may change the estimate; when it is 'low', further research is very likely to seriously influence our confidence in the estimated effect, and is likely to change the estimate; and when it is 'very low', any estimate of effect is very uncertain. With the quality of the evidence taken into account, potential benefits were weighed against potential harms and, if feasible, a recommendation for management made. As recommended by the GRADE Working Group, we used four classifications of recommendation: 'do it', 'probably do it', 'probably don't do it' and 'don't do it'. 'Do it' or 'don't do it' indicate a judgement that most well informed people (i.e. patients) would make. '"Probably do it" or "probably don't do it" indicate a judgement that a majority of well informed people would make but a substantial minority would not' (GRADE Working Group 2004).

> 'A recommendation to use or withhold an intervention does not mean that all patients should be treated identically. Nor does it mean that clinicians should not involve clinicians in the decision, or explain the merits of the alternatives. However, because most well informed patients will make the same choice, the explanation of the merits of the alternatives may be relatively brief. A recommendation is intended to facilitate an appropriate decision for an individual patient or a population. It should therefore reflect what people would likely choose, based on the evidence and their own values or preferences in relation to the expected outcomes. A recommendation to "probably do something" indicates a need for

clinicians to more fully and carefully consider patients' values and preferences when offering them the intervention.' (GRADE Working Group 2004)

In instances where the evidence was insufficient to make a recommendation for practice, we reserved judgement.

We have not considered economic data in this iteration of the guidelines.

x. Ensuring 'fitness for purpose'

To ensure the guidelines' 'fitness for purpose' we engaged our diverse target audience to become expert panellists in the development process using Delphi methods. Our strategy was as follows.

- The core group wrote the framework of the guidelines.
- Each of the framework's three sections was then populated by one subsection: a sample of its proposed content.
- The draft was distributed to the Delphi expert panel, so the panellists could express their views (up to six comments each) on the broad structure of the guidelines as well as more detailed aspects of their level and style of reporting.
- The comments were collated and redistributed to the panel, who were asked to indicate 'agree', 'disagree' or 'no opinion' in relation to each.
- We proceeded with the guidelines development as directed by the consensus of opinion (the majority).

In our opinion, engaging stakeholders in an early, formative role is an improvement on the norm in guidelines development.

xi. References to APPENDIX A

Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain. *Cochrane Database of Systematic Reviews* 2003, Issue 1. Art. No.: CD004016. DOI: 10.1002/14651858.CD004016

Buchbinder R, Green S, Youd JM, Johnston RV, Cumpston M. Arthrographic distension for adhesive capsulitis (frozen shoulder). *Cochrane Database of Systematic Reviews* 2008, Issue 1. Art. No.: CD007005. DOI: 10.1002/14651858.CD007005

Cochrane Handbook for Systematic Reviews of Interventions 5.0.2., September 2009, [Online], Available: http://www.cochrane.org/resources/handbook/

Green S, Buchbinder R, Hetrick SE. Physiotherapy interventions for shoulder pain. *Cochrane Database of Systematic Reviews* 2003, Issue 2. Art. No.: CD004258. DOI: 10.1002/14651858.CD004258

Green S, Buchbinder R, Hetrick SE. Acupuncture for shoulder pain. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Art. No.: CD005319. DOI: 10.1002/14651858.CD005319

GRADE Working Group (2004) Grading the quality of evidence and strength of recommendations. Accessible at: http://www.BMJ.com

Verhagen AP, de Wet HCW, de Bie RA, Kessels AGH, Boers M, Bouter L, Knipschild PG (1998) The Delphi list: A criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus, *Journal of Clinical Epidemiology*, 51, 1235–1241.

APPENDIX A2: Search and results for diagnostic tests

Search strategy

The following search strategy was run across the Medline, CINAHL, AMED and SportDiscus databases, from inception to 20 January 2012, in the EBSCO host platform:

1. TX frozen shoulder
2. TX adhesive capsulitis
3. 1 and 2/OR
4. TX diagnos*
5. TX test#
6. 4 and 5/OR
7. 3 and 6/AND

(TX = all text)

Screening criteria

The screening criteria, based on titles and abstracts in the first instance, were as follows.

Inclusion criteria

Category 1 (prospective clinical studies) Reports of prospective, primary, clinical research, available in full text, and with explicit reference in the title or abstract to any of the following.

1.1. A diagnostic test accuracy study, *within the reported study*, evaluating physical tests for diagnosing contracted (frozen) shoulder against any reference standard (the validity of reference standards will be considered on a case-by-case basis).

1.2. A diagnostic test accuracy study, *within the reported study*, evaluating physical tests for diagnosing contracted (frozen) shoulder in terms of whether the test outcomes usefully inform management.

1.3. A primary focus, *within the reported study,* on describing the baseline presentations of *specific* diagnostic physical tests in a sample of patients with presumptive contracted (frozen) shoulder.

1.4. A primary focus, *within the reported study*, on evaluating the reliability of physical tests for diagnosing contracted (frozen) shoulder.

Category 2 (expert opinion based on laboratory studies)

2.1. Expert opinion based on laboratory-based research evaluating physical tests for diagnosing contracted (frozen) shoulder.

Category 3 (expert opinion)

3.1. Expert consensus on physical tests for diagnosing contracted (frozen) shoulder.

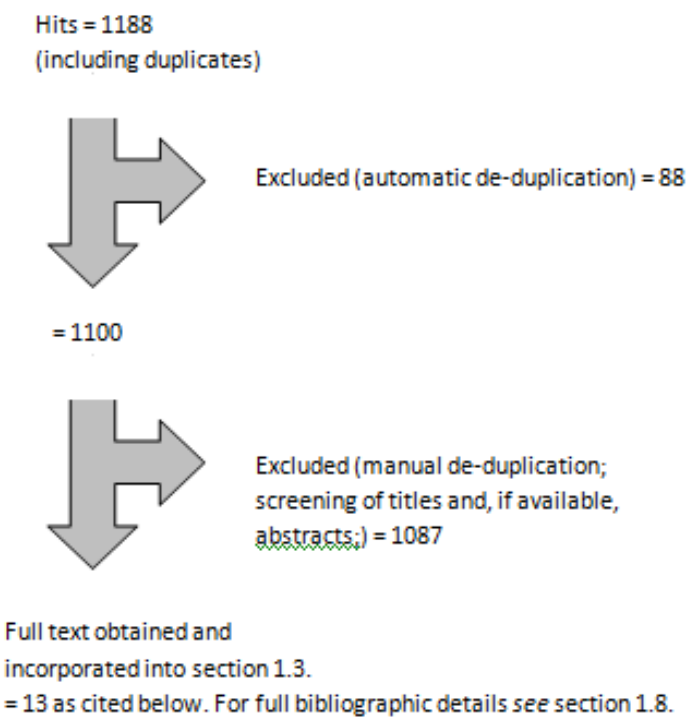
3.2. Individual expert opinion on physical tests for diagnosing contracted (frozen) shoulder.

Exclusion criteria

In keeping with the exclusions stated in the guidelines' protocol (APPENDIX A), we excluded: studies whose focus was on shoulder pain associated with stroke, associated with significant trauma (fracture or dislocation), secondary to surgery, or associated with systemic inflammatory conditions.

Also excluded were studies reporting tests which would require specialised equipment for replication in the clinical setting, and studies not reported in the English language.

Search results



Binder et al (1984); Bulgen et al (1984); Carbone et al (2010); Hanchard, Howe and Gilbert (2005); Hanchard et al (2011); Kerimoglu et al (2007); Mitsch et al (2004); Mullaney et al (2010); Rundquist et al (2003); Rundquist and Ludewig (2004); Tveita et al (2008a); Walmsley, Rivett and Osmotherly (2009); Wolf and Cox (2010).

APPENDIX B: Table of trials considered for inclusion 

Trial	Buchbinder et al (2007)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: YES; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	149 patients diagnosed with frozen shoulder: probably a mix of pain-predominant and stiffness-predominant. ***Inclusion criteria:*** age ≥ 18 years, symptoms of pain and stiffness in predominantly 1 shoulder for ≥ 3 months, and restriction of passive motion ≥ 30° in ≥ 2 planes of movement, measured to onset of pain with a gravity inclinometer. ***Exclusion criteria:*** pain ≥ 7/10 on VAS at rest; systemic inflammatory joint disease; radiologic evidence of shoulder osteoarthritis, fracture, or calcification; reason to suspect a complete rotator cuff tear (arm elevation weakness, positive drop arm sign, high-riding humerus on shoulder radiograph, or complete rotator cuff tear on ultrasound); contraindications to arthrogram and/or distension such as current warfarin therapy; allergy to local anesthetic or iodinated contrast; pregnancy; likely not to attend for treatment or comply with follow up; inability to partake in moderate exercise; previous post-distension physiotherapy; and lack of written informed consent. ***Mean age ± SD, % female: Physiotherapy group*** 55 ± 9 years, 68%; ***Placebo group*** 55 ± 8 years, 58%. ***Setting*** Recruitment was from primary care and 'specialized practice' [secondary or tertiary care]. Trial took place in Victoria, Australia.
Intervention/ Comparison(s)	Arthrographic joint distension + physiotherapy *versus* arthrographic joint distension + placebo physiotherapy. ***Arthrographic distension*** of the glenohumeral joint with steroid and normal saline was done under radiologic guidance at one of several community-based radiology practices. Patients received physiotherapy or sham physiotherapy from experienced physiotherapists, twice weekly for 2 weeks then once weekly for 4 weeks (8 visits, 30 minutes each). The physiotherapist-patient interaction was standardised. ***Physiotherapy:*** The goals were to maintain and increase active and passive glenohumeral range by stretching soft tissue structures adjacent to the joint; to improve strength, particularly within newly gained passive range; and to regain proprioception and normal shoulder and trunk biomechanics. Specific interventions included: passive and self-executed muscle stretching techniques to stretch muscles passing over the glenohumeral joint, cervical and thoracic spine mobilisation, glenohumeral joint passive accessory glides, glenohumeral joint passive physiologic mobilisation including rotation, strength and coordination exercises for rotator cuff and scapular stabilisers, and proprioceptive challenge. At the end of the 6-week program, patients were instructed to maintain their 10-minute daily home exercise program, recording these sessions in a logbook. ***Placebo physiotherapy:*** Patients underwent 8 sessions of sham ultrasound and application of a non-therapeutic gel. They received no instruction in exercise techniques and no manual therapy. This protocol had been used previously with successful blinding demonstrated in 81% of placebo-treated participants.
Accepted outcome(s)	SPADI (a self-administered tool scored out of 100, with higher scores indicating greater pain or disability). Overall assessment of pain, pain at night, activity-related pain and pain at rest on a 10-point Likert scale. Adverse effects/events by open-ended questions. ***Timing of assessments:*** (1) Baseline; (2) End-point: 6 weeks; (3) Follow-up: 12 and 26 weeks.
Period of data collection	March 2002−April 2005.
Notes	More patients in the placebo group had post-operative capsulitis than those in the active

	group: 17 (23%) *versus* 9 (12%).
Trial	Bulgen et al (1984)*
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: NO; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: NO.
Population	42 patients explicitly diagnosed with 'frozen shoulder' and apparently at the pain-predominant stage, since the ***inclusion criteria*** stipulate, in addition to restricted active and passive movement in all ranges (including > 50% restriction of external rotation), that participants be unable to lie on the affected side. ***Mean age (range), % female:*** 59 (44–74) years, 67%. ***Setting:*** Secondary or tertiary care. Trial took place in a Rheumatology Research Centre in a UK hospital.
Intervention/ Comparison(s)	Mobilisation *versus* ice *versus* steroid injection *versus* no treatment. The ***mobilisation group*** received Maitland's mobilisations from a research physiotherapist 3 times weekly for 6 weeks. The ***steroid injection group*** received 20 mg methyl prednisolone acetate 20 mg and 0.5 ml 1% lignocaine hydrochloride injected into the subacromial bursa, and a similar amount into the shoulder joint by the anterior route, weekly, for three weeks. The ***ice group*** had ice packs followed by proprioceptive neuromuscular facilitation (PNF) supervised by the same research physiotherapist. ***All patients*** were taught pendular exercises and advised to do them for 2–3 minutes every hour. Non-salicylate analgesics and diazepam 5 mg at night were available as required.
Accepted outcome(s)	Pain at rest, pain on movement and night pain were initially recorded on a 10 cm VAS and by verbal reports: 'better', 'same', or 'worse' (adverse events). The VAS was later abandoned but the verbal reports retained. Passive ranges of movement were also measured. ***Timing of assessments:*** (1) Baseline, (2) In-trial and end-point: weekly for 6 weeks (3) Follow-up: monthly for a further 6 months.
Period of data collection	Unspecified
Notes	Data presentation incompatible with meta-analysis or tabulation, but trial included in review by Green, Buchbinder and Hetrick (2003) and the present review for narrative purposes. (Bulgen et al. concluded that there was 'little long term advantage in any of [their] treatment regimens over no treatment, but that steroid injections may benefit pain and range of movement in the early stages [though not statistically significantly so]. There [appeared] to be little place for physiotherapy alone, and, if used, it should not be continued for more than four weeks'.)
Trial	Calis et al (2006)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: NO; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	95 shoulders diagnosed with adhesive capsulitis in 90 patients. ***Inclusion criteria:*** ≥ 1 month's pain; limited active and passive shoulder movement, with decreased range of passive movement of ≥ 20% in ≥ 3 ranges; negative Neer's test. ***Exclusion criteria:*** Previous injection of involved shoulder; Allergy to local anaesthetics, steroids or sodium hyaluronate; coagulation disorders; cervical radiculopathy, fracture dislocation or rotator cuff tears; haematological, infectious, neurological, endocrine, cardiovascular, hepatic, renal or malignant disease; severe osteoporosis. ***Mean age ± SD, % female: Group 1*** 60 ± 10 years, 58%; ***Group 2*** 56 ± 11 years, 64%; ***Group 3*** 52 ± 10 years, 62%; ***Group 4*** 59 ± 7 years, 70%

	Setting: Secondary or tertiary care. Trial took place in Erciyes University Medical Faculty, Kayseri, Turkey.
Intervention/ Comparison(s)	***Group 1:*** 30 mg sodium hyaluronate (orthovisc) was injected into the shoulder joint using a posterior approach, weekly for 2 weeks. ***Group 2:*** 40 Mg triamcinilone acetonide (Kenakort-A) was injected into the shoulder joint using a posterior approach. ***Group 3:*** Physiotherapy comprised a 20-minute hot pack, ultrasound at 1.5 W/cm^2 for 5 minutes, transcutaneous electrical nerve stimulation at the patient's tolerance for 20 minutes and stretching exercises daily for 10 days. No other details were given. ***Group 4:*** All patients, including control patients, were advised on a home exercise programme including stretching and Codman (pendular) exercises, and the use of paracetamol if necessary.
Accepted outcome(s)	Pain severity, measured on a 10 cm VAS; passive external rotation; Constant score. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline: (2) In –trial and end-point: None; (3) Follow-up: 15 days, 3 months.
Period of data collection	Unspecified
Notes	There were 3 patients with bilateral involvement in ***Group 1***, and 1 in each of ***Groups 2*** and ***3***.
Trial	Carette et al (2003)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: NO*; Blinding of subjects: YES†; Blinding of therapists: YES†; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES. *Gender was not evenly distributed between the groups, so analyses were adjusted for this. †In the injection groups. ‡Primary outcome measure, but not secondary outcomes, analysed by intention-to-treat.
Participants	93 patients aged ≥ 18 and symptomatic < 1 year with adhesive capsulitis. Pain-predominant and stiffness-predominant stages were included (but managed differently from the physiotherapy perspective – *see* below). ***Inclusion criteria:*** Shoulder pain with limitation of both active and passive movements of the glenohumeral joint of ≥ 25% in at least 2 directions *versus* the contralateral shoulder or normal values (reference supplied). Patients were required to have a total score ≥ 30 on Shoulder Pain And Disability Index (SPADI). ***Exclusion criteria:*** Capsulitis secondary to another cause including inflammatory, degenerative, metabolic or infectious arthritis, CVA or fracture; known blood coagulation disorder or allergy to radiologic contrast material. From March 1997, recruitment difficulties led to the acceptance of patients with diabetes mellitus. ***Mean age ± SD, % female: Group 1*** 55 ± 10 years, 65%; ***Group 2*** 57 ± 9 years, 61%, ***Group 3*** 55 ± 11 years, 67%; ***Group 4*** 54 ± 8 years, 46%. ***Setting:*** Secondary care. Trial took place in outpatient rheumatology clinics in 7 centres across Quebec and Ontario, Canada.
Intervention/ Comparison(s)	Before randomisation, the physiotherapists responsible for baseline and follow up assessments taught all patients a 10-minute ***home exercise programme*** to be done twice daily for 3 months. This included active and auto-assisted exercises in all ranges. Advice about intensity, frequency, progression of the exercises, heat and ice applications, and suitable shoulder positions was also given. Compliance was diarised during the first 3 months of the trial. Injections were done under fluoroscopic guidance by trained radiologists on the day of randomisation and comprised, in ***Group 1, 40 mg triamcinilone hexacetonide*** (2 ml) or, in ***Group 2, isotonic saline*** (2 ml). The syringes were prepared by the hospital pharmacist and covered in foil so that neither the injector nor the patient knew what substance was injected. Patients randomised to ***Groups 3 and 4*** received ***injection + physiotherapy***, starting their physiotherapy programme 1 week after injection (of triamcinilone or saline). This comprised 3 x 1-hour sessions given each week for 4 weeks (12 sessions). Physiotherapy

	differed according to whether the capsulitis was 'acute' (meeting ≥ 3 of the following criteria) or 'chronic': (1) pain at rest ≥ 4 cm on a 10 cm VAS; (2) pain at rest present ≥ 75% of the day; (3) pain on active shoulder elevation ≥ 4 cm on a 10 cm VAS; (4) night pain; (5) spasm or 'empty' end-feel in at least 2 directions of passive motion. Patients with acute adhesive capsulitis received TENS followed by mobilisation techniques, active ROM exercises and ice application. Those with chronic adhesive capsulitis received ultrasound (to heat the deep joint structures) prior to mobilisation techniques, active and auto-assisted ROM techniques, isometric strengthening exercises and ice application. The 14 physiotherapists who took part in the trial (2 per centre) were each experienced in shoulder conditions and mobilisation techniques and each attended a 1-day training session before the trial for standardisation. Patients and their GPs were asked to limit concurrent interventions: all medications other than acetaminophen were stopped. A supply of the latter was given to patients with a form to record their use. Information on acetaminophen or other medication use was obtained at each follow-up.
Accepted outcomes	***Shoulder Pain And Disability Index (SPADI)*** with decrease in total score ≥ 10 indicating clinically significant improvement in shoulder pain and function; and an increase > 10 indicating worsening of shoulder pain and function (reference given). ***Passive external rotation*** measured with a hydrogoniometer. Usually, each patient was measured by the same physiotherapist, blind to treatment allocation, through the trial. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline: SPADI and passive external rotation (2) End-point: SPADI at 6 weeks (primary outcome) and passive external rotation at 6 weeks (secondary outcome); (3) Follow-up: SPADI and passive external rotation at 3, 6 and 12 months (secondary outcomes).
Period of data collection	November 1996 – June 2000
Notes	
Trial	Cheing, So and Chao (2008)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: YES.
Participants	70 patients diagnosed with idiopathic frozen shoulder by an orthopaedic surgeon. The stage appears to have been pain-predominant since the ***Inclusion criteria*** state night pain, in addition to localised pain over one shoulder and restricted active and passive shoulder ROM. ***Exclusion criteria:*** History of trauma; fractures; history of shoulder surgery; cervical or thoracic pain syndrome; complex regional pain syndrome; malignancy; anticoagulant therapy; or acupuncture to the affected shoulder in the past 6 months. ***Age range, % female:*** 33−90 years, 83%. ***Setting:*** Secondary or tertiary care. Trial took place in Hong Kong.
Intervention/ Comparison(s)	***Electro-acupuncture:*** Patients received 10 sessions (2–3 times weekly) from the same physiotherapist (accredited to practice acupuncture) over a 4-week period. Following skin sterilisation with an isopropyl skin wipe, sterile, stainless steel acupuncture needles (0.30 x 40 mm) were inserted 15–25 mm intramuscularly into 3 acupoints including one trigger point, one local point (LI 15: Jianyu) and one distal point (ST38: Tiaokou). Trigger points were identified by areas of greatest tenderness around the painful shoulder. Needles were stimulated manually until the patient felt a needling response (*de qi*) locally. The two needles in the shoulder region were connected to an EA device and stimulated with an alternating frequency of 2–100 Hz at a pulse duration of 100–400 microseconds for 20 minutes. The intensity was adjusted to just below the threshold of pain. The distal needle was retained for 20 minutes and manually lifted and thrusted every 10 minutes. At the first session patients were taught a home exercise programme. This involved following a chart and performing a

	standard set of shoulder mobilising exercises 5 times daily. The exercises comprised active assisted: flexion (using an overhead pulley), external rotation (using a cane), horizontal adduction (posterior capsular stretch) and internal rotation (using a towel). Each patient was given an exercise registration card to monitor compliance and asked to continue the exercise programme until the 6-month review. ***Interferential electrotherapy (IFE).*** These patients received 10 sessions of IFE over 4 weeks. A Phyaction Guidance E Unit was used to deliver current sweeping from 80–120 Hz *via* 4 suction electrodes in a co-planar arrangement around the shoulder region. The intensity was adjusted to just below pain threshold and the duration was 20 minutes. The patients were instructed to perform 'the same set of home exercise programmes' as those in the EA group, and an exercise registration care was also given to each subject. ***Control.*** These patients received no treatment for 4 weeks, but were invited to attend the assessment sessions at baseline and at the end of the fourth week. Afterwards, they received regular physiotherapy from other physiotherapists: no further data were extracted from them.
Accepted outcomes	Constant Murley Assessment Score; VAS for pain 'at the moment'. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) End-point: 4 weeks; (3) Follow-up (for the electro-acupuncture and IF groups only): 8, 12, and 24 weeks.
Period of data collection	Unspecified
Notes	

Trial	Dacre, Beeney and Scott (1989)*
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: NO.
Population	62 patients with 'painful stiff shoulder' apparently at the pain-predominant stage, since the ***Inclusion criteria*** state painful stiff shoulder for $\geq$ 4 weeks, and pain at night causing sleep disturbance and inability to lie on the affected side, in addition to inability to use the affected arm with restriction of movement and loss of full function. ***Exclusion criteria:*** predisposing causes such as stroke, generalised arthritis, or cervical spondylosis; or highly localised lesions, such as bicipital tendinitis. ***Mean age, % female:*** 60 years, 55%. ***Setting:*** Secondary or tertiary care. Trial took place in London, England.
Intervention/ Comparison(s)	Physiotherapy alone *versus* steroid injection alone *versus* a combination of the two. Physiotherapy was performed for 4–6 weeks by one therapist who was free to choose the method, though mobilisation was the mainstay. Steroid injections comprised 20 mg triamcinolone 'injected anteriorly around the shoulder joint' by one physician.
Accepted outcome(s)	Pain assessed on a 10 cm visual analogue scale, with separate scores for day pain, night pain, and pain during active and passive movement. Passive movement of both affected and unaffected shoulders measured with a goniometer included glenohumeral external rotation. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) End-point: 6 weeks; (3) Follow-up: 26 weeks.
Period of data collection	Unspecified
Notes	Only illustrative examples of results were given, in graphic form, and it was not possible to accurately impute quantitative values to these. This data presentation was incompatible with meta-analysis or tabulation but trial included in review by Green, Buchbinder and Hetrick (2008) and the present review for narrative purposes. The authors concluded: 'No treatment

	showed any advantage which was clinically relevant and significant at the 5% level.'
Trial	Ginn and Cohen (2005)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: YES.
Population	138 volunteers with shoulder pain, of whom 77 had decreased abduction and/or flexion. ***Inclusion criteria:*** Unilateral pain over the shoulder and/or upper arm > 1 month's duration and aggravated by active shoulder movements; able to understand spoken English. ***Exclusion criteria:*** Bilateral shoulder pain; shoulder instability; shoulder pain due to inflammatory or destructive disease or trauma in the preceding 4 weeks; referred pain from the spine. ***Mean age and range and % female (for whole sample):*** 55 years (22–90), 41%. ***Setting:*** Secondary care. Trial took place in a metropolitan public hospital in Sydney, Australia.
Intervention/ Comparison(s)	***Multiple treatment modalities (MTM***): Patients attended twice weekly for treatment, specifics of which were at the discretion of their treating physiotherapist (n = 6). Electrotherapy options were interferential, ultrasound, hot packs and ice packs. Passive mobilisation of the shoulder, sternoclavicular and acromioclavicular joints were also permissible. Range-of-motion exercises, which could be conducted with or without equipment, and which were not required by the protocol to be pain free, focused on abduction, flexion, extension, horizontal flexion and hand-behind back, all with excessive scapular movement discouraged. Exercises were progressed from active-assisted through active to resisted. Patients were also instructed in a daily home exercise programme. ***Steroid injection:*** A single injection of 40 mg methylprednisolone acetate and lidocaine was given subacromially. Afterwards, the patient was asked to use the shoulder normally. ***Target exercise treatment:*** This was a daily home routine aimed at restoring normal muscle function and hence dynamic stability and muscle co-ordination. It involved stretching shortened muscles, strengthening weakened muscles, improving co-ordination between muscles, and retraining scapulohumeral rhythm. Exercises were required to be pain free. Specific exercises in each case were chosen by the treating physiotherapist (n = 2), who reviewed the patient weekly for monitoring and progression.
Accepted outcome(s)	The only outcome reported for the painful stiffness subgroup was perceived change: 'improved', 'stable' or 'deteriorated'. This therefore included adverse events. ***Timing of assessments:*** (1) Baseline; (2) End-point: 5 weeks; (3) Follow-up: None.
Period of data collection	46-month period: dates unspecified.
Notes	
Trial	Guler-Uysal and Kozanoglu (2004)
Methods	Eligibility criteria specified: YES; Random allocation: NO; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: YES.
Population	40 patients (28 female; age range 43–82 years, mean 56 ± 8.6 years) diagnosed with shoulder capsulitis, probably a mix of pain-predominant and stiffness-predominant. ***Inclusion criteria:*** Shoulder pain $\geq$ 2 months with no major shoulder trauma, marked loss of active and passive

	shoulder motion, VAS score ≥ 30 mm, normal AP and axillary lateral radiographs of the shoulder joint. ***Exclusion criteria:*** Polyarthritis, neurological disease or cervical neuropathy, medical conditions such as cardiac disease, infections, coagulation disorders, adhesive capsulitis secondary to shoulder dislocation, fracture, reflex sympathetic dystrophy or rotator cuff tears. ***Mean age ± SD, % female:*** 56 ± 9 years, 70%. ***Setting:*** Secondary or tertiary care. Trial took place in a physical medicine department in Adana, Turkey.
Intervention/ Comparison(s)	2 groups of 21 each. The ***Cyriax group*** received 3, 1-hour sessions weekly, comprising 'deep friction massage and manipulation' performed by the same experienced physical therapist. The ***physical therapy group*** were invited to the hospital every weekday for a 1-hour session comprising hot packs wrapped in towelling (20 minutes) and continuous SWD (20 minutes). ***Both groups*** performed active stretching and pendular exercises after each session, and were instructed in a standardised home exercise programme comprising passive ROM and pendular exercises to be performed daily. Use of NSAIDs or analgesic was not permitted throughout the trial.
Accepted outcome(s)	Physical assessment was repeated by the same blinded observer. ROM was measured using a long-arm goniometer, and the patient supine, after every session. (It is unclear who performed these measurements). Treatments were stopped when 80% of normal range was attained. Attainment of 80% of normal range was therefore the trial's primary outcome. Normal range was taken as 180° for flexion and abduction, 70° for internal- and 90° for external rotation (rotations being measured in 90° of shoulder abduction); so that minimum ranges of 150°, 150°, 55° and 70°, respectively, were required for a patient to be considered 'recovered'. Other accepted outcomes are spontaneous pain, pain on motion, and night pain on a 100 mm VAS, and passive range of external rotation (measured at 90° of abduction with a long-armed goniometer). Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline, (2) In-trial and end-point: 1 and 2 weeks; (3) Follow-up: None.
Period of data collection	Unspecified
Notes	This is a perplexing study, because deep transverse friction, while originated by Cyriax, was not applied by him to contracted (frozen) shoulder. Details of the technique, not provided in the report, are therefore not available in the source cited. Moreover the term 'manipulation' is undefined.
Study	Johnson et al (2007)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: NO; Intention-to-treat: NO; point measures and measures of variability: YES.
Population	18 patients diagnosed with adhesive capsulitis or frozen shoulder by any of 4 orthopaedic surgeons and referred for outpatient physiotherapy. Probably a mix of pain-predominant and stiffness predominant. ***Inclusion criteria:*** External rotation restriction that worsened with shoulder abduction, idiopathic or primary adhesive capsulitis (i.e. insidious onset with no history of major trauma but not excluding minor injuries), unilateral, age 25−80 years, normal X-ray within the previous 12 months. ***Exclusion criteria:*** External rotation restriction that lessened with shoulder abduction, previous shoulder surgeries to the affected shoulder, previous manipulations under anesthesia of the affected shoulder, shoulder girdle motor control deficits associated with neurological disorders (eg, stroke, or Parkinson's disease). ***Mean age ± SD, % female: Anterior mobilisation group*** 55 ± 8 years, 80%; ***Posterior mobilisation group*** 50 ± 7 years, 75%. ***Setting:*** Secondary or tertiary care. Study took place in California, USA.

Intervention/ Comparison(s)	***Anterior mobilisation group:*** 6 therapy sessions (2−3 per week) comprising therapeutic ultrasound to the anterior capsule (typically 3 MHz at 1.5 W/cm^2 continuous for 10 minutes, intended to heat the capsule) then anterior mobilisations. During lateral traction, Kaltenborn grade III mobilisations were performed at the end-range of available combined abduction and external rotation, with non-oscillatory stretches of $\geq$ 1 minute. Each session included a total of 15 minutes' sustained stretch. This was followed by upper body ergometer exercise in pain-free flexion range to reduce post-mobilisation soreness. ***Posterior mobilisation group:*** as above except that ultrasound (1 MHz) was applied to the posterior capsule, (1 MHz), the mobilisation was posterior, and the starting position was progressed to maximum flexion and external rotation. ***Both groups:*** Handout instructions were given on pain free activities of daily living on entering the study.
Accepted outcome(s)	5 items of the 21-item self-assessment function questionnaire developed by L'Insalata et al (full reference given). Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) End-point: 2 or 3 weeks; (3) Follow-up: None.
Period of data collection	October 2003 – January 2005
Notes	
Study	Khan et al (2005)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: NO; Intention-to-treat: NO; point measures and measures of variability: NO.
Population	35 patients attending outpatients of the Departments of Physical Medicine or Department of Radiology of a tertiary referral medical college. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder, thus: ***Inclusion criteria:*** Age 13–69 years, shoulder pain > 1 month, restricted movement. ***Exclusion criteria:*** Lack of consent, trauma to or around the shoulder in the past 2 months, pain and restriction of the shoulder secondary to indentified causes (e.g. hemiplegia, cervical radiculopathy, IHD, rheumatological syndromes, infective conditions, reflex sympathetic dystrophy, part of a systemic illness), pregnancy and lactation. ***Mean age ± SD, % female: Arthrography group*** 50 ± 17 years, 50%; ***Physiotherapy-only group*** 50 ± 10 years, 35%. ***Setting:*** Tertiary care. Study conducted in Bangladesh, India.
Intervention/ Comparison(s)	***Arthrography group:*** A posterior approach was made using a 24 G needle: 2 cc xylocaine, 10 cc 75% urovideo and 1 cc (40 mg) depot medrol, drawn together in normal saline were injected under fluoroscopic guidance. ***All patients received physiotherapy:*** comprising therapeutic exercises (hold-relax, rotator cuff, pulley, pendular and wall-climbing exercises), TENS 3 days a week and infra-red 3 days a week. Length of course of physiotherapy is unspecified.
Accepted outcome(s)	Pain scored on a 0–100 VAS. Adverse events: exacerbations in pain reported on an individual basis. ***Timing of assessments:*** (1) Baseline; (2) In-trial: Every visit; (3) Follow-up: 8 weeks.
Period of data collection	December 1996−November 1997
Notes	
Study	Kivimäki et al (2007)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.

Population	125 patients with stiff, painful shoulders recruited from 3 regional hospitals. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder. ***Inclusion criteria:*** Adult patients with gradually increasing shoulder pain and stiffness screened on the basis of X-ray and physical examination by physical medicine and rehabilitation specialists; $\leq 140^{o}$ elevation and $\leq 30^{o}$ passive external rotation. ***Exclusion criteria:*** arthritis, traumatic bone or tendon changes. Suspected cuff tears were ultrasound scanned and, if confirmed, excluded. ***Mean age ± SD, % female: Manipulation group*** 53 ± 8 years, 71%; ***Control group*** 53 ± 9 years, 65%. ***Setting:*** Secondary or tertiary care. Study took place in Southern Finland.
Intervention/ Comparison(s)	The ***manipulation group*** underwent manipulation under anaesthetic within 2 weeks of randomisation. With the patient supine, the physician elevated the humerus into scaption while supporting the scapula against the patient's thoracic cage. In the elevated position, the humerus was gently rotated internally and externally. Any cracking sound was recorded. Normal or near-normal mobility was attained during these procedures. The ***manipulation*** and ***control groups*** received physiotherapy advice in 2 sessions and written instructions for a daily training, which included pendular exercises and stretching techniques for the shoulder joint.
Accepted outcome(s)	Modified Shoulder Disability Questionnaire (with 2 questions omitted from the standard 16-point questionnaire), pain intensity on an 11-point scale, passive external rotation using a universal goniometer. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) End-point: None; (3) Follow-up: 3, 6 and 12 months.
Period of data collection	June 1999–September 2002
Notes	

Study	Lee et al (1973)*
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: NO; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: NO.
Population	80 outpatients (gender unspecified) with 'periarthritis' of the shoulder, defined as pain with limitation of passive movement. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder. ***Age and % female:*** not stated in original article, but mean age reported as 58 years by Green, Buchbinder and Hetrick (2000), presumably following correspondence with authors. ***Setting:*** Secondary or tertiary care. Study took place in Leeds, England.
Intervention/ Comparison(s)	4 groups of 20 each. ***Group 1*** received a course of infrared and graduated active exercises according to tolerance. ***Group 2*** received an intra-articular injection of 25 mg hydrocortisone acetate *via* the anterior approach below the coracoid process, followed by the same graduated exercises. ***Group 3*** received an injection of 25 mg hydrocortisone acetate into the biceps tendon sheath, followed by the same graduated exercises. ***Group 4*** was a control and received only analgesia.
Accepted outcome(s)	Movements measured were active external and internal rotation with the arm by the side and active and passive abduction; but a single outcome was generated from these components. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) In-trial and end-point: weekly for 6 weeks (for ***groups 1–3***) and 6 weeks (for ***group 4***); (3) Follow-up: None.
Period of data collection	Unspecified

Notes	Group averages (means?) were presented graphically without error bars. There was no statistical analysis. This data presentation was incompatible with meta-analysis or tabulation but the trial was included in the review by Green, Buchbinder and Hetrick (2008) and the present review for narrative purposes. (The active intervention groups all fared better than the control at every time point; among these groups, that receiving intra-articular injection plus exercises fared best. Injection of the biceps tendon sheath conferred no benefit over heat and exercises alone: in both of these groups benefits reached a plateau at week 3.)
Study	Leung and Cheing (2008)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	30 patients suffering from 'stiffness phase' [stiffness-predominant] idiopathic frozen shoulder as diagnosed by an orthopaedic surgeon. ***Inclusion criteria:*** Shoulder pain and limited movement for at least 8 weeks. ***Exclusion criteria:*** History of trauma to the shoulder, acute signs of inflammation over the shoulder, intrinsic shoulder pathology, taking analgesic or anti-inflammatory drugs, metal implants, impaired sensation of hot and cold, pregnancy or a cardiac pacemaker. ***Mean age ± SD, % female:*** 60 ± 13 years, 70%. ***Setting:*** Secondary or tertiary care. Study took place in Hong Kong.
Intervention/ Comparison(s)	***Shortwave diathermy (SWD).*** SWD was applied by the through-and-through method, with subjects seated. Intensity was adjusted until comfortable warmth was perceived, and this perception was maintained by further adjustments throughout the treatment if necessary. 20 minutes treatment was given 3 times a week for 4 weeks. ***Hot pack.*** An electrical 35.5 x 68.5 hot pack was used, with its temperature set at 63^{o} C. Patients were instructed that only comfortable warmth should be perceived, and the temperature was adjusted as necessary to maintain this perception throughout the treatment. 20 minutes treatment was given 3 times a week for 4 weeks. Immediately after either heat treatment, patients were asked to perform 4 ***stretching exercises*** in a fixed sequence: external rotation; flexion; hand behind the back; and horizontal adduction (posterior capsular stretch). Each stretch was sustained for 30 sec, followed by 10 sec rest, and repeated 4 times. Patients were asked to repeat the stretches at home every day. A therapist checked for compliance with the exercise regime. In the ***stretching exercises only*** group, the procedure was identical.
Accepted outcome(s)	Measures included the American Shoulder and Elbow Surgeons Assessment form (ASES). This has a patient self-completed section designed to measure pain and functional limitation, (reference given). A further section of the ASES was physician-completed, and involved measurement of ROM. Data for external rotation were separately reported, but unclear was whether this was passive or active range. All assessments were performed by the same physiotherapist who was blinded to subject and intervention order throughout. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) In-trial and end-point: Week 2 and 4; (3) Follow-up: Week 8.
Period of data collection	Unspecified
Notes	

Study	Nicholson (1985)*
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: NO; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: YES.
Population	20 patients explicitly diagnosed with 'adhesive capsulitis' as indicated by the presence of shoulder pain and limited passive movement at the glenohumeral joint. Probably a mix of pain-predominant and stiffness-predominant stages. ***Mean age (range), % female:*** 53 (20–77 years), 50%. ***Setting:*** Care setting unclear. Study took place in Alabama, USA.
Intervention/ Comparison(s)	A 4-week course of ***mobilisation plus active exercises*** *versus* ***active exercises alone***. Choice of mobilisation techniques was based on assessment of accessory movements on a patient-by-patient basis.
Accepted outcome(s)	Measurements included: completion of a pain questionnaire, of which no further details are given; active internal and external rotation and abduction; and passive abduction. Adverse effects/events were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) In-trial and end-point: Weekly for 4 weeks; (3) Follow-up: None.
Period of data collection	Unspecified
Notes	Included in review by Green, Buchbinder and Hetrick (2003).
Study	Pajareya et al (2004)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	122 patients attending an orthopaedic and rehabilitation clinic. ***Inclusion criteria:*** Shoulder pain and limitation of passive shoulder ROM in all directions that interfered with ADL. Attending the orthopaedic and rehabilitation clinic. ***Exclusion criteria:*** Secondary adhesive capsulitis; 'intrinsic' causes of shoulder problems such as history of fracture or dislocation, or 'extrinsic' causes such as neuromuscular disorders, generalised arthritis, bilateral involvement, contraindications to NSAIDs or susceptibility to bleeding. ***Mean age ± SD, % female: Control group*** 58 ± 10 years, 76%; **Physiotherapy group:** 56 ± 11 years, 60%. ***Setting:*** Secondary or tertiary care. Study took place in Siriraj Hospital, Thailand.
Intervention/ Comparison(s)	**Control group** received ibuprofen 400 mg 3x daily for 3 weeks and an information sheet. This gave advice on protecting the shoulder from vigorous activities such as pushing or pulling. They were advised to use their arms normally for reaching and other ADL. They were asked to have no adjuvant therapy for the duration of the study except oral acetaminophen (up to 6g/day). They were asked to record if they received additional treatment [additional to acetaminophen?] and to keep a home exercise diary. ***Physiotherapy group:*** in addition to the above received a hospital-based physiotherapy programme, 3 x weekly by one of 3 research physiotherapists using standardised technique. Each session comprised: 20 minutes' shortwave diathermy (no further details given) then mobilisation and passive stretching to tolerance. If pain occurred before end-range, exercise (*see* below) was considered contraindicated, but the subsequent management of any such patients is unspecified. On non-physiotherapy days members of the ***physiotherapy group*** were advised to apply a hot

	pack for 20 minutes, then, after 5 minutes' interval, to do active assisted pulley exercises for 5 min, and active exercises using a towel and wall.
Accepted outcome(s)	SPADI. (External rotation was measured, but unclear was whether this was passive or active range.) ***Adverse events: The physiotherapy group*** were asked (a) whether or not they experienced pain for > 2 hours after treatment and (b) whether they had more disability next morning; ***All patients*** were asked by a blinded rater 'Have the trial drugs and/or treatment programme upset you in any way?' and examined for signs of bruises or burns during evaluation of movement. ***Timing of assessments:*** (1) Baseline; (2) End-point: 3 weeks; (3) Follow-up: 6, 12 and 24 weeks, though an undefined outcome – 'successful treatment' – was used, and any treatment was allowed after week 3.
Period of data collection	January–September 2001
Notes	
Study	Ryans et al (2005)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: YES; Blinding of assessors: YES; Intention-to-treat: NO; point measures and measures of variability: YES.
Population	80 adults recruited from 20 local general practices. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder, thus: ***Inclusion criteria:*** > 18 years, painful shoulder in C5 distribution, > 4 weeks' but < 6 months' duration, limitation of active and passive ROM > 25% in both abduction and external rotation compared with the other shoulder. ***Exclusion criteria:*** Previous intra-articular injection or physiotherapy for this episode, evidence of glenohumeral arthritis on plain X-ray, clinical evidence of a complete cuff tear or significant cervical spine disease, history of significant trauma to the shoulder, inflammatory joint disease or a CVA affecting the shoulder, bilateral adhesive capsulitis. ***Mean age ± SD, % female: Group A*** 56 ± 6 years, 45%; ***Group B*** 52 ± 9 years, 68%; ***Group C*** 53 ± 8 years, 70%; ***Group D*** 55 ± 9 years, 53%. ***Setting:*** Primary care. Study took place in Belfast, Northern Ireland.
Intervention/ Comparison(s)	***Injection group.*** 3 ml comprising 1 ml triamcinilone (20 mg) and 2 ml normal saline was injected, half by an anterior approach (anterior glenohumeral) and half by a lateral approach (lateral subacromial), without guidance, by a single clinician. ***Physiotherapy group.*** 8 standardised sessions were given over 4 weeks by a single therapist or a nominated deputy. The sessions included PNF, Maitland mobilisations –which were progressed as the condition improved – standardised interferential and active exercise therapy using gym equipment. For patients receiving ***injection and physiotherapy***, the interval between the two is unspecified. ***General.*** Patients who were not already taking analgesics were advised to take 1 or 2 500 mg paracetamol tablets 4–6 hourly as required, up to a maximum of 8 tablets a day. Analgesics and NSAIDs taken were recorded in a medication diary. Patients were taught a home exercise programme using a video and instruction sheet. They were asked to make a record, in their medication diary, of when they did the programme.
Accepted outcome(s)	22-point Shoulder Disability Questionnaire (SDQ), 100 mm VAS for daytime pain at rest, passive external rotation (to nearest 2^{o}) using a Myrin™ OB goniometer. Adverse effects/events in individuals were not specified as outcomes. ***Timing of assessments:*** (1) Baseline; (2) End-point: None; (3) Follow-up: 6, 16 and 24 weeks (but results not presented for 24 weeks).

Period of data collection	October 1998–April 2002
Notes	
Study	Van der Windt et al (1998)*
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	108 patients visiting one of 60 participating GPs. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder, thus: ***Inclusion criteria:*** Painful, limited passive glenohumeral mobility, with external rotation relatively more restricted than abduction and internal rotation. ***Exclusion criteria:*** Indications that any condition other than 'capsular syndrome' was contributory to symptoms were regarded as an exclusion criterion. Other exclusions were bilateral symptoms; a steroid injection or physiotherapy in the preceding 6 months; contraindications to treatment; surgery, dislocation, or fractures in the shoulder region; insulin dependent diabetes; systemic disorders of the musculoskeletal system; neurological disorders. ***Mean age ± SD, % female: Injection group*** 58 ± 10 years, 47%; ***Physiotherapy group*** 60 ± 11 years, 59%. ***Setting:*** Primary care. Study took place in the Netherlands.
Intervention/ Comparison(s)	Up to 3 intra-articular injections of 40 mg ***triamcinilone acetonide***, by the posterior route, over 6 weeks *versus* 12, 30-minute ***physiotherapy*** sessions over 4 weeks comprising passive joint mobilisations and exercises and, optionally, ice, hot packs, or electrotherapy. Acupuncture, high-velocity thrusts and ultrasound were not permitted. Patients were allowed to continue taking drugs for pain if they had started before enrolment, and drugs could also be prescribed for severe pain.
Accepted outcome(s)	Measures included: 16-item Shoulder Disability Questionnaire (SDQ); 100-point VAS for day and night pain and improvement in passive range of external rotation. Adverse effects/events were recorded by the clinician and by patients on their own forms. ***Timing of assessments:*** (1) Baseline; (2) In-trial and end-point: 3 weeks; (3) Follow-up: 7, 13, 26 and 52 weeks.
Period of data collection	Unspecified
Notes	Included in review by Green, Buchbinder and Hetrick (2008).
Study	Vermeulen et al (2006)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: YES; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point measures and measures of variability: YES.
Population	100 patients with stiffness-predominant frozen shoulder ('shoulder pain is apparent mainly in the end-range of ROM') recruited by one orthopaedic consultant from 6 hospitals. ***Inclusion criteria:*** ≥ 50% loss of passive movement of the shoulder joint relative to the non-affected side in ≥ 1 of flexion, abduction and external rotation, duration of ≥ 3 months, ability to complete questionnaire in Dutch. ***Exclusion criteria:*** previous manipulation under anaesthetic of the affected shoulder; other conditions affecting the shoulder (e.g. rheumatoid arthritis, osteoarthritis, chondral damage, Hill-Sachs lesions, osteoporosis or malignancies); neurological deficits; pain or disorders of neck, elbow, wrist or hand; steroid injection in the preceding 4 weeks. Diabetes was not an exclusion criterion. ***Mean age ± SD, % female:***

	Group 1 52 ± 8 years, 65%; ***Group 2*** 52 ± 9 years, 67%. ***Setting:*** Secondary or tertiary care. Study took place in Leiden, the Netherlands.
Intervention/ Comparison(s)	***Both groups:*** Mobilisations: with both hands close to the humeral head, the therapist applied inferior, posterolateral, anteromedial and oscillatory glides, and oscillatory distraction. If range of movement increased during treatment, the techniques were performed in greater elevation and abduction. In the last 3 minutes of the treatment session, passive PNF patterns were performed in the pain-free range, followed by pendular exercises in prone. Concurrent interventions apart from self- or physician-prescribed pain medications were disallowed in the first 3 months of the study. ***Group 1:*** High grade mobilisations (Maitland's grade III–IV) with standard precautions. The duration of time on stretch depended on the individual patients' responses. ***Group 2:*** Low grade mobilisations (Maitland's grade I–II), again, with standard precautions. ***Both groups:*** Treatments were twice weekly for 12 weeks. Thereupon further management was decided by the orthopaedic consultant and patient. For continued physiotherapy, if required, patients were referred to private practice.
Accepted outcome(s)	Shoulder rating score; pain during movement, at rest, and at night using a VAS; passive external rotation measured using a goniometer. ***Adverse events:*** Participants' opinions on their shoulder function (global change) relative to baseline were sought, but 'much worse', 'worse' and 'no change' categories were combined in the *Results*. Follow up was at 3, 6 and 12 months. ***Timing of assessments:*** (1) Baseline; (2) End-point: 3 months; (3) Follow-up: 6 and 12 months.
Period of data collection	August 1999−March 2002
Notes	The therapists administering the high grade mobilisation were trained, whereas those administering the low grade mobilisations were not. There was no non-intervention group, so it is unclear whether either intervention is better than doing nothing.
Study	Yang et al (2007)
Methods	Eligibility criteria specified: YES; Random allocation: YES; Concealed allocation: YES; Groups similar at baseline: YES; Blinding of subjects: NO; Blinding of therapists: NO; Blinding of assessors: YES; Intention-to-treat: YES; point mea sures and measures of variability: YES.
Population	28 patients with painful, stiff shoulder recruited from a Department of Physical Medicine and Rehabilitation. Probably a mix of pain-predominant and stiffness-predominant frozen shoulder, thus: ***Inclusion criteria:*** Painful, stiff shoulder for $\geq$ 3 months, limited range of movement ($\geq$ 25% *versus* the contralateral shoulder in at least 2 of flexion, abduction or internal and external rotation) and consent of patient and physician. ***Exclusion criteria:*** Diabetes, history of surgery on affected shoulder, rheumatoid arthritis, history of severe trauma, fracture in the shoulder region, rotator cuff rupture, tendon calcification. ***Mean age ± SD, % female: Group A-B-A-C*** 53 ± 7 years, 93%; ***Group A-C-A-B*** 58 ± 10 years, 79%. ***Setting:*** Secondary or tertiary care. Study was conducted at the National Taiwan University Hospital.
Intervention/ Comparison(s)	***A: 10-15 repetitions of mid-range mobilisation*** as described by Maitland and Kaltenborn, with the supine patient's shoulder abducted 40°. ***B: End-range mobilisation*** as described by Vermeulen et al. and Maitland; 10–15 repetitions of 'intensive mobilising techniques' were applied with the humerus at end-range in different directions. ***C: Mobilisations with movement (MWMs)*** as described by Mulligan. A belt was placed round the seated patient's proximal humerus to glide the humeral head appropriately. One of the therapist's hands was used over the appropriate aspect of the head of humerus, while the other applied counter pressure to the scapula. 'The glide was sustained during slow active shoulder movements to the end of the pain-free range and released after return to the starting position.' The

	technique was repeated in 3 sets of 10, with 1 minute rest between sets. ***All groups:*** No instruction in home exercises was given, and the patients were frequently asked not to do exercises. The Sequence of interventions was **A-B-A-C** and **A-C-A-B** with each component being 3 weeks: hence a total of 12 weeks.
Accepted outcome(s)	A self-administered scale, the Flexi-level scale of Shoulder Function (FLEX-SF). Adverse effects/events in individuals were not specified as an outcome. ***Timing of assessments:*** (1) Baseline; (2) In-trial and end-point: 3, 6, 9 and 12 weeks; (3) Follow-up: None.
Period of data collection	Unspecified
Notes	

Trials marked '*' were included in the review by Green, Buchbinder and Hetrick (2003)

APPENDIX C: Table of excluded studies

1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Ahn	2008	Frozen shoulder	Adhesiolysis	Not an RCT; not directly relevant to physiotherapy
Ainsworth	2007	Shoulder pain	Ultrasound	No separate analysis for capsular pattern subgroup
Ainsworth	2008	Shoulder pain	Ultrasound	Not an RCT (reply to a comment)
Amir-Us-Saqin	2007	Frozen shoulder	MUA plus steroid injection with and without immobilisation	Not directly relevant to physiotherapy
Amoretti	2006	Frozen shoulder	Capsular distension	Not an RCT (cohort study)
Bang	2000	Shoulder impingement syndrome	Exercise and physiotherapy	Not frozen shoulder
Bergman	2004	Shoulder dysfunction and pain	Manipulative therapy in addition to usual medical care	Patients with Frozen shoulder cannot be identified as a subgroup
Berry*	1980	Painful-stiff shoulder	Acupuncture, steroid injection, physiotherapy	Not frozen shoulder
Binder*	1984	Rotator cuff tendinitis	Pulsed electromagnetic fields	Not frozen shoulder
Bingöl	2005	Shoulder pain	Low-power laser	Patients with frozen shoulder cannot be identified as a subgroup
Boylan	2005	Shoulder pain	Soft-tissue massage	Not primary research: summary of article by van den Dolder 2003
Bron	2007	Common shoulder disorders	Trigger point physiotherapy	RCT in progress
Brox*	1993/7	Rotator cuff disease	Exercise, arthroscopic surgery	Not frozen shoulder
Brox	2003	Shoulder pain	Overview including steroid injections and physiotherapy	Not an RCT (descriptive review/monograph)
Buchbinder	2003	Frozen shoulder	Oral steroids	Not directly relevant to physiotherapy
Buchbinder	2006	Frozen shoulder	Oral steroids	Not an RCT (systematic review); not directly relevant to physiotherapy
Cleland	2002	Frozen shoulder	Physiotherapy	Not an RCT (systematic review)

1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Conroy*	1998	Shoulder impingement syndrome	Physiotherapy	Not frozen shoulder
Dal Conte*	1990	Calcific tendinitis	Pulsed electromagnetic fields	Not frozen shoulder
De Bruijn	2005, 2007	Shoulder complaints	Education and activation programme	Patients with frozen shoulder cannot be identified as a subgroup
Diercks	2004	Frozen shoulder	Supervised neglect v. intensive physiotherapy	Not an RCT (control and intervention groups were not contemporary)
Downing*	1986	Subacromial bursitis	Ultrasound	Not frozen shoulder
Ebenbichler*	1999	Calcific tendinitis	Ultrasound	Not frozen shoulder
England*	1989	Suprasinatus and biceps tendinitis	Laser	Not frozen shoulder
Garaets	2005	Shoulder pain (chronic)	Graded exercise programme v. usual care	Patients with frozen shoulder cannot be identified as a subgroup
Garaets	2006	Shoulder pain (chronic)	Graded exercise programme v. usual care	Duplication of 2005 report
Ginn*	1997	Shoulder pain	Physiotherapy	Patients with frozen shoulder cannot be identified as a subgroup
Ginn	2004	Shoulder pain with capsulitis subgroup	Various combinations of physiotherapy interventions and steroid injections	Not an RCT (cohort study)
Green	2003	Frozen shoulder	Steroid injections and physiotherapy, separately and in combination	Not an RCT (commentary on Carette 2003)
Gulik	2007	Frozen shoulder	Analgesic nerve block	Not an RCT (case study); not directly relevant to physiotherapy

1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Gursel	2004	'pain and limitation of [shoulder] motion', but unclear is whether this limitation pertained to active or passive range	Physiotherapy with and without ultrasound	Reported baseline ranges of motion not commensurate with frozen shoulder
Halverson	2002	Frozen shoulder	Capsular distension	Not an RCT (case series)
Hamdan	2003	Frozen shoulder	Manipulation under anaesthesia, injection and physiotherapy	Not an RCT
Hay	2003	Shoulder pain	Steroid injection v. physiotherapy	The subgroup with frozen shoulder was not separately analysed
Herrera-Lasso*	1993	Bicipital or supraspinatus tendinitis, subdeltoid bursitis or periarthritis	Ultrasound, TENS	The subgroup with frozen shoulder was not separately analysed
James	2005	Shoulder pain	Steroid injection v. physiotherapy	Patients with frozen shoulder cannot be identified as a subgroup
Karatas	2002	Frozen shoulder	Comparison of two types of suprascapular nerve block	Not directly relevant to physiotherapy
Koel	2008	Shoulder pain	Ultrasound	Not an RCT (comment)
Leclaire*	1991	Shoulder periarthritis	Magnetotherapy	Ambiguity of trial inclusion criteria
Loew	2004	Frozen shoulder	Inspection for iatrogenic damage post MUA	Not an RCT (observational study)
Nykanen*	1995	Rotator cuff disease	Ultrasound	Not frozen shoulder
Perron*	1997	Calcific tendinitis	Iontophoresis, ultrasound	Not frozen shoulder
Piotte	2004	Frozen shoulder	Distension therapy plus physiotherapy	Not an RCT
Pirotta	2007	General	Acupuncture	Not an RCT (descriptive review)
Polimeni	2006	Shoulder pain	Ultrasound and (non-standard) physiotherapy	Not an RCT (cohort study); no frozen shoulder subgroup identifiable

1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Reid*	1996	Anterior instability	Exercise, EMG biofeedback	Not frozen shoulder
Rendeiro	2006	Frozen shoulder	Added effect of manipulation after interscalene block to a course of physiotherapy	Not an RCT (non-randomised controlled trial); not a full report (conference abstract)
Roy	2007	Frozen shoulder	Overview	Not an RCT (descriptive review)
Saunders*	1995	Supraspinatus tendinitis	Laser	Not frozen shoulder
Saadat Niaki	2005	Frozen shoulder	Comparison of sites for blocks using steroid with local anaesthetic	Not an RCT
Shah	2007	Frozen shoulder	Multiple steroid injections	Not an RCT (systematic review)
Shehab*	2000	Peri-articular shoulder pain	TENS, ultrasound, ice, stretches	No frozen shoulder subgroup identifiable
Smidt	2003	Shoulder pain	Discussion on importance of diagnosis	Not an RCT (commentary)
Speed	2002	Shoulder pain	Overview	Not an RCT (review)
Taverna*	1990	Shoulder peri-arthritis	Laser	Not in English language (Italian)
Teys	2008	'inability to elevate the arm greater than 100º in the plane of the scapula because of the presence of [anterior shoulder] pain'	Mulligan's mobilisations-with-movement	The inclusion criterion is not specific to frozen shoulder
Thomas	2005	Shoulder pain	Injection v. physiotherapy	Not an RCT (review)
Van den Dolder	2003	Shoulder pain	Soft-tissue massage	No frozen shoulder subgroup identifiable
van den Hout	2005	Frozen shoulder	High-grade v. low-grade mobilisation techniques	Not an RCT (economic evaluation conducted alongside Vermeulen 2006)

1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Van der Heijden	1999	Shoulder pain	Interferential, ultrasound, exercises	No frozen shoulder subgroup identifiable
van der Windt	2003	Shoulder pain	Steroid injections and physiotherapy	Not an RCT (leader)
Vecchio*	1993	Rotator cuff tendinitis	Laser	Not frozen shoulder
Wang	2006	Shoulder pain	Customised v. standard exercises	No frozen shoulder subgroup identifiable
Watson	2007	Frozen shoulder	Capsular distension	Not an RCT (cohort study)
Whitman	2003	Frozen shoulder	Manipulation under local anaesthetic block v. mobilisation	Not an RCT (case report); no full report
1st Author	Year	Target condition	Intervention	Reason(s) for exclusion
Winters*	1997/9	Shoulder pain	Steroid injection, manipulation, physiotherapy	No frozen shoulder subgroup identifiable

Asterisked studies were included in the Cochrane review by Green, Buchbinder and Hetrick (2003)

APPENDIX D: References to excluded studies 

This reference list is limited to articles identified in the supplementary search but excluded from analysis (*see* APPENDIX A: Methods, and APPENDIX C: Table of excluded studies).

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APPENDIX E: GRADE evidence profile tables

i. Physiotherapy versus other physiotherapy

Author(s) **Carette et al (2003), Ryans et al (2005)**
Question i.i Should we add outpatient physiotherapy to home exercises for both stages of contracted (frozen) shoulder?
Settings Primary care, Canada; secondary care, Northern Ireland.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Outpatient physiotherapy and home exercises	Home exercises alone	Relative (95% CI)	Absolute		
Improvement in combined pain-function outcome (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	46	42	-	SMD 0.11 higher (0.3 lower to 0.53 higher)	⊕⊕OO LOW	CRITICAL
Improvement in combined pain-function outcome (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[1]	none	42	35	-	SMD 0.06 higher (0.39 lower to 0.51 higher)	⊕OOO VERY LOW	CRITICAL
Improvement in combined pain-function outcome: SPADI (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	26	23	-	MD 1.7 higher (12.78 lower to 16.18 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain, 100 mm VAS (6 weeks)												

2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[3]	none	46	42	-	MD 7.09 higher (5.22 lower to 19.4 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in pain, 100 mm VAS (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[1]	none	42	35	-	MD 6.72 higher (6.27 lower to 19.71 higher)	⊕OOO VERY LOW	CRITICAL
Improvement in pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	26	23	-	MD 0.1 higher (15.01 lower to 15.21 higher)	⊕⊕OO LOW	CRITICAL
Improvement in passive external rotation, degrees (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[4]	none	46	42	-	MD 6.68 higher (0.53 to 12.82 higher)	⊕⊕⊕O MODERATE	IMPORTANT[5]
Improvement in passive external rotation, degrees (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[6]	none	37	35	-	MD 1.44 higher (6.59 lower to 9.48 higher)	⊕⊕OO LOW	IMPORTANT[5]
Improvement in passive external rotation, degrees (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[6]	none	26	23	-	MD 1.2 higher (7.95 lower to 10.35 higher)	⊕⊕⊕O MODERATE	IMPORTANT[5]

[1] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.
[2] Unclear risk of bias.
[3] 95% CI crossed zero and adjusted threshold for MCID favouring addition of outpatient physiotherapy.
[4] 95% CI did not cross zero but potentially 'fragile' as total population small.
[5] Probably not critical from patients' perspective.
[6] 95% CI crossed zero. Threshold for MCID not known, but unlikely to lie inside 95% CI on either side of zero. 95% CI potentially 'fragile' however, as total population small.

Author(s) **Ginn and Cohen (2005)**
Question i.ii Should we use a home muscle function retraining programme or outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder?
Settings Secondary care, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Muscle function retraining programme	Outpatient physiotherapy and home exercises	Relative (95% CI)	Absolute		
Patients' global impression of change (5 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	17/23 (73.9%)	22/26 (84.6%)	RR 0.87 (0.65 to 1.17)	110 fewer per 1000 (from 296 fewer to 144 more)	⊕⊕⊕O MODERATE	CRITICAL[2]
								84.6%		110 fewer per 1000 (from 296 fewer to 144 more)		

[1] *See* 95% confidence limits for absolute effect.
[2] Outcome critical but unvalidated.

Author(s) **Ginn and Cohen (2005)**
Question i.ii-A Should we use a home muscle function retraining programme or outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder? (Adverse events.)
Settings Secondary care, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Muscle function retraining programme	Outpatient physiotherapy and home exercises	Relative (95% CI)	Absolute		
Adverse effects/events (5 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	1/23 (4.3%)	1/26 (3.8%)	RR 1.13 (0.07 to 17.07)	5 more per 1000 (from 36 fewer to 618 more)	⊕⊕⊕O MODERATE	CRITICAL
								3.8%		5 more per 1000 (from 35 fewer to 611 more)		

[1] *See* 95% confidence limits for absolute effect.

Author(s) **Vermeulen et al (2006)**
Question i.iii Which should we use for stiffness-predominant contracted (frozen) shoulder: high-grade mobilisations or low-grade mobilisations?
Settings Secondary care, Leiden, The Netherlands.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	High-grade mobilisations	Low-grade mobilisations	Relative (95% CI)	Absolute		
Improvement in SRQ (3 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 2.00 higher (10.07 lower to 14.07 higher)	⊕⊕OO LOW	CRITICAL
Improvement in SRQ (6 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 4.5 higher (2.4 lower to 11.4 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in SRQ (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 6.6 higher (0.61 lower to 13.81 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in night pain, 100 mm VAS (3 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 3.8 higher (9.75 lower to 17.35 higher)	⊕⊕OO LOW	CRITICAL
Improvement in night pain, 100 mm VAS (6 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 7.1 higher (7.1 lower to 21.3 higher)	⊕⊕OO LOW	CRITICAL

Improvement in night pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 7.8 higher (4.91 lower to 21.3 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement pain at rest, 100 mm VAS (3 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[3]	none	47	49	-	MD 7.1 lower (17.9 lower to 3.7 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in pain at rest, 100 mm VAS (6 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 2 lower (13.74 lower to 9.74 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain at rest, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 0.9 lower (9.88 lower to 11.68 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain on use, 100 mm VAS (3 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 2.6 higher (8.46 lower to 13.66 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain on use, 100 mm VAS (6 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	47	49	-	MD 0.5 higher (10.19 lower to 11.19 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain on use, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 6.6 higher (4.99 lower to 18.19 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in passive external rotation, degrees (3 months)												

1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[4]	none	47	51	-	MD 1.4 higher (3.5 lower to 6.3 higher)	⊕⊕⊕O MODERATE	IMPORTANT[5]
Improvement in passive external rotation, degrees (6 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[4]	none	47	49	-	MD 4.1 higher (1.03 lower to 9.23 higher)	⊕⊕⊕O MODERATE	IMPORTANT[5]
Improvement in passive external rotation, degrees (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[6]	none	47	49	-	MD 6.5 higher (0.27 to 12.73 higher)	⊕⊕⊕O MODERATE	IMPORTANT[5]

[1] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.
[2] 95% CI crossed zero and adjusted threshold for MCID favouring high-grade mobilisations.
[3] 95% CI crossed zero and adjusted threshold for MCID favouring low-grade mobilisations.
[4] 95% CI crossed zero. Threshold for MCID not known, but unlikely to lie within 95% CI on either side of zero. 95% CI potentially 'fragile', however, as total population small.
[5] Probably not critical from patients' perspective.
[6] 95% CI did not cross zero. Threshold for MCID not known, but unlikely to lie inside 95% CI. 95% CI potentially 'fragile', however, as total population small.

Author(s) **Vermeulen et al (2006)**
Question i.iii-A Which should we use for stiffness-predominant contracted (frozen) shoulder: high-grade mobilisations or low-grade mobilisations? (Adverse events.)
Settings Secondary care, Leiden, The Netherlands.

Quality assessment							Summary of findings					
							No of patients		Effect		Quality	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	High-grade mobilisations	Low-grade mobilisations	Relative (95% CI)	Absolute		
Adverse effects/events (short term)												
1	randomised trials	no serious limitations	no serious inconsistency	serious[1]	very serious[2]	none	6/46 (13%)	6/49 (12.2%) 12.2%	RR 1.07 (0.37 to 3.07)	9 more per 1000 (from 77 fewer to 253 more) 9 more per 1000 (from 77 fewer to 253 more)	⊕OOO VERY LOW	CRITICAL[3]
Adverse effects/events (medium term)												
1	randomised trials	no serious limitations	no serious inconsistency	serious[1]	very serious[2]	none	6/46 (13%)	5/48 (10.4%) 10.4%	RR 1.25 (0.41 to 3.82)	26 more per 1000 (from 61 fewer to 294 more) 26 more per 1000 (from 61 fewer to 293 more)	⊕OOO VERY LOW	CRITICAL[3]
Adverse effects/events (long term)												
1	randomised trials	no serious limitations	no serious inconsistency	serious[1]	very serious[2]	none	4/47 (8.5%)	9/49 (18.4%) 18.4%	RR 0.46 (0.15 to 1.4)	99 fewer per 1000 (from 156 fewer to 73 more) 99 fewer per 1000 (from 156 fewer to 74 more)	⊕OOO VERY LOW	CRITICAL[3]

[1] 'Adverse events' and 'No change' categories were pooled.
[2] *See* 95% confidence limits for absolute effect.
[3] Outcome critical but unvalidated.

Author(s) **Yang et al (2007)**
Question i.iv Which should we add to home exercises for both stages of contracted (frozen) shoulder: high-grade mobilisations or mobilisations with movement (MWMs)?
Settings Secondary care, Taiwan.

Quality assessment							Summary of findings					
							No of patients		Effect		Quality	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	MWMs and home exercises	High-grade mobilisations and home exercises	Relative (95% CI)	Absolute		
Improvement in FLEX-SF (6 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	13	14	-	MD 1.9 higher (3.61 lower to 7.41 higher)	⊕⊕OO LOW	CRITICAL

[1] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.

Author(s) **Leung and Cheing (2008)**
Question i.v Should we add shortwave diathermy (SWD) to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?
Settings Secondary care, Hong Kong.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	SWD, outpatient physiotherapy and home exercises	Outpatient physiotherapy and home exercises	Relative (95% CI)	Absolute		
Improvement in ASES (8 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	10	10	-	MD 17.50 higher (1.76 to 33.24 higher)	⊕⊕⊕O MODERATE	CRITICAL

[1] 95% CI did not cross zero and mostly exceeded adjusted threshold for MCID favouring SWD, but potentially 'fragile', as total population small.

Author(s) **Leung and Cheing (2008)**
Question i.vi Should we add hot packs to outpatient physiotherapy (without passive mobilisations) and home exercises for stiffness-predominant contracted (frozen) shoulder?
Settings Secondary care, Hong Kong.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Hot packs, outpatient physiotherapy and home exercises	Outpatient physiotherapy and home exercises	Relative (95% CI)	Absolute		
Improvement in ASES (8 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	10	10	-	MD 4 higher (10.38 lower to 18.38 higher)	⊕⊕OO LOW	CRITICAL

[1] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.

Author(s): **Leung and Cheing**
Question i.vii Should we add shortwave diathermy (SWD) or hot packs to outpatient physiotherapy (without passive mobilisations) and exercises for stiffness-predominant contracted (frozen) shoulder?
Settings Secondary care, Hong Kong

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	SWD, outpatient physiotherapy and exercises	Hot packs, outpatient physiotherapy and exercises	Relative (95% CI)	Absolute		
Improvement in ASES (8 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	10	10	-	MD 13.5 higher (2.16 lower to 29.16 higher)	⊕⊕⊕O MODERATE	CRITICAL

[1] 95% CI crossed zero and adjusted threshold for MCID favouring SWD.

ii. Physiotherapy versus other treatments

Author(s) **van der Windt et al (1998)**
Question ii.i Which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) or intra-articular steroid injections?
Settings Primary care, The Netherlands.

Quality assessment							Summary of findings					Importance
							No of patients		Effect			
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Steroid injections	Outpatient physiotherapy	Relative (95% CI)	Absolute	Quality	
Improvement in SDQ (7 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	52	56	-	MD 25 higher (14.81 to 35.19 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in SDQ (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	52	56	-	MD 10 higher (1.88 lower to 21.88 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in SDQ (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[3]	none	52	56	-	MD 4 higher (8.64 lower to 16.64 higher)	⊕⊕OO LOW	CRITICAL
Improvement in night pain, 100 mm VAS (7 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[4]	none	52	56	-	MD 14 higher (3.06 to 24.94 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in night pain, 100 mm VAS (6.5 months)												

1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[3]	none	52	56	-	MD 1 higher (13.53 lower to 15.53 higher)	⊕⊕OO LOW	CRITICAL
Improvement in night pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[3]	none	52	56	-	MD 2 higher (11.59 lower to 15.59 higher)	⊕⊕OO LOW	CRITICAL
Improvement in day pain, 100 mm VAS (7 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[4]	none	52	56	-	MD 12 higher (3.69 to 20.31 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in day pain, 100 mm VAS (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[3]	none	52	56	-	MD 0 higher (10 lower to 10 higher)	⊕⊕OO LOW	CRITICAL
Improvement in day pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[3]	none	52	56	-	MD 3 higher (6.24 lower to 12.24 higher)	⊕⊕OO LOW	CRITICAL
Improvement in passive external rotation, degrees (7 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[5]	none	52	56	-	MD 15 higher (9.31 to 20.69 higher)	⊕⊕⊕O MODERATE	IMPORTANT[6]
Improvement in passive external rotation, degrees (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[5]	none	52	56	-	MD 9 higher (1.64 to 16.36 higher)	⊕⊕⊕O MODERATE	IMPORTANT[6]

[1] 95% CI did not cross zero and substantially exceeded adjusted threshold for MCID favouring intra-articular steroid injections, but potentially 'fragile', as total population small.
[2] 95% CI crossed zero and adjusted threshold for MCID favouring intra-articular steroid injections.
[3] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.

[4] 95% CI did not cross zero and mostly exceeded adjusted threshold for MCID favouring intra-articular steroid injections, but potentially 'fragile', as total population small.
[5] 95% CI did not cross zero. MCID not known, but probably crossed by 95% CI on the side favouring intra-articular steroid injections. 95% CI potentially 'fragile', however, as total population small.
[6] Probably not critical from patients' perspective.

Author(s) **van der Windt et al (1998)**
Question ii.i-A Which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) or intra-articular steroid injections? (Adverse events.)
Settings Primary care, The Netherlands.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Intra-articular steroid injections	Outpatient physiotherapy	Relative (95% CI)	Absolute		
Adverse events												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	30/57 (52.6%)	32/57 (56.1%)	RR 0.94 (0.67 to 1.31)	34 fewer per 1000 (from 185 fewer to 174 more)	⊕⊕⊕O MODERATE	CRITICAL
								56.1%		34 fewer per 1000 (from 185 fewer to 174 more)		

[1] *See* 95% confidence limits for absolute effect.

Author(s) **Ginn and Cohen (2005)**
Question ii.ii Which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or a subacromial steroid injection?
Settings Secondary care, Sydney, Australia

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Muscle function retraining programme	Subacromial steroid injection	Relative (95% CI)	Absolute		
Patients' global impression of change (5 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	17/23 (73.9%)	17/22 (77.3%) 77.3%	RR 0.96 (0.69 to 1.33)	31 fewer per 1000 (from 240 fewer to 255 more) 31 fewer per 1000 (from 240 fewer to 255 more)	⊕⊕⊕O MODERATE	CRITICAL[2]

[1] *See* confidence limits for absolute effect.
[2] Outcome critical but unvalidated.

Author(s) **Ginn and Cohen (2005)**
Question ii.ii-A Which should we use for both stages of contracted (frozen) shoulder: a home muscle function retraining programme or a subacromial steroid injection? ('Deteriorated' classifications.)
Settings: Secondary care, Sydney, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Muscle function retraining programme	Subacromial steroid injection	Relative (95% CI)	Absolute		
'Deteriorated' classifications												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	1/23 (4.3%)	1/22 (4.5%)	RR 0.96 (0.06 to 14.37)	2 fewer per 1000 (from 43 fewer to 608 more)	⊕⊕⊕O MODERATE	CRITICAL
								4.5%		2 fewer per 1000 (from 42 fewer to 602 more)		

[1] See 95% confidence limits for absolute effect.

Author(s) **Ginn and Cohen (2005)**
Question ii.iii Which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) and home exercises or a subacromial steroid injection?
Settings Secondary care, Sydney, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Subacromial steroid injection	Outpatient physiotherapy (with passive mobilisations) and home exercises	Relative (95% CI)	Absolute		
Patients' global impression of change (5 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	17/22 (77.3%)	22/26 (84.6%) 84.6%	RR 0.91 (0.69 to 1.21)	76 fewer per 1000 (from 262 fewer to 178 more) 76 fewer per 1000 (from 262 fewer to 178 more)	⊕⊕⊕O MODERATE	CRITICAL[2]

[1] *See* 95% confidence limits for absolute effect.
[2] Outcome critical but unvalidated.

Author(s) **Ginn and Cohen (2005)**
Question ii.iii-A Which should we use for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) and home exercises or a subacromial steroid injection? ('Deteriorated' classifications.)
Settings Secondary care, Sydney, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Subacromial steroid injection	Outpatient physiotherapy (with passive mobilisations) and home exercises	Relative (95% CI)	Absolute		
'Deteriorated' classifications (5 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	1/22 (4.5%)	1/26 (3.8%)	RR 1.18 (0.08 to 17.82)	7 more per 1000 (from 35 fewer to 647 more)	⊕⊕⊕O MODERATE	CRITICAL
								3.8%		7 more per 1000 (from 35 fewer to 639 more)		

[1] *See* 95% confidence limits for absolute effect.

iii. Physiotherapy versus combinations of physiotherapy and other treatments

Author(s) **Carette et al (2003), Ryans et al (2005)**
Question iii.i Which should we add to home exercises for both stages of contracted (frozen) shoulder: outpatient physiotherapy (with passive mobilisations) or an intra-articular steroid injection?
Settings Secondary care, Canada; primary care, Northern Ireland.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Steroid injection and home exercises	Outpatient physiotherapy (with passive mobilisations) and home exercises	Relative (95% CI)	Absolute		
Improvement in combined pain-function outcome (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	46	42	-	SMD 0.52 higher (0.1 to 0.95 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in combined pain-function outcome (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	39	39	-	SMD 0.34 higher (0.11 lower to 0.79 higher)	⊕⊕OO LOW	CRITICAL
Improvement in combined pain-function outcome: SPADI (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	26	23	-	MD 4.6 higher (9.13 lower to 18.33 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain, 100 mm VAS (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency[5]	no serious indirectness	serious[3]	none	46	42	-	MD 8.42 higher (3.73 lower to 20.57 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in pain, 100 mm VAS (4-6 months)												

2	randomised trials	serious[2]	serious[6]	no serious indirectness	very serious[4]	none	42	36	-	MD 3.24 lower (33.17 lower to 26.68 higher)	⊕OOO VERY LOW	CRITICAL
Improvement in pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	26	23	-	MD 6.5 higher (8.61 lower to 21.61 higher)	⊕⊕OO LOW	CRITICAL
Improvement in passive external rotation, degrees (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency[5]	no serious indirectness	serious[7]	none	46	42	-	MD 3.03 higher (3.37 lower to 9.43 higher)	⊕⊕⊕O MODERATE	IMPORTANT[8]
Improvement in passive external rotation, degrees (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[7]	none	42	36	-	MD 4.61 higher (2.77 lower to 12 higher)	⊕⊕OO LOW	IMPORTANT[8]
Improvement in passive external rotation, degrees (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[7]	none	26	23	-	MD 0.8 lower (7.58 lower to 5.98 higher)	⊕⊕⊕O MODERATE	IMPORTANT[8]

[1] 95% CI did not cross zero and mostly exceeded adjusted threshold for MCID favouring an intra-articular steroid injection, but potentially 'fragile', as total population small.
[2] Unclear risk of bias.
[3] 95% CI crossed zero and adjusted threshold for MCID favouring an intra-articular steroid injection.
[4] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.
[5] Heterogeneity plausibly explicable by clinical factors. *See* section 2.3.3.1.
[6] Heterogeneity may reflect bias in Ryans (2005) at this time point. *See* section 2.3.3.1.
[7] 95% CI crossed zero. Threshold for MCID not known, but unlikely to lie inside 95% CI on either side of zero. 95% CI potentially 'fragile', however, as total population small.
[8] Probably not critical from patients' perspective.

iv. Adding physiotherapy to other treatments

Author(s) **Buchbinder et al (2007)**
Question iv.i Should we add outpatient physiotherapy (with passive mobilisations) and home exercises to distension for both stages of contracted (frozen) shoulder?
Settings Primary and secondary care, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Distension, outpatient physiotherapy (with mobilisations) and home exercises	Distension alone	Relative (95% CI)	Absolute		
Improvement in SPADI (6 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	75	73	-	MD 0.5 lower (7.6 lower to 6.6 higher)	⊕⊕OO LOW	CRITICAL
Improvement in SPADI (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[1]	none	74	70	-	MD 2.4 lower (9.69 lower to 4.89 higher)	⊕⊕OO LOW	CRITICAL
Improvement in global pain (6 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	75	73	-	MD 0 higher (0.69 lower to 0.69 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in global pain (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[2]	none	74	70	-	MD 0.1 lower (0.93 lower to 0.73 higher)	⊕⊕⊕O MODERATE	CRITICAL

[1] 95% CI crossed zero and adjusted threshold for the MCID on both sides of zero.
[2] 95% CI crossed zero. Threshold for MCID not known, but unlikely to lie inside 95% CI on either side of zero. 95% CI potentially 'fragile', however, as total population small.

Author(s) **Buchbinder et al (2007)**
Question iv.i-A Should we add outpatient physiotherapy (with passive mobilisations) and home exercises to distension for both stages of contracted (frozen) shoulder? (Adverse events.)
Settings Primary and secondary care, Australia.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Distension and outpatient physiotherapy	Distension	Relative (95% CI)	Absolute		
Adverse effects/events (6 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	0/75 (0%)	1/73 (1.4%)	RR 0.32 (0.01 to 7.84)	9 fewer per 1000 (from 14 fewer to 94 more)	⊕⊕⊕O MODERATE	CRITICAL
								1.4%		10 fewer per 1000 (from 14 fewer to 96 more)		
Adverse effects/events (6.5 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	3/74 (4.1%)	4/70 (5.7%)	RR 0.71 (0.16 to 3.06)	17 fewer per 1000 (from 48 fewer to 118 more)	⊕⊕⊕O MODERATE	CRITICAL
								5.7%		17 fewer per 1000 (from 48 fewer to 117 more)		

[1] *See* 95% confidence limits for absolute effect.

Author(s) **Pajareya et al (2004)**
Question iv.ii Should we add outpatient physiotherapy (with passive mobilisations) to non-steroidal anti-inflammatory drugs (NSAIDs) for both stages of contracted (frozen) shoulder?
Settings Secondary care, Thailand.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Outpatient physiotherapy and NSAIDs	NSAIDs	Relative (95% CI)	Absolute		
Improvement in SPADI (3 weeks)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	60	59	-	MD 8.6 higher (3.28 to 13.92 higher)	⊕⊕⊕O MODERATE	CRITICAL

[1] 95% CI did not cross zero and exceeded adjusted threshold for MCID favouring addition of physiotherapy, but potentially 'fragile', as total population small.

v. Adding physiotherapy elements to combinations of physiotherapy and other treatments

Author(s) **Carette et al (2003), Ryans et al (2005)**
Question v.i Should we add outpatient physiotherapy (with passive mobilisations mobilisations) to an intra-articular steroid injection and home exercises for both stages of contracted (frozen) shoulder?
Settings Secondary care, Canada; primary care, Northern Ireland.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Outpatient physiotherapy (with mobilisations), intra-articular steroid injection and home exercises	Intra-articular steroid injection and home exercises	Relative (95% CI)	Absolute		
Improvement in combined pain-function outcome (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	41	42	-	SMD 0.34 higher (0.1 lower to 0.77 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in combined pain-function outcome (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[3]	none	38	36	-	SMD 0.02 higher (0.44 lower to 0.47 higher)	⊕OOO VERY LOW	CRITICAL
Improvement in combined pain-function outcome: SPADI (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	21	23	-	MD 1.8 higher (12.62 lower to 16.22 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain, 100 mm VAS (6 weeks)												

2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	41	42	-	MD 7.93 higher (2.69 lower to 18.56 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in pain, 100 mm VAS (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[4]	none	38	36	-	MD 1.65 higher (10.21 lower to 13.51 higher)	⊕OOO VERY LOW	CRITICAL
Improvement in pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	21	23	-	MD 4.2 lower (20.15 lower to 11.75 higher)	⊕⊕OO LOW	CRITICAL
Improvement in passive ER, degrees (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[5]	none	41	42	-	MD 7.47 higher (0.52 to 14.42 higher)	⊕⊕⊕O MODERATE	IMPORTANT[6]
Improvement in passive ER, degrees (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[7]	none	38	36	-	MD 3.3 higher (4.68 lower to 11.29 higher)	⊕⊕OO LOW	IMPORTANT[6]
Improvement in passive ER, degrees (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[3]	none	21	23	-	MD 7.2 higher (2.51 lower to 16.91 higher)	⊕⊕⊕O MODERATE	IMPORTANT[6]

[1] 95% CI crossed zero and adjusted threshold for MCID favouring addition of steroid injection.
[2] Unclear risk of bias.

[3] 95% CI crossed zero. MCID not known, but threshold may lie inside the 95% CI on the side favouring addition of outpatient physiotherapy.
[4] 95% CI crossed zero and adjusted threshold for MCID on both sides of zero.
[5] 95% CI did not cross zero. Threshold for MCID not known, but may lie within 95% CI on the side favouring addition of outpatient physiotherapy. 95% CI potentially 'fragile', however, as total population small.
[6] Probably not critical from patients' perspective.
[7] 95% CI crossed zero. Threshold for MCID not known, but unlikely to lie within 95% CI on either side of zero. 95% CI potentially 'fragile', however, as total population small.

vi. Adding other treatments to physiotherapy

Author(s) **Carette et al (2003), Ryans et al (2005)**
Question vi.i Should we add steroid injection to outpatient physiotherapy (with passive mobilisations) and home exercises for both stages of contracted (frozen) shoulder?
Settings Secondary care, Canada; primary care, Northern Ireland.

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Intra-articular steroid injection with outpatient physiotherapy (with passive mobilisations) and home exercises	Outpatient physiotherapy (with passive mobilisations) and home exercises	Relative (95% CI)	Absolute		
Improvement in combined pain-function outcome (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious[1]	none	41	46	-	SMD 0.89 higher (0.45 to 1.34 higher)	⊕⊕⊕O MODERATE	CRITICAL
Improvement in combined pain-function outcome (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	38	41	-	SMD 0.36 higher (0.08 lower to 0.8 higher)	⊕⊕OO LOW	CRITICAL
Improvement in combined pain-function outcome: SPADI (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	21	26	-	MD 2.8 higher (11.22 lower to 16.82 higher)	⊕⊕OO LOW	CRITICAL
Improvement in pain, 100 mm VAS (6 weeks)												
2	randomised	no serious	no serious	no serious	serious[6]	none	41	46	-	MD 16.72 higher (4.29 to 29.14	⊕⊕⊕O	CRITICAL

	trials	limitations	inconsistency[5]	indirectness						higher)	MODERATE	
Improvement in pain, 100 mm VAS (4-6 months)												
2	randomised trials	serious[2]	Serious	no serious indirectness	very serious[4]	none	37	43	-	MD 1.17 lower (22.85 lower to 20.51 higher)	⊕OOO VERY LOW	CRITICAL
Pain, 100 mm VAS (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious[4]	none	21	26	-	MD 6.5 higher (8.61 lower to 21.61 higher)	⊕⊕OO LOW	CRITICAL
Passive ER, degrees (6 weeks)												
2	randomised trials	no serious limitations	no serious inconsistency[5]	no serious indirectness	serious[7]	none	41	46	-	MD 10.48 higher (3.87 to 17.09 higher)	⊕⊕⊕O MODERATE	IMPORTANT[8]
Passive ER, degrees (4-6 months)												
2	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[7]	none	37	43	-	MD 7.4 higher (0.05 to 14.76 higher)	⊕⊕OO LOW	IMPORTANT[8]
Passive ER, degrees (12 months)												
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	Serious[7]	none	21	26	-	MD 6.4 higher (3.04 to 15.84 higher)	⊕⊕⊕O MODERATE	IMPORTANT[8]

[1] 95% CI did not cross zero and substantially exceeded adjusted threshold for MCID favouring injection, but potentially 'fragile', as total population small.
[2] Unclear risk of bias.
[3] 95% CI crossed zero and threshold for adjusted MCID favouring injection.
[4] 95% CI crossed zero and threshold for adjusted MCID on both sides of zero.

[5] Heterogeneity plausibly explicable by clinical factors. *See* section 2.3.6.1.
[6] 95% CI did not cross zero and mostly exceeded adjusted threshold for MCID favouring injection, but potentially 'fragile', as total population small.
[7] 95% CI did not cross zero. Threshold for MCID not known, but may lie within 95% CI on the side favouring injection. 95% CI potentially 'fragile', however, as total population small.
[8] Probably not critical from patients' perspective.

Author(s)	**Kivimäki et al (2007)**
Question vi.ii	Should we add MUA to home exercises for both stages of contracted (frozen) shoulder?
Settings	Secondary care, Finland.

Data not reported in GRADE-usable format.

APPENDIX F: Delphi panellists

Our invited Delphi panel included patients and targeted physiotherapists (shoulder experts and musculoskeletal generalists from primary and secondary care settings), managers and specialist shoulder surgeons. With a view to optimising the guidelines' usefulness across the range of intended users, the aim was to reach agreement—at an early stage in the guidelines' development—on factors such as layout, and depth and style of reporting. It was expressly *not* our intention that achieving a consensus on 'best practice' would fall within panel's remit, nor that the panel would evaluate the final product[14]. Instead, its role was formative.

Specifically, we chose our Delphi expert panel to represent the following groups:

- patients receiving physiotherapy for frozen (contracted) shoulder;
- other members of the public;
- targeted shoulder specialist physiotherapists;
- a sample of musculoskeletal generalist physiotherapists; and
- targeted managers and specialist shoulder surgeons.

The individual Delphi panellists were:

- Mrs Christine Baldwin (service user/member of the public)
- Mr David Burton, Consultant Orthopaedic Surgeon, Darlington Memorial Hospital, Darlington
- Professor Andrew Carr, Nuffield Professor of Orthopaedic Surgery, Nuffield Orthopaedic Hospital, Oxford
- Mr Drew Coverdale, private physiotherapy practitioner and Lecturer, MACP
- Dr John Fordham, Consultant Rheumatologist, James Cook University Hospital, Middlesbrough
- Mr Garry Goodchild (service user/member of the public)
- Mrs Anne Hardy, Extended Scope Practitioner in Physiotherapy, Middlesbrough and Redcar & Cleveland Community Services
- Mrs Denise Jones, Lecturer in Physiotherapy, Teesside University, and private practitioner
- Dr Jeremy Lewis, Consultant Physiotherapist, St. Georges Hospital London and Research Lead, Therapy Department, Chelsea and Westminster Hospital, London
- Ms Jane Moser, Specialist Physiotherapist, Nuffield Orthopaedic Hospital, Oxford
- Mrs Janice Murphy (service user/member of the public)
- Professor Amar Rangan, Consultant Orthopaedic Surgeon, James Cook University Hospital, Middlesbrough and visiting professor, Teesside University
- Dr Jim Robertson, General Practitioner with Special Interest in Musculoskeletal, Middlesbrough and Redcar & Cleveland Community Services
- Mr Paul Thurland, Assistant Director, Specialist Services, Middlesbrough and Redcar & Cleveland Community Services.

[14] This role fell to the CSP's Good Practice Panel (methods) and external reviewers (specialist subject content)

APPENDIX G: Delphi survey and Guidelines Development Group's responses

Comments/suggestion		Consensus	Action
1	The draft is well-written and clear	Agreed	Not required
2	There is too much detail in section 1.2	Disagreed	Not required
3	There is too much detail in section 1.3	Disagreed	Not required
4	There is too much detail in section 1.4	Disagreed	Not required
5	Section 1.2 is very good	Agreed	Not required
6	Section 1.3 is very good	Agreed	Not required
7	The explanation of types of studies (section vi) is clear and easy to understand	Agreed	Not required
8	The clinical diagnosis section (1.3.) is very good	Agreed	Not required
9	Overall very useful	Agreed	Not required
10	Good format	Agreed	Not required
11	Logical	Agreed	Not required
12	Would benefit from a bullet-point summary of recommendations after each section	Agreed	Change implemented
13	Would benefit from a final overall bullet-point summary of recommendations	Agreed	Change implemented
14	Would benefit from findings of survey of physiotherapists being summarized separately from the published evidence, in bullet-points	Disagreed	Not required
15	The change of terminology from 'frozen shoulder' to 'contracted shoulder' is not justified	Disagreed	Not required
16	Use of both of the terms 'frozen shoulder' and 'contracted shoulder' is confusing	Disagreed	Not required
17	The guidelines are attempting to reach too wide a readership	Agreed	Decision was made to develop a separate patient information leaflet
18	The pain management service should be involved in the management of frozen shoulder	Disagreed	Not required
19	Parts of the non-technical sections might be heavy going for lay readers	Agreed	Not required
20	Very thorough literature search – gives credence to the guidelines	Agreed	Not required
21	Clear definition of terms including the genesis of the term 'contracted shoulder' rather than the term 'frozen shoulder'	Agreed	Not required
22	Great introduction – up to date theory underpinning current understanding of pathology	Agreed	Not required

Comments/suggestion		Consensus	Action
23	The use of your symbols is confusing and not intuitive. Consider open book for everyone and microscope for the more technical understanding	Agreed	Change implemented
24	The entire guidelines are heavily influenced by the Cyriax model and I question if this introduces bias	No opinion	Not required
25	Section on errors in measurement of ROM useful, pertinent and relevant	Agreed	Not required

APPENDIX H: Deviations from protocol

We deviated from our pre-defined protocol in four instances, as set out below.

Our aims originally included, 'to standardise physiotherapists' diagnosis, assessment and management of contracted (frozen) shoulder' and to 'standardise a care pathway for patients/service users utilising best practice in the diagnosis, assessment and physiotherapy management of contracted (frozen) shoulder'. We abandoned both because we felt they were excessively prescriptive.

Our objectives included 'to identify and systematically appraise the best available evidence relating to the physiotherapy management of contracted (frozen) shoulder'. We modified this to 'to systematically review the best available evidence relating to the physiotherapy management of contracted (frozen) shoulder'. This more precisely reflected our intended and actual conduct of the review.

Finally, we did not anticipate that our systematic review of physiotherapy management for contracted (frozen) shoulder would identify so many comparisons, nor that so many would be in trials with a moderate-to-high risk of bias. Our response to this contingency was to restrict further analysis to trials which we judged, by transparent processes, to have a low risk of bias. We took this course with the users of the guidelines in mind, in the interests of conciseness and clarity.

APPENDIX I: Guidelines Development Group profiles

Co-leads

Nigel Hanchard PhD, MSc, MCSP, HPC, FCO (Fellow of the Cyriax Organisation), PGD (tertiary level teaching), PGD (injection therapy) is an experienced clinician and teacher at pre- and post-registration levels, and formerly led the pre-registration MSc in Physiotherapy at Teesside University. He is a faculty member of the M-level module, 'diagnosis and treatment of shoulder conditions' at Teesside University. He has conducted research into the diagnosis and treatment of shoulder pain, and is a recipient of the CSP's Robert Williams award for work in this area. His publications include first authorship of the CSP shoulder impingement guidelines and review and primary research articles. He is a member of the international Cochrane workgroup developing systematic diagnostic reviews, a Cochrane author and an editor of the Cochrane Bone, Joint and Muscle Injuries Group; and a co-applicant on and member of the Advisory Group for a major HTA-funded investigation into contracted (frozen) shoulder. His other memberships include the British Elbow and Shoulder Society and the CSP's Dynamic Ultrasound Group.

Lorna Goodchild MSc, MCSP, HPC, MMACP, PGC (Sports Injury Management), PGD (injection therapy) is an Extended Scope Physiotherapist based at James Cook University Hospital, Middlesbrough. She has six years' experience as an upper limb specialist working in collaboration with a consultant shoulder surgeon. Responsibilities of her post include conducting new patient assessment clinics where patients presenting with complex shoulder problems are triaged. She orders investigations and lists patients for surgical procedures. She also conducts clinics for preoperative assessment and postoperative review. She is a faculty member of the M-level module, 'diagnosis and treatment of shoulder conditions', a guest lecturer of the M-level 'sports injury management' module and examiner for the MSc 'Management of patients with neuro-musculoskeletal dysfunction' at Teesside University. She is a published researcher, and her co-authorships include a Cochrane review. She is a member of the Trial steering committee for the HTA funded ProFHER Trial (Proximal Fractures of the Humerus Evaluation by Randomisation); as well as a co-applicant on and member of the Advisory Group for a major HTA-funded investigation into contracted (frozen) shoulder. Her society memberships include the British Elbow and Shoulder Society.

Members

Dot Davison BSc, MCSP, HPC is a community-based clinical specialist physiotherapist in general musculoskeletal management, with experience in guidelines development.

Sibongile Mtopo MSc, BSc (Hons), MCSP, HPC, MBAHT is a specialist physiotherapist (upper limb and hand). Her current role involves dealing with complex hand and shoulder disorders. She has a keen interest in research and evidence-based practice.

Tracey O'Brien MCSP, HPC, PGD (Manipulative Therapy), MSOM, PGD (Injection Therapy) is an experienced clinician in musculoskeletal medicine who has a special interest in shoulders. She has six years' experience working as an extended scope practitioner for Middlesbrough, Redcar and Cleveland Community Services as part of the Musculoskeletal Service. Her role includes triaging orthopaedic referrals and providing upper and lower limb clinical assessment clinics in the community. This includes ordering investigations and direct referral into the orthopaedic and rheumatology directorates. She has been involved as an investigator and facilitator in several clinical trials.

Christine Richardson MCSP, HPC, PG Dip (injection therapy) is a community-based clinical specialist physiotherapist in musculoskeletal, with a special interest in shoulder disorders.

Martin Scott MSc, BSc, MCSP, HPC is a clinical specialist physiotherapist (shoulders). He is a founder member of the International Board of Shoulder & Elbow Therapists and a winner of the British Elbow & Shoulder Society AHP Fellowship (2005). He has presented scientific papers and posters of original research at national and international conferences of shoulder surgery & physiotherapy since 2001, and lectures internationally on the shoulder and physiotherapy.

Jackie Thompson MCSP, HPC, PGD (mobilisation/manipulative therapy), PGD (injection therapy). Jackie Thompson is an Extended Scope Physiotherapist with a special interest in the shoulder. She works alongside the upper limb consultant surgeons in joint clinics and triages the referrals into the orthopaedic directorate.

Mary Wragg MCSP, HPC, MSOM, MMACP (assoc), PGD (injection therapy) is an ESP shoulder specialist who works in collaboration with a consultant shoulder surgeon. She independently conducts clinics where she diagnoses and triages shoulder conditions, ordering special investigations at her discretion, and is authorised to list patients for surgical procedures such as decompression, stabilization and arthroplasty. She also reviews patients post-operatively at her ESP-led shoulder clinic.

Helen Watson BSc, MCSP, HPC, PGD (injection therapy) has been a clinical specialist and Extended Scope Physiotherapist in shoulders at the Freeman Royal Hospital since 2001. Her research experience includes running clinical trials and interpreting clinical data. She has co-authored primary research articles in peer-reviewed journals and presented research papers nationally and internationally.

APPENDIX J: Revisions history

Version 1.2 (minor revision) contained changes to the front cover and amended citation information.

Version 1.3 (minor revision) contained a corrected title to Table 3d and removal of redundant rows in Tables 3c and 3d (the authors thank Corinne Birch MCSP for bringing these items to their attention). The recommendation to use the terminology 'pain-predominant' and 'stiffness-predominant' was made explicit in Summary Table 1.6.

Version 1.4 (minor revision) contained a correction to Tables 2.2 and 2.3 and accompanying text, other minor corrections and reformatting.

Version 1.5 (minor revision) contained clarification of the search results and filtering process with inclusion of a new table (2.2), addition of summary outcome statements for each comparison in section 2, and minor corrections and reformatting.

Version 1.6 (minor revision) expanded the section on diagnosis. The forest plots were edited so that the control (or less comprehensive or less invasive intervention) was always to the left. The GRADE evidence profiles were streamlined. Corrections were made to pain outcomes in Figures 2.3-4, 2.9-10 and 2.15-16 and related text, and heterogeneity was re-evaluated statistically. Minor corrections were implemented.

Version 1.7 (minor revision) expands slightly on the intention-to-treat principle.