

**School of Health & Social Care**

**The Comparative Effectiveness of Sub-Acromial Corticosteroid Injection and Physiotherapy for Musculoskeletal Shoulder Pain: A Systematic Review.**

**Andrew Powley**

Dissertation Module

Module code: RMH4009-N-CJ1-2015

A dissertation submitted in partial fulfilment of the requirements of the University of Teesside for the degree of MSc Advanced Clinical Practice

Supervisors: Nigel Hanchard and Dave Grover

Submitted: May 2017

Word Count: 13,400

This research programme was conducted in the School of Health & Social Care, University of Teesside with the collaboration of the Ministry of Defence and the Infantry Training Centre, Catterick Garrison.

The copyright of this Dissertation belongs to the author under the terms of the United Kingdom Copyright acts as qualified by the University of Teesside Regulations and Polices.

Due acknowledgement must always be made of the use of any material contained in, or derived from, this Dissertation.

**Abstract**

Background

Shoulder pain is a common presentation in primary care with an estimated UK prevalence of anywhere between 6.9% and 20%. There is currently a lack of evidence about the efficacy of the most commonly used interventions in treating shoulder pain such as Corticosteroid injection and Physiotherapy. It has also been seen that the tests used to diagnose shoulder pain is a failed paradigm and that patients should be sub-grouped based on a pragmatic design and by easily identifiable symptoms rather than given specific labels which does not aid in the treatment process.

Objective

To compare the efficacy of Sub-Acromial Corticosteroid injections and Physiotherapy modalities as treatments for musculoskeletal shoulder pain in the short, medium, and long term.

Outcome measures

The primary outcome measure was shoulder functional disability as measured by a patient reported outcome tool. The secondary outcome measure was pain intensity as measured by a visual analogue scale.

Results

Both interventions produced significant improvements over baseline at all time points for both outcome measures. There was some evidence that there was a trend towards exercise based Physiotherapy interventions for the primary outcome measure in the short and medium term. However, this trend seemed to disappear at long term follow-up. There was also some low quality evidence to support the use of Corticosteroid injection in the early phases of treatment for the secondary outcome measure and Physiotherapy for the medium to long term follow-up.

Conclusion

Both Sub-Acromial Corticosteroid injection and Physiotherapy significantly improves function and decreases pain in subjects with shoulder pain, but methodological shortcomings meant no firm conclusions could be made to establish if one treatment was significantly superior to the other. The effectiveness of Sub-Acromial Corticosteroid injection was similar to that of Physiotherapy interventions in subjects with shoulder pain.

**Acknowledgements**

I would like to express personal thanks to my wife and children who have supported me through this process, especially the last 2 years completing this dissertation. I would also like to thank both Nigel Hanchard and Dave Grover for their support and guidance. Finally, thanks to my colleagues at ITC who have provided me with much needed moral support.

**Contents**

Title page 1-2

Abstract 3-4

Aknowlegements 5

Contents 6

List of Contents 7

List of Tables 8

List of Figures 8

**List of Contents**

**1.0 Introduction 8**

1.1 Description of the condition 8

1.2 Description of the intervention and how they might work 17

1.3 Importance of this review 23

**2.0 Aims and Objectives 24**

**3.0 Methods 26**

3.1 Study Methodology 26

3.2 Review Criteria 27

3.3 Search Strategy 29

3.4 Selection of Studies 32

3.5 Assessment of Quality 35

3.6 Data Extraction 37

3.7 Data Analysis Methods 40

**4.0 Results 42**

**5.0 Discussion 61**

**6.0 Conclusions 68**

**7.0 References 69**

**8.0 Appendix 82**

8.1 PEDRO Scale 82

8.2 Data Extraction Tables 83-91

8.3 Full Database Search Strategy 92-95

**List of Tables**

3.1 The Search Strategy (PICO) 31

3.2 First Stage of Selection 33

3.3 Second Stage of Selection 34

3.4 Data Extraction Form 38

4.1 Results of First Stage of Selection (Database Search) 42

4.2 Table of Excluded Studies 44

4.3 Results of Methodological Quality Checks 45

4.4 Summaries of the Included Articles 46

4.5 – 4.12 Modified Vote Counting Tables for the Primary 51-60

 and Secondary Outcome Measures.

**List of Figures**

4.1 Flow Chart of Study Selection Process 43

**Introduction**

Description of the Condition

Musculoskeletal shoulder pain is a common problem in the UK and the world. A UK based epidemiological study by Linsell et al (2006) utilised a primary care database with population N=658569, to identify people aged 18 and over who presented/consulted with shoulder pain in the year 2000. They found that the national prevalence and incidence rates were 2.36% and 1.47% respectively. It was also seen that prevalence increased linearly with age, peaking at 50 years, and that 13.6% of patients were still consulting with a health care professional at 3 year follow-up. Prevalence was found to be significantly higher in females than males (p<0.001) but there were no differences in incidence rates.

Another UK based epidemiological study conducted by Walker-Bone et al, (2004) looked at the prevalence and incidence rates of upper limb disorders in the general population. This study, conducted in the Southampton area, assessed 6038 people aged 25-64 who responded to a survey of a randomly selected population of 9696. It was found around half (3152) of those surveyed had experienced upper limb pain. Findings were broken down into site specific areas and likely diagnosis of the upper limb and results were extrapolated to the general population. Estimates of prevalence for the two most common shoulder diagnosis of Adhesive Capsulitis and Rotator cuff tendinitis were stated. Prevalence of Adhesive Capsulitis was 8.2% among men and 10.1% among women and Rotator Cuff Tendinopathy was 4.5% among men and 6.1% among women. A weakness of this study, however, was that it did not survey anyone over the age of 64. As it is known that prevalence increases into the older age groups, expanding the survey past this age may have led to even higher prevalence rates.

The data from both these studies suggest that shoulder pain is a common reason for presenting to Primary Care in the UK and that it is most common among the 50 years and over group. It is also more prevalent among women than men, and that while most cases seem to resolve, in some cases, the pain can last for several years without resolution of symptoms. It is also clear that while prevalence is high among people presenting to primary care, the actual prevalence among the general population who have not presented, may be a lot higher.

Following on from the UK data, a Systematic Review of worldwide epidemiological studies’ conducted by Luime et al (2004), which included a total of 18 studies meeting inclusion criteria, found figures of 6.9 - 26% for point prevalence and 6.7–66.7% for lifetime prevalence across the world. This study also found incidence rates of 9.5 per 1000 patients although this only used data from a single study which met inclusion criteria. The prevalence rates in this study varied quite considerably, but this is more evidence that shoulder pain is highly prevalent worldwide and not just specific to the UK.

Shoulder pain can have a number of negative effects both on the individual and on society. A study by Jones et al (1998) who conducted a household survey of people with work related illness found that 3.8 million working days a year are lost in the UK due to upper limb conditions. In addition, a Dutch study by Kuijperset al (2006), looked into the healthcare costs of shoulder pain among primary care consulters. They followed a cohort of (N = 587) patients who kept a costs diary for a 6 month follow-up period. The mean cost each patient generated was 689 Euro and the conclusion was that this was a relatively low amount. However, what they did not account for was the long term impact of this problem. In addition, some employees working in the UK public and private sectors are covered for full pay when unable to work for up to 6 months. Costs after this time when sick pay generally either stops or half’s would potentially lead to a huge increase in costs when extrapolated to the UK economy.

In a study by Chipchase et al (2000), patients (N=81) with chronic shoulder pain who were waiting for shoulder surgery were asked about their ability to work via a functional ability and specific shoulder questionnaires. Preoperatively, 73% felt that they were not able to work full time at their usual job. Also, it is known that a proportion of patients continue to experience shoulder pain up to 3 years after first presenting (13.6%), and therefore it could be assumed that people who have long term pain symptoms will sustain considerably more costs.

Shoulder pain can occur as the result of a variety of disorders including referred pain from the neck or internal organs, neurovascular disorders, and systemic conditions of the musculoskeletal system. Most cases, however, are the result of benign soft tissue lesions of the shoulder joint complex (Uhthoff et al, 1990).

The causes of shoulder pain were investigated in a systematic review of studies looking at occupational risk factors associated with shoulder pain. This review by Van Der Windt et al (2000) pooled data from 29 studies but found that heterogeneity among studies was high which made conclusions difficult. They were however, able to identify that the three main occupational causes of shoulder pain were individual factors, physical work load factors, and the psychosocial working environment. In terms of physical work load, they reported that increased levels of muscle activity with few periods of low activity during awkward and static postures, and during repetitive movements, may result in shoulder pain. Also, the psychosocial aspect relates to the possibility of learned pain behaviour where the person is unable to cope with a poor social working environment. This may in turn increase stress and muscle tone leading to shoulder pain.

Another study by Miranda et al (2001) who conducted a prospective study among subjects (N = 2094) in Finland working for a forestry company used a questionnaire to examine the causes shoulder pain in a manual form of occupation. With a 90% response rate over a 1 year follow-up, they found that physical work with a heavy load, awkward work postures, mental stress, and obesity were the main risk factors associated with shoulder pain. Of note, they also found that among the subjects who undertook regular exercise that physical exercise had more protective than impairing effects on shoulders.

In terms of specific shoulder pathologies, a prospective study by Ostor et al (2005) looked at the incidence rate of Shoulder disorders in Primary care. This study was conducted over a one month period in the Cambridge area across 2 large Primary care practices. It was reported that Sub-Acromial Impingement Syndrome (SAIS) was the most common diagnosis made by practitioners (85%). This diagnosis includes rotator cuff tendinopathy, Sub-Acromial bursitis, and partial and full thickness rotator cuff tears.

SAIS refers to possible aetiologies of shoulder pain including a spectrum ranging from Sub acromial Bursitis and Rotator Cuff Tendinopathy to partial and full‐thickness Rotator Cuff tears (Harrison et al, 2011). These patients generally present with a painful but mobile shoulder in that they are able to move the shoulder joint through a full range of movement, but it is painful to do so. The pain normally occurring when the shoulder is flexed or abducted in mid-range. The exact aetiology of SAIS remains the subject of debate and there are various theories as to what gives rise to the patient’s signs and symptoms.

A theory thought to give rise to SAIS is due to intrinsic degeneration of the rotator cuff. Proposed intrinsic aetiologies explained in a review of SAIS by Khan et al (2013) include diminished vascular supply, aging, and tensile forces leading to rotator cuff failure from weakness and damage to the supraspinatus tendon. In the intrinsic theory model, degenerative changes or trauma are thought to weaken the supraspinatus to a point it is no longer able to centre the humeral head in the glenoid. When the humeral head migrates superiorly (as the person raises their arm), the Sub acromial space narrows, abutting the tuberosity and cuff against the under surface of the acromion.

A pathology-pain model has also been described by Cook and Purdam (2009) which relates specifically the theory that injury to the rotator cuff tendons are at fault in SAIS and can be divided into three stages. These are the reactive, disrepair, and degeneration phases. Reactive tendinopathy demonstrates an alteration of the tendon matrix due to increased water content, with only minimal longitudinal collagen separation, all of which is a short-term homogenous thickening resultant from acute overload. As a contrast, dysrepair/degenerative tendinopathy differs significantly, with apoptosis, tenocyte exhaustion, collagen separation and neovascular in-growth all being present. It is thought that tendons in the reactive and disrepair state have the ability to repair but that once the continuum has reached the degeneration phase, repair is no longer possible.

Another relatively common disorder of the shoulder is Adhesive Capsulitis, or Frozen Shoulder. In a systematic review of the literature by Favjee et al (2011) on the effectiveness of conservative and surgical interventions, its prevalence was estimated to be between 2-5% and the age group this condition affects is primarily the 50-70 year old group. The condition can be broadly divided into two categories: primary, in which there are no obvious causes, and secondary, where a cause is identified. Generally, frozen shoulder is a self-limiting condition, although about 10% of patients experience long-term problems.

Although the characteristics of Frozen Shoulder are well documented, the pathophysiology is less well understood. Its exact pathophysiology is yet an unanswered question and possible causes include those outlined by Mahjan et al (2016) in a prospective study on the causes and outcome of Frozen Shoulder. These included autoimmune connective tissue disorder, recurrent haemarthosis, reactive arthropathy, crystal arthropathy, infection, trauma, algodystrophy, suprascapular nerve entrapment and rotator cuff degeneration. Although these causes are proposed, there is no advocated treatment specific to any one cause. In addition, imaging is rarely needed unless a secondary pathology is suspected.

Due to the complex regional anatomy and the frequent coexistence of multiple pathologies, diagnosing shoulder pain is a major challenge for health care practitioners. There are a plethora of Special tests that have been developed over the years with the intention of aiding the health care practitioner in making a specific diagnosis of shoulder pain. The reliability and validity of many of these tests, however, remains questionable.

It was identified in a study by Cadogan et al (2011), which looked at the reliability of Orthopaedic Special tests, that only a small number of these have demonstrated sufficient diagnostic accuracy (validity) to be of clinical use. What compounds the situation even further is that a systematic review by May et al (2010) which pooled the data of 36 studies on the reliability of physical examination tests used in shoulder pain, found that no examination procedure had acceptable levels of reliability and instead recommended that patients be sub-grouped using reliable clinical characteristics rather than special tests. These ‘special orthopaedic tests’ have been found to be sensitive for shoulder pain in that they can identify a painful shoulder but they are not specific as they can also reproduce pain in asymptomatic shoulders.

To take this a step further, a systematic review by Shellingerhout et al (2008) pooled data from RCTs which looked at studies that have divided subjects into sub-groups of shoulder pain based on specific diagnostic criteria. They used 5 main categories including Impingement Syndrome, Frozen shoulder, Calcific Tendinitis, Rotator Cuff Tendinitis and Rotator Cuff tear. It was seen that within these sub-groups there was a large range of diagnostic criteria and physical tests used between the RCTs to identify subjects as part of the inclusion criteria. For example, from the 21 RCTs looking at Frozen shoulder, it was seen that there were major inconsistencies regarding the amount of restriction (number of degrees), the kind of restriction (active and/or passive), and the direction of the restriction (e.g., abduction, external rotation). Similar findings were reflected across all of the sub-groups and so the authors concluded that as a result of the divide in diagnostic criteria, shoulder pain should be classified in more general terms without the requirement for subgroups.

Although the combined studies in the review arrived at the same diagnostic sub-group, they did it using different diagnostic criteria and tests to determine which sub-group the subjects should be placed in. These findings would suggest that the approach of sub-grouping patients into specific diagnoses of shoulder pain has failed, and instead research should focus more on generic musculoskeletal shoulder pain. Sub-groups could then be formulated based on their response to current forms of treatment.

This approach of treating patients in terms of general shoulder pain rather than sub-grouping would seem appropriate for other reasons. Firstly, it has been demonstrated that the various Sub-Acromial conditions described in literature correlate poorly, not only with physical examination, but also with imaging such as MRI findings.

A prospective study by Krief and Huguet (2006) looked at patients (N=1079) who had been referred for MRI scan for symptomatic shoulder pain. Each subject completed the same questionnaire based looking at pain, impairment, and function. It was found that there was no statistical relationship between the level of pain, impairment, and disability as reported on the questionnaire and the location and size of full-thickness tears of the rotator cuff. In addition to this, it was also seen that patients with biceps tendinopathy did not experience increased pain when compared with patients without biceps tendinopathy or with biceps tendon rupture.

Another study which dismisses the notion of structural soft tissue damage on imaging correlating to symptoms was conducted by Grish et al (2011). In this study 51 subjects were consecutively enrolled from a separate study on bone density on patients with knee pain. All subjects included in the study reported no symptoms, trauma, or treatment involving either shoulder as determined by a sport medicine trained Orthopaedic shoulder surgeon. The Sonographers were blinded to the subjects dominant side and the left or right shoulder was ultrasound scanned by randomisation. It was found, in these asymptomatic subjects, that 78% had bursal thickening, 65% had signs of Acromio-clavicular joint Osteoarthritis, 39% had Supraspinatus tendinosis and 25% had Subscapularis tendinosis. In total, asymptomatic shoulder abnormalities on ultrasound scanning were found in 96% of the subjects.

As well as these findings being relevant to how subjects are included and sub-grouped in research studies, questions have also been raised around using a biomedical diagnosis based on specific physical and imaging studies and their relevance to clinical outcomes. A narrative systematic review conducted by Littlewood et al (2013), looked at the epidemiology of rotator cuff tendinopathy and found strong evidence that using a specific structural biomedical diagnosis such as bursal thickening, calcification and partial rotator cuff tear were not associated with clinical outcomes.

These findings call into question the value of imaging with the aim of obtaining a specific diagnosis of shoulder pain. If patients with the same findings on imaging have different levels of pain, impairment, and function, then these patients may respond very differently to the same treatment and so should be sub-grouped based on this response. Avoiding unnecessary imaging would also have huge cost saving implications.

From this evidence, it can be seen that not only has sub-grouping patients with shoulder pain using specific diagnostic physical tests and imaging studies failed, but also that when this happens it is not associated with clinical outcomes. This outlines the need to combine the results of studies that have used subjects with Shoulder pain irrespective of the suspected structure at fault.

It has been reported in a large prospective study of patients with shoulder pain (N=101) with an 18 month follow-up, that around 50% of all presented episodes of musculoskeletal shoulder pain resolved within 6 months. However, in the remaining patients, 51% considered themselves as ‘cured’ at 18 month follow-up (Winters et al, 1999). This further outlines the need for a better understanding of the most appropriate evidence based treatment interventions for this population.

Description of the Interventions and how they might work

In addition to the classification of shoulder pain changing, the treatment for shoulder pain has also changed over the years. Historically, a dutch study found that after being diagnosed by a GP, patients were generally started on a course of non-steroidal anti-inflammatory drugs. If this had not resulted in relief of symptoms, then patients were often referred for a course of Physiotherapy or treated with a local injection of corticosteroid as outlined in a year long study of Dutch general practice (Van der Widt et al, 1995).

The most common treatment interventions for shoulder pain can be seen from surveys of clinicians who see this kind of presentation in Primary care settings. A survey of UK based Physiotherapists (N=289) looking at the diagnosis and management of Frozen Shoulder was conducted by Hanchard et al (2011). An anonymous online questionnaire was developed and placed on a website widely accessed by UK Physiotherapists requesting them to respond. It was found that in ‘pain predominant’ frozen shoulder the most common forms of treatment were advice/education (96%), injection (80%), gentle exercise (79%), superficial heat/cold (69%) and acupuncture (68%). In the ‘stiffness predominant’ presentations it was seen that the common interventions were quite different and included stretching (93%), advice/education (88%), joint mobilisations (87%), function-based exercises (75%) and hands-on soft-tissue techniques (59%).

It can be seen from these findings that irrespective of the presentation, advice and education was the most widely used intervention, followed by exercise based therapy. However, the most common intervention used for stiffness which was stretching was not utilised at all for pain predominant symptoms. In addition, the second most common intervention for pain predominance (injection) was not considered for presentations where stiffness was the main limiting factor. These findings suggest that current practice varies considerably (even within one specific sub-group of shoulder pain) and adds to the conclusions of Shelingerhaut (2010), that treatment of shoulder pain should be studied in a more generalised fashion.

After oral medication, Physiotherapy is often the first line intervention used as it is widely accessible by general practitioners. Therapeutic exercise regimes and associated physical treatments are advocated to restore shoulder mobility and stability by improving range of movement and enhancing shoulder muscle function (Bang, 2000).

The Physiotherapy interventions considered in this review included Exercise Therapy, Manual Therapy, Kinesio Taping, Acupuncture, and Laser Therapy. These are all treatments that are available to Physiotherapists in the Primary Care setting and are within a Physiotherapists scope of practice. There are other treatments available to Physiotherapists such as Electrotherapy, for example, but only the interventions listed were found in the search strategy described later in this review.

Exercise Therapy has been the focus of several studies looking at its effectiveness in the treatment of Shoulder Pain. A study by Ginn et al, (1997) utilised a prospective RCT design to compare exercise based therapy against no intervention. This study randomised subjects (N=66) into either exercise or control groups. The exercise group received 1 month of Shoulder muscle strengthening exercise (specifically aimed at the rotator cuff), while the controls received no treatment. Each subject in the intervention group received 4-10 sessions in 30 days and assessors were blinded to interventions.

It was found that over the trial period there were significant improvements in the intervention group in two of the three patient reported outcomes and also in pain free range of movement. It was reported that 50% of the control group had worse functional disability scores and 32% had a reduction in range compared to base measurements. They concluded that exercise intervention is an important component of Shoulder pain rehabilitation and that ‘no intervention’ was associated with worse outcomes.

Although a weakness of the Ginn et al study was the short term follow-up, another very similar study by Brox et al, (1998) showed that these results were also applicable to long term follow-up. The effectiveness of rotator cuff strengthening was thought to be important as these muscles help to stabilise the humeral head in the Shoulder Acetabulum during movement.

Kinesio taping is a relatively new treatment modality used by Physiotherapists to treat a variety of musculoskeletal injuries. Kinesio tape differs from traditional athletic tape in that instead of being rigid, it is elastic, and utilises these elastic properties to promote tissue healing by looking to increase the space between the skin and fascia (Kase, 2006).

Unfortunately, until the last few years, there were few RCTs that looked specifically at the effectiveness of Kinesio tape, with much of the research being in the form of case studies. There was, however, a systematic review conducted by Mostafavifar et al (2012) which pooled all the available RCTs looking at the effectiveness of Kinesio tape for musculoskeletal injuries. They found 6 studies which looked at the upper limb, lower limb and spine and found insufficient evidence to support the use of kinesio tape following musculoskeletal injury, although a perceived benefit could not be discounted.

Acupuncture as a treatment modality for musculoskeletal injury has been used by Physiotherapists for a number of years and is one of the first external courses many new graduate Physiotherapists like to enrol on and is therefore widely offered in many Physiotherapy departments. In Chinese medicine, Shoulder pain is considered one of the indications most amenable to treatment with acupuncture (Stux et al, 2003).

However, problems have arisen with proving the effectiveness of Acpuncture in clinical studies due to the wide variation in methodology used in trials. These vary from issues with blinding, needle placement, points chosen, treatment duration, and comparing to sham acupuncture rather than other treatment modalities. Despite this, Acupuncture remains a very popular treatment modality among UK Physiotherapists for Shoulder pain as seen in the survey of UK Physiotherapists by Hanchard et al (2011) mentioned earlier in this review. It was seen that of 269 Physiotherapists, 68% used Acupuncture as a treatment for contracted Frozen Shoulder.

Unfortunately, the clinical effectiveness of Acupuncture has recently been negatively affected in that it has been removed as a recommended treatment for Low Back Pain from the most recent NICE guidelines (NICE, 2016). This was due to there being insufficient high quality evidence to recommend its effectiveness for Low back pain. As there are no NICE guidelines specifically for Shoulder pain its popularity is likely to be maintained in this population.

Low-level laser therapy (LLLT) has been used as a non-pharmacological alternative to treat painful musculoskeletal conditions for around three decades (Chow et al, 2009). While laboratory research consistently shows that low energy irradiation from lasers alters cellular processes, producing among others anti-inflammatory effects and increased collagen turnover (Lopes-Martins et al., 2007). These processes are thought to increase the bodies healing response and aid in pain reduction.

Laser therapy is a passive treatment utilised by Physiotherapists in the treatment of various soft tissue injuries and involves the user holding a light pen over the injured tissue for a dose dependant time. Traditionally, laser therapy has been mainly utilised as an ‘add on’ modality, often in conjunction with other treatments such as exercise therapy.

The effectiveness for LLLT as a treatment for Shoulder pain both as a stand alone treatment and as part of a combination therapy package was investigated in a recent Systematic Review by Haslerud et al (2014). They found that after a detailed search of the databases that 13 studies met their inclusion criteria.

They found that significant and clinically important pain relief was found with weighted mean differences over placebo, for LLLT as a stand alone therapy and also as an adjunct to exercise therapy. The review demonstrated that optimal LLLT can offer clinically relevant pain relief and initiate a more rapid course of improvement, both alone and in combination with physiotherapy interventions.

Corticosteroid injections consist of a dose of ant-inflammatory medication combined with a short acting anaesthetic. The aim of the anti-inflammatory drug is to treat any underlying soft-tissue inflammation over a course of about 2 weeks until it is absorbed by the body. The aim of adding the anaesthetic to the anti-inflammatory drug is for two reasons. Firstly, it is thought to provide some instant pain relief which can help the injector by indicating if the target tissue has been infiltrated, and also to create some volume so that the medication reaches as much of the target tissue as possible. This is needed more so in larger anatomical structures such as the Sub-Acromial space, and is required less so in smaller soft tissue lesions where much less anaesthetic is required (Saunders and Longworth, 2006).

Looking at the evidence that surrounds the use of Sub-Acromial Corticosteroid injections for shoulder pain, it can be seen that the findings of RCTs very considerably. A study which found positive results of using Corticosteroid injections was conducted by Hong et al (2011). They recruited 79 volunteers by way of posters in various medical centres with unilateral shoulder pain and randomly allocated the subjects to a high dose group, a low dose groups, and a control group.

This was a study with a high amount of internal validity and due to it being randomised and double blinded. It also utilised a sound method by ensuring that although the dosage of Triamcinalone was different between groups, the total volume of fluid being injected was the same and so the total volume was equal in all groups.

It was seen that for primary outcome measures (pain), there were significant differences (P<0.001) in both treatment groups at all follow-up intervals from baseline compared to control. For patient reported outcome measures (functional disability), there were also significant improvements in both groups at all follow-up sessions compared to baseline and no difference with control. Active range of movement also produced significant improvements in both treatment groups at all follow-up sessions but not control.

This fairly high quality study demonstrated that Sub-Acromial Corticosteroid injection was significantly superior to placebo for all outcome measures up to 8 weeks with no differences between high and low dose. This also reinforces the belief that the smallest effective dose should be used when performing injection therapy (Saunders and Longworth (2006). Unfortunately, this study only had a follow-up of 2 months which does not give an indication of any long term benefits of injection therapy for Shoulder pain. For that reason, this systematic review has looked to combine studies that have both short and long term follow-up to gain insight if the initial benefits of CSI are consistent, and if these results can be carried over into the longer term when compared to Physiotherapy modalities.

A disadvantage of injection therapy compared to Physiotherapy is that there are generally more potential side effects and contraindications with injections that do not tend to exist with Physiotherapy. The main risks with injection are less than 1 in 100, but include infection, anaphylactic shock and weakening of the tendons (Buchbinder et al, 2003). Also, a common side effect of injection therapy is post-injection flare which can be quite distressing for the individual. This experience refers to a delayed post injection transient increase in pain which can occur in the first 24-48 hours after injection.

A study by Goldfarb et al (2007) investigated the rate of post injection flare on subjects following a corticosteroid injection. This prospective RCT took subjects (N=125) and assessed them all for post-injection flare in the days following injection. They defined a flare as an increase of 2 points or more on the visual analogue scale which is a standardised pain measurement tool. They found that the rate of flare occurrence was 33% in the first 2 days after the injection which slowly resolved over the course of 7 days. Despite this type of reaction being relatively common and distressing, it is seldom reported in most research papers. This type of reaction could almost be considered as a significant adverse event, but will rarely be documented as such.

Looking further at the treatment of Shoulder pain, it has been found that only 22-50% of GPs offer Corticosteroid Injections for shoulder problems (Silman, 2001). This may be due to the lack of training and confidence of GPs to inject, or patients dislike of invasive techniques such as injections. It has also been seen that the only Shoulder injections most GPs are comfortable performing is via the Sub-acromial approach. This is due to Shoulder joint injections being a much deeper anatomical structure that require accurate needle placement and precision to ensure the needle penetrates the joint capsule (Johansson, et al, 1999).

Importance of this review

With such a high incidence rate, especially in the working population, Shoulder pain is an important condition to treat effectively. When planning treatment, both General Practitioners and Physiotherapists need to understand which intervention is the most effective for patients. As well as objective effectiveness, there are patients who would perhaps benefit from one intervention over the other, especially if they are self-employed and do not have time to participate in a rehabilitation programme.

In summary, it can be said that Shoulder pain is a common problem which presents and is treated in primary care settings. The assessment of the Shoulder in terms of diagnosis and sub-grouping is a failed paradigm, and so there is a need to combine the results of studies looking more pragmatically at Shoulder pain as a range of diagnoses and not isolated to specific structures. This will aid healthcare professionals in identifying cases of musculoskeletal Shoulder pain based on a simple Orthopaedic examination without the needing to spend extra time on trying to isolate a structure through ‘Special tests’ which have been shown to be unreliable. It can then be identified which of the current treatment options available in Primary care are associated with better outcomes.

Currently, there are no specific national guidelines to influence clinicians on the optimal management of Shoulder pain, and without intervention, the symptoms can last over 6 months resulting in ongoing disability and poor outcomes. A Systematic Review comparing the most commonly available and used interventions in Primary Care is therefore warranted to inform best practice.

**Aims and Objectives**

The primary aim of this study is to take two of the most commonly used treatments in Primary Care and establish if any difference exists in the effectiveness between CSI and Physiotherapy interventions in the treatment of Musculoskeletal Shoulder Pain.

More specifically, the primary objective is to determine which intervention, if any, is superior and has the greater effect on patient focused outcome measures in both short and long term follow-up. There are numerous patient reported outcome measures used in Primary care settings to help establish the effectiveness of treatment interventions. Two of the most popular include the Shoulder Pain and Disability Index scores (SPADI) and the Constant-Murley Scores (CMS).

The SPADI is a well validated 100 point, 13 item questionnaire that is divided into two sections, a five item pain scale and an 8 item disability scale (Williams et al, 1995). It has been shown to be accurate and responsive to change with the minimal clinically important difference being a change between 8 and 13 points (Roy et al, 2009).

The Constant-Murley Score is a similar outcome measure to the SPADI and in trials it has been found to have a high Intertester and Intratester reliability (Rocourt et al, 2008). Intertester reliability relates to the how the tool performs between testers and the intrarelater reliability is the ability of the tool to reproduce consistent findings when repeated by the same assessor. High rates of these types of reliability mean that the tool can be used repeatedly by both the same assessor and different assessors with confidence that the same result will be achieved irrespective of who is conducting the test.

The secondary objective is to determine which interventions have the greater effect on improving pain scores as measured by the Visual Analoge Scale (VAS). The VAS is a simple tool that is often used to measure pain and disability and has been found to have a moderate to high level of reliability but can have a questionable level of validity (Boonstra et al, 2008). This means that the test can be easily reproduced due to the simple scale that is used, but what it is measuring is less defined. However, it is pragmatic and widely used in practice due to its simplicity, but it lacks the specificity of more detailed measures such as the SPADI and CMS.

It is important to state that only subjective measures were considered as the primary and secondary outcome measures. There was no inclusion of range of movement due to the fact that in Sub-acromial pain, patients often have full range of movement, whereas in frozen shoulder there is often reduced range and so comparing movement as an objective measure in this review would not be appropriate due to the pragmatic nature of the inclusion criteria.

**Methods**

Study Methodology

The type of research design chosen to investigate the research question is a Systematic Review. Systematic reviews are defined as an overview of primary studies that use explicit and reproducible methods (Greenhalgh, 1997). The reason for choosing a systematic review to answer the research question is due to the fact that the randomised control trials that exist on this subject have not managed to demonstrate a consistent benefit of using one intervention over the other. Some RCTs have demonstrated improvements for each individual treatment (Dacre, 1989 but very few have demonstrated any significant benefit of using one over the other to treat shoulder pain.

Further more, although a quantitative approach has been selected, by using primary outcome measures such as the SPADI and Constant scores which could be described as post-positivist, it allows for some subjective detail to be explored. This is in contrast to early studies in this field which generally relied on objective measures to accept/reject the hypothesis. It is now widely accepted that pure positivism such as this has now conceded not all phenomena can be explained by pure objective study (Cowan, 2009). The importance of patient choice when selecting treatments and how the injury/condition affects their daily life are relatively new outcome measures, but are now accepted as being just as relevant in judging the success of interventions as pure objective measures.

It was seen that by filtering through the available evidence and combining trials, the results of these different studies could be formally compared to establish both generisability and hetrogeneity of findings. The advantages of conducting a systematic review for shoulder pain at this time allows for a more pragmatic approach to be taken towards inclusion criteria as suggested by Shellingerhaut (2008). The results were then pooled and findings discussed which would give a broader impression of the benefits of the interventions studied rather than sub-grouping into specific diagnoses. This allowed for conclusions to be made about the comparative effectiveness of injections and Physiotherapy modalities as a treatment for shoulder pain.

Although the Systematic review is considered the gold standard of research, one potential weakness of this type of design can be due to increased power from combining studies. This is generally considered a strength of a review as it gives the study power, however, it can occasionally be a disadvantage, since it is possible to detect small biases as well as true effect (Schlesselman and Collins, 2003).

Review Criteria

The focused question was developed using the PICO structure as detailed by Glasziou et al (2005). They recommended that breaking down the question into four components that facilitates the identification of relevant information and help retrieve focused literature. Without going through this process, there is a risk of returning research articles that are not appropriate to be included in the review. Examples of not having a focused question would potentially result in retrieving too many articles to practically read and articles that do not contain the required information to help answer the research question. It also allows the researcher to be very specific in selecting the exact parameters that studies must contain to be considered for inclusion in the review.

The PICO abbreviation identifies the four parameters used to form the research question and search strategy. The letter P identifies the problem or population being studied which in this case is people with Shoulder pain. The participants included anyone over the age of 18 presenting with shoulder pain including the upper arm but arising from the shoulder which was aggravated by active or passive shoulder movement. Exclusion criteria included subjects with referred pain from the neck/Cervical Spine area, pain arising from neurological conditions, and any history of inflammatory arthritis and also subjects in whom corticosteroid injection is contraindicated. The inclusion and exclusion criteria were left relatively open to make the findings as generalisable as possible and to reflect the nature of Shoulder pain and the pragmatic approach required by avoiding specific diagnostic labels.

The letters I and C represent the Intervention and the Comparative intervention respectively, in this case comparing Physiotherapy and Corticosteroid injection The Intervention of Sub-Acromial corticosteroid injection was used with inclusion criteria of studies that have performed a Sub-Acromial Injection of steroid combined with a local anasthetic. There are three approaches to the Sub-Acromial joint, namely anterior, posterior, and lateral. This review did not discriminate against any of these approaches. Excluded trials were those that used Gleno-humeral injections or Acriomioclavicular joint injections and also Sub-Acromial injections which have used either steroid or anaesthetic alone. This was due to the fact that in Primary care, it is far more common to perform a combination injection than steroid or anaesthetic alone. The reason for this is that the histologic and pathological effect of corticosteroid injections is still poorly understood and also that including anaesthetic into the injection not only helps to give the patient some immediate pain relief but also increases the volume of injection. This increases the liklehood that more of the steroid will reach the target tissue (Saunders and Longworth, 2006).

The comparative intervention was Physiotherapy and includes the typical interventions provided by Physiotherapists in treating Shoulder pain that are provided in the primary care setting. These included the core interventions of Physiotherapy, namely exercise therapy such as stretching and strengthening exercises, but could also include manual therapy such as joint mobilisations/manipulations, and electrotherapy such as Ultrasound and low level laser. Other treatments provided by Physiotherapists and within the scope of Physiotherapy practice such as Acupuncture, dry needling, and various forms of massage were also included, again to reflect the pragmatic nature of treatment. To prevent researcher bias, there were no Physiotherapeutic interventions that were excluded from the study.

The letter O represents Outcomes, which in this case the primary outcome is function but while also considering range of motion and pain as secondary outcome measures. This was decided based on the elements of treatment that are of most importance to the patient when being treated for a musculoskeletal injury. Studies were included that used a patient reported outcome measure such as the SPADI, SF-36, or Constant Murley score. Included studies were also required to utilise a measure of pain such as the Visual Analouge Scale (VAS). Studies were excluded if they did not use at least one of these outcome measures as this would not allow direct comparison between studies.

The PICO method of question formation was chosen instead of other methods such as the FINER criteria as outlined by Hulley et al, (2007). The FINER criteria highlight useful points that may increase the chances of developing a successful research project, but where the FINER criteria outline the important aspects of the question in general, the PICO format was considered to be more focused and logical to follow, especially when considering a question based on quantitative research.

Search Strategy

A search strategy is the process used to translate the clinical query (research question) into a format that the search engine can understand (Gillespie and Gillespie, 2003**x**Gillespie and Gillespie, 2003Gillespie, L.D. and Gillespie, W.J. **Finding current evidence: Search strategies and common databases.** *Clinical Orthopaedics and Related Research*. 2003; 413: 133–145

[CrossRef](http://www.nurseeducationtoday.com/servlet/linkout?suffix=e_1_5_1_2_16_2&dbid=16&doi=10.1016/j.nedt.2012.02.022&key=10.1097%2F01.blo.0000079324.41006.dc&cf=) | [PubMed](http://www.nurseeducationtoday.com/servlet/linkout?suffix=e_1_5_1_2_16_2&dbid=8&doi=10.1016/j.nedt.2012.02.022&key=12897603&cf=)[See all References](http://www.nurseeducationtoday.com/article/S0260-6917%2812%2900066-4/fulltext#references)Gillespie and Gillespie, 2003). This process is important so that the search only returns articles that have the best chance of containing the information that the researcher is looking for. A structured search will prevent too many hits from unwanted and irrelevant papers thereby saving time and increasing the likelehood that only relevant papers will be returned.

The search strategy used to find relevant articles was conducted using a comprehensive search of the academic databases of MEDLINE, CINAHL, AMED, EMBASE and Sport Discuss. The limits were set to Academic Journal articles published between 2003 and 2015 due to the fact a previous similar systematic review was conducted in 2003 (Van Der Windt et al, 2003). This review, however, had low study numbers due to the lack of available primary research at the time and concluded that there was insufficient evidence about the long term effectiveness of injections or physiotherapy compared with a wait and see policy. They also stated that due to the huge difference between interventions (ie a one off injection/passive treatment compared to a course of Physiotherapy) that the choice was not clear cut and patients’ expectations and preferences may affect the outcome.

In addition to the index search terms used in the database search, free text searching was also utilised in both Google and Google Scholar. It has been stated that to ensure that a search is comprehensive, sensitive and specific, free text searching, also known as ‘natural language’ should be used in addition to, or instead of, index term searching (Lahlafi 2007). This process was used to extend the search for relevant articles beyond the published trials that are found in database searching.

Another reason to search wider than the medical databases was to guard against Publication bias, which refers to the fact that positive results have a better chance of being published, are published earlier, and are published in journals with higher impact factors. It has been found that conclusions exclusively based on published studies can be misleading (Egger and Smith, 1995). Search terms used in Google/Scholar included free text sentences such as ‘Physiotherapy or injection in people with shoulder pain’.

The identification of RCTs was used following the strategy described by Alderson et al, (2004) from the Chochrane handbook. This was used with relevant keywords related to Physiotherapy and CSI as outlined in Table 1.0 below which shows how the search strategy was conducted. To further expand the search, the reference lists of relevant studies were also searched. This was to ensure that data from unpublished trials were not ignored as it has been seen that only using published studies can lead to an overestimation of the treatment effect and increases publication bias (Higgins et al, 2008).

The precision of the search strategy was left fairly open and not too strict. This was due to the fact that having a strategy that is too precise can lead to some potential studies being missed (Lefebvre et al, 2008).

With a limited amount of research in this area, the search strategy had to be open and pragmatic using various search terms and synonyms. The table below demonstrates how the structured search (database) strategy was performed using the PICO format outlined in the previous section.

**Table 3.1 - The Search Strategy (PICO)**



As it can be seen from the table, Boolean operators were used to combine the PICO elements allowing the search to be replicated by a third party. This is also said to increase the sensitivity (using ORs) and specificity (using ANDs) to narrow the search by using a range of words or phrases that are variations of the same theme (Meats et al, 2007). Boolean Operators are simple words (AND, OR, NOT or AND NOT) used as conjunctions to combine or exclude keywords in a search, resulting in more focused and productive results. This saves time and effort by eliminating inappropriate hits that must be scanned before discarding. The terms were entered into the Database search to be found in the title and abstract as many article titles do not always give a true reflection of what was studied in the paper.

When looking at the PICO search strategy, it can be seen that various synonyms were used to aid in the search process. This was due to the fact that there are various terms used in this subject area that have the same meaning. For example, the first column is the ‘Population’ with Shoulder pain which is also commonly referred to as Sub-Acromial Impingement or bursitis, and Stiff shoulder or painful shoulder. The second column is the Intervention of Physiotherapy, expanded to include the common treatments in this discipline such as mobilisation, manipulation, strengthening and exercise and also the American term ‘Physical Therapy’. The Comparative treatment is ‘Corticosteroid injection’, also known as ‘Cortisone, ‘Hydrocortisone’ in the United States, and also ‘Injections’, as some studies do not specify the type of injections they have used in the Abstract. The final column is the ‘Outcome’ which includes ROM, function, or pain which are the Primary Outcome measures and Secondary outcome measures respectively.

The search terms were combined as in Table 1.0 above and the exact search as it was performed can be seen in Appendix A. The search returned 149 articles.

Selection of Studies

The aim of the study selection process is to ensure that only relevant studies are included in the review and to minimise biases when certain studies are excluded due to pre-formed opinions (Slavin, 1995). The selection of studies was based on both the PICO elements and the inclusion/exclusion criteria as set out in the ‘Review Criteria’ sub-section. Study selection criteria are intended to identify primary studies that provide direct evidence about the research question (Kitchenham, 2004).

Table 2.1 below outlines how studies were selected in the first stage of selection. This involved the reading of each articles’ Title and Abstract followed by a decision on whether the article was to be rejected or retained and continue to the second stage of selection.

**Table 3.2 – First Stage of Selection**

|  |  |
| --- | --- |
| **PICO** | **Meets Criteria Yes/No** |
| **Population**Adults with unilateral shoulder pain? |  |
| **Intervention**Physiotherapy/Exercise |  |
| **Comparative Intervention**Corticosteroid Injection |  |
| **Outcomes**Uses at least one of the Outcome Measures specified? |  |

To be retained, after reading the Title and Abstract, an article must have answered ‘yes’ to all of the questions above. The second stage of selection involved reading the entire article of all the remaining 15 papers. To ensure against researcher bias, these 15 papers were also read by a second person (a Physiotherapist), independent to the study, and the articles getting to final selection had to be agreed for inclusion by both parties or the article was not included. This section was conducted by the author and a second reviewer due to the subjectivity of including articles where there is doubt over inclusion. The importance of a second reviewer is essential as it has been shown that on average a single researcher is likely to miss 8% of eligible studies, whereas a pair of researchers have been shown to capture up to 100% of eligible studies (Edwards et al, 2002).

Following the second stage of selection a list of excluded articles was kept with reasons for their non-inclusion. The list of these articles with reasons for their exclusion can be found in Appendix B. This was to protect against selection bias and increase the transparency of the selection process (Goodman, 1992). The aim of this second stage of selection was to ensure specificity of articles by focussing more on research that meets the specific inclusion and exclusion criteria of this review. To make it through the second stage of selection each article had to answer ‘yes’ to all of the criteria outlined in Table 1.3.

**Table 3.3 – Second Stage of Selection**

|  |  |
| --- | --- |
| **Criteria** | **Meets Criteria Yes/No** |
| Is it a prospective design? |  |
| Is the injection Sub-Acromial? |  |
| Injection a combination of Cortisone and Anaesthetic? |  |
| Pain arising from the shoulder only? |  |
| No Rheumatoid/Systemic illness? |  |
| Physiotherapy interventions used within scope of practice? |  |

The findings from the first and second stage selection processes can be found in the results section along with a flow chart which documents the exact number of articles included and excluded at each stage of selection.

Assessment of Quality

The assessment of quality of each paper was aided by the use of a reliable and validated tool. Assessment of methodological quality needed to be considered as differences in the quality of methods across studies can indicate that the results of some trials are more biased than those of others (MacCauley and best, 2007). There is also evidence that low-quality studies provide biased estimates of treatment effectiveness. For example, trials that are not blinded or do not use concealed allocation tend to show greater effects of intervention than RCTs with these features (Shultz et al, 1995). It is therefore essential to assess the quality of study that is being included in the review.

To ensure against allocation bias, the internal validity of each RCT was scored by the author and also a second independent reviewer using a standardised set of validity criteria from the PEDro organisation. The PEDro scale is an 11-item scale designed for rating methodological quality of RCTs which has been used to rate the quality of over 3,000 RCTs in the PEDro database. A copy of the PEDro assessment tool can be found in Appendix 8.1.

This tool has been validated for use and in a reliability study it was found that the reliability of ratings of PEDro scale items varied from “fair” to “substantial,” and the reliability of the total PEDro score was “fair” to “good” (Maher at al, 2003). A study was not excluded for a poor methodological score alone but was observed in the data synthesis section where it was decided whether the results from the low scoring studies could be pooled with the higher quality studies. This is because errors and biases from poorer quality studies can affect a potential met-analysis/data synthesis and give misleading results (Popay et al, 2005).

One possible weakness with the PEDRO framework is that is gives an equal weighting to each of the 11 items of quality. This is a potential weakness of this particular framework as it is known that the three most important items which have a direct effect on the Internal validity of a study are items 2, 3, and 7. Internal validity refers to the extent to which differences identified between groups are a result of the intervention being tested and not due to extraneous variables that have not been accounted for (Eldridge et al, 2008). If a study has poor internal validity it cannot be concluded any change in the dependant variable (outcome) is due to change of the independent variable (intervention).

Item 2 refers to Randomisation of the subjects into groups. Randomisation is generally seen as essential in securing internal validity of a study. The purpose of random assignment is to distribute known and unknown variables so that the comparison groups are equivalent in all respects apart from the intervention which they received (Brown, 1999). Herbert (2005), however, goes a step further in saying that although randomised groups will be comparable, they may not be identical which can lead to articles overestimating the true effect of an intervention.

Item 3 refers to allocation bias. This item is important as election bias or allocation bias occurs where there are systematic differences between comparison groups in terms of prognosis or responsiveness to treatment. Concealed assignment prevents investigators being able to predict which intervention will be allocated next and using that information to select which participant receives which treatment.

Item 7 refers to blinding of assessors so that the researcher is unable to manipulate the findings of any objective measure. Blinding of assessors is required to reduce the potential for biases such as placebo bias or measurement bias to affect the results. When these features are present, error and sources of bias are eliminated, therefore differences between the groups in outcome measure scores following the intervention are considered to be due to the effect of the intervention and is another way of eliminating extraneous variables (Proctor, 1998).

To be considered as having a low risk of bias, studies must have random allocation, allocation concealment, and blinding of assessors. If a study had none or only one of these features it was considered to be of high risk of bias, and if a study has two features present was of some risk of bias.

These three items have been shown to have a definite effect on the internal validity of a study and are therefore of more concern to the reader to minimise bias. For this reason, the totals from the PEDRO score were taken into consideration, however, the main focus of commenting on quality was taken from the three items of internal validity described rather than based on an overall score of quality.

Data Extraction

The data extracted from each study was put into a tabulated form with sub-headings for each item. This was to ensure that the data collected from each article was standardised and detailed and also based on the PICO elements outlined earlier.

Details on selection criteria, interventions, outcome measures, length of follow-up, adverse reactions, study size, analysis, and data presentation were extracted for each trial. The results of data extraction were used mainly to consider the generalizability of study findings (external validity) and to evaluate clinical heterogeneity across trials. An example of this table is presented below with the remainder in Appendix 8.2.

**Table 3.4 – Data Extraction Form**

|  |  |
| --- | --- |
| **Reference** | Rhon, D.I. (2014) One Year outcome of Sub-Acromial Corticosteroid Injection Compared with Manual Physical Therapy for the Management of the Unilateral Shoulder Impingement Syndrome |
| **Study design** | RCT |
| **Location** | Military Outpatient Unit in the US |
| **Sample size** | 104 patients  |
| **Population** | Males and Females between 18 and 65 years |
| **Intervention** | One 40mg Triamcinalone Acetonide injection into the Sub-Acromial space. Up to 3 injections allowed but had to be more than 1 month apart during the follow-up period. 38% had more than one injection. |
| **Comparative Intervention** | Combination of joint mobilisations, manual stretches and strengthening/home exercises. Treatment not identical. Treated twice weekly over 3 weeks.  |
| **Primary Outcomes** | SPADI  |
| **Secondary Outcomes** | NPRS pain measurement (0-10)  |
| **Quality outcomes (3)** | Randomised, Assessor blinding, Allocation blinding until after collection of baseline outcomes.  |
| **Duration of Study follow-up** | 1 month, 3 months, 6 months, 1 year.  |
| **Results** | Both interventions had statistically and clinically significant improvements within groups from baseline on SPADI (>12 points). This improvement was maintained at all follow-up points in both groups. There was no significant difference at any time point between groups. NPRS had significant improvement within groups at all time points but neither group achieved a clinically significant improvement (>2 points) at any follow-up between groups. |
| **Notes** | No adverse events. Physiotherapy and CSI produced similar outcomes. However subjects in the CSI group had more shoulder related healthcare use through 1 year.  |

Table 3.4 represents a data extraction form which accurately records the information obtained from the primary studies. Data extraction was performed by the author and a second person independent to the study (a Physiotherapist) and disagreements resolved by consensus among reviewers. This process has been shown to result in significantly less errors compared to one researcher extracting the data and a second reviewer checking it for accuracy although does take more time to perform (Buscemi et al, 2006).

Details from selection criteria, interventions, outcome measures, length of follow-up, study size, analysis and data presentation were extracted for each trial. The results of the data extraction were used to consider the external validity which refers to the extent that the results of a study can be generalised to other individuals or settings (Eldridge et al, 2008). This is also important in the process of evaluating clinical heterogeneity across trials. The data extraction form was a standardised form, the importance of which was to provide consistency whilst reducing bias and improving validity and reliability (Altman, 1991).

Data Analysis Methods

The purpose of data analysis is to draw the results of the review together, observe any consistent effects, and investigate reasons for any inconsistencies or heterogeneity. This allows unbiased conclusions to be drawn from the evidence collected (Deeks et al, 2003).

The initial synthesis was largely descriptive by summarising the included studies in predominately tabulated form which is presented in the Results section. This details the interventions, subject numbers, and outcomes as well as the quality outcomes from the PEDro assessment tool. This process determined that the results were similar and reliable enough to synthesise and pool (CRD report, 2008). This was despite the fact that some of the articles used different outcome measures such as the SPADI and Constant score. However, as these both contain elements of patient reported outcomes and essentially measure the same construct, the results of these were able to be pooled. This was also the case for the pain ratings that some of the studies used. For example, the study by Rhon (2014) used an NPRS rather than a VAS as used by Gasparre (2012). These results were also able to be pooled due to them both measuring pain and both being measured on 10 point scales.

A meta-anaylsis was not performed due to the variability of outcome measures used. It was found that, in regards to this reviews primary outcome measure of patient reported function that, 2 studies used the SPADI, one used the Oxford shoulder score and SR-36, one used a Shoulder Pain and Disability Index, and one used a functional limitation questionnaire. Although these are all patient reported outcome measures, the values are different and would likely be inappropriate to attempt a meta-analysis.

Looking at the secondary outcome measure, it was seen that six out of the seven papers reviewed used the secondary outcome of pain intensity measured via VAS or equivalent on a 10 point or 100-point scale. Only the study by Cloke (2008) did not use a secondary outcome measure, perhaps due to the fact it was a pilot study.

The data analysis was performed using a Narrative synthesis approach. A Narrative synthesis refers to an approach to the systematic review and synthesis of findings from

multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis (ref). While a Narrative synthesis does involve the presentation of data and tables, the priority is to present the findings in a textual way.

The preliminary data that is presented includes the summaries of the included studies which details the interventions of each study along with the results of both the primary and secondary outcomes. The differences between baseline measurement and each follow-up point has been calculated and presented as a number and also as a percentage change. Percentages were calculated due to the varying outcome measures used. The results of these tables were used to inform the following ‘vote counting tables’ in identifying whether there was any trend/significance favouring a particular intervention.

The further narrative synthesis of the data was then placed into Modified Vote Counting tables as described in the ESRC Narrative Synthesis Guidance by Poppay (2006). This involved presenting the frequency of different types of results across included studies which have been shown to be a useful way of producing an initial description of patterns across included studies (Cwikel et al, 2000).

The purpose of the vote counting tables was to be able to identify both similarities and heterogeneity amongst studies based on specific variables which may have influenced the results. These different variables are termed ‘moderator variables’ and each variable has its own column. Several moderator variables have been presented which were thought to have an effect on the outcome of each study. Some of these variables include ‘risk of bias’, ‘expertise of treatment’ and ‘population size’.

The strengths of vote counting tables are that it makes it easily identifiable where the similarities and heterogeneity is occurring among studies based on the important variables identified which may have affected the results of the studies. The weakness though, is that if they are misused, it can lead to authors just counting votes resulting in a ‘most votes wins’ outcome. If an author does not go on to investigate why these similarities/heterogeneity has occurred then the results may be misinterpreted.

The tables are presented separately staring with the primary outcome measure followed by the secondary outcome measure, which have been grouped due to the fact that although different outcome instruments are used, they all measure the same construct. As such, there are separate tables for each outcome measure at each time point that have been divided into initial, short-term, medium term and long term results.

The tables highlight whether there was a significant difference between groups at each time point or just a trend towards one intervention. The time points have been modified into ‘time ranges’ due to the fact that each study has slightly different follow-up points and if exact time points were used then there would have been too many vote counting tables and patterns would have been very difficult to identify. The value of >10% difference between groups was used as a marker to identify if there was a trend towards a particular intervention and the key for the tables is outlined in the Results section.

**Results**

This section presents the results of each stage of selection and starts with the results of the search strategy. A table that demonstrates the search strategy and how the PICO terms were combined with relevant Boolean operators can be found in the ‘Selection of Studies’ sub heading. The database results of this search is presented in the table below.

**Table 4.1 – Results of 1st stage of selection (database search)**

 Select / deselect all  

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Search ID# | **Search Terms** | **Search Options** | **Actions** |
|  | S36 | S9 AND S19 AND S29 AND S35  | **Search modes** - Boolean/Phrase | **View Results** (149)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |

The full table, which outlines each stage of the search strategy with the various search terms and how these were combined with the Boolean operators can be seen in Appendix 8.3.

The flow chart below demonstrates the results of the 3 stages of selection with details of numbers that were successful/unsuccessful at each stage.

**Figure 4.1 – Flow Chart of Study Selection Process**

Titles and Abstracts identified and screened n = 149

Stage 1

Excluded n = 134

Unable to obtain further information required to make assessment n = 1

Full copies retrieved and assessed for eligibility n = 15

Stage 2

Excluded studies not meeting inclusion criteria n = 7

Studies meeting all inclusion criteria and included in the review n = 7

Full copies retrieved and assessed for eligibility n = 14

Stage 3

The following table details the excluded studies and the reasons for exclusion. This allows for full transparency of why these studies were rejected.

**Table 4.2 – Table of Excluded Studies**

|  |  |
| --- | --- |
| **Study Reference** | **Reason for exclusion**  |
| Celik, D. (2009) The contribution of Sub-acromial injection to the Conservative Treatment of Impingement Syndrome.  | Authors selected the 56 subjects for inclusion rather than being based on a list of inclusion/exclusion criteria. Retrospective design. |
| Winters, J.C. (1997) Comparison of physiotherapy, manipulation, and corticosteroid injection for treating shoulder complaints in general practice: randomised, single blind study | Multiple injection sites including Gleno-humeral and Acromioclavicular joint. Also included subjects with shoulder girdle symptoms.  |
| Dacre, J.E. (1989) Injections and Physiotherapy for the Painful Stiff Shoulder. | Injections were Intra-articular and not Sub-acromial. |
| Gasparre , G. (2012) Effectiveness of Ultrasound Guided Injections combined with Shoulder Exercises in the Treatment of Sub-Acromial Adhesive Bursitis. | Study used a retrospective design. Not an RCT.  |
| Van der Windt (1998) Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial | Injections were Intra-articular and not Sub-acromial. |
| Bergman, G.J. (2010) Manipulative Therapy in Addition to Usual Care for Patients With Shoulder Complaints: Results of Physical Examination Outcomes in a Randomized Controlled Trial | Included subjects who had cervico-thoracic pain. Also, injections included the Gleno-humeral joint as well as Sub-acromial.  |
| Klinikleri, T. (2005) Comparison of local corticosteroid injection and conventional physical therapy in management of the painful shoulder. | Physiotherapy group did not appear to include exercise therapy. Unable to obtain further information as full text unavailable in English language.  |

The table below details the results of quality checks based on the three items of internal validity mentioned earlier. These have been listed as ‘high quality’ for articles that include all three items, ‘medium quality’ for articles that contain two of the three items, and low quality for articles that contain only none or only one of the items.

**Table 4.3 – Results of methodological quality checks**

|  |  |
| --- | --- |
| **Reference** | **Study Quality rating** |
| Rhon, D.I. (2014) One Year outcome of Sub-Acromial Corticosteroid Injection Compared with Manual Physical Therapy for the Management of the Unilateral Shoulder Impingement Syndrome | Medium quality as allocation was revealed after the baseline measurements were completed.  |
| Hay, E.M. (2003) A Pragmatic Randomised Control Trial of Local Corticosteroid Injection and Physiotherapy for the Treatment of New Episodes of Unilateral Shoulder Pain in Primary Care. | High Quality |
| Cloke, D.J. (2008) A Pilot Randomized Control Trial of Treatment for Painful Arc of the Shoulder | Low quality. No mention of assessor or allocation blinding.  |
| Kelle, B (2014) Low level laser and local corticosteroid injection in the treatment of subacromial impingement syndrome:a controlled clinical trial. | Low quality. No random selection, no assessor blinding and no random allocation. |
| Ginn, K.A. (2005) Exercise Therapy for Shoulder Pain Aimed at Restoring Neuromuscular Control: A Randomized Comparative Clinical Trial. | High quality.  |
| Subasi,V (2016) Comparison of efficacy of kinesiological taping and subacromial injection therapy in subacromial impingement syndrome. | Low quality. Random allocation but no random selection or assessor blinding.  |
| Johansson, K (2011) Subacromial corticosteroid injection or acupuncture with home exercises when treating patients with subacromial impingement syndrome in primary care – a randomised clinical trial. | Medium quality. Random allocation and assessor blinding but no random selection. |

The table below shows brief summaries of the findings of each of the included articles for both primary and secondary outcomes at each follow-up point. The change from baseline has been calculated and presented as a percentage along with the authors conclusions.

**Table 4.4 – Summaries of the Included Articles**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Validity rating** | **Study Groups (number of subjects** | **Follow-up and Final assessment** | **Success Rate per group:Primary outcome** | **Pain** | **Authors Conclusions** |
| Hay (2003) | High | i 1x40 mg subacromial methylprednisolone and lidocaine (104) ii 8 x Physiotherapy sessions. Advice, exercises + U/S/mobilisations if required (103) | Baseline6 weeks,6 months | Shoulder function: mean (change) i 3.5ii 4i 3 (0.5) 15%ii 3 (1.0) 25%i 2 (1.5) 43%ii 1 (3.0) 75% | VAS - median Baseline (change)i 5ii 5i 3 (2.0) 40%ii 3 (2.0) 40%i 2 (3.0) 60%ii 1 (4.0) 80% | No significant differences between groups for pain or function.  |
| Ginn (2005) | High | i 1x40mg subacromial methylprednisolone plus lidocaine (48) ii Home-based daily exercise programme supervised by physio weekly for 5 weeks (48)iii 10x passive joint mobilisation, electrotherapy/heat/ice plus ROM exercises (42)  | Baseline5 weeks | Functional limitation: mean (change)i 6.9ii 8.0iii 8.4i 5.2 (1.7) 25%ii 4.6 (3.4) 43%iii 5.3 (3.1) 37% | Pain (0-10): median (change)i 1.9ii 1.5iii 2.6i 0.2 (1.7) 90%ii 0.3 (1.2) 80%iii 1.0 (1.6) 62% | No significant differences between groups for pain or function. |
| Rhon (2014) | Medium | i 1-3x40mg triamcinolone acetonide (52)ii Physiotherapy sessions twice weekly for 3 weeks. Man therapy and home exercises (46) | Baseline1 month3 months6 months1 year | SPADI: meani 46 ii 44.9i 23.2 (22.8) 50%ii 22.2 (22.7) 49%i 24.8 (21.2) 46%ii 21.0 (23.9) 53%i 22.2 (23.8) 52%ii 21.5 (23.4) 52%i 23.1 (22.9) 50%ii 21.6 (23.3) 52% | NPRS (0-10):median (change)i 3.3ii 3.8i 1.7 (1.6) 48%ii 1.6 (2.2) 58%i 2.6 (0.7) 21%ii 1.8 (2.0) 53%i 2.2 (1.1) 33%ii 1.7 (2.1) 55%i 2.5 (0.8) 24%ii 2.1 (1.7) 45% | Significant improvements for both function and pain outcomes at all time points. No differences between groups at any point.  |
| Cloke (2008) | Low | i 1-3x40mg methylprednisolone and 10mls lidocaine (26)ii 6 sessions of Physiotherapy over 18 weeks max (22)iii Combination of interventions i and ii (22) | Baseline 18 weeks1 year | Oxford shoulder score:mean (change)i 28.85 ii 29.95iii 26.35i 29.81 (-0.96) -3%ii 27.73 (2.22) 7%iii 27.8 (-1.45) -5%i 26.47 (2.38) 8%ii 28.94 (2.22) 3%iii 23.79 (2.56) 10% | No measure of pain. | No significant changes in OSS of any group at intervention or trial end. No significant differences between groups at any time point.  |
| Kelle (2014) | Low | i 2x9mg betamethasone and 3mls lidocaine 10 days apart (45)ii Sham Laser 150 seconds, 3 x week for 3 weeks (45)iii Low level laser @904nm for 150 seconds 3 x week for 3 weeks (45)  | BaselinePost-rx3 months6 months | UCLA:mean (change from baseline)i 17.0ii 17.3iii 17.5i 27.4 (10.4) 38%ii 20.2 (2.9) 14%iii 25.9 (8.4) 32%i 27.2 (10.2) 37%ii 19.8 (2.5) 13%iii 26.6 (9.1) 34%i 26.8 (9.8) 37%ii 19.9 (2.6) 13%iii 26.1 (8.6) 33% | VAS: Pain (change from baseline)i 27.7ii 21.4iii 25.0i 10.0 (17.7) 64%ii 18.4 (3) 14%iii 11.1 (13.9) 56%i 8.7 (19) 69%ii 16.5 (4.9) 23%iii 11.6 (13.4) 53.6%i 8.9 (18.8) 68%ii 16.3 (5.1) 24%iii 11.5 (13.5) 54% | Injection significantly better than laser immediately post treatment but no difference at any other time point. Both interventions had significant improvements within groups over baseline and sham at all time points.  |
| Subasi (2016) | Low | i 1x1cc betamethasone and prilocaine 4cc.ii Kinesio tape – 3 strips using insertion/origin and space correction. 1 x week for 3 weeks.  | Baseline 1 month3 months | SPADI: mean (change from baseline)i 74.8 ii 76.9i 46.6 (28.2) 38%ii 43.0 (33.9) 44%i 27.2 (47.6) 64%ii 26.7 (50.2) 65% | VAS: mean (change from baseline)i 6.8ii 6.6i 4.0 (2.8) 41%ii 3.83 (2.77) 42%i 2.7 (4.1) 60%ii 2.8 (3.8) 58% | Significant improvements were seen in all outcome measures within groups at both time points (P<0.05). No significant differences between groups in any outcome measure at any time point |
| Johansson (2011) | Medium | i 40mg methylprednisolone and 8-10mls 1% prilocaineii Acupuncture 30 mins, twice weekly for 5 weeks. 10 total sessions. | Baseline 6 weeks3 months6 months12 months | Adolfsson-Lysholm: mean (change from baseline)i 69ii 70i 82 (13) 19%ii 82 (12) 17%i 85 (16) 23%ii 88 (18) 26%i 85 (16) 23%ii 90 (20) 29%i 88 (19) 28%ii 91 (21) 30% | VAS: mean (change from baseline)i 71 ii 73i 75 (4) 6%ii 81 (8) 11%i 78 (7) 10%ii 85 (12) 16%i 79 (8) 11%ii 84 (11) 15%i 80 (9) 13%ii 82 (9) 12% | Both treatment groups had significant within group improvements at all timescales for pain (P<0.001). There were no significant differences between groups at any time point for pain or function (P=0.16). |

The following tables are modified vote counting tables (Popay, 2006) which show each study identification and all the moderator variables associated with the studies. These are included to attempt to explain any heterogeneity between results of the included studies. The tables are separated into initial (0-6 weeks), short term (7 weeks to 3 months), medium term (4 months to 6 months) and long term (1 year+) for both the primary and secondary outcome measures.

**Key for Tables 4.5 – 4.12**

**Table 4.5 – Modified Vote Counting Table for Primary Outcome measure in the Initial Term (0-6 weeks).**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Hay (2003) | Sub-Acromial injection  | Physiotherapy Advice and exercises | Low risk of bias | 57 | Patients own GP. Experienced Physiotherapists | 33 had one injection and 11 of 44 had a second injection | 8 sessions in 6 weeks | 207 |
| Ginn (2005) | Sub-Acromial Injection | Home based programme supervised by Physiotherapist | Low risk of bias | 55 | Consultant Rhumatologist.2 Physiotherapists of unknown expertise.  | One injection only.  | One supervised session per week for 5 weeks.  | 138 |
| Rhon (2014) | Sub-Acromial injection | Manual therapy and home exercise | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT  | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days.  | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Subasi (2016) | Sub-Acromial injection | Kinesio tape | High risk of bias | 54 | A single Physician of unstated expertise.A single Physiotherapist of unstated expertise. | One injection only | Tape applied once a week for 3 weeks and left on for 5 days at a time. | 70 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.6 – Modified Vote Counting Table for Primary Outcome measure in the Short Term (7 weeks to 3 months)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Rhon (2014) | Sub-Acromial injection | Manual therapy and home exercise | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT  | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days. | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Subasi (2016) | Sub-Acromial injection | Kinesio tape | High risk of bias | 54 | A single Physician of unstated expertise.A single Physiotherapist of unstated expertise. | One injection only | Tape applied once a week for 3 weeks and left on for 5 days at a time. | 70 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.7 – Modified Vote Counting Table for Primary Outcome measure in the medium term (4 – 6 months)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Hay (2003) | Sub-Acromial injection  | Physiotherapy Advice and exercise | Low risk of bias | 57 | Patients own GP. Experienced Physiotherapists | 21 subjects in injection group went on to have Physiotherapy.  | 8 sessions in 6 weeks. 29 subjects in Physio group went on to have an injection | 207 |
| Cloke (2008) | Sub-Acromial Injection. | Physiotherapy | high risk of bias | 55 | No details of who performed injections.Physiotherapists of unknown expertise.  | Up to 3 injections every 6 weeks for the 18 week follow-up. | 6 sessions over 18 week follow-up.  | 70 |
| Rhon (2014) | Sub-Acromial injection | Physiotherapy  | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days. | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.8 – Modified Vote Counting Table for Primary Outcome measure in the Long term (1 year)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Cloke (2008) | Sub-Acromial Injection. Sub-Acromial injection + exercise | Physiotherapy | high risk of bias | 55 | No details of who performed injections.Physiotherapists of unknown expertise.  | Up to 3 injections every 6 weeks for the 18 week follow-up. | 6 sessions over 18 week follow-up.  | 70 |
| Rhon (2014) | Sub-Acromial injection | Physiotherapy  | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists of fellowship training in MPT. | Up to 3 injections. 38% had more than one. 19% of subjects went on to receive Physiotherapy. | 6 sessions, twice a week over 3 weeks. 20% crossed over to receive a CSI. | 104 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.9 – Modified Vote Counting Table for Secondary Outcome measure in the Initial Term (0-6 weeks).**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Hay (2003) | Sub-Acromial injection  | Physiotherapy Advice and exercises | Low risk of bias | 57 | Patients own GP. Experienced Physiotherapists | 33 had one injection and 11 of 44 had a second injection | 8 sessions in 6 weeks | 207 |
| Ginn (2005) | Sub-Acromial Injection | Home based programme supervised by Physiotherapist | Low risk of bias | 55 | Consultant Rheumatologist.2 Physiotherapists of unknown expertise.  | One injection only.  | One supervised session per week for 5 weeks.  | 138 |
| Rhon (2014) | Sub-Acromial injection | Manual therapy and home exercise | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT. | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days.  | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Subasi (2016) | Sub-Acromial injection | Kinesio tape | High risk of bias | 54 | A single Physician of unstated expertise.A single Physiotherapist of unstated expertise. | One injection only | Tape applied once a week for 3 weeks and left on for 5 days at a time. | 70 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.10 – Modified Vote Counting Table for Secondary Outcome measure in the Short Term (7 weeks to 3 months)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Rhon (2014) | Sub-Acromial injection | Manual therapy and home exercise | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT  | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days. | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Subasi (2016) | Sub-Acromial injection | Kinesio tape | High risk of bias | 54 | A single Physician of unstated expertise.A single Physiotherapist of unstated expertise. | One injection only | Tape applied once a week for 3 weeks and left on for 5 days at a time. | 70 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.11 – Modified Vote Counting Table for Secondary Outcome measure in the medium term (4 – 6 months)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Hay (2003) | Sub-Acromial injection  | Physiotherapy Advice and exercise | Low risk of bias | 57 | Patients own GP. Experienced Physiotherapists | 21 subjects in injection group went on to have Physiotherapy.  | 8 sessions in 6 weeks. 29 subjects in Physio group went on to have an injection | 207 |
| Rhon (2014) | Sub-Acromial injection | Physiotherapy  | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Kelle (2014) | Sub-Acromial injection | Low level laser | High risk of bias | 49 | Unknown injector.Therapist of unstated profession and experience | Two injections. One at baseline and a second after 10 days. | 3 sessions a week over 3 weeks. Total of 9 sessions. | 90 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Table 4.12 – Modified Vote Counting Table for Secondary Outcome measure in the long term (1 year))**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference** | **Intervention** | **Comp Intervention** | **Quality** | **Mean age** | **Expertise of treatment** | **Number of injections** | **Length of Physio intervention** | **Sample size** |
| Rhon (2014) | Sub-Acromial injection | Physiotherapy  | Some risk of bias | 41 | Physician with Sport med fellowship.Graduate Physiotherapists with fellowship training in MPT | Up to 3 injections. 38% had more than one. | 6 sessions, twice a week over 3 weeks. | 104 |
| Johansson (2011) | Sub-Acromial injection | Acupuncture | Some risk of bias | 46 | A GP of unstated expertise.A Physiotherapist of unstated expertise but pre-trained on needle location. | One injection, but 12 subjects had a second injection.  | 10 A/C sessions over 5 weeks at 30 mins per session.  | 91 |

**Discussion**

The aim of this study was primarily to establish which intervention of either Sub-Acromial Corticosteroid injection or Physiotherapy was the most effective at improving patients functional disability, while also considering the patient reported pain experience as a secondary outcome measure. The research question has not been fully answered by this review based on the fact that there was only one, poor quality study that found any significant difference between the interventions. This only occurred at one time point and pertained to the secondary outcome measure alone.

From the modified vote counting tables, it was seen that for the primary outcome measure, there were no significant differences between the interventions at any time point. There was a trend favouring Physiotherapy interventions in the initial and medium term time points in three studies that had high subject numbers and low to some risk of bias. This trend was seen in three studies that included home based exercises as provided by a Physiotherapist. In the studies which included Physiotherapy interventions outside of manual therapy and exercise, there was no trend identified that favoured either intervention at any time point. This would suggest that a Physiotherapy intervention to address Shoulder pain in the period up to 6 months follow-up needs to include some kind of exercise based therapy. That said, looking at the long term follow-up, there was no difference between Physiotherapy or injection at 1 year. This may suggest that there is a definite time period in the natural history of Shoulder pain where Physiotherapy may be effective in improving a patients function and disability.

When looking deeper at the trend towards favouring the studies that included manual therapy and exercise as part of the Physiotherapy intervention for the primary outcome measure, it can be seen from the vote counting tables that two of the studies were of high methodological quality and one, (Ginn, 2005) was of low quality. This was based on the fact that this study did not utilise either assessor or allocation blinding. Although it is generally accepted that blinding is the most important tool in maintaining internal validity, it is difficult to sustain in a pragmatic trial involving a physical therapy due to the nature and demand of achieving external validity (Godwin, 2003).

These findings which appear to support the inclusion of home based exercises has increasing support in the recent literature in the treatment of Shoulder pain.  A systematic review was conducted by Littlewood et al (2012) which looked at exercise as a treatment for Rotator Cuff Tendinopathy.  This study combined results from 5 RCTs all with low risk of bias and found that the evidence was supportive in the use of exercise in improving pain and functional disability.  The main limitation of this study though was low subject numbers and lack of control groups.  Since this review, there have been further trials which have advocated the use of exercise based Physiotherapy for treating Shoulder pain.

An RCT by Andersen et al (2011) randomly assigned participants into 2 or 12 minutes of resistance training 5 times a week for 10 weeks.  They found that exercising with resistance band for as little as 2 minutes a day resulted in clinically significant improvements in shoulder pain scores for the 10 week follow-up period.  This good quality study included large subject numbers and had a high level of internal validity.  The only real weakness was the relatively low follow-up of 10 weeks.

It was observed that the Cloke (2008) trial also used the joint lowest subject numbers (n=70) which results in reduced power. However, when considering that the Physiotherapy protocols for all these three studies (Rhon, Ginn, and Cloke) were quite similar in content and duration, combining them increases the power and external validity of the combined studies. External validity refers to the extent that the results of a study can be generalised to other individuals or settings (Eldridge et al, 2008). To ensure external validity, a study needs a large sample size, low drop out numbers, and appropriate sampling methods. It was seen that these studies combined, sampled over 370 subjects and encourages a conclusion that there is some benefit from Manual therapy and exercise in the initial to medium term (up to 6 months).

Unfortunately, two of the trials that had a positive trend towards Physiotherapy, (namely Hay and Ginn) did not include a follow-up time point in the ‘short-term’ time range and so it can only be speculated that if they had included a follow-up point in this category that it would also have showed a positive trend towards the Physiotherapy intervention.

When looking at injection therapy, it was seen that there was no significant difference or trend in any study that favoured this intervention over Physiotherapy for the primary outcome measure at any time point.

When looking at the moderator variables to consider why this may have occurred, it can be seen that two of the studies (Hay 2003, and Cloke, 2008) that demonstrated a positive trend for Physiotherapy used injectors of unknown expertise. Indeed, the study by Hay (2003) used the patient’s own GP to administer injections and admits that only most of the GPs delivering the injections had some prior experience injecting shoulders and that the accuracy of placement of injections was not validated. This is a potential source of bias, as it is documented that needle insertion based on correct anatomical location correlates with improved outcomes (Hollingworth, 1983). Therefore, this trend based on vote counting alone suggests if the main aim of treatment in patients with Shoulder pain is to improve function, Corticosteroid injection should not be the treatment of choice. However, a more detailed look at the methodology of these studies means that this conclusion can not be fully supported. Had the injectors either been trained to deliver Sub-acromial injections or experts in the subjects field, it would have made the trend towards Physiotherapy more applicable.

As it can be seen from the modified vote counting tables, only one study demonstrated a significant improvement between interventions. This was for the secondary outcome measure of pain in the initial term from the study by Kelle (2014). There were no other significant differences between groups at any other time point for either primary or secondary outcome measures.

Interestingly, it was seen that the study by Ginn (2005) also found a trend favouring injection in the initial term for pain outcomes, and this study was at a much lower risk of bias than the Kelle study. It also had better internal validity and larger sample size increasing the power and generisability of the study. The study by Kelle was very poorly controlled and lacked any real internal validity, including no random selection or allocation. Despite this, although it is generally accepted that random allocation is part of a gold standard trial, there are systematic reviews to suggest that studies with non-randomised researcher controls can sometimes produce similar estimates of effects to those of randomised controlled trials (Concato at al, 2000).

When exploring the moderator variables for possible reasons as to why the Kelle study found such a significant difference between groups, it can be seen that all subjects in the injection group received two injections. The first was given at the start of the trial and a second at day 10. In comparison, very few subjects in the other studies received more than one injection. In the study by Rhon (2014), 38% had a second injection and just over 25% in the Hay and Johansson studies had a second injection. The remaining 2 studies only offered one injection.

In contrast to the findings of Kelle and Ginn which found a benefit for injection for pain in the initial term, the study by Rhon (2014) showed a trend towards Physiotherapy. Exploration of key characteristics of these trials revealed certain factors which might explain this heterogeneity. First, Rhon (2014) provided primarily manual therapy and exercise twice a week for 3 weeks and then left subjects to continue alone with home exercises. This intervention closely follows standard practice whereas the studies by Ginn and Kelle had the Physiotherapy intervention stop after the 5 week and 3 week point respectively. In contrast, Rhon (2014) encouraged subjects to continue with their exercises throughout the whole 1 year follow-up which may explain the continued positive trend towards the Physiotherapy intervention in this study which extended to long term follow-up.

It was felt that the Rhon (2014) study had the most pragmatic design of the seven included studies. This was due, in part, to them allowing subjects to continue their exercises throughout the 1 year follow-up period, but also due to the fact that they allowed subjects the opportunity to consult with the study physician at any point in the one year follow-up for consideration of further injections (up to 3 in the year). Although this practice could be said to affect the internal validity in a negative way, it does go some way to increasing the external validity, as this best resembles normal clinical practice. In practice, patients are far more likely to be treated by their health care professional based on their individual presentations rather than a pre-determined protocol.

Second, both Ginn and Kelle gave no details regarding the expertise of the therapist delivering the Physiotherapy intervention. It is stated by Ginn that the injections in their study were delivered by a consultant Rheumatologist (an expert in their field) but neither study describes the expertise of the therapists. If the interventions were not expertly delivered, this would potentially introduce a bias favouring injection. In contrast, the study by Rhon (2014) stated that the Physiotherapy intervention was delivered by fellowship trained therapists with additional qualifications in manual therapy.

Thirdly, It may well be that in the Kelle study, a combination of two high dose injections just 10 days apart lead to the significant difference in the initial term, as it was seen by the short-term (3 months), the difference in VAS scores was no longer showing a significant difference or trend towards either intervention. In addition to this, it would not be normal clinical practice to give a second injection to a patient in such a short space of time. It is generally recommended that (in practice) a second injection only be given after at least 6 weeks to assess whether there has been any improvement from the first, otherwise there could be some ethical implications of re-injecting the same structure if there has not been a positive reaction to the first injection (Saunders and Longworth, 2006).

The study by Kelle (2011) compared injection to LLTT and was the only study included which did so. This may be another reason which explains the significant difference between groups for the secondary outcome measure. As explained in the sub-section ‘how the interventions might work’, it has been seen that Laser therapy has insufficient evidence to establish its clinical effectiveness in musculoskeletal injury. This contrasts to the established positive effects of exercise based interventions in treating these types of pathology.

Unfortunately, the study by Ginn (2005) did not follow-up subjects beyond the first 5 weeks and so a continuing trend for injection could not be established from this study for injection therapy. The study by Kelle (2014) did follow-up in the short and medium terms but by the short-term follow-up the significant difference favouring Injection was not present.

Findings for Physiotherapy interventions in the secondary outcome measure followed a similar pattern to that of the primary outcome measure. It was seen that in the short and medium term, there was a trend towards Physiotherapy interventions in the better quality studies which mirrored the findings of the primary outcome.

Only two studies evaluated subjects at 1 year follow-up and there was a trend in the study by Rhon (2008) which favoured Physiotherapy for the pain outcome measure. As stated previously, this was perhaps due to the fact that subjects were allowed to continue their exercises throughout the 1 year follow-up period.

The findings of this suggest that in patients with Shoulder pain (when the aim is to reduce pain), that injection therapy may be superior in the early/acute stages of the process. This would agree with the basis of current practice relating back to the survey of UK Physiotherapists by Hanchard et al (2011). This questionnaire of UK Physiotherapists showed that injection is the treatment of choice in patients with Shoulder pain where the main symptom is pain rather than stiffness. However, after around 6 weeks, the effectiveness may reduce and Physiotherapy could be more effective in reducing pain symptoms as the natural history of the problem proceeds.

It was reassuring to see that all but one of the studies, by Cloke (2008) found a significant difference between baseline and all follow-up points for both Physiotherapy and Corticosteroid injection on within groups analysis. As mentioned earlier, a reason for this may be due to the low subject numbers or the fact that it did not include an outcome measure for pain.

It would also have been interesting to see more studies with a control or placebo group receiving no physical treatment or sham treatment to contrast how these interventions compare to the natural history of the condition.

There was only one study, (Kelle, 2014), which included a placebo group, that in this case received sham laser. Despite its methodological shortcomings, no other study included in the review attempted to control for the placebo effect. Placebo groups are generally seen more in drug trials and are defined as effects of an intervention that are due to subjects expectations of a beneficial effect of therapy (Herbert, 2005). This is demonstrated when patients appear to benefit from an intervention that has no physiological effect.

There are various limitations associated with this review. Firstly, the age range of studies was limited to 2003 onwards. This was purposefully done both to limit the amount of included studies to a manageable number for analysis, and also due to there having been a similar systematic review by Van der Windt (2003). Although this study concluded that there was insufficient evidence about the long term effectiveness of injections or physiotherapy compared with a wait and see policy, perhaps combining the results with this review may have lead to more of a trend towards one of the interventions.

Secondly, the wide variety of shoulder function and disability outcome measures used was very wide ranging. This prevented any real statistical analysis from taking place and in effect forced the review to take the path of a narrative synthesis. Although these outcome measures all essentially measured the same construct and demonstrated good reliability and validity, it did make comparison more difficult than it would have been if they all used a standard outcome measure. In comparison, the pain measurement was much easier to follow as most had used a variation of the visual analogue scale.

Another limitation was that there were only single studies retrieved for Kinesio tape, laser, and acupuncture. The fact that only individual studies were found for these interventions made direct comparison hard between these studies and the ones that included manual and exercise based Physiotherapy interventions. In addition to this, these individual studies were generally a lower quality and had poorer internal validity than the other studies.

When considering what path future studies should take that look at musculoskeletal shoulder pain, it is recommended that RCTs should be as pragmatic as possible so as to replicate clinical practice as far as is possible. This would include taking the line of Shelllingerhaut (2008) and May (2010) by not labelling subjects with shoulder pain into specific diagnostic categories, and instead including all patients with shoulder pain. This would allow for further systematic reviews to be able to inform practice at the primary care level more effectively and simple pathways could be produced for practitioners who encounter shoulder pain based on the patients most significant symptom (functional disability or pain). This would also increase the external validity of studies and make them far more applicable to clinical practice.

It seems there is little point conducting future research where the protocol is so rigid that it does not correlate at all with what happens in Primary care and the challenges of working in this kind of environment.

It is also recommended to make future systematic reviews more valid, that there is some kind of agreement on a specific Patient Reported Outcome Measure (PROM) that should be used in research protocols. If this was the same as tool as used in the majority of Primary care settings, all the better. The most common is the SPADI, but as it can be seen from this review, there are several other PROMs that are widely used making direct statistical comparison difficult.

As this is the second review that has found no significant differences between corticosteroid injection and Physiotherapy for shoulder pain, future research could focus on alternative injections such as hyaluronic acid or platelet rich plasma (PRP). Although these medications are still considered in their infancy (compared to corticosteroid), there have been some promising results from early trials of these drugs including a systematic review advocating faster healing times in tendon and ligament injuries (Taylor et al, 2011).

When considering ethical issues surrounding this subject area, what was slightly surprising in the included studies was a huge under reporting of adverse reactions/events, particularly involving injection therapy. This was possibly the one real ethical issue that was present in all of the studies. It was seen that all studies actively sought and were granted ethical approval by their relevant academic or institutional organisations (as detailed in the tables of included studies), but the reporting of adverse events was very poor throughout. There was only one study, by Johansson (2011) that reported adverse events including a few minor complications where acupuncture needles had caused bruising. However, none of the studies reported any adverse events relating to injection therapy, which seems odd, considering the total number of injections performed amongst the 7 studies.

What is known, is that minor adverse reactions to injection therapy are not uncommon and indeed, post-injection flare can be a common and very distressing painful experience. This describes the temporary increase in symptoms that can be experienced in the 24-48 hours after corticosteroid injection. In a systematic review of RCTs that used corticosteroid injection, it was found that post-injection flare was reported in 19 of 87 studies (22%). It was also seen that after extra-articular injection, the incidence of major adverse events ranged from 0-5.8% and that of minor adverse events from 0-81% (Brinks et al, 2010). The reporting of these events would be helpful in establishing the risk of a patient developing one of these side effects which may influence patient choice about the treatment they wish to receive.

**Conclusion**

In conclusion, this systematic review demonstrated the positive effects of both corticosteroid injection and Physiotherapy modalities in patients presenting with musculoskeletal shoulder pain. Both interventions can be said to be similarly effective at both short and long term follow-up for both functional disability and pain outcomes. There is some low quality evidence to suggest that injection may be superior to Physiotherapy in the first 6 weeks where pain relief is the goal of treatment, but that this effect dissipates as time progresses.

It was also found that there was some evidence to suggest a trend favoring Physiotherapy interventions that include manual therapy and exercise as the core treatments for function/disability in the short and medium terms (up to 6 months) but no difference long term. There was also a trend towards Physiotherapy for treating pain in the medium and long term. However, methodological shortcomings and a lack of significant results between groups prevent any firm conclusions.

**References**

Alderson, P., Green, S., & Higgins, J. P. T. (2004). Cochrane reviewers’ handbook 4.2. 2 [updated March 2004]. *The Cochrane Library*, *1*, 1-59

Altman, D. G. (1990). *Practical statistics for medical research*. CRC press.

Bang, M. D., & Deyle, G. D. (2000). Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. *Journal of Orthopaedic & Sports Physical Therapy*, *30*(3), 126-137.

Bøhmer, Audhild S., Peer H. Staff, and Jens Ivar Brox. (1998) Supervised exercises in relation to rotator cuff disease (impingement syndrome stages II and III): a treatment regimen and its rationale, *Physiotherapy Theory and Practice* 14.2: 93-105.

Boonstra, Anne M. Schiphorst Preuper, Henrica R. b d; Reneman, Michiel F. Posthumus, Jitze B. Stewart, Roy E. (2008) Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain, International Journal of Rehabilitation Research, Issue: Volume 31(2), pp 165-169.

Brinks, A., Koes, B. W., Volkers, A. C., Verhaar, J. A., & Bierma-Zeinstra, S. M. (2010). Adverse effects of extra-articular corticosteroid injections: a systematic review. *BMC musculoskeletal disorders*, *11*(1), 206.

Brown, S.J. (1999) *Knowledge for healthcare practice: a guide to using research evidence*. London: WB Saunders Company.

Buchbinder, R., Green, S., & Youd, J. M. (2003). Corticosteroid injections for shoulder pain. *The Cochrane Library.*

Buscemi, N., Hartling, L., Vandermeer, B., Tjosvold, L., & Klassen, T. P. (2006). Single data extraction generated more errors than double data extraction in systematic reviews. Journal of clinical epidemiology, 59(7), 697-703.

Cadogan, A., Laslett, M., Hing, W., McNair, P., & Williams, M. (2011). Interexaminer reliability of orthopaedic special tests used in the assessment of shoulder pain. *Manual therapy*, *16*(2), 131-135.

Chipchase, L. S., O'Connor, D. A., Costi, J. J., & Krishnan, J. (2000). Shoulder impingement syndrome: preoperative health status. *Journal of shoulder and elbow surgery*, *9*(1), 12-15.

Chow, R. T., Johnson, M. I., Lopes-Martins, R. A., & Bjordal, J. M. (2009). Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomised placebo or active-treatment controlled trials. *The Lancet*, *374*(9705), 1897-1908.

Cloke, D. J., Watson, H., Purdy, S., Steen, I. N., & Williams, J. R. (2008). A pilot randomized, controlled trial of treatment for painful arc of the shoulder. *Journal of Shoulder and Elbow Surgery*, *17*(1), S17-S21.

Cook, J. L., & Purdam, C. R. (2009). Is tendon pathology a continuum? A pathology model to explain the clinical presentation of load-induced tendinopathy. *British journal of sports medicine*, *43*(6), 409-416.

Concato, J., Shah, N., & Horwitz, R. I. (2000) *‘*Randomized, controlled trials, observational studies, and the hierarchy of research designs’*. New England Journal of Medicine,* 342(25), pp. 1887-1892.

Cowan, D. (2009) Research Issues in Health and Social Care, M and K Publishing Ltd, London.

Crawshaw, D. P., Helliwell, P. S., Hensor, E. M., Hay, E. M., Aldous, S. J., & Conaghan, P. G. (2010). Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial. *Bmj*, *340*, c3037.

Dacre, J. E., Beeney, N., & Scott, D. L. (1989). Injections and physiotherapy for the painful stiff shoulder. *Annals of the rheumatic diseases*, *48*(4), 322-325.

Deeks, J. J., Dinnes, J., D'amico, R., Sowden, A. J., Sakarovitch, C., Song, F., & Altman, D. G. (2003). Evaluating non-randomised intervention studies. *Health technology assessment (Winchester, England)*, *7*(27), iii-x.

Dickens, V. A., Williams, J. L., & Bhamra, M. S. (2005). Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. *Physiotherapy*, *91*(3), 159-164.

Egger, M., & Smith, G. D. (1998). Meta-analysis bias in location and selection of studies. *Bmj*, *316*(7124), 61-66.

Eldridge, S., Ashby, D., Bennett, C., Wakelin, M., & Feder, G. (2008). ‘Internal and external validity of cluster randomised trials: systematic review of recent trials’. *Bmj*, *336*(7649), pp. 876-880.

Edwards, P., Roberts, I., Clarke, M., DiGuiseppi, C., Pratap, S., Wentz, R., & Kwan, I. (2002). Increasing response rates to postal questionnaires: systematic review. *Bmj*, *324*(7347), 1183.

Engstrand C; Krevers B; Kvist J (2012) Interrater reliability in finger joint goniometer measurement in Dupuytren's disease, AMERICAN JOURNAL OF OCCUPATIONAL THERAPY, 66(1), pp 98-103.

Favejee, M. M., Huisstede, B. M. A., & Koes, B. W. (2011). Frozen shoulder: the effectiveness of conservative and surgical interventions—systematic review. *British journal of sports medicine*, *45*(1), 49-56.

Gillespie, L. D., Gillespie, W. J., Robertson, M. C., Lamb, S. E., Cumming, R. G., & Rowe, B. H. (2003). Interventions for preventing falls in elderly people. *Cochrane Database Syst Rev*, *4*(4).

Ginn, K. A., Herbert, R. D., Khouw, W., & Lee, R. (1997). A randomized, controlled clinical trial of a treatment for shoulder pain. *Physical therapy*, *77*(8), 802-809.

Ginn, K., & Cohen, M. (2005). Exercise therapy for shoulder pain aimed at restoring neuromuscular control: a randomized comparative clinical trial. *Journal of Rehabilitation Medicine*, *37*(2), 115-122.

Glasziou, P., & Haynes, B. (2005). The paths from research to improved health outcomes. *Evidence Based Nursing*, *8*(2), 36-38.

Goldfarb, C. A., Gelberman, R. H., McKeon, K., Chia, B., & Boyer, M. I. (2007). Extra-articular steroid injection: early patient response and the incidence of flare reaction. *The Journal of hand surgery*, *32*(10), 1513-1520.

Goodman C. Step 2: specify inclusion criteria for studies. In: Literature searching

and evidence interpretation for accessing health care practices. Stockholm: Swedish

Council on Technology Assessment in Health Care; 1993.

Greenhalgh, T. (1997). How to read a paper: papers that report diagnostic or screening tests. *Bmj*, *315*(7107), 540-543.

Girish, G., Lobo, L. G., Jacobson, J. A., Morag, Y., Miller, B., & Jamadar, D. A. (2011). Ultrasound of the shoulder: asymptomatic findings in men.*American Journal of Roentgenology*, *197*(4), W713-W719.

Hanchard, N. C., Goodchild, L., Thompson, J., O’Brien, T., Davison, D., & Richardson, C. (2011). A questionnaire survey of UK physiotherapists on the diagnosis and management of contracted (frozen) shoulder. *Physiotherapy*,*97*(2), 115-125.

Hand, C., Clipsham, K., Rees, J. L., & Carr, A. J. (2008). Long-term outcome of frozen shoulder. *Journal of Shoulder and Elbow Surgery*, *17*(2), 231-236.

Haslerud, S., Magnussen, L. H., Joensen, J., Lopes‐Martins, R. A. B., & Bjordal, J. M. (2014). The Efficacy of Low‐Level Laser Therapy for Shoulder Tendinopathy: A Systematic Review and Meta‐Analysis of Randomized Controlled Trials. *Physiotherapy Research International*, *20*(2), 108-125.

Hay, E. M., Thomas, E., Paterson, S. M., Dziedzic, K., & Croft, P. R. (2003). A pragmatic randomised controlled trial of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care. *Annals of the rheumatic diseases*, *62*(5), 394-399.

Harrison, A. K., & Flatow, E. L. (2011). Subacromial impingement syndrome.*Journal of the American Academy of Orthopaedic Surgeons*, *19*(11), 701-708.

Herbert, R. Jamtvedt, G. Mead, J. Hagen, K.B. (2005) *Practical evidence-based Physiotherapy*. Edinburgh: Elseiver.

Higgins, J., & Altman, D. G. (2008). Assessing risk of bias in included studies. *Cochrane handbook for systematic reviews of interventions: Cochrane book series*, 187-241.

Hodgson, J. T., Clegg, T. A., & Elliott, R. C. (1998). *Self-reported work-related illness in 1995: results from a household survey*. Sudbury: HSE books.

Hollingworth, G. R., Ellis, R. M., & Hattersley, T. S. (1983). Comparison of injection techniques for shoulder pain: results of a double blind, randomised study. *Br Med J (Clin Res Ed)*, *287*(6402), 1339-1341.

Hong, J. Y., Yoon, S. H., Moon, D. J., Kwack, K. S., Joen, B., & Lee, H. Y. (2011). Comparison of high-and low-dose corticosteroid in subacromial injection for periarticular shoulder disorder: a randomized, triple-blind, placebo-controlled trial. *Archives of physical medicine and rehabilitation*,*92*(12), 1951-1960.

Hulley S, Cummings S, Browner W, (2007) *Designing clinical research. 3rd ed*, Philadelphia (PA): Lippincott Williams and Wilkins.

Johansson, K., Bergström, A., Schröder, K., Foldevi, M., & Linde, K. (2011). Subacromial corticosteroid injection or acupuncture with home exercises when treating patients with subacromial impingement in primary care–a randomized clinical trial. *Deutsche Zeitschrift fuer Akupunktur*, *54*(2), 30-31.

Jones, J. R., Hodgson, J. T., Clegg, T. A., & Elliott, R. C. (1998). Self-reported work-related illness in 1995: Results from a household survey.*Sudbury, UK: HSE Books*.

Kase, K., Martin, P., & Yasukawa, A. (2006). *Kinesio Taping in Pediatrics: Fundamentals and Whole Body Taping*. Kinesio.

Kelle, B., & Kozanoglu, E. (2014). Low-level laser and local corticosteroid injection in the treatment of subacromial impingement syndrome: a controlled clinical trial. *Clinical rehabilitation*, *28*(8), 762-771.

Khan KS, Ter Riet G, Glanville J, Sowdon AJ, Kleijnen J. Undertaking systematic reviews of research on effectiveness: CRD's guidance for carrying out or commissioning reviews: CRD report 4. 2nd ed. York: NHS Centre for Reviews and Dissemination, 2001.

Khan, Y., Nagy, M. T., Malal, J., & Waseem, M. (2013). The painful shoulder: shoulder impingement syndrome. *The open orthopaedics journal*, *7*(1).

Kitchenham, B. (2004). Procedures for performing systematic reviews. *Keele, UK, Keele University*, *33*(2004), 1-26.

Krief, O. P., & Huguet, D. (2006). Shoulder pain and disability: comparison with MR findings. *American Journal of Roentgenology*, *186*(5), 1234-1239.

Kuijpers, T., van Tulder, M. W., van der Heijden, G. J., Bouter, L. M., & van der Windt, D. A. (2006). Costs of shoulder pain in primary care consulters: a prospective cohort study in The Netherlands. *BMC Musculoskeletal Disorders*, *7*(1), 1.

Lachin, J.M. (2004) ‘The role of measurement reliability in clinical trials’, *Clin. Trials*, pp. 1553–566.

Lahlafi, A. (2007). Conducting a literature review: how to carry out bibliographical database searches. *British Journal of Cardiac Nursing*, *2*(12), 566-569.

Lanyon, P., Pope, D., & Croft, P. (1995). Rheumatology education and management skills in general practice: a national study of trainees. *Annals of the rheumatic diseases*, *54*(9), 735-739.

Lefebvre, C., Manheimer, E., & Glanville, J. (2008). Searching for studies. *Cochrane handbook for systematic reviews of interventions. New York: Wiley*, 95-150.

Linsell, L., Dawson, J., Zondervan, K., Rose, P., Randall, T., Fitzpatrick, R., & Carr, A. (2006). Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology*, *45*(2), 215-221.

Littlewood, C., May, S., & Walters, S. (2013). Epidemiology of rotator cuff tendinopathy: a systematic review. *Shoulder & Elbow*, *5*(4), 256-265.

Long TJ, Convey JJ, Chwalek AR. Completing dissertations in the behavioural sciences and education: a systematic guide for graduate students. San Francisco: Jossey-Bass, 1985.

Luime, J. J., Koes, B. W., Hendriksen, I. J. M., Burdorf, A., Verhagen, A. P., Miedema, H. S., & Verhaar, J. A. N. (2004). Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scandinavian journal of rheumatology*, *33*(2), 73-81.

MacAuley, D., & Best, T. (Eds.). (2008). *Evidence-based sports medicine*. John Wiley & Sons.

Mahajan, S., Gadi, D., Gupta, R., Singla, S., Setia, P., Gupta, S., & Kaur, R. (2016). A prospective study on causes and functional outcome of frozen shoulder. *International Journal of Medicine*, *4*(1), 23-25.

Maher, C. G., Sherrington, C., Herbert, R. D., Moseley, A. M., & Elkins, M. (2003). Reliability of the PEDro scale for rating quality of randomized controlled trials. *Physical therapy*, *83*(8), 713-721.

Martins, R. A. B. L., Correa, J. C., Iversen, V. V., Joenson, J., & Bjordal, J. M. (2007). Low-level laser therapy reduces inflammatory cell migration in mice with lipopolysaccharide-induced peritonitis. *Photomedicine and laser surgery*, *25*(4), 245-249.

May, S., Chance-Larsen, K., Littlewood, C., Lomas, D., & Saad, M. (2010). Reliability of physical examination tests used in the assessment of patients with shoulder problems: a systematic review. *Physiotherapy*, *96*(3), 179-190.

Miranda, H., Viikari-Juntura, E., Martikainen, R., Takala, E. P., & Riihimäki, H. (2001). A prospective study of work related factors and physical exercise as predictors of shoulder pain. *Occupational and Environmental Medicine*, *58*(8), 528-534.

Mostafavifar, M., Wertz, J., & Borchers, J. (2012). A systematic review of the effectiveness of kinesio taping for musculoskeletal injury. *The Physician and sportsmedicine*, *40*(4), 33-40.

Neer, C. S. (1983). Impingement lesions. *Clinical orthopaedics and related research*, *173*, 70-77.

Oh, J. H., Oh, C. H., Choi, J. A., Kim, S. H., Kim, J. H., & Yoon, J. P. (2011). Comparison of glenohumeral and subacromial steroid injection in primary frozen shoulder: a prospective, randomized short-term comparison study. *Journal of Shoulder and Elbow Surgery*, *20*(7), 1034-1040.

Östör, A. J. K., Richards, C. A., Prevost, A. T., Speed, C. A., & Hazleman, B. L. (2005). Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology*, *44*(6), 800-805.

Petticrew, M., & Roberts, H. (2008). *Systematic reviews in the social sciences: A practical guide*. John Wiley & Sons.

Popay, J., & Williams, G. (Eds.). (2005). *Researching the people's health*. Routledge.

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., ... & Duffy, S. (2006). Guidance on the conduct of narrative synthesis in systematic reviews. *ESRC methods programme*, *15*(1), 047-71.

Proctor, S. (1998). Linking philosophy and method in the research process: the case for realism. *Nurse Researcher*, *5*(4), 73-90.

Rhon, D. I., Boyles, R. B., & Cleland, J. A. (2014). One-year outcome of subacromial corticosteroid injection compared with manual physical therapy for the management of the unilateral shoulder impingement syndrome: a pragmatic randomized trial. *Annals of internal medicine*, *161*(3), 161-169.

Rocourt, M. H., Radlinger, L., Kalberer, F., Sanavi, S., Schmid, N. S., Leunig, M., & Hertel, R. (2008). Evaluation of intratester and intertester reliability of the Constant-Murley shoulder assessment. *Journal of Shoulder and Elbow Surgery*, *17*(2), 364-369.

NICE Guidelines (2016) Low back pain and sciatica in over 16s: assessment and management, National Institute for Health and Care Excellence.

Rousson, V, Gasser T, Siefirt B (2002) ‘Assessing intrarater, interrater and test-retest reliability of continuous measurements’, *Stat Med*, Nov 30,21(22), pp. 3431-46.

Roy, J. S., MacDermid, J. C., & Woodhouse, L. J. (2009). Measuring shoulder function: a systematic review of four questionnaires. *Arthritis Care & Research*, *61*(5), 623-632.

Saunders, S. Longworth, S. (2006) *Injection Techniques in Orthopaedic and Sports Medicine: A Practical Manual for Doctors and Physiotherapists.* Elsevier/Churchill Livingstone.

Schellingerhout, J. M., Verhagen, A. P., Thomas, S., & Koes, B. W. (2008). Lack of uniformity in diagnostic labeling of shoulder pain: time for a different approach. *Manual therapy*, *13*(6), 478-483.

Schulz K, Chalmers I, Hayes R, Altman D. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA*.1995 ;**273**:408–412.

Shultz, K. S., & Koshino, H. (1998). Evidence of reliability and validity for Wise's attitude toward statistics scale. *Psychological Reports*, *82*(1), 27-31.

Silman, A. J., & Hochberg, M. C. (2001). *Epidemiology of the rheumatic diseases* (No. Ed. 2). Oxford University Press.

Slavin, R. E. (1995). Best evidence synthesis: an intelligent alternative to meta-analysis. *Journal of clinical epidemiology*, *48*(1), 9-18.

Stux, G. (2003). Technique of acupuncture. In *Basics of acupuncture* (pp. 240-251). Springer Berlin Heidelberg.

Subaşı, V., Çakır, T., Arıca, Z., Sarıer, R. N., Filiz, M. B., Doğan, Ş. K., & Toraman, N. F. (2016). Comparison of efficacy of kinesiological taping and subacromial injection therapy in subacromial impingement syndrome. *Clinical rheumatology*, *35*(3), 741-746.

Taylor, D. W., Petrera, M., Hendry, M., & Theodoropoulos, J. S. (2011). A systematic review of the use of platelet-rich plasma in sports medicine as a new treatment for tendon and ligament injuries. *Clinical journal of sport medicine*, *21*(4), 344-352.

Uhthoff, H. K., & Sarkar, K. (1990). An algorithm for shoulder pain caused by soft-tissue disorders. *Clinical orthopaedics and related research*, *254*, 121-127.

van der Windt, D. A., Thomas, E., Pope, D. P., de Winter, A. F., Macfarlane, G. J., Bouter, L. M., & Silman, A. J. (2000). Occupational risk factors for shoulder pain: a systematic review. *Occupational and environmental medicine*, *57*(7), 433-442.

Walker‐Bone, K., Palmer, K. T., Reading, I., Coggon, D., & Cooper, C. (2004). Prevalence and impact of musculoskeletal disorders of the upper limb in the general population. *Arthritis Care & Research*, *51*(4), 642-651.

Williams Jr, J. W., Holleman Jr, D. R., & Simel, D. L. (1995). Measuring shoulder function with the Shoulder Pain and Disability Index. *The Journal of rheumatology*, *22*(4), 727-732.

Winters, J. C., Sobel, J. S., Groenier, K. H., Arendzen, J. H., & Meyboom-de Jong, B. (1999). The long-term course of shoulder complaints: a prospective study in general practice. *Rheumatology*, *38*(2), 160-163.

Yamamoto, N., Muraki, T., Sperling, J. W., Steinmann, S. P., Itoi, E., Cofield, R. H., & An, K. N. (2010). Contact between the coracoacromial arch and the rotator cuff tendons in nonpathologic situations: a cadaveric study.*Journal of shoulder and elbow surgery*, *19*(5), 681-687.

**Appendix 8.1**

**PEDro scale**

1. eligibility criteria were specified no yes where:

2. subjects were randomly allocated to groups (in a crossover study, subjects

were randomly allocated an order in which treatments were received) no yes where:

3. allocation was concealed no yes where:

4. the groups were similar at baseline regarding the most important prognostic

indicators no yes where:

5. there was blinding of all subjects no yes where:

6. there was blinding of all therapists who administered the therapy no yes where:

7. there was blinding of all assessors who measured at least one key outcome no yes where:

8. measures of at least one key outcome were obtained from more than 85%

of the subjects initially allocated to groups no yes where:

9. all subjects for whom outcome measures were available received the

treatment or control condition as allocated or, where this was not the case,

data for at least one key outcome was analysed by “intention to treat” no yes where:

10. the results of between-group statistical comparisons are reported for at least one

key outcome no yes where:

11. the study provides both point measures and measures of variability for at

 least one key outcome no yes where:

**Appendix 8.2: Data Extraction Tables for all studies**

|  |  |
| --- | --- |
| **Reference** | Rhon, D.I. (2014) One Year outcome of Sub-Acromial Corticosteroid Injection Compared with Manual Physical Therapy for the Management of the Unilateral Shoulder Impingement Syndrome |
| **Study design** | RCT |
| **Location** | Military Outpatient Unit in the US |
| **Sample size** | 104 patients  |
| **Population** | Males and Females between 18 and 65 years |
| **Intervention** | One 40mg Triamcinalone Acetonide injection into the Sub-Acromial space. Up to 3 injections allowed but had to be more than 1 month apart during the follow-up period. 38% had more than one injection. |
| **Comparative Intervention** | Combination of joint mobilisations, manual stretches and strengthening/home exercises. Treatment not identical. Treated twice weekly over 3 weeks.  |
| **Primary Outcomes** | SPADI  |
| **Secondary Outcomes** | NPRS pain measurement (0-10)  |
| **Quality outcomes (3)** | Randomised, Assessor blinding, Allocation blinding until after collection of baseline outcomes.  |
| **Duration of Study follow-up** | 1 month, 3 months, 6 months, 1 year.  |
| **Results** | Both interventions had statistically and clinically significant improvements within groups from baseline on SPADI (>12 points). This improvement was maintained at all follow-up points in both groups. There was no significant difference at any time point between groups. NPRS had significant improvement within groups at all time points but neither group achieved a clinically significant improvement (>2 points) at any follow-up.  |
| **Notes** | No adverse events. Physiotherapy and CSI produced similar outcomes. However subjects in the CSI group had more shoulder related healthcare use through 1 year.  |
| **Ethics** | Ethical approval obtained.  |

|  |  |
| --- | --- |
| **Reference** | Hay, E.M. (2003) A Pragmatic Randomised Control Trial of Local Corticosteroid Injection and Physiotherapy for the Treatment of New Episodes of Unilateral Shoulder Pain in Primary Care.  |
| **Study design** | RCT |
| **Location** | Staffordshire, multicentre GP practices. |
| **Sample size** | 207 subjects. 103 Physio, 104 Injection. |
| **Population** | Males and Females aged 18 and over. |
| **Intervention** | Injection of 40mg Methylprednisolone mixed with 4mls Lidocaine into Subacromial space given by pts own GP using standardised technique. Could return within 4 weeks for second injection. |
| **Comparative Intervention** | 13 Physiotherapists delivered up to 8 sessions in first 6 weeks using standardised content but additional treatments such as U/S and manual therapy were allowed.  |
| **Primary Outcomes** | Shoulder Disability Questionaire |
| **Secondary Outcomes** | Global assessment of change, VAS pain scale, ROM, Co-interventions. |
| **Quality outcomes (3)** | Randomised, Assessor blinding, Allocation blinding.  |
| **Duration of Study follow-up** | Baseline, 6 weeks, 6 months. |
| **Results** | 94 subjects in Injection group had an injection. In Physio Group all received exercises and advice but only 42 had all 8 sessions. Mean no of sessions was 6. Mean improvement in disability scores were 2.56 for Physio and 3.03 for CSI at 6 weeks. At 6 months 5.97 for Physio and 4.55 for CSI. No sig difference between groups at either time point. A minimum 50% drop in disability score achieved by 60% in Phyiso group and 53% in CSI group. No sig difference. There were no sig differences between groups for VAS or ROM scores at any time point although all improved within groups.  |
| **Notes** | No mention of adverse events.After 6 week assessment GPs could prescribe other treatments if indicated. 57% of CSI subjects visited their GP vs 40% of Physio group. In Physio group 29 subjects went on to receive a CSI and 5 had second course of Physio. Only 11 subjects in CSI group had a second injection and 21 received Physio. Makes it hard to analyse results after 6 week follow-up due to pragmatic nature of study. |
| **Ethics** |  Ethical approval obtained. |

|  |  |
| --- | --- |
| **Reference** | Cloke, D.J. (2008) A Pilot Randomized Control Trial of Treatment for Painful Arc of the Shoulder. |
| **Study design** | RCT |
| **Location** | Primary Care centres in Newcastle/North Tyneside. |
| **Sample size** | 112 subjects into 4 groups |
| **Population** | Males and Females aged 18 and over.  |
| **Intervention** | A course of injections of 40mg Methylprednisolone and 10mls Lidocaine into Subacromial space. Max of 3 injections at 6 week intervals.  |
| **Comparative Intervention/s** | 6 sessions of Exercise and Manual Therapy over a maximum of 18 weeks.A combination of Injection and Physiotherapy.  |
| **Primary Outcomes** | Oxford Shoulder Score (OSS) |
| **Secondary Outcomes** | Short-form 36 (SF-36) Physical health total and need for surgery at 1 year.  |
| **Quality outcomes (3)** | Randomised, but no mention of allocation or assessor blinding. |
| **Duration of Study follow-up** |  Baseline, 18 weeks (Intervention end), and 1 year (Trial end). |
| **Results** | 90 subjects (80%) completed the trial. For primary outcome measures, no significant differences were found within groups at any time point. Neither the effect of receiving injection or Physiotherapy was significant. There were no significant improvements of combining Physio and Injection.  |
| **Notes** | There was no detail of how the combination group was treated. Only 55% returned the questionnaire at the 1 year follow-up which reduces power of their long term conclusions. |
| **Ethics** | Ethical approval obtained. |

|  |  |
| --- | --- |
| **Reference** | Ginn, K.A. (2005) Exercise Therapy for Shoulder Pain Aimed at Restoring Neuromuscular Control: A Randomized Comparative Clinical Trial.  |
| **Study design** | RCT |
| **Location** | Metropolitan Public Hospital |
| **Sample size** | 138 subjects into 3 treatment groups.  |
| **Population** |  Males and Females over 18 years of age. |
| **Intervention** | One injection only of 40mg Methylprednisolone with Lidocaine.  |
| **Comparative Intervention/s** | Specific exercises individually determined by the Physiotherapist. Subjects had one session per week and home exercises to be completed every day. |
| **Primary Outcomes** | Pain Intensity on VAS |
| **Secondary Outcomes** | Functional limitation questionnaire, ROM. |
| **Quality outcomes (3)** | Randomised, Assessor blinding, Allocation blinding. |
| **Duration of Study follow-up** |  Baseline, 5 weeks  |
| **Results** | For mean pain intensity (VAS) Injection group improved from 1.9 at baseline to 0.2 at 5 weeks, difference = 1.7. Exercise group also improved from 1.5 to 0.3, difference = 1.2. Both values significantly better within, but not between groups. Functional limitation for injection group improved from 6.9 to 5.2 and for exercise group also improved from 8.0 to 4.6. Both significant within, but not between groups. All ROM measurements were significantly better within groups at 5 weeks but no difference between groups.  |
| **Notes** | No subject or therapist blindingNo adverse events documented.  |
| **Ethics** | Ethical approval obtained.  |

|  |  |
| --- | --- |
| **Reference** | Kelle and Kozanoglu, (2014) Low-level Laser and local corticosteroid injection in the treatment of Subacromial Impingement Syndrome: a controlled clinical trial. |
| **Study design** | Controlled trial |
| **Location** | Curkova University Faculty of Medicine |
| **Sample size** | 135 subjects into 3 treatment groups. Injection n = 45, Sham laser = 45. Laser = 45.  |
| **Population** |  Males n= 30 and Females n = 105 over 18 years of age. Mean age of 49 years well matched between groups.  |
| **Intervention** | An injection of Betamethasone with Lidocaine at day one and again at day 10. Administered by assessor who was one of the investigators.  |
| **Comparative Intervention/s** | Low level laser for 150 seconds 3 x a week for 3 weeks (9 sessions). Sham Laser following same protocol as Laser but machine ‘off’. All subjects followed standard exercise programme over 3 weeks.  |
| **Primary Outcomes** | Shoulder function using UCLA rating score. |
| **Secondary Outcomes** | Pain intensity on VAS |
| **Quality outcomes (3)** | Not randomised, No assessor blinding, No allocation blinding. |
| **Duration of Study follow-up** |  Baseline, post-treatment, three months, six months.  |
| **Results** | For mean pain intensity (VAS 0-100mm) Injection group improved from 61.9mm at baseline to 23.6mm post treatment, difference = 38.3mm which was significantly better than Laser and sham laser groups. Both injection and Laser groups were statistically better than sham laser at all three follow-ups. No difference between injection and Laser groups at 3 or 6 months. Significantly better UCLA scores of injection and Laser versus sham laser at all follow-ups. No significant difference between injection and Laser at any time point. All groups improved significantly within groups at all time points.  |
| **Notes** | No subject, assessor or therapist blinding.14 subjects lost to follow-up in the Sham Laser group. No randomisation.No adverse events documented and no system included for adverse event reporting. |
| **Ethics** | Ethical approval obtained.  |

|  |  |
| --- | --- |
| **Reference** | Johansson et al (2011) Subacromial corticosteroid injection or Acupuncture with home exercises when treating patients with Subacromial impingement syndrome in primary care – a randomised clinical trial. |
| **Study design** | Randomised controlled trial |
| **Location** | Five primary health care centres in Sweden.  |
| **Sample size** | 123 subjects into 2 treatment groups. Injection n = 65 with 49 analysed, Acupuncture = 58 with 42 analysed.. |
| **Population** |  Males n= 38 and Females n = 53 over 18 years of age. Mean age of 46 years. No difference in background characteristics or baseline measures.  |
| **Intervention** | An injection of 40mg Methylprednisolone with Prilocaine at baseline plus option of a second which occurred in 25% of the subjects. |
| **Comparative Intervention/s** | Standard needle placement but by several PTs with pre-training. Treatment sessions were 30 mins, twice weekly for 5 weeks. A/C followed by standard home exercises targeting ROM and strength of the R.Cuff ? duration/sessions. |
| **Primary Outcomes** | Self-reported Shoulder function using Adolfson-Lysholm shoulder assessment questionnaire |
| **Secondary Outcomes** | Pain intensity on VAS  |
| **Quality outcomes (3)** | No random selection, Assessor blinding, Random allocation. |
| **Duration of Study follow-up** |  Baseline, 6 weeks, 3 months, 6 months. 12 months.  |
| **Results** | Both treatment groups reported significant within group improvements at all timescales for pain (P<0.001). There were no significant differences between groups at any time point or 12 months (P=0.16).  |
| **Notes** | Double blinded study with both assessor and therapist blinding32 subjects lost to follow-up which is huge drop out rate.No random selection.Adverse events documented as nil at 6 week follow-up but only for acupuncture group.Duration the AC group performed home exercises for is not stated.  |
| **Ethics** | Ethical approval not stated. |

|  |  |
| --- | --- |
| **Reference** | Subasi et al (2014) Comparison of efficacy of kinesiological taping and sub-acromial injection therapy in sub-acromial impingement syndrome.  |
| **Study design** | Randomised controlled trial |
| **Location** | Outpatient clinic of Antalya training and research hospital, Turkey. |
| **Sample size** | 70 subjects randomly allocated into 2 treatment groups. Injection n = 35, Kinesio tape = 35. |
| **Population** |  Males n= 23 and Females n = 47 over 18 years of age. Mean age of 54. No difference in background characteristics or baseline measures (P>0.05). |
| **Intervention** | A single injection of 40mg Betamethasone with Prilocaine at baseline. |
| **Comparative Intervention/s** | Kinesio tape applied in a standard pattern using 3 strips with space correction and mechanical correction techniques by the same Physiotherapist. Tape applied once a week for 3 weeks and left on for 5 days at a time. All subjects received the same home exercise programme including stretching and strengthening exercises for 7 days a week for 3 months.  |
| **Primary Outcomes** | SPADI  |
| **Secondary Outcomes** | VAS, ROM |
| **Quality outcomes (3)** | No random selection, Random allocation, No assessor blinding. |
| **Duration of Study follow-up** | Baseline, 4 weeks and 3 months. |
| **Results** | Significant improvements were seen in all outcome measures within groups at both time points (P<0.05). No significant differences between groups in any outcome measure at any time point. |
| **Notes** | No random selection or blinding of assessors, therapists, or subjects.Exercise programme for 3 months, 7 days a week - ? compliance. No subjects lost to follow-up. No random selection or blinding.Adverse events not documented.All subjects advised not to place arm above head height during ADLs. |
| **Ethics** | Ethical approval obtained. |

**Appendix 8.3 - The Search Strategy (Database)**

 Select / deselect all  

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Search ID# | **Search Terms** | **Search Options** | **Actions** |
|  | S36 | S9 AND S19 AND S29 AND S35  | **Search modes** - Boolean/Phrase | **View Results** (149)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S35 | S30 OR S31 OR S32 OR S33 OR S34  | **Search modes** - Boolean/Phrase | **View Results** (2,531,047)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S34 | AB quality of life  | **Search modes** - Boolean/Phrase | **View Results** (270,634)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S33 | AB disability  | **Search modes** - Boolean/Phrase | **View Results** (182,217)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S32 | AB function  | **Search modes** - Boolean/Phrase | **View Results** (1,657,526)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S31 | AB range of motion  | **Search modes** - Boolean/Phrase | **View Results** (45,792)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S30 | AB pain  | **Search modes** - Boolean/Phrase | **View Results** (586,273)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S29 | S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28  | **Search modes** - Boolean/Phrase | **View Results** (59,541)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S28 | AB depomedrone  | **Search modes** - Boolean/Phrase | **View Results** (16)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S27 | AB dexamethasone  | **Search modes** - Boolean/Phrase | **View Results** (48,443)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S26 | AB betamethasone  | **Search modes** - Boolean/Phrase | **View Results** (3,899)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S25 | AB kenalog  | **Search modes** - Boolean/Phrase | **View Results** (150)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S24 | AB triamcinolone  | **Search modes** - Boolean/Phrase | **View Results** (5,827)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S23 | AB glucocorticoid injection  | **Search modes** - Boolean/Phrase | **View Results** (320)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S22 | AB sub-acromial injection  | **Search modes** - Boolean/Phrase | **View Results** (2)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S21 | AB cortisone injection  | **Search modes** - Boolean/Phrase | **View Results** (282)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S20 | AB corticosteroid injection  | **Search modes** - Boolean/Phrase | **View Results** (2,388)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S19 | S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18  | **Search modes** - Boolean/Phrase | **View Results** (687,944)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S18 | AB electrotherapy  | **Search modes** - Boolean/Phrase | **View Results** (1,096)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S17 | AB acupuncture  | **Search modes** - Boolean/Phrase | **View Results** (21,517)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S16 | AB laser  | **Search modes** - Boolean/Phrase | **View Results** (203,900)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S15 | AB taping  | **Search modes** - Boolean/Phrase | **View Results** (3,004)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S14 | AB manipulation  | **Search modes** - Boolean/Phrase | **View Results** (77,872)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S13 | AB exercise  | **Search modes** - Boolean/Phrase | **View Results** (335,462)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S12 | AB mobilisation  | **Search modes** - Boolean/Phrase | **View Results** (11,234)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S11 | AB physical therapy  | **Search modes** - Boolean/Phrase | **View Results** (32,782)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S10 | AB physiotherapy  | **Search modes** - Boolean/Phrase | **View Results** (23,640)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S9 | S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8  | **Search modes** - Boolean/Phrase | **View Results** (14,174)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S8 | AB painful arc  | **Search modes** - Boolean/Phrase | **View Results** (132)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S7 | AB subacromial bursitis  | **Search modes** - Boolean/Phrase | **View Results** (163)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S6 | AB adhesive capsulitis  | **Search modes** - Boolean/Phrase | **View Results** (939)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S5 | AB frozen shoulder  | **Search modes** - Boolean/Phrase | **View Results** (1,118)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S4 | AB rotator cuff tendonitis  | **Search modes** - Boolean/Phrase | **View Results** (106)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S3 | AB rotator cuff tendinopathy  | **Search modes** - Boolean/Phrase | **View Results** (328)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S2 | AB sub-acromial impingement  | **Search modes** - Boolean/Phrase | **View Results** (20)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |
|  | S1 | AB shoulder pain  | **Search modes** - Boolean/Phrase | **View Results** (12,347)**View Details**[**Edit**](http://web.b.ebscohost.com.ezproxy.tees.ac.uk/Legacy/Views/UserControls/Ehost/) |