LATERAL VERSUS POSTERIOR APPROACH TO SHOULDER INJECTION IN PATIENTS WITH SUBACROMIAL IMPINGEMENT SYNDROME:

A MIXED METHODS STUDY

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Abstract

Objectives: To determine the effectiveness of lateral approach to subacromial injection compared to posterior approach for the treatment of subacromial impingement syndrome (SAIS); and to establish the experiences of SAIS patients receiving these injections associated with better clinical outcomes.

Design: This study used a mixed methods approach that combines a pragmatic randomised control trial to investigate which injection approach is better and a semi-structured qualitative interview to investigate the experiences of SAIS patients receiving these injections.

Settings: Out-patients community musculoskeletal service

Sample: 80 patients with SAIS for the randomised control study and 20 participants for the semi-structured qualitative interview.

Interventions: The *Intervention group* received a single subacromial injection with a 21-gauge Green needle with a 40 mg/ml of Kenalog and a 4 ml 1% of Lidocaine through a lateral approach. The *Control group* received an identical treatment except that the location was by a posterior approach.

Outcome measures: Difference in improvements in the overall patient reported outcome measures (PROMs) and shoulder pain and disability index score (SPADI) at 8 and 12 weeks follow-up between the two groups.

Results: A moderate but statistically and clinically significant difference in improvement in day-time pain (mean change score) occurred in favour of the lateral group (mean = 3.7) compared with the posterior group (mean = 2.3) between week 0 to 8 (1.4 points [95% CI 0.3 to 2.6, p = 0.018]). However, there were no statistically significant differences between the groups in night-time pain, shoulder function and SPADI scores. There was a statistically and clinically significant difference (p = 0.001) within the groups for all clinical outcomes between week 0 to 8 and between week 0 and 12. This was confirmed by participants from the semi-structured interviews which were conducted 12 weeks after the injection.

Conclusion: There were no real significant differences in the treatments; however, both forms of treatment were associated with significant improvement in shoulder pain, function and disability. This was confirmed by participants from the semi-structured interviews, who felt that they improved not only because of the effect of the cortisone injection, but also because of other factors such as education about their treatment, exercise information, the experience and skills of the injecting clinicians, access to treatment as well as good customer service.

Glossary and Abbreviations

Word	Meaning
ACJ	Acromioclavicular Joint
BMI	Body Mass Index
CSP	Chartered Society of Physiotherapy
ESP	Extended Scope Practitioner
GHJ	Glenohumeral Joint
GP	General Practitioner
ITT	Intention to treat analysis
L	Lateral
MCID	Minimum Clinically Important Difference
MRI	Magnetic Resonance Imaging
MSK	Musculoskeletal
NHS	National Health Service
NPS	Numeric Pain Score
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
P	Posterior
PGDs	Patient Group Directions
PIS	Participant Information Sheet
PROMs	Patient Reported Outcome Measures
RCT	Randomised Clinical Trial
RCIS	Rotator Cuff Impingement Syndrome
ROM	Range of Movement
SAIS	Subacromial Impingement Syndrome
SIS	Shoulder Impingement Syndrome
SOM	Society of Orthopaedic Medicine
SPADI	Shoulder Pain and Disability Index
VAS	Visual Analogue Scale

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CHAPTER 1 INTRODUCTION

1.1 Introduction and Background

Shoulder pain is one of the most common musculoskeletal conditions affecting the general population and a common reason for consulting their general practitioner (GP) (Linsell et al 2006). In the UK, the incidence of shoulder pain is very common and one in three people will suffer from shoulder pain at some point (Van der Heijden 1999, Linsell et al 2006). For the first time, a UK report in 2011 - 2012 says that the prevalence of work related upper limb disorders including shoulder pain exceeded those of low back pain (Health & Safety Executive 2012). Of all the disorders of shoulder pain, subacromial impingement syndrome (SAIS) is the most common.

As a preamble, before taking you through the journey of this research it is imperative to give a little background of myself. I am an Extended Scope Practitioner (ESP) Physiotherapist working in a community musculoskeletal service. My job entails among others the provision of cortisone injection not necessarily as a stand-alone treatment but as an adjunct to rehabilitation for patients with shoulder pathologies such as SAIS. The use of cortisone injection for the management of SAIS is supported by the recent systematic review by Diercks et al (2014) and an extensive review undertaken by Hanchard et al (2004). Traditionally ESPs are trained to inject the shoulder either through a lateral or posterior approach. Whilst shoulder cortisone injection can be provided either through a posterior (back) or a lateral (side) approach to patients with

SAIS, in my practice, I have observed that the posterior is predominantly used even though anatomically the structures of the subacromial region are closer to the lateral than the posterior border of the shoulder. Whilst a cortisone injection is effective in relieving symptoms of pain and inflammation in people with SAIS, we do not know if people are more or less likely to benefit if they are injected from the side or the back of the shoulder. This knowledge gap was my main motivation for undertaking this study.

This thesis set out to find out whether people with SAIS who are injected from the side (lateral) of their shoulder would have better pain relief and improved shoulder function compared to those who are injected from the back (posterior) of the shoulder. All participants in the study were referred by their GP with shoulder pain and during their first appointment, were identified by an injecting clinician through a face-to-face assessment to determine if they have a diagnosis of SAIS and would benefit from a cortisone injection.

The remaining part of this chapter focuses on the background information on the development of this research. It considers the incidence and definition of both shoulder pain and SAIS, the cost implication of SAIS and subacromial injection for treatment of SAIS. It also considers the uncertainty of evidence regarding needle placement in subacromial injections and the experiences of patients receiving these injections as a gap in current knowledge and therefore the purpose of this study.

1.2 Shoulder Pain - Why it is a Problem

Shoulder pain is a common and often persistent musculoskeletal problem (Van der Heijden 1999, Roquelaure et al 2006, Diercks et al 2014). Shoulder pain is associated with significant morbidity and it increases linearly with age peaking at 50 years (Van der Heijden 1999, Linsell et al 2006). In the UK, shoulder disorders rank fourth only to disorders of the back, knee and chest in frequency of occurrence, affecting all ages (Jordan et al 2010). Shoulder pain is often associated with difficulties with performing functional activities such as getting dressed (Linsell et al 2006), throwing a baseball (Seroyer et al 2009), impaired ability to sleep (Kromer et al 2009), hence affecting mood and concentration (Green et al 2003).

The cumulative annual prevalence and incidence of shoulder disorders such as SAIS in the UK's general medical practice has been reported to be 2.36% and 1.47 % respectively (Linsell et al 2006). According to Greving et al (2012) it accounts for approximately 12 % of GP contacts in primary care. In Australia, it has been reported that shoulder disorders account for 1.2% of all GP encounters, ranking third only to back and neck disorders as reasons for musculoskeletal consultations (Bridges-Webb 1992). A Dutch study by Luime et al (2004) has reported one-year prevalence rates for shoulder disorders as ranging from 5% to 47%. Figures obtained from the US National Ambulatory Medical Care Survey (NAMCS) 1993 to 2000 show that 1% of all office visits to GPs are for shoulder pain, and that 25% of these visits are to primary care

doctors (Wofford 2005). These lower figures reflect that not all shoulder pain sufferers consult their GP, while Hanchard et al (2013) reports this to be in the region of 50-80%, Bongers (2001) approximates this to be in the order of 40-50%.

In addition to the high incidence, shoulder dysfunction is often persistent and recurrent with 64% of suffers reporting ongoing symptoms after 3 years (Linsell et al 2006). Some studies have demonstrated persisting pain and disability from 12 months (Van der Windt et al 1995) to 18 months (Chard 1991) in up to 50% of cases. 50% of patients referred to primary care with new episodes of shoulder pain would experience complete resolution at 6 months rising to only 60% after a year (Van der Windt et al 1996). Linsell et al (2006) found that during a 3 year follow up period of patients consulting for shoulder disorders in UK primary care, 22.4% of patients were referred to secondary care, 30.8% were prescribed non-steroidal anti-inflammatory drugs (NSAIDs), and 10.6% were given a cortisone injection by their GP.

1.3 What is Shoulder Pain?

Shoulder pain is a symptom rather than a distinct pathology. Shoulder disorders such as SAIS, frozen shoulder, shoulder instability and acromioclavicular dysfunction are the most common causes of shoulder pain (National Health Service 2012). SAIS is a frequent cause of shoulder pain (Picavet & Schouten 2003, Hanchard et al 2013); and it accounts for 44% to 65% of all complaints of

shoulder pain during a GP visit (Vecchio et al 1993, Van der Windt et al 1995). This is consistent with a UK study that found SAIS was the most common reason for people consulting for shoulder problems in the UK primary care setting (Linsell et al 2006). This result was based on a large, nationwide sample.

Two systematic reviews (Van der Windt et al 2000, Van Rijn 2010) found occupational risk factors for shoulder pain such as lifting heavy loads, working in awkward postures, engaging in repetitive movements and being exposed to vibration. Psychosocial factors that were identified include mental stress, work pressure, lack of control at work and job satisfaction (Van der Windt et al 2000, van Rijn 2010). The clinical manifestation of SAIS varies widely because it is a collection of soft tissue pathologies rather than a distinct pathology (Lewis 2008), and it mainly causes shoulder pain, limiting range of movement, affecting patient function and quality of life. Some patients experience severe acute or chronic pain and loss of function (Bokor et al 1993). Pain often located at the anterior-lateral aspect shoulder and radiates to the side of the arm especially when the arm is elevated (Lewis et al 2001). Pain is also aggravated with placing the arm behind the back, arm elevation or overhead activities associated with daily living (Lewis et al 2005). Night pain may be present in SAIS, and is particularly associated with rotator cuff tears (Zuckerman et al 1991), but it is also a common feature of adhesive capsulitis (Hanchard et al 2004).

1.4 Definition of Subacromial Impingement Syndrome

During the elevation of the shoulder, the humeral tuberosities pass close under the coracoacromial arch, leaving little clearance for the intervening soft tissues (Hanchard et al 2004, Hanchard et al 2013). These consist of superficial to deep structures such as the subacromial bursa, the rotator cuff tendons, and the long head of biceps. If there is not enough space, these soft tissues can become pinched. This is called SAIS or otherwise rotator cuff impingement syndrome (Lewis 2008), shoulder impingement syndrome, painful arc syndrome (Hanchard et al 2004), and subacromial pain syndrome (Lewis 2011). Therefore, SAIS is a collection of soft tissue pathologies rather than a specific pathology (Lewis 2008). In practice, a diagnosis of SAIS is still based on findings of a clinical examination for the majority of patients (Dinnes et al 2003).

1.5 Cost Implications of Subacromial Impingement Syndrome

The impact of shoulder pain on the economy is high because the cost involved in its management is huge (Lewis 2011). Using figures from a comprehensive evaluation of shoulder disorders (Garg et al 2010) Arthritis Research UK, has estimated the cost of shoulder pain in the general population to be in the region of £100 million. In 2005 a multicentre randomised clinical trial (RCT) conducted in the UK found that the total mean costs, per patient, for cortisone injection and physiotherapy treatment of unilateral shoulder pain were £71.28 and £114.60 respectively (James et al 2005). Ketola et al (2009) reported that in London, the average cost of surgery/post-surgical rehabilitation for patients with shoulder

impingement syndrome is estimated at £3500 (Ketola et al 2009). In New York, USA, it was reported to be $4860. Although these figures indicate that the cost of cortisone injection, physiotherapy and surgery for SAIS varies widely, physiotherapy and surgery have each been reported to cost more when compared to cortisone injections (James et al 2005 & Ketola et al 2009). From these figures, the combined cost of physiotherapy and cortisone injection for SAIS is less compared to surgery (James et al 2005, Ketola et al 2009). The reports and figures from these studies show therefore that SAIS is a significant health burden on the health-care budget, for patients, healthcare practitioners, and policy makers (Bennell et al 2007 & Garg et al 2010).

1.6 Subacromial Injection for Treatment of Subacromial Impingement Syndrome

Subacromial injection is the recommended treatment for patients with SAIS, particularly where physiotherapy has failed or pain is limiting exercise (Hanchard et al 2004, Lewis 2011 & Diercks et al 2014). The result of a literature search demonstrates that cortisone injection is commonly used in SAIS. A recent systematic review and meta-analysis of RCTs shows that cortisone injections provide moderate pain relief for patients with rotator cuff disorders up to two months after the injection (Mohamadi et al 2016), but the benefit was not sustained after this time. Previous systematic reviews that investigated the effectiveness of cortisone injection in treatment of shoulder pain (Johansson et al 2002, Buchbinder et al 2003, Arroll & Goodyear-Smith 2005) have reported varying methodological quality and heterogeneity of populations and commented

that sample sizes were generally small. However, their conclusions were nevertheless similar: subacromial cortisone injection is effective in the management of SAIS and more effective when compared with placebo, acupuncture, ice, heat and exercise. Both the Johansson et al (2002) and Arroll & Goodyear-Smith (2005) reviews agree that cortisone injection is superior to NSAIDs in reducing pain and improving shoulder function, with the latter study reporting improvement lasting up to 9 months. The findings of those reviews are consistent with the recommendations of the National Institute for Clinical Excellence (NICE 2015), a systematic review (Hanchard et al 2004) that was commissioned by the Chartered Society of Physiotherapy (CSP) and a recent Dutch review (Diercks et al 2014) which recommends that cortisone injection should be provided to patients with SAIS.

1.7 Evidence for Approaches to Subacromial Injections and Patient Experience

Anterior, posterior and lateral approaches of subacromial injections are described in the literature (Sardelli & Burks 2008, Marder et al 2012, Saunders 2010, Saunders & Longworth 2012) with the latter two most commonly used (Saunders 2010). However, there is no concrete evidence supporting the use of posterior route of needle placement in SAIS over the lateral approach. Yet anecdotal evidence suggests that clinicians, including musculoskeletal Extended Scope Practitioners (ESPs), have mainly used the former approach. Previous RCTs (Henkus et al 2006, Kang et al 2008, Goel et al 2012, Marder et al 2012) and one comparative study (Sardelli & Burks) have investigated needle

placements in SAIS using an MRI, radiographic contrast dye, radiopaque contrast and arthroscopy respectively as the reference standard. However, in normal musculoskeletal practice (primary care setting) where most people with shoulder pain are diagnosed and managed (Hanchard et al 2013), ESPs commonly inject the shoulder without the use of imaging as a reference for evaluation. Furthermore, the findings of these efficacy studies suggest that there is conflicting evidence supporting the use of a posterior route of needle placement over a lateral approach in the treatment of patients with SAIS. None of these studies directly evaluates the influence of psychosocial factors such as patient experiences regarding lateral or posterior needle placement in SAIS. Despite these limitations, these studies provide some useful information for future research.

There is paucity of evidence in the subjective experience of SAIS patients receiving subacromial injections. A UK qualitative study was found that described the experience of patients' living with a symptomatic rotator cuff tear (RCT) their symptoms, the impact upon their daily lives and the coping strategies utilised by these patients (Minns et al 2014). A previous qualitative study has explored patients' experiences with frozen shoulder and their treatment with Bowen technique (Carter 2002), and a semi-structured qualitative study investigated the patients' perceptions and priorities regarding frozen shoulder (Jones et al 2013). Although these studies have provided useful information on the qualitative

experience of patients with shoulder pathology, they lack information on the experiences of patients with SAIS receiving cortisone injection.

To my knowledge, just one study (Nyman et al 2012) was found that investigated the experiences of patients with supraspinatus tendinitis who had received both physiotherapy and cortisone injection or had undergone open or arthroscopic shoulder surgery. Although 26 participants were interviewed only three of them received cortisone injection after receiving physiotherapy. The findings of these studies and others are presented throughout this study.

1.8 The Knowledge Gaps in Current Research

Four key gaps in the current research evidence were identified from the discussion and the issues raised in the preceding sections of this chapter. The first is the lack of consensus regarding the superiority of a posterior versus a lateral to subacromial injection in treatment of patients with SAIS among authors of previous shoulder studies. Secondly, these studies used an imaging tool as the reference standard for evaluating needle placement accuracy making it difficult to replicate them in normal community musculoskeletal service where most people with shoulder pain are diagnosed and treated (Hanchard et al 2013). Thirdly, none of these studies considered the qualitative experience of patients' receiving these injections. Finally, a lack of mixed research that combined a pragmatic RCT and qualitative semi-structured interview was identified as a significant gap in knowledge.

1.9 Purpose of the Study

The purpose of this pragmatic study was to compare the effectiveness of a lateral and a posterior approach to subacromial injection for patients with SAIS. It was also to establish the experiences of patients with SAIS receiving these subacromial injections. The expectation is that this study will add to the body of knowledge required to help clinicians make effective treatment choices on needle placement for patients with SAIS and to understand the experiences of those patients receiving the treatment. A greater knowledge of both aspects is more likely to provide better improvement that is vital for patients, funding providers and researchers. There is currently very little qualitative research into the experiences of patients with SAIS receiving subacromial injections. This study will therefore provide health professionals, researchers and policy makers with a better understanding of the experiences of SAIS patients receiving subacromial injections and thus how best to manage them.

To address the gap in the current knowledge regarding both aspects of subacromial injections and the experiences of patients receiving these injections, two main research questions were formulated. The first question is whether a lateral approach to subacromial injection is better in the treatment of SAIS compared to a posterior or standard approach. The second question is what are the experiences of patients with SAIS receiving these injections.

1.10 Chapter Summary

Chapter 1 has introduced the research topic and presented why shoulder pain is a problem, described it and defined SAIS. It highlighted the use of cortisone injection for treatment of SAIS patients, the lack of concrete evidence on needle placement to subacromial, lack of literature on the qualitative experiences of patients receiving subacromial injections, the knowledge gap and the purpose of the study. The reminder of the study is organised into five chapters.

1.11 Introduction to Chapters Two to Six

Chapter 2 presents a review of the literature on the shoulder joint and rotator cuff muscles, SAIS with particular reference to its clinical presentation, classification, aetiology, diagnostic difficulties and clinical assessment. It also includes discussion on the current trend in National Health Service (NHS) musculoskeletal practice, the role of ESP in musculoskeletal practice, current treatment for SAIS, issue of needle placement in subacromial injections, the evidence on needle placement in subacromial injections and patient experience. The research question, null and alternative hypothesis and the aims of the research are also discussed in this chapter. In Chapter 3 the research design and the methodology that were used for this study are discussed. The sample populations, sample size calculation, interventions, treatment procedure, baseline comparability, instruments used to collect both the quantitative and the qualitative data and the measures followed are also discussed. Chapter 4 presents the data analysis and results of both the quantitative and qualitative analysis. In Chapter 5 the discussion on the findings of

both the quantitative and the qualitative data are presented. Chapter 6 contains the limitations of the study, reflection on my practice, implications of the study, recommendations for further research and conclusion.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter deals with the literature search for both the quantitative and qualitative study. The discussion of the quantitative literature review will include general review of literature on the shoulder, SAIS, and current trends in the NHS musculoskeletal practice, the role of ESPs in musculoskeletal practice, current treatment for SAIS, issue of needle placement in subacromial injections, the evidence on needle placement in subacromial injections. The qualitative aspect will focus on research within the of context musculoskeletal physiotherapy such as the experiences of patients with SAIS receiving subacromial injections. The research question, null and alternative hypothesis and the aims of the research are also discussed.

2.2 Data Source and Search Strategy

Following on from the research questions, the search strategy for the literature review was in two parts:

1. Quantitative literature search
2. Qualitative literature search

2.2.1 Quantitative Literature Search

The search strategy was aimed at optimally retrieving relevant papers that were appropriate to the research question, as well as minimising retrieval of irrelevant

papers (Higgins & Green 2006). To achieve this objective, a number of widely accepted databases were searched. These include:

I. A search for papers was conducted through the search engine of the University of Essex Ebscohost, using CINAHL (Cumulative Index to Nursing & Allied Health Literature) Complete, MEDLINE (Medical Literature Analysis and Retrieval System) and E-Journey database with full text from 1980 to April 2014 and updated in December 2016 via the Chartered Society of Physiotherapy (CSP) Ebscohost

II. The updated search through the Chartered Society of Physiotherapy (CSP) Ebscohost, contained AMED (Allied and Complimentary Medicine), MEDLINE, CINAHL Plus with Full Text, SportDiscus and EBSCO Ebooks

III. Reference Lists: These were searched from the relevant primary and review studies

IV. Grey Literature: The following were searched via –
    a. SIGIE (System for Information on Grey Literature in Europe)

V. Conference Proceedings: These were searched via:
    a. ZETOC
    b. ISI (Institute for Scientific Information) web of science

VI. Cochrane Library

VII. PEDro (Physiotherapy Evidence Database)

VIII. The Internet: The following were searched
    a. Department of Health (http://www.dh.gov.uk)
    b. Google Scholar (http://www.scholar.google.co.uk)

c. Google (http://www.google.co.uk)

IX. Relevant Clinical Guidelines

a. NICE (National Institute for Clinical Excellence)

b. The CSP (Chartered Society of Physiotherapy)

c. SIGN (Scottish Intercollegiate Guidelines Network)

In addition to the above, relevant physiotherapy textbooks were consulted for information on the anatomy, assessment and management of shoulder pain and subacromial impingement syndrome.

The search was limited to human subjects published in the English language. Non-English language studies for example, Chinese and German were not included because of the challenges of translation into English language such as cost and time. According to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green 2006), an electronic search strategy should in general have three sets of terms. These include terms to search for -

1. The population of interest – subacromial impingement syndrome
2. The intervention(s) investigated – cortisone injection
3. The types of study design to be included – non-RCTs, RCT

The search strategy began with the use of multiple terms that describe SAIS such as shoulder pain and shoulder impingement syndrome. These terms were linked together using the Boolean operator “OR” to ensure that articles retrieved

contained at least one of the search terms. The same process was repeated for a second and a third set of terms related to the intervention (cortisone injection) and the study design (qualitative studies, systematic reviews, RCTs, non-RCTs) respectively. These three sets of terms were then combined together with the Boolean operator “AND”. This allows for the retrieval of studies that are relevant to the study design and address both the population of interest and the intervention to be investigated. The following 'MESH' headings and keywords were used; ‘shoulder pain’, ‘shoulder impingement syndrome’, ‘subacromial impingement syndrome’, ‘shoulder$’, ‘subacromial$’, ‘supraspinatus$’, ‘rotator cuff$’, ‘bursitis’, ‘impinge$’, ‘tendonitis’, ‘tendinitis’, ‘pain’, ‘pathology$’ in combination with ‘cortisone injection’ or ‘hydrocortisone injection’ or triamcinolone acetonide injection or Kenalog injection, and not limited to ‘clinical trials’.

The following lines: S10, S15 and S21 of the updated search through the Chartered Society of Physiotherapy (CSP) Ebscohost were used respectively to identify records related to the population (SAIS) and intervention (cortisone injection) and studies of the appropriate design. See Table 1 for detailed description.

Table 1: Quantitative Search - Combined Results of the CSP Electronic Database Searches of AMED, CINAHL, CINAHL Plus with Full Text, CSP Online Library Catalogue, eBook Collection (EBSCOhost), MEDLINE, SPORTDiscus

#	**Search Terms**	**Combined Results from above Database Searches**
S1	Shoulder pain	18,952
S2	Subacromial impingement syndrome	2,848
S3	Shoulder impingement syndrome	3,789
S4	Rotator cuff	20,575
S5	Rotator cuff tendinopathy	435
S6	Supraspinatus tendonitis	91
S7	((shoulder$ or subacromial$ supraspinatus$ or rotator cuff$) adj6 (bursitis or impinge$ or tendonitis or tendinitis or pain$ or pathology$)).mp.	1,732
S8	((Sub-acromial or Subacromial) adj4 (bursitis$ or impinge or impingement or compression or decompression)).mp.	495
S9	Bursitis	7,095
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8	135,289
S11	INJECTIONS	470,468
S12	((steroid$ or corticosteroid$ or sub-acromial or subacromial) adj5 (inject$).mp	391
S13	((steroid$ or corticosteroid$ or sub-acromial or subacromial) adj5 (inject$ or Kenalog or Triamcinolone$ or Depo-Medrone or Methlyprednisolone$ or Lidocaine)).mp	15
S14	((steroid$ or corticosteroid$ or sub-acromial or subacromial) adj5 (inject$ or approach$ or route$ or posterior$ or lateral$ or anterior$).mp	714
S15	S10 OR S11 OR S12 OR S13	488,894
S16	(Reviews$ or Clinical trial$ or Controlled trial$).pt.	3,390,654
S17	(random$ or randomize$).mp.	531,091
S18	(placebo$ or no treatment$).mp.	353,472
S19	((single or double) adj (blind$ or mask$)).mp.	635
S20	S15 OR S16 OR S17 OR S18	3,814,037
S21	S10 AND S15 AND S20	4,265

2.2.1.1 Results of the Quantitative Search

A total of 4265 citations were retrieved from the CSP Ebscohost electronic databases and additional 25 papers were also found from the reference lists and grey literature. There were 3041 citations after removal of 1249 duplicates. After careful evaluation of the titles and/or abstracts, a total of 3002 articles that were not related to the study were excluded from the 3041 citations and 39 full text articles were left. Of the 39 potentially eligible studies, 17 were excluded with reasons and 22 articles that were possibly relevant to this study were identified (see Figure 1 for details). Titles and abstracts of these remaining articles were then hand searched for studies that directly evaluated the effects of different needle approaches to subacromial injection or effects of cortisone injection in the treatment of SAIS. Several of these literatures broadly discussed the terms SAIS and cortisone injection. However, seven systematic reviews (van der Heijden GJ et al 1996, Johansson et al 2002, Buchbinder et al 2003, Arroll & Goodyear-Smith 2005, Koester et al 2007, Gaujoux-Viala et al 2009, Mohamadi et al 2016), were identified that directly evaluated the effects of cortisone injection in the treatment of SAIS. Seven RCTs (Adebajo 1990, Blair 1996, Winter et al 1997, Plafki et al 2000, Akgun et al 2004, Penning et al 2012, Min et al 2013) were identified that evaluated the effects of cortisone injection in the treatment of SAIS. Three non RCTs (Eustace 1997, Yamakado 2002, Esenyel 2003), directly evaluated the effect of one approach of cortisone injection in the treatment of SAIS. Four RCTs (Henkus et al 2006, Kang et al 2008, Goel et al 2012 and Marder et al 2012) and one non RCT (Sardelli & Burks 2008) directly evaluated

the effects of different approaches of cortisone injection in SAIS treatment. See Tables 2 and 3 for details of included studies.

Figure 1: Flow Chart for the Quantitative Search Results

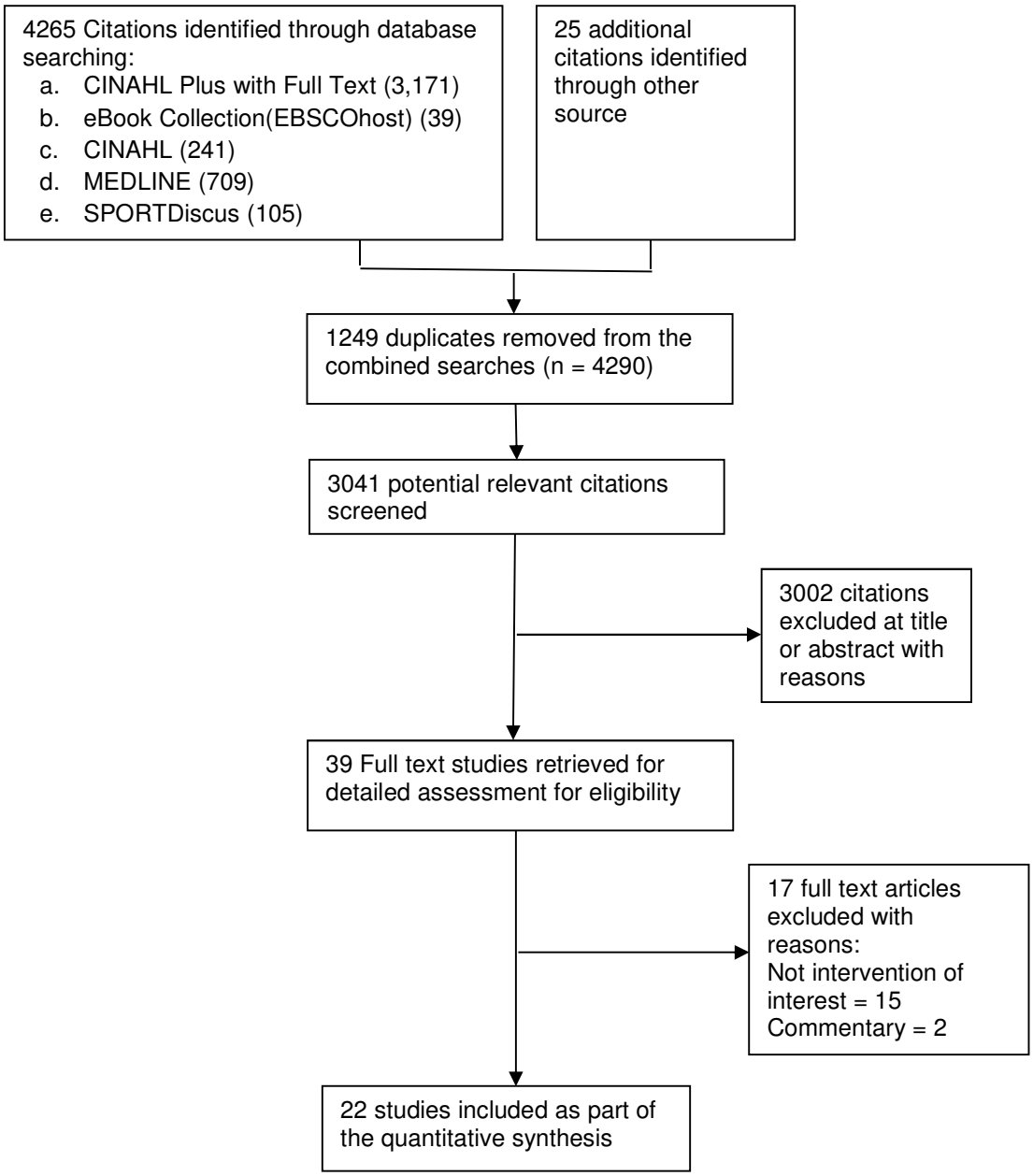


Table 2: A Summary of the Characteristics of Some the included Studies (Non RCTs & RCTs)

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
Adebajo (1990)	RCT	n = 60	Group 1: (20 patients): 50 mg diclofenac 3 times a day for 28 days + subacromial injection of 3ml of 0.5% lignocaine Group 2: (20 patients): diclofenac placebo tablets + subacromial injection of 2ml 0.5% lignocaine & 1ml of 80mg/ml triamcinolone hexacetomide. Group 3: (20 patients): diclofenac placebo tablets + subacromial injection of 3ml 0.5% lignocaine. All patients instructed in pendulum and wall climbing exercises to perform at home.	1. Overall pain severity assessed by 10cm VAS (0 = no pain, 10 = severe pain) 2. Limitation of function on 4-point scale (0 = no 1 = mild, 2 = moderate and 3 = severe limitation of function respectively) 3. Active and passive ROM measured to the nearest 5 degrees with a pendulum goniometer.	Outcome assessed at baseline and 4 weeks	Both groups 1 and 2 forms of treatment were superior to placebo in improving shoulder pain, active abduction and function. Triamcinolone injection showed the greatest effect in these respects, and was significantly superior to diclofenac when patients showing improvements in all 3 variables together (responders) were considered.	The weakness of this study includes the short follow-up period.
Akgun et al (2004)	RCT	n = 48	Group 1: 10 cc of 1% lignocaine + 40 mg of steroid for the 1st and 2nd injections, group 2: 10 cc of 1% lignocaine + 40 mg of steroid for the 1st injection and only 10 cc of 1% lignocaine for the 2nd injection, group 3: only 10 cc of 1% lignocaine for the 1st and 2nd injections. All the patients had NSAID plus pendulum exercises.	Shoulder pain during rest, activity, and causing disturbance of sleep was evaluated using a VAS. Shoulder function was investigated by total Constant score.	Baseline, 1 and 3 months' post treatment	All the groups showed significant improvements in shoulder pain and function at the first and second evaluation. Group 1 patients had more favourably improved values in pain causing sleep disturbance and functional limitation than the other 2 groups only in the 1st month after therapy onset.	Although the results of this study supported the use of cortisone injections for SAIS, the same sample size was small.

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
Blair 1996	RCT	n = 40	Group 1 (21 patients): 6ml of 1% lidocaine without epinephrine. Group 2 (19 patients): 2ml containing 40 mg of triamcinolone acetonide per ml with 4 ml of 1% lidocaine without epinephrine. All patients underwent a standardised program of physiotherapy.	Assessed at baseline and every 4 weeks until completion of study (not defined) - (mean duration of follow up was 33 weeks (range: 12-55) and 28 weeks (range: 12-52) in corticosteroid and placebo groups respectively). 1. Performance of 5 ADL. 2. Overall subjective assessment of pain on 4-point scale injection. 3. Detailed physical examination and measurement of ROM using a goniometer	Assessed at baseline and every 4 weeks (mean duration of follow up was 33 weeks and 28 weeks in corticosteroid and placebo groups respectively).	At follow-up evaluation, at a mean of 33 weeks in corticosteroid group and 28 weeks in placebo group, the corticosteroid group was significantly better with respect to pain and range of motion but there was no significant difference between the two groups with respect to improvement in performance of activities of daily living.	Although the results of this study supported the use of cortisone injections for SAIS, the same sample size was small. The variation in the follow-up periods between the groups could make the pooling of the results for systematic review and meta-analysis difficult.
Esenyel 2003	Non RCT	48 patients (29 women, 19 men; mean age 46.5 years; range 23 to 58 years)	Contrast material was added to a mixture of steroid and local anesthetic solution.	Shoulder function and pain were evaluated by VAS, range of movement of the joint, and Constant scores.	Before treatment, 30 minutes & two weeks post injections	The injections were placed accurately in 42 patients (87%), while in six patients (12.5%), delivery to the target site failed. Although both groups showed significant improvements 30 minutes after the injections ($p<0.05$). Only the injections that were accurately placed showed significant improvement	This was a non RCT and although accurately placed injections improved shoulder outcomes, the follow-up periods were very short, therefore the

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
						after 2 weeks	evidence is limited
Eustace 1997	Non RCT	n = 37	Local injections of a mixture of triamcinolone and radiographic contrast material using a standardised technique	VAS, joint ROM, a five-point global rating scale of maximum and current benefit	Before and two weeks after the injection	14 of the 38 procedures (37%) were judged to be accurately placed: four of the 14 attempted subacromial injections (29%) and 10 of the 24 attempted glenohumeral injections (42%). There were significant differences in relation to outcome between the accurately placed and the inaccurately placed groups	This was a non RCT and the follow-up periods were short and sample size was short, therefore the evidence is limited
Goel et al 2012	RCT	n = 50, Aged ≥ 18 (23 women & 27 men), mean age 64.5 years (42-87 years), Anteriolateral group (n = 22), posterior group (n = 28)	A combination of 3mls 0.5% bupivacaine and 3 mls of radiographic dye	VAS & Constant-Murley Score to assess pain & function respectively	Pre-injection & 30 minutes after the injection	22 injections (78.5%) were accurately placed in SAIS with the posterior approach and in 14 patients (63.6%) with anterolateral approach. This difference was statistically significant (P< 0.05). Only patients who received injection accurately in SAS with either method had a reduction in pain of an average of 4 points on VAS, and improvement in the Constant score of average 14 points.	Although this RCT showed that the posterior route of shoulder injection is more accurate compared to the anterolateral, it has failed to demonstrate clinical effectiveness due to the short follow-up periods

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
Henkus et al 2006	RCT	n = 35 (22 women, 11 men; average age, 46 years; range, 25 to 64 years)	A mixture of bupivacaine, methylprednisolone, and gadolinium-DTPA directly followed by MRI to determine the actual site of Injection	The Constant Score, Simple Shoulder Test, and VAS for pain	Within 24 hours and 6 weeks after infiltration	13 injections (76%) were in the subacromial bursa with a posterior approach and 10 (69%) with an anteromedial approach. A positive correlation between the injection confidence of the orthopaedic surgeon and the MRI was found in 66%. Only injection of the subacromial bursa alone resulted in a significant decrease of the pain (P = .004) and an increase in the functional scores. Injection in the bursa and rotator cuff muscle showed a significant increase in pain (P = .032) but no change in clinical scores. The body mass index (BMI) had no influence on the scores	The weakness of this study includes the short follow-up period and small sample size.
Kang et al 2008	RCT	n = 58 (28 men and 30 women)	A subacromial injection of corticosteroids, local anesthetic, and contrast dye from 1 of 3 locations: anterolateral, lateral, or posterior	Accuracy was confirmed by 3 radiographic views of the shoulder, while clinical ratings were assessed by the UCLA shoulder score and a 10-point VAS pain	During the initial, post-injection, and 3-month visits.	Overall accuracy was 70%, with no difference among the 3 portals. Accuracy was not related to BMI. Also, accurate injections did not significantly improve the UCLA score, pain scale, or patient satisfaction at 3 months. In contrast, accurate injections produced a positive	The use of composite interventions of NSAIDs, physical therapy and cortisone injection/local anaesthetic on each patient makes it was

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
						Neer's impingement test more often (35/39 vs 9/16; P = .009). Overall, there was an improvement in the UCLA score (26.2-32.2; P < .001) and a decrease in the pain scale (7.2-3.43; P < .001) at 3-month follow-up. In conclusion, the accuracy of injection was 70%	difficult to single out the contributions of the additional effects of cortisone injection alone.
Marder et al 2012	RCT	n = 75	Radiopaque contrast medium, corticosteroid, and local anesthetic.	Accuracy of injection into the bursa - intra & extrabursa. Pain VAS	Between thirty minutes and one hour after injection, after exercising the arm, the patient was asked again to record the level of pain	The rate of accuracy varied 56% -posterior route, 84% -anterior route, and 92% -lateral route (p = 0.006; chi-square test). The accuracy through posterior route was significantly lower compared to the anterior or the lateral route (p < 0.05 for both comparisons; Poisson regression). The accuracy of injection was significantly lower in females than in males (p < 0.006; chi-square test). Among males, no differences between the routes were noted (with accuracy rates of 89% for the posterior route, 92% for the anterior route, and 93% for the lateral route). Among females, accuracy	The use of a single experienced orthopaedic consultant to complete the arthroscopic evaluation of the needle distance might have introduced assessment bias - limiting intra-rater reliability

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
						rate was lower for the posterior route than for either the anterior or the lateral route (38%- posterior route, 77% - anterior route, and 91% - lateral route) ($p < 0.05$).	
Min et al (2013)	RCT	n = 32	40 mg triamcinolone; and the NSAID syringe contained 60 mg ketorolac.	Arc of motion, VAS for evaluating pain, and the UCLA (The University of California at Los Angeles) shoulder rating scale	At 1 month follow-up	At 1 month follow-up, both groups showed increased ROM and reduced pain. The steroid group decreased in active abduction while the NSAID group increased (steroid: 134°, NSAID: 151°, P = .03). The mean improvement in the UCLA shoulder scale at 4 weeks was 7.15 for the NSAID group and 2.13 for the steroid group (P = .03). Subgroup analysis of the UCLA scale demonstrated an increase in both forward flexion strength (P = .04) and patient satisfaction (P = .03) in the NSAID group.	The weakness of this study includes the short follow-up period and small sample size.
Penning et al 2012	RCT	n = 159 patients (84 women and 75 men, mean age of	Subacromial injections using lidocaine with one of hyaluronic acid (51 patients), corticosteroid (53 patients) or placebo (55 patients).	Primary outcome was pain on a VAS, and secondary outcomes included the CMS score, shoulder pain score, functional mobility score, shoulder	Assessed at 3, 6, 12 and 26 weeks	Corticosteroid injections were more effective in reducing pain than hyaluronic acid injections and placebo in the first 3 to 12 weeks. At 26 weeks, the cortisone group showed better reduction	Although the authors report that the other outcome measures showed similar results

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
		53 (20 to 87)		disability questionnaire and pain-specific disability score.		in pain than the hyaluronic acid group, but it was not more effective than the placebo group.	with the pain scale, the presentation of the results lacked sufficient clarity.
Plafki et al 2000	RCT	n = 50	Group 1(10 patients): 10ml injection of pure 0.5% bupivacaine Group 2(20 patients): 10mg injection of triamcinolone acetonide (corticosteroid) with 10ml 0.5% bupivacaine Group 3(20 patients): 4mg injection dexamethasone-21-palmitat (lipoid corticosteroid, equivalent to 2.5mg dexamethasone) with 10 ml of 0.5% bupivacaine. All injections were into subacromial bursae with positioning verified by ultrasound. All patients received standardised physiotherapy program (cryotherapy and strengthening exercises)	1) impingement signs 2) pain scale 3) Patte score - judges subjective estimation of pain, function, force and overall handicap (excellent when score > 85%) 4) Ultrasound examination	Assessed at baseline, 1, 6 and 26 weeks	Treatment in group 1 had to be stopped because of inefficacy. In groups 2 and 3 favorable results were achieved in 19 out of 40 patients	The fact that group 1 (the placebo arm) only had 10 participants while the other intervention groups had 20 participants each warrant cautious interpretation of the study.
Sardelli & Burks 2008	Non RCT	n = 30 (18 men and 12 women)	Arthroscopic evaluation of needle length distance to the subacromial bursa using a spinal needle	Needle length from lateral, anterior and posterior routes to the subacromial space	No follow-up	The mean distance with anterior route was 2.9 +/- 0.6 cm. The mean distance with lateral route was 2.9 +/- 0.7 cm. The	This was an accuracy study therefore it does not

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
						mean distance with posterior needle placement was 5.2 +/- 1.1 cm. The mean BMI for the group of patients was 27.5. The minimum was 18.7, and the maximum was 42.8.	demonstrate efficacy of subacromial cortisone injection in SAIS patients
Winter et al 1997	RCT	n = 114	First week: All received 50 mg diclofenac sodium three times daily. Then on the basis of reassessment they were divided into diagnostic groups. Within the synovial group, patients were allocated to group A (47 patients): corticosteroid injection (1-3 injections as needed at baseline, 1 week and after 2 weeks, of 1 ml of 40 mg/ml triamcinolone acetonide with 9 ml of 10 mg/ml lignocaine) into 2 out of 3 synovial structures (glenohumeral joint, capsule, subacromial space and ACJ; Group B (32 patients): manipulation and mobilisation of cervical spine, upper thoracic spine, upper ribs, ACJ joint, GHJ once weekly	1) Pain assessed by the shoulder pain score (6 item questionnaire and 101-point numerical pain scale) (7 points = no pain to 28 =severe pain) 2) active and passive ROM of GHJ, cervical spine, upper thoracic spine, palpating the muscle tendons on the head of humerus, the ACJ, and the upper ribs 3) felt "cured" (defined as disappearance of shoulder complaints or a decrease to such an extent that they were no longer difficult, did not need treatment, or no longer interfered with normal working) or if treatment failed	Assessment at baseline and 2, 6, 11 weeks.	In the shoulder girdle group duration of complaints was significantly shorter after manipulation compared with physiotherapy (P < 0.001). Also the number of patients reporting treatment failure was less with manipulation. In the synovial group duration of complaints was shortest after corticosteroid injection compared with manipulation and physiotherapy (P < 0.001). Drop out due to treatment failure was low in the injection group (17%) and high in the manipulation group (59%) and physiotherapy group (51%).	Loss to follow up was greater than 50% in the manipulation and physiotherapy groups compared to the injection group which was 17%, this could limit the conclusions of the study

Study	Design	Sample Size	Intervention	Outcome Measures	Follow-up	Summary of Findings	Limitations
			with a maximum of 6 treatments) Group C (35 patients): physiotherapy twice a week. Could use exercise therapy, massage, physical applications but no mobilization and manipulation techniques were allowed.				
Yamakado 2002	Non RCT	n = 53 patients (34 women and 19 men; mean age, 74.5 years; range, 49 to 91)	A mixture of 0.5 mL (2.5 mg) betamethasone acetate and 3 mL of radiographic contrast material (iotrolan) and 7 mL of 1% lidocaine using a lateral approach	Radiographs of the shoulder joint were taken immediately after the injection to determine the structure reached by the injection. Pain expressed as Neer & Hawkins impingement signs were obtained before and 15 minutes after the injection, and subjectively assessed using a 4-point self-administered pain score. Pain reduction due to subacromial & intradeltoid injection was compared.	Before and 15 minutes after the injection,	Thirty-nine of the 56 injections (70%) were judged to have reached the subacromial bursa. Twelve (21%) were seen to have entered the deltoid muscle; 2 (4%) were in the glenohumeral joint; and 3 (5%) were subcutaneous. A comparison of subacromial bursal with intradeltoid injection showed no significant differences in pain reduction expressed as impingement signs (1.5 vs 1.7 in the Neer impingement sign and 1.6 vs 1.6 in the Hawkins impingement sign, respectively).	The weakness of this study include the short follow-up period which is not applicable in normal clinical practice where injection follow-up periods are much longer

Table 3: Summary of Findings of Some Key Systematic Reviews included In the Study

Author	Review's Aim	Findings	Conclusion
Arroll & Goodyear-Smith (2005)	To determine the effectiveness of intra-articular and subacromial injections of corticosteroid for treatment rotator cuff tendonitis and frozen shoulder.	Seven studies were reviewed for corticosteroids versus placebo and three for corticosteroids versus NSAIDs. The relative risk for improvement for subacromial corticosteroid injection for rotator cuff tendonitis was 3.08 (95% confidence interval [CI] = 1.94 to 4.87). The number needed to treat based on the pooled relative risk was 3.3 (95% CI = 1.8 to 7.7) patients to obtain one improvement. The relative risk for high dose (50 mg of prednisone or more) was 5.9 (95% CI = 2.8 to 12.6). The relative risk for improvement with steroids compared with NSAIDs was 1.43 (95% CI = 0.95 to 2.16). The number needed to treat for corticosteroids versus NSAIDs was 2.5 (95% CI = 1 to 9) for one significant study. The relative risks for intra-articular steroid injection for rotator cuff tendonitis were not statistically significant.	Subacromial injections of corticosteroids are effective for improvement for rotator cuff tendonitis up to a 9-month period. They are also probably more effective than NSAID medication. Higher doses may be better than lower doses for subacromial corticosteroid injection for rotator cuff tendonitis
Buchbinder et al (2003)	To determine the efficacy and safety of corticosteroid injections in the treatment of adults with shoulder pain	Twenty-six trials met inclusion criteria. The number, site and dosage of injections varied widely between studies. The number of participants per trial ranged from 20 to 114 (median 52 participants). Methodological quality was variable. For rotator cuff disease, subacromial steroid injection was demonstrated to have a small benefit over placebo in some trials however no benefit of subacromial steroid injection over NSAID was demonstrated based upon the pooled results of three trials. For adhesive capsulitis, two trials suggested a possible early benefit of intra-articular steroid injection over placebo but there was insufficient data for pooling of any of the trials. One trial suggested short-term benefit of intra-articular corticosteroid injection over physiotherapy in the short-term (success at seven weeks RR=1.66 (1.21, 2.28)	Although several studies were reviewed, the overall evidence is limited because of the small sample sizes, variable methodological quality and heterogeneity of the studies. However, subacromial corticosteroid injection for rotator cuff disease and intra-articular injection for adhesive capsulitis may be beneficial although their effect may be small and not well-maintained.
Gaujoux-Viala et al (2009)	To assess the efficacy and safety of steroid injections for patients with tendonitis of the shoulder or elbow.	In all, 20 RCTs were analysed (744 patients treated by injections and 987 patients treated by controls; 618 shoulders and 1113 elbows). The pooled analysis indicated only short-term effectiveness of steroids compared to the controls for pain and function [example, pain at week 1–3 ES=1.18 95% CI 0.27 to 2.09), pain at week 4–8 ES=1.30 (95% CI 0.55 to	Steroid injections are well tolerated and more effective for tendonitis in the short-term than pooled other treatments, though similar to NSAIDs. No long-term benefit was shown.

Author	Review's Aim	Findings	Conclusion
		pain at week 12–24 ES=−0.38 (95% CI −0.85 to 0.08) and 2.04), pain at week 48 ES=0.07 (95% CI −0.60 to 0.75)]. Sensitivity analyses indicated similar results whatever the localisation, type of steroid and type of comparator except for NSAIDs: steroid injections were not significantly better than NSAIDs in the short-term. Compared with other treatments, steroid injections appeared more effective in acute or subacute tendonitis. The main side effects were transient pain after injection and skin modification.	
Johansson et al (2002)	To determine which treatments for patients with subacromial pain are trusted by (GPs) and physiotherapists, and to compare trusted treatments with evidence from a systematic critical review of the scientific literature	Forty studies were included. The methodological quality varied and only one treatment had definitive evidence for efficacy for non-specific patients, namely injection of corticosteroids.	Clinicians' trust in corticosteroids injected into the subacromial bursa is supported by definitive evidence for short-term efficacy. Acupuncture is a trusted treatment for subacromial pain and supported by tentative evidence for efficacy. The tentative evidence for ultrasound therapy as being ineffective in patients with subacromial pain, together with evidence from earlier reviews, leads us to question both the trust in this therapy and its use in practice. This study has demonstrated very little congruence between the trust that primary care clinicians demonstrate for specific therapies and the available scientific evidence for their efficacy
Koester et al (2007)	To investigate whether subacromial corticosteroid injections are effective in the treatment of rotator cuff disease	Nine RCTs (number of participants unclear) were included in the review. The included RCTs met between four and eight of the eight validity assessment criteria. Four out of 6 RCTs reported a statistically significant improvement in pain on a visual analogue scale for patients receiving cortisone subacromial injection, relative to controls. One reported night-time pain relief at 1 month, but no differences at 3 months. Three out of 7 RCTs reporting ROM found a statistically significant improvement, ranging from 14 to 45 degrees. Two RCTs found no difference between	There is little reproducible evidence to support the efficacy of subacromial corticosteroid injection in managing rotator cuff disease.

Author	Review's Aim	Findings	Conclusion
		subacromial cortisone injection and control groups on measures of function. Of the 2 RCTs that did find a significant difference, one reported that this was not significant at the 3-month follow-up. Among the 9 RCTs included, a single case of mild skin hypopigmentation at the site of injection was reported for CSI, with no complications reported in the control groups	
Mohamadi et al (2016)	Do corticosteroid injections reduce pain in patients with rotator cuff tendinosis 3 months after injection, and if so, what is the number needed to treat (NNT)? (2) Are multiple injections better than one single injection with respect to pain reduction at 3 months	Fourteen RCTs were included in the systematic review, although 3 of these studies had a Jadad score (a measure of methodological quality) of less than 3, so only 11 RCTs (n=726) were included in the meta-analysis. Corticosteroid injection did not reduce pain intensity in adult patients with rotator cuff tendinosis more than a placebo injection at the 3-month assessment. The largest effect on pain relief was between 4 and 8 weeks with a SMD of 0.52 (range, 0.27–0.78) (p \0.001). At least five patients must be treated for one patient's pain to be transiently reduced to no more than mild. Repeated injections were not found to be more effective than a single injection at any time	Cortisone injection into the shoulder provides some short term pain relief for patients with rotator cuff tendinosis and cannot modify the natural course of the disease
Van der Heijden GJ et al (1996)	The study was designed to assess the efficacy of steroid injections for shoulder disorders.	Only three out of the 16 studies scored more than 50 points, indicating a generally poor quality of methods. Most studies reported small sample sizes. The flaws most often found were incomparability of co-interventions and poor blinding of therapist. The methods assessment was frequently hampered by incomplete information about randomization, prognostic comparability, compliance, outcome measures included, blinding of patients and blinding of outcome measurement.	The evidence in favour of the efficacy of steroid injections for shoulder disorders is scarce. The methods of most studies appear to be of poor quality. The few studies that appear to be credible do not provide conclusive evidence about which patients at what time in the course of shoulder disorders benefit most from steroid injections

2.2.2 Qualitative Literature Search

The strategy for the qualitative study mirrored that of the quantitative search (see section 2.2.1) and covered similar a period. In the qualitative search strategy specific subject headings and additional text words describing the population of interest (such as shoulder pain, subacromial impingement syndrome) were used to identify relevant studies. These were combined using the Boolean operator 'AND' with subheadings of: patient experience, education, patient perception, patient attitude, exercise information, information, information leaflet, qualitative interview and qualitative study.

2.2.2.1 Searching Other Resources

The other resources that were searched for the qualitative study included those mentioned in pages 15 and 16 (items II - IX). References of the review articles were screened to identify potentially relevant qualitative studies.

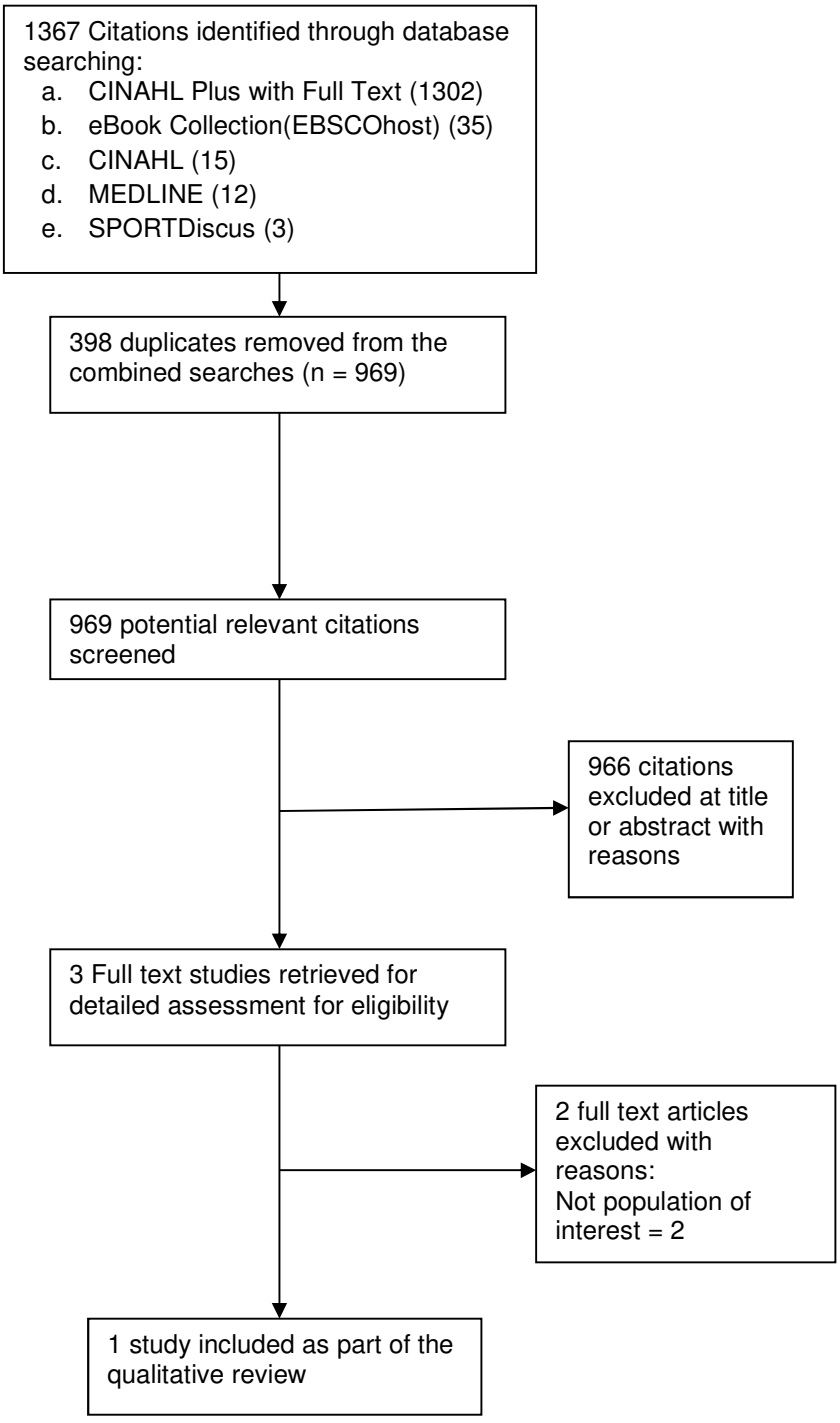
2.2.2.2 Results of the Qualitative Search

A total of 1367 articles were retrieved from the CSP Ebscohost electronic databases for the qualitative search (see Table 4). There were 969 citations after removal of 398 duplicates. After careful evaluation of the titles and/or abstracts, 966 articles that were not related to the study were excluded from the 969 citations and 3 articles that were possibly relevant to this study were identified (see Figure 2 for details). Of this number, only one article was found to be directly relevant to this thesis.

Table 4: Qualitative Searches - Combined Results of the CSP Electronic Database Searches of AMED, CINAHL, CINAHL Plus with Full Text, CSP Online Library Catalogue, eBook Collection (EBSCOhost), MEDLINE, SPORTDiscus

#	Search Terms	Combined Results from above Database Searches
S1	shoulder pain	18,968
S2	Subacromial impingement syndrome	2,848
S3	Shoulder impingement syndrome	3,791
S4	Rotator cuff	20,583
S5	Rotator cuff tendinopathy	435
S6	Supraspinatus tendonitis	91
S7	(shoulder$ or subacromial$ supraspinatus$ or rotator cuff$) adj6 (bursitis or impinge$ or tendonitis or tendinitis or pain$ or pathology$)	1,733
S8	(Sub-acromial or Subacromial) adj4 (bursitis$ or impinge or impingement or compression or decompression)	495
S9	Bursitis	7,097
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9	135,337
S11	INJECTIONS	470,563
S12	(steroid$ or corticosteroid$ or sub-acromial or subacromial) adj6 (inject$ or Kenalog or Triamcinolone$ or Depo-Medrone or Methlyprednisolone$ or Lidocaine)	390
S13	(steroid$ or corticosteroid$ or sub-acromial or subacromial) adj6 (inject$ or Kenalog or Triamcinolone$ or Depo-Medrone or Methlyprednisolone$ or Lidocaine)	78633
S14	(steroid$ or corticosteroid$ or sub-acromial or subacromial) adj6 (inject$ or approach$ or route$ or posterior$ or lateral$ or anterior$)	529,828
S15	S11 OR S12 OR S13 OR S14	488,894
S16	Clinical trial$ or Controlled trial$ or Qualitative study$ or Interview$).pt.	1,905,338
S17	(random$ or randomize$).mp	13
S18	(patient experience [mh] OR perception OR understanding OR education patient OR education [mh])	1,771,520
S19	(patient centred care [mh] OR information booklet [tw] OR book* [tw] OR pamphlet* [tw] OR leaflet* [tw] OR poster* [tw] OR education* [tw] OR information* [tw])	11
S20	S16 OR S17	1,905,338
S21	S18 OR S19	1,771,526
S22	S10 AND S15 AND S20 AND S21	1,367

Figure 2: Flow Chart for the Qualitative Search Result



2.3 Discussion of the Literature Review

The findings of both the quantitative and qualitative literature review will be discussed in this section.

2.4 Discussion of the Quantitative Literature Review Findings

This section and the associated subsections describe the quantitative literature review on the anatomy shoulder joint and rotator cuff muscles, SAIS with particular reference to its clinical presentation, classification, aetiology, diagnostic difficulties and clinical assessment. It discusses the outcomes used in the study and their justification. It also includes discussion on the current trend in National Health Service (NHS) musculoskeletal practice, the role of ESP in musculoskeletal practice, current treatment for SAIS, issue of needle placement in subacromial injections and the evidence on needle placement in subacromial injections.

2.4.1 Anatomy of SAIS

2.4.2 The Shoulder

The human shoulder joint is a complex structure consisting of the glenohumeral joint, acromioclavicular joint, sternoclavicular joint and scapulothoracic joint. As the major joint in the shoulder complex, the glenohumeral joint which is primarily a ball and socket type of synovial joint permits the greatest range of any joint in the body (Terry & Chopp 2000, Zheng et al 2016). The glenohumeral joint cavity is cushioned by articular cartilage covering the face of the glenoid fossa and the

head of the humerus, which is about four times the size of the glenoid fossa (Terry & Chopp 2000). This makes the joint very mobile allowing movement in all directions including flexion, extension, abduction, adduction, circumduction (rotation through 360 degrees), internal rotation, external rotation, and horizontal flexion (Haering et al 2014, Kesson & Atkins 2005). However, the laxity of the glenohumeral articular surface challenges the stability of the shoulder (Masters & Burley 2007, Zheng et al 2016). Yamamoto & Itoi (2014) in a review of biomechanics of the shoulder and rotator cuff repair report that the capsulolabral ligament complex together with the rotator cuff muscles provides the dynamic support (Yamamoto & Itoi 2014). However, Zheng et al (2016) in a review of the clinical implications and modelling techniques of the shoulder complex have argued that the understanding about the individual contributions of these supporting structures to joint stability and mobility and their relations with each other are still limited. This view was supported by Yamamoto & Itoi (2014) in a review of shoulder biomechanics. The humerus has two tuberosities – the greater and the lesser. The greater tuberosity has three facets into which the tendons of the supraspinatus, infraspinatus, and teres minor insert (Terry & Chopp 2000). The lesser tuberosity is where the tendon of subscapularis inserts. These muscles form the rotator cuff.

2.4.3 Rotator Cuff Muscles

The ‘‘rotator cuff’’ comprises four muscles; the subscapularis, the supraspinatus, the infraspinatus and the teres minor, and their tendons which surround and

stabilize the shoulder joint during movement (see Figures 3 & 4) (Ogilvie-Harris & Demaziere 1993, Galatz et al 2001). They maintain the head of the humerus in the glenoid fossa (Kesson & Atkins 2005), and are involved with the deltoid muscle during shoulder elevation (Nordin & Frankel 1989). Previous authors hold a common view that the four rotator cuff tendons are separate entities (Basmajian & DeLuca 1985, Romanes 1986, Williams 1995) and because of this, muscle and tendon-specific tests have been developed (Cyriax & Cyriax 1993). However, with passage of time it is now clear that all four tendons fuse to form the rotator cuff (Hanchard et al 2011), except for subscapularis which is separate and joined to the rest of the cuff through the rotator interval (Funk 2005). The clear implication of this anatomical structure is that it is not possible clinically to distinguish individual tendon pathology selectively (Lewis & Tennent 2007). However, our understanding of the anatomy, mechanics and the biology of the rotator cuff is important to our treatment plans (Funk 2005).

Figure 3: Rotator Cuff Muscles

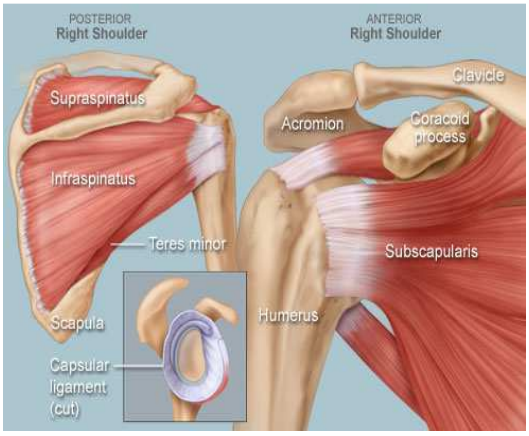
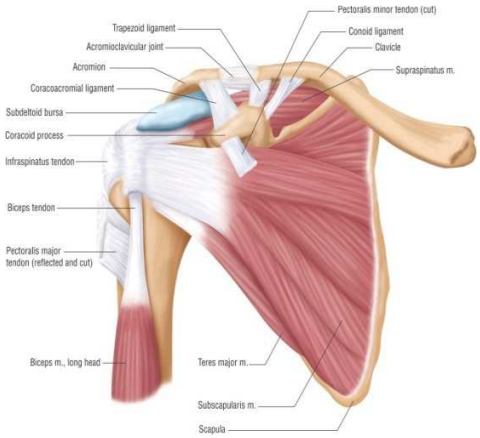


Figure 4: Long Head of Biceps



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At the neck of the humerus, the insertion of the rotator cuff is interrupted only by the bicipital groove, through which the long head of the biceps brachii tendon passes laterally and distally from its origin on the superior lip of the glenoid. This tendon, together with those of the rotator cuff has been identified as a source of shoulder pain through degeneration and overuse (Kesson & Atkins 2005).

Several bursae (large lubricating sac) have been identified with the shoulder joint including the subdeltoid (subacromial), subscapular and subcoracoid bursae. However, the bursa most commonly involved with shoulder pathology such as SAIS is the subacromial bursa, which lies between the acromion, the deltoid, and the joint capsule (Hanchard et al 2013). It also lies under the acromion and the coracoacromial ligament and between the supraspinutus tendon (O'Sullivan & Siegelman 2012). The pinching of the subacromial bursa, the rotator cuff tendons, and the long head of biceps between the acromion superiorly and the greater tuberosity of the humerus below are called SAIS (Neer & Welsh 1997, Masters & Burley 2007). Irritation of the bursa and cuff (due to degeneration, and reversible by conservative treatment) and rotator cuff full thickness have been implicated as a continuum of impingement severity (Neer & Welsh 1997).

2.4.4 Subacromial Impingement Syndrome

Subacromial impingement syndrome is frequently used as an umbrella term to describe a variety of conditions such as rotator cuff impingement syndrome (RCIS), subacromial bursitis, rotator cuff tendonitis, shoulder impingement

syndrome (SIS), supraspinatus tendonitis and painful arc syndrome (Lewis et al 2001). Lewis (2008), in a literature review on assessment of rotator cuff tendinopathy/SAIS, identified rotator cuff tendonitis, supraspinatus tendonitis and subacromial bursitis as diagnostic labels associated with rotator cuff disease. Furthermore, the CSP, in its clinical guidelines for impingement syndrome, referred to SAIS as RCIS or SIS or painful arc syndrome (Hanchard et al 2004). It has been reported that these conditions may act independently or in combination, and can manifest as anterior or anterior-lateral-superior shoulder pain (Lewis et al 2001). For the purpose of this research, SAIS will be used to refer to any of the above-mentioned conditions.

2.5 Diagnosis of SAIS

2.5.1 Clinical Symptoms of Subacromial Impingement Syndrome

The clinical manifestation of SAIS varies from patients experiencing only mild discomfort and transient weakness, to severe acute or chronic pain and loss of function (Bokor et al 1993). Pain is often located at the anterior lateral aspect of the shoulder and radiates to the side of the arm (Lewis et al 2001). Classically, there is a painful arc during elevation or lowering of the arm, or both, as the humeral tuberosities pass under the coracoacromial arch (Hanchard et al 2004, Neer 1983). Pain is also aggravated with placing the arm behind the back (American Academy of Orthopaedic Surgeons 2008), arm elevation or overhead activities associated with daily living (Lukasiewicz et al 1999, Ludewig & Cook 2002, Lewis et al 2005). Night pain may be present in RCIS, and is particularly

associated with rotator cuff tears (Zuckerman et al 1991), but it is also a common feature of adhesive capsulitis (Hanchard et al 2004). However, if linked with age, night pain can be suggestive of RCIS (Hanchard et al 2004). This is consistent with the Litaker et al (2000) study that demonstrated arthrographically determined cuff tears which were significantly ($P < 0.05$) correlated with three factors: age (> 65), night pain and weak external rotation.

Hanchard et al (2013) in a review of physical tests for shoulder impingements and local lesions of bursa, tendon or labrum that may accompany impingement reports that clinicians tend to use two or three positive clinical findings to diagnose SAIS. These would include positive painful arc (Cyriax & Cyriax 1982), positive impingement sign (Neer & Welsh 1997) and tender palpation of the greater tuberosity. Although the sensitivities and specificities of these orthopaedic tests varies, in practice a diagnosis of impingement syndrome is still based on findings of a clinical examination for a majority of patients (Dinnes et al 2003). Due to the subjective nature of these tests by various clinicians having different assessment and interpretative skills, there has been variation in testers' expertise (Hanchard 2005).

2.5.2 Neer and Welsh's (1977) Classification of Impingement Syndrome

The three stages of impingement suggested by Neer & Welsh (1977) are the most widely reported (Hanchard et al 2004, Lewis et al 2005). This classification was borne out of the many propositions regarding the aetiology of SAIS.

Stage 1: Reversible subacromial edema and haemorrhage of the bursa and cuff occurs, usually in the under-25 age group, because of overuse (Fongemie et al 1998, Hanchard et al 2004).

Stage 2: Irreversible impingement by conservative treatment and typically found in the 25–40 age groups and represents irreversible changes, such as fibrosis and tendinitis. Accordingly, Hawkins & Kennedy (1980) suggest there may be a catching sensation with the reversal of elevation or extension.

Stage 3: Impingement is marked by bony changes and cuff tears, usually in those aged over 40 (Neer & Welsh 1977).

According to Lewis et al (2005), although the stages are clinically distinct, they may represent a continuum, with some cases overlapping. Furthermore, three important arguments have been made about this classification (Hanchard et al 2004). Firstly, it has been suggested that the onset of stage I is not strictly limited to those less than 25 years old, but could occur at any age, given the right conditions such as excess overhead activity (Zuckerman et al 1991). Secondly, as discussed by Hanchard et al (2004), when problems do occur in the under 25s, underlying instability should be specifically investigated. This suggestion is supported in Parker & Seitz's (1997) consecutive series of 50 patients with "shoulder impingement/instability overlap syndrome" whose ages ranged up to 38 years with mean age of 26. Thirdly, a RCT has demonstrated that stage II is

responsive to appropriate conservative treatment such as cortisone injection; and it is possible that components of stage III involving partial thickness cuff may also respond positively to conservative treatment (Brox et al 1997). These findings support the assertion that SAIS is reflective of a spectrum of soft tissue pathologies, rather than a diagnostic label relating to pathology in a specific structure (Lewis 2010). In a review of rotator cuff tendinopathy, Lewis (2010) concludes that a considerable body of research is necessary to understand fully the pathohistology of rotator cuff tendinopathy and its relationship with bursal pathology.

Recently, Cook & Purdam (2009) presented a generic model to explain the continuum of tendon pathology based on existing knowledge of the clinical, histological and imaging framework of tendon pathology. Lewis (2010) suggests that due to the regional anatomical and/or biomechanical considerations of tendons, variation of this generic model may be required for the management of rotator cuff tendons. Adopting Cook & Purdam generic tendon model, Lewis (2010) proposed a new model to explain the pathoaetiology and management of rotator cuff tendons and subacromial bursa. A brief description of this model is discussed below.

2.5.3 Lewis (2010) New Model for Rotator Cuff Tendinopathy

According to Lewis (2010), this new model consists of the underloaded tendon stage, normal tendon overload, underloaded/normal tendon overload, reactive tendinopathy tendon disrepair and tendon degeneration.

In practice, patients who present with any of the *underloaded, normal tendon or underloaded/normal tendon stages of tendinopathy,* are not likely to present to physiotherapy or musculoskeletal clinic requiring intensive treatment because pain is likely to resolve with rest, gentle exercises, pain medication, and natural resolution. However, if pain is persistent and interfering with daily activities such as lifting, then physiotherapy or cortisone injection to the painful shoulder might be considered.

In the *reactive and disrepair stages*, the subacromial bursa has been implicated. Some authors (Gotoh et al 1998, Sakai et al 2001) have reported abnormal neuropeptite (substance P) and cytokine levels in the reactive stage; with increased swelling within the tendon, and bursal effusion. This is similar to the disrepair stage characterized by significant areas of swelling and tendon degeneration (Lewis 2010).

Pain may be present in both stages, and it indicates that the subacromial bursa is involved (Lewis 2010). The use of cortisone injection has been suggested to help relieve pain and inflammation caused by the bursa inflammation and tendon

cell proliferation/protein production or intratendinous swelling (Lewis 2010). More importantly, it is being found that pain-relieving injections that reach the bursa produce superior pain relief than those that target other structures (Henkus et al 2006, Marder et al 2012). Lewis (2010) also suggested relative rest, cryotherapy, manual therapy, taping, use of NSAIDs (ibuprofen), modified shoulder activity below 90 degrees and dietary changes to help reduce pain and improve shoulder function. However, evidence for this is equivocal. Surgery is usually considered as the last option if conservative treatments such as physiotherapy and cortisone injection have been unsuccessful.

The *tendon degenerative stage* is characterised with significant structural tendon failure, with diagnostic imaging evidence of large partial-thickness, full-thickness and massive rotator cuff tears. Evidence exists that even in the presence of significant structural pathology (partial or full thickness tear), shoulder range of movement and muscle power may be improved when pain has subsided (Ben-Yishay 1994, Brox et al 1997 & Steenbrink et al 2006). Surgical consideration to repair the rotator cuff should be based on the individual patient's functional ability and requirements, size of the cuff tear and the amount of fat infiltration into the muscle because the presence of fatty streaks has been associated with negative surgical outcomes (Goutallier et al 2003, Liem et al 2007).

2.5.4 Aetiology of Subacromial Impingement Syndrome

2.5.4.1 The Subacromial Space

The space between the undersurface of the acromion and the superior aspect of the humeral head is termed the impingement interval (Fongemie et al 1998) or supraspinatus outlet (Neer & Poppen 1987) and the subacromial space (Neer 1972). Using radiographic evidence it measures approximately 1.0 to 1.5 centimetres (Umer et al 2012). The subacromial space is defined inferiorly by the humeral head and superiorly by the anterior edge and under surface of the anterior third of the acromion, coracoacromial ligament and the acromioclavicular joint (Neer 1972, Umer et al 2012). It is surrounded by the tendons of the rotator cuff and long head of the biceps tendon, the bursa and the coracoacromial ligament (Lewis et al 2001). This space is normally narrow and when the arm is abducted or elevated, the greater tuberosity moves closer to the acromion, narrowing the space further. SAIS has been suggested to result from pathology of any of the contents of the subacromial space (Lewis et al 2001, Hanchard et al 2013). However, it has been argued that the aetiology and pathogenesis of SAIS remains unclear (Lewis et al 2001, Lewis et al 2005). Recently, Lewis (2010) proposed a new model to explain the pathoaetiology and management of rotator cuff tendons and subacromial bursa. This new model suggests that pain and inflammation caused by SAIS is due to the bursa inflammation and tendon cell proliferation/protein production or intratendinous swelling of the rotator cuff tendons.

2.5.4.2 Factors Associated with Subacromial Impingement Syndrome

Neer (1972, 1983) argued that 95% of all rotator cuff lesions and 100% of impingement pathology are attributed to friction between the acromion and the surrounding structures within the subacromial space. Neer (1972,1983) further described the “impingement sign”, a clinical procedure used to reproduce symptoms, and the “impingement test”, a 10 cc (10 ml) injection of 1.0% xylocaine into the subacromial space, to reduce symptoms such as inflammation and pain (Lewis et al 2001).

However, Neer’s concept of SAIS has been challenged and the literature (Jobe 1997, Kibler 1998, Ogata & Uhthoff 1990, Riand et al 1998) suggests that the aetiology of SAIS is multifactorial (Lewis et al 2001). Broadly speaking, it is divided into intrinsic (intratendinous) and extrinsic (extratendinous) factors (Bigliani & Levine 1997, Lewis 2008), and can be further characterized into primary (intrinsic or extrinsic) and secondary aetiology, occurring because of another process such as shoulder instability or neurological injury. The intrinsic (intratendinous) factors include muscle weakness and degeneration of the rotator cuff due to increasing age, trauma, overuse, tension overload, and the extrinsic (extratendinous) factors are inflammation of the rotator cuff tendons and the bursae surrounding the subacromial space (Neer 1972, Fu et al 1991, Banas et al 1995, Bigliani & Levine 1997, Paletta et al 1997, Cook & Purdam 2009). Also, os acromiale (an unfused distal acromial epiphysis) (Neer 1972, Bigliani & Levine 1997), acromial morphology (Solem-Bertoft et al 1993, Ludewig & Cook

1996, Wang et al 1999), the attachment of the coracoacromial ligament (Farley et al 1994, Soslowsky et al 1994) and changes in the acromioclavicular joint (Edelson 1995) have been implicated as extrinsic factors.

Examples of secondary aetiology include weak or dysfunctional rotator cuff and scapular musculature (Warner et al 1990, Ludewig & Cook 2000), and capsular laxity or tightness (Tyler et al 2000).

The predominance of joint side rotator cuff pathology has led a number of investigators to argue that impingement also occurs on the articular side of the tendon. This involves pinching of intra-articular (internal joint) structures at the extremes of movement (Hanchard et al 2013). The model is known as internal (undersurface) impingement and may be subcategorised as anterior-superior or posterior-superior impingement. The aetiology of anterior superior impingement is not clear and it occurs rarely compared to posterior-superior impingement (Garofalo et al 2010). Anterior-superior impingement is thought to be caused by trauma or degenerative changes and is related to the biceps pulley lesion (which is made up by the superior glenohumeral ligament and coracohumeral ligament) and the instability of the long head of the biceps tendon (Habermeyer et al 2004, Garofalo et al 2010). Paley et al (2000) have suggested that posterior internal impingement occurs when the articular side of the supra or infraspinatus tendons are entrapped with the posterior/superior glenoid labral complex in a position of shoulder abduction and external rotation. This type of impingement however is

commonly associated with athletes who engage in overhead activities such as throwing (Cavallo & Spear 1998, Paley et al 2000). This phenomenon was originally identified by Walch et al (1992) in an arthroscopy study involving 17 athletes with unexplained shoulder pain on throwing. They found that with the glenohumeral joint at 90 degrees of abduction and external rotation, the supraspinatus and infraspinatus tendons rotate posteriorly rubbing on the posterior-superior glenoid lip, and become pinched between the humeral head and the posterosuperior glenoid labrum (Walch et al 1992). This argument is also based on the findings of Edelson & Tietz (2000) who investigated a cohort 1232 shoulders in clinical impingement test positions and the work of Jobe (1996) on shoulder impingement. Hanchard et al (2013) have argued that it is unclear to what extent internal impingement is limited to overhead sporting activities and whether instability is a prerequisite (Jobe 1996). Lewis (2008) has emphasized that definitive evidence for internal impingement is incomplete and until available, clinicians should be cautious interpreting this model (Claver 2009).

Research findings suggest that controversy exists regarding the pain-generating mechanisms in patients with impingement syndrome (Johansson 2002). These potential mechanisms have been suggested to occur singularly or in combination (Lewis et al 2001, Michener et al 2004). Therefore, it is unclear as to the role of each individual mechanism, the relationships between these factors, or the association with functional loss and disability (Lewis et al 2001, Michener et al 2004). However, recent research suggests that mainly the bursa inflammation

and tendon cell proliferation/protein production or intratendinous swelling causes the pain-generating mechanisms in patients with SAIS (Henkus et al 2006, Cook & Purdam 2009, Lewis 2010). Therefore, the role of each individual mechanism, the relationships between these factors, and the association with functional loss and disability, although previously unclear, is now becoming obvious.

2.5.5 Diagnostic Difficulties

Interpreting the evidence concerning the diagnosis of shoulder pathology is challenging because it has been reported that there is great variation in the diagnostic criteria applied (Green et al 1999, Stevenson 2006, Lewis 2008). In a majority of studies, diagnosing SAIS is based largely on the presence of a positive impingement sign such as Neer's or Hawkins Kennedy (Kuhn 2009), despite recent studies assigning them low specificity values. The tests are designed to apply mechanical compression to the tissue of interest however, it is inconceivable that they would not stretch or compress other structures during the procedure (Lewis 2010). In general the tests that have a high sensitivity (ability of a test to discover pathology when it is present) have a low specificity (ability to rule out pathology when it is not) and vice versa (Claver 2009). Most of the difficulties encountered in making a clinical diagnosis of this condition come from the fact that this is a syndrome rather than a discrete pathology. No one test or finding in isolation is in itself diagnostic; instead, in practice we tend to rely on common patterns of presentation (Murrell & Walton 2001, Park et al 2005). Several investigative procedures such as x-ray, ultrasound, or magnetic

resonance imaging (MRI) have been suggested to demonstrate SAIS (Kieft et al 1990).

Dinnes et al (2003), in a systematic review, found that overall sensitivity and specificity of ultrasound scan for full-thickness rotator cuff tears was 87% and 96% respectively. For MRI the overall pooling for full-thickness tears demonstrated similar values (89% and 93%). However, MRI pooled sensitivity estimates for partial thickness were much lower (44%) even though specificity remained high at 90%. Ultrasound sensitivity was slightly higher (67%) for partial-thickness tears. Dinnes et al (2003) therefore argued that Ultrasound is the most valuable test to rule out a partial-thickness tear. However, they uncovered no studies that directly compared the test characteristics of ultrasound scan and MRI. X-rays are not routinely indicated in the diagnosis of shoulder impingement syndrome, as degenerative changes in the acromioclavicular joints and rotator cuff are common (NHS Radiographic Standard Operating Protocols 2008). Tennent et al (2003), in a review of the special tests associated with shoulder examination for rotator cuff, suggest that clinical examination remains a fundamental part of the diagnosis of shoulder pathology. Because of the difficulties in interpreting the evidence concerning the diagnosis of shoulder pathology, the CSP has recommended guidelines for assessment/diagnosis of shoulder impingement syndrome (Hanchard et al 2004). This will be discussed in the next section.

2.5.6 Clinical Assessment of Subacromial Impingement Syndrome

The clinical manifestation of SAIS varies widely.

2.5.7 Subjective Assessment of Subacromial Impingement Syndrome

This includes age, pain and function.

2.5.7.1 Age

Shoulder assessment should begin with questioning about the patient's age because it can give some indication of the possible stage of SAIS according to Neer & Welsh's (1997) classification. However, patients with SAIS have similar age ranges with those of other shoulder pathologies such as adhesive capsulitis and acromioclavicular joint dysfunction (Hanchard et al 2004). Frost et al (1999) have shown that the incidence of structural rotator cuff tendon pathology including full thickness tears increases with age. However, large numbers of people with full thickness tears may have asymptomatic shoulders and full function (Frost et al 1999). In a study of 420 cadaver scapulas, Nicholson et al (1996) concluded that incidence of acromion bony spurs increased with age. Different authors have reported different ages with patients with posterior superior glenoid impingement. While Cavallo & Speer (1998) reports that it occurs in patients under 35 years, Jobe (1996) reported age ranges of 20-55, with a mean age of 36 years. The inequality between these author's accounts may be due to differences in patient populations with the mechanism of injury related to a sporting activity or not (Hanchard et al 2004).

2.5.7.2 Pain

Some SAIS patients experience only mild discomfort whereas others experience severe acute or chronic pain (Bokor et al 1993). Pain often radiates from the front of the shoulder to the side of the arm (Lewis et al 2001), with possible sharp or catching pain during movement (Hanchard et al 2004). Classically, there is a painful arc during forward or downward movement of the arm, or both, as the humeral tuberosities pass under the coraco-acromial arch (Hanchard et al 2004, Neer 1983). The presence of a painful arc of movement between 60 and 120 degrees is suggestive of supraspinatus tendinopathy (Cyriax & Cyriax 1982). Pain is also aggravated with placing the arm behind the back (American Academy of Orthopaedic Surgeons 2008), arm elevation or overhead activities associated with daily living (Lukasiewicz et al 1999, Ludewig & Cook 2002, Lewis et al 2005). Night pain, causing difficulty lying on the affected side is commonly present in SAIS, and is particularly associated with rotator cuff tears (Zuckerman et al 1991), but it is also a common feature of adhesive capsulitis (Hanchard et al 2004). However, if linked with age (> 65), night pain and weak external rotation can be suggestive of rotator cuff tears (Litaker et al 2000, Hanchard et al 2004).

In practice, shoulder pain is generally measured using the numeric pain scale (NPS) and visual analogue pain scale (VAS). Although both scales are well validated, the NPS scale can be administered verbally by telephone or by self-completion through the post, compared to the VAS (Jensen 1986). The NPS is a single 11-point numeric scale (with 0 as “no pain” and 10 as the “worse

imaginable pain") to measure pain intensity in adults (Hawker et al 2011). It allows patients to measure their level of pain accordingly using a whole number (0-10 integers) that corresponds to their pain intensity (Rodriguez 2001). A systematic review that compared NPS, verbal rating scales (VRS), and VAS for assessment of pain intensity in adults found that NPS had better responsiveness, easier to use, and most applicability compared to VAS/VRS (Hjermstad et al 2011). Since day time and night time pain as usually associated with SAIS (Zuckerman et al 1991, Hanchard et al 2004), this study used NPS to record them at baseline and follow-up periods as part of the patient reported outcome measures (PROMs) (see Appendix 5). This is because it is a self-assessment measure that has enhanced the patient's participation during telephone follow-up such as cortisone injection outcome. This is consistent with previous authors (Akgun et al 2004) who in a RCT that evaluated the effects of subacromial injections in SAIS patients used a similar pain scale to measure shoulder pain at day time, and night time causing disturbance of sleep.

2.5.7.3 Function

Shoulder function should be measured subjectively before and after treatment to evaluate success of treatment outcomes such as cortisone injection. There are numerous measurement tools such as Shoulder Pain Disability Index questionnaire (SPADI), Disabilities of the Arm, Shoulder and Hand questionnaire (DASH), American Shoulder and Elbow Surgeon questionnaire (ASES), Shoulder Disability Questionnaire (SDQ-UK), Constant Murley score

and Simple shoulder test (SST) that can be considered when evaluating outcome from shoulder interventions. However, SPADI was choose for this study because it is a self-assessment measure that has provided the benefits of emphasising the patient's involvement in the process and enhancing telephone follow-up such as cortisone injection outcome. SPADI is a self-report questionnaire designed to measure pain and disability specifically associated with shoulder pain of musculoskeletal origin (Roach et al 1991). It has thirteen items covering two domains (pain and disability), which are scored on a numerical rating scale between zero (no pain/difficulty) and ten (worst pain imaginable/so difficult it requires help). The pain dimension consists of five questions concerning the severity of a patient's pain. Functional activities are measured with eight questions designed to assess the degree of difficulty a patient has with different activities of daily living (Roach et al 1991). Each domain carries equal weighting in the overall score that is expressed as a percentage where zero represents no pain or disability and 100% represents maximum pain and disability. A recent systematic review by Thoomes-de Graaf et al (2016) has recommended the use of SPADI over the DASH, SDQ-UK and SST for measurement of shoulder pain and functional limitation for English, Norwegian and Turkish users because it more user friendly and easier to understand. A study that compared the responsiveness of Shoulder Disability Questionnaire (SDQ), SPADI and Western Ontario Rotator Cuff (WORC) index in SAIS confirmed that both the SDQ and SPADI scores were more suitable for assessment of SAIS compared to WORC (Dogu et al 2013). However, the

authors reported that WORC is better for psychological impact assessment of SAIS.

A minimally important clinical difference (MICD) is the smallest change in an outcome that a patient would identify as important following an intervention (Jaeschke et al 1989). A MICD for the SPADI is 8-13% (Roy et al 2009). In practice, it is easy to administer and requires minimal time for a patient to complete and Roy et al (2009) reports that it is not only very reliable, but a valid region-specific measure for the shoulder. It is also able to discriminate between patients whether they are improving or not (Roy et al 2009, Breckenridge & McAuley 2011). This study used SPADI as both baseline and follow-up measures. This is consistent with recent RCTs that used SPADI as the primary outcome to compared corticosteroid injection with manual physical therapy in the management of patients with shoulder impingement syndrome (Rhon et al 2014, Roddy et al 2015).

2.5.7.4 Objective assessment of Subacromial Impingement Syndrome

This includes physical inspection, physical tests, measurement of shoulder range of movements (ROMs) and assessment of instability. Physical inspection of the shoulder and scapular muscle bulk, cervical, upper thoracic and static scapular posture and scapulohumeral rhythm is vital. Physical tests of patients with SAIS include palpation of the rotator cuff tendons such as supraspinatus,

infraspinatus, teres and subscapularis, which can be challenging because it is difficult to identity their individual tendons.

During measurement of shoulder movement, it is important to make a differential diagnosis due to the complexities of shoulder pathologies such as SAIS, SAIS secondary to instability, intracapsular causes of impingement, ACJ arthritis and adhesive capsulitis (Hanchard et al 2004). This is because none of these is mutually exclusive (Hanchard et al 2004). Clinically shoulder ROM is usually measured by universal goniometer or visual inspection (Hanchard et al 2004). Although few studies have evaluated these methods their reliability in shoulder pain patients has been reported as high (Hanchard et al 2004). Although this study will not be investigating shoulder ROM using a goniometer, it will measure shoulder function subjectively using the SPADI measure both before and after cortisone injection therapy, because shoulder function is a predictor of shoulder ROM.

There are basically three types of shoulder/scapular instability (dislocation or subluxation) namely: anterior, which may result from repeated small (micro) trauma to the anterior shoulder capsule; multi-directional that is associated with generalised musculoskeletal laxity (Parker & Seitz 1997) and posterior, which is an isolated finding, and is not common. A number of tests for these problems include load and shift, sulcus, anterior apprehension and relocation test for anterior instability (Hanchard et al 2004, Hanchard et al 2013). In this study, a

participant who tested positive following any of these manoeuvres was excluded because the study is investigating patients with SAIS patients who do not have dislocation or obvious subluxation.

2.5.7.5 Tests of Rotator Cuffs and Long Head of Biceps

The rotator cuff muscles - supraspinatus, infraspinatus, subscapularis and teres minors and the long head of biceps constitute the contractile tissues around the shoulder. Clinical evaluation of these structures includes active and resisted active shoulder movements, done in mid-range in order to minimise on non-contractile tissues such as (joint capsule, ligaments, bursae, blood vessels, and cartilage) and increased specificity (Hanchard et al 2004). Table 5 below summarises the tests of rotator cuffs and long head of biceps (Hanchard et al 2004).

Table 5: Summary of Tests of Rotator Cuffs and Long Head of Biceps

Muscle	Action
Supraspinatus	Abduction
Infraspinatus	External rotation
Subscapularis	Internal rotation
Teres minor	Adduction
Biceps	Elbow flexion

During testing of contractile tissues around the shoulder, pain is assumed to indicate a minor lesion (tendon strain), combined pain and weakness a more significant lesion such as a partial tear, and painless weakness either a

neurologic problem (such as suprascapular neuritis) or a complete cuff tendon tear (Cyriax 1982).

In this study, a participant that tested positive (i.e. pain present during testing) following any of these manoeuvres was included. Other tests that capture pain during shoulder manoeuvre are specific impingement tests.

2.5.7.5.1 Specific Impingement Tests (Hanchard et al 2004, Lewis 2005, Hanchard et al 2013)

Generally, the tests and signs used to identify signs of impingement include Neer's sign, Hawkins-Kennedy and the painful arc. These tests will be used to recruit a homogeneous group of subjects with SAIS.

2.5.7.5.2 Neer's Sign (1983)

This test is done with the patient in a sitting or standing position. The clinician stabilises the clavicle and the scapula with one hand. With the patient’s arm internally rotated, the clinician passively flexes the arm with the other hand. This procedure compresses the greater tuberosity against the antero-inferior border of the acromion constricting the subacromial structures, and reproduction of pain and/or apprehension indicates a positive test.

Neer (1972) in a cadaveric study observed that impingement could occur between the acromion and supraspinatus, infraspinatus and the long head of biceps when the arm is in the test position in approximately 10% of the

specimens. He however warned that while the sign could signify impingement, there were other conditions such as capsulitis that could also reproduce pain during the manoeuvre (Neer 1983, Neer & Welsh 1997). He advised that full elevation and external rotation should be present to eliminate the presence of frozen shoulder and reduce that chance of recording false positive findings. He therefore recommended a re-assessment of the sign following an injection of local anaesthesia to the subacromial injection space and, if pain was relieved (a positive Neer's test), a diagnosis of subacromial impingement could be confirmed. Confirmation of subacromial impingement using Neer's sign has been confirmed by other authors (Valadie et al 2000, Kim & McFarland 2004).

2.5.7.5.3 Hawkins-Kennedy Test (1980)

This test is performed with the patient either sitting or standing. The clinician positions the patient’s arm at 90 degree of forward flexion and then internally rotates the shoulder. Reproduction of anterior shoulder pain and/or apprehension is a positive sign for the supraspinatus, subscapularis and/or long head of biceps tendon pathology (Placzek & Boyce 2006). However, pain could be felt in superior shoulder indicating ACJ pathology, whereas posterior shoulder pain may indicate infraspinatus, teres minor and/or posterior joint capsule pathology (Placzek & Boyce 2006). Some authors (Calis et al 2000, MacDonald et al 2000), have reported that a positive test response cannot be confidently ascribed to impingement. However, if the result is negative, impingement is very unlikely (Hanchard et al 2004).

2.5.7.5.4 Painful Arc

The patient actively abducts the arm. The presence of painful arc of movement between 60 degrees and 120 degrees suggests SAIS (Cyriax & Cyriax 1982). Although a positive painful arc suggests impingement, absence of an arc sign does not rule it out completely (Hanchard et al 2004).

Several authors such as Hegedus et al (2008) have investigated physical examination tests of the shoulder. A systematic review by Hegedus et al (2008) identified 45 such studies. Pooled sensitivity and specificity for the Neer's test was 79% and 53% respectively and for the Hawkins-Kennedy test was 79% and 59% respectively. Park et al (2005) in a composite examination found that a combination of Hawkins-Kennedy sign, painful arc and infraspinatus muscle test yielded the best post-test probability (proportion of patients with that particular test result who have the target disorder) at 95% for any degree of impingement syndrome. These findings are similar with the Murrell & Walton (2001) who found that supraspinatus weakness, weakness in external rotation and a positive Neer's or Hawkins-Kennedy impingement sign were the most diagnostic for rotator cuff disease, yielding a 98% likelihood of a partial or full thickness rotator cuff tear for patients who tested positive for all three or were positive for two and were aged 60 or older. A systematic review by Hanchard et al (2013) concluded that there is insufficient evidence upon which to base selection of physical tests for shoulder impingement in primary care. This is because the clinical trials that attempt to establish criterion based validity of these tests are hampered by the

accuracy of the reference standard (Claver 2009). However, a more recent systematic review (Diercks et al 2014) on guideline for diagnosis and treatment of subacromial pain syndrome has recommended a combination of the Hawkins-Kennedy test, the painful arc test, and the infraspinatus muscle strength test should be used.

The above tests (Neer's sign, Hawkins-Kennedy and the painful arc) have been widely used in both clinical practice and shoulder research (Lewis 2005). Participants with a positive sign of these tests were included in this current study.

2.5.7.6 Specific Tests for Complete Rotator Cuff Tears

Tests for cuff tears include the drop-arm, lift off, drop sign and external rotation lag sign. Participants with a positive sign of these tests were excluded in my study. Other tests used to exclude participants from this study included cervical spine tests such as Spurling’s test.

2.6 Context of Treatment

Treatment of patients with SAIS using subacromial injections primarily takes place in the community or primary care where most people with shoulder pain are diagnosed and managed (Hanchard et al 2013).

2.6.1 Current Musculoskeletal Practice – National Health Service

With the disbanding of the Primary Care Trusts (PCTs) in April 2013 and the setting up of Clinical Commissioning Groups, most National Health Service (NHS) Trusts in collaboration with GPs have commissioned their musculoskeletal services from community providers in order to deal with the backlog of patients awaiting specialist musculoskeletal treatments and reduce waiting times (Suckley 2012). These patients awaiting specialist musculoskeletal interventions include those where previous physiotherapy treatments such as manual mobilization or exercise have failed to resolve their pain. Consequently, these patients might need other interventions such as injection therapy. This arrangement has increased the use of Extended Scope Practitioners (ESPs) (working in collaboration with rheumatologists, orthopaedic and spinal consultants) to provide such services. ESP's therefore perform aspects of care such as assessing, diagnosing, treating and discharging patients that originally may have been performed a GP (Suckley 2012).

2.6.2 The Role of Extended Scope Practitioner in Musculoskeletal Practice

An MSK ESP is a specialist physiotherapist that has extended their scope of practice beyond the recognised scope of physiotherapy practice to include the provision of cortisone injection and requesting investigations such as magnetic resonance imaging (MRI) scan, ultrasound scan, x-ray and blood tests (Cumbria Partnership NHS Foundation Trust 2013). Although the Chartered Society of Physiotherapy (CSP) does not provide a definition for an ESP, it states that an

ESP is someone who has extended their scope of practice beyond immediate post graduate level to include training, supervision and working alongside rheumatologists and orthopaedic consultants.

ESPs should be able to manage a wide range of musculoskeletal conditions including common and long term, chronic conditions such as shoulder pain. They should also be able to identify patients with urgent musculoskeletal pathologies such as suspected fractures, infections, tumours or those needing emergency surgeries (acute rupture tendons). They also need to recognise musculoskeletal conditions which do not fit a musculoskeletal diagnosis and when the need is therefore to refer onward to the acute hospital.

Most ESPs hold a postgraduate qualification such as Master of Science (MSc) or have a Certificate in Injection Therapy from a recognised training University. Since the introduction of injection therapy by the CSP in 1995, many of these ESPs provide soft tissue and joint injections to patients with musculoskeletal pain such as SAIS (Lewis 2011). In today's current healthcare climate, where GPs and funding providers fund two or three treatment sessions, notwithstanding the condition or needs of the patient, cortisone injection is even more relevant. It takes centre stage with a maximum of three treatment sessions for injections normally recommended within timescales of varying length (Haslock et al 1995, Saunders & Longworth 2012). However, this is guided by previous treatment outcomes, patient experience and clinical judgement.

2.6.3 Community-Based Musculoskeletal Specialist Services

In 2013, the Government handed over health-care commissioning and control of £70 billion of the NHS budget to GPs (Department of Health 2010, Suckley 2012). This move has made services such as musculoskeletal services that originally would have been managed in hospitals available in the community, so that patients can easily access them (Suckley 2012). In the UK, it is estimated that every year, over £15 billion of the NHS disbursement is for GP referrals to hospitals (Suckley 2012). A review commissioned by The Kings Fund that investigated GP referrals suggested a range of different referral management systems (Imison & Naylor 2010) such as primary-care-based musculoskeletal interface clinics known as Clinical Assessment and Treatment Services (CATS) (Suckley 2012). These specialist musculoskeletal services, led by GPs with special interest in musculoskeletal medicine (GPswSI) or ESPs are mainly established to reduce the number of referrals to hospitals by managing most within primary care (Suckley 2012). They achieve this by triaging, assessing and treating patients in the community. These services have provided more capacity for physiotherapists who have extended their scope of practice to include cortisone injection as one of the main treatment options in managing musculoskeletal pain.

2.6.4 Current Treatment Provision

2.6.4.1 Physiotherapeutic Interventions for SAIS in General

Physiotherapy is aimed at reducing pain, strengthening weakened muscles and preventing functional disability (Bennell et al 2007) using manual and exercise therapy, laser, cold or heat therapy, ultrasound therapy, electromagnetic fields, transcutaneous electrical nerve stimulation (TENS), deep transverse frictional massage, acupuncture and advice on rest (Green et al 2003, Michener et al 2004). The CSP (Hanchard et al 2004) and a Cochrane review (Buchbinder et al 2003) have both concluded that the most effective treatment for musculoskeletal shoulder pain is not known. However, the CSP has recommended advice, rest, non-steroidal anti-inflammatory drugs (NSAIDs), cortisone injection and a programme of pain-free shoulder exercise as an effective form of physiotherapy but acknowledge that there is no evidence for any one type of physiotherapy treatment over another.

2.6.4.2 Physiotherapy Intervention in Subacromial Impingement Syndrome

Physiotherapy is important in the management for SAIS (Glazier et al 1998); however, subacromial injection is now commonly used in the initial treatment of patients with pain and inflammation (Harrison & Flatow 2011). Where physiotherapy has failed to improve symptoms of SAIS or the shoulder is acutely painful, the most commonly available treatment option is subacromial cortisone injection (Hanchard et al 2004 & Diercks et al 2014). Where corticosteroid injection is used as an adjunct to physiotherapy, it may help to reduce the

number of physiotherapy sessions substantially (Hanchard et al 2013). Based on a review of evidence of the causative factors of SAIS and the justification for surgery, Lewis (2011) and (Hanchard et al 2004) concluded that surgical intervention should be considered only if physiotherapy and/or cortisone injection is unsuccessful.

Subacromial injection is mainly directed to improve outcomes of pain and function in SAIS patients. Research evidence suggests that in practice, post injection shoulder outcomes such as shoulder pain and function can be measured subjectively either via a telephone interview or by filling out and returning the outcome measures by post (Roddy et al 2015). Therefore, in this study shoulder pain and function were recorded subjectively using the SPADI and PROMs both as baseline measures before the subacromial injections and as outcome measures by telephone contact with the patient.

2.6.4.3 Use of Cortisone Injections in General

Several international professional bodies such as the American College of Rheumatology (2000), Dutch College of General Practitioners (Winters et al 2008), CSP (Hanchard et al 2004) and Dutch Orthopaedic Association (Diercks et al 2014) have recommended the use of injection therapy for the management of hip, knee and shoulder disorders. Advocates of cortisone injection, including primary care clinicians and musculoskeletal practitioners, say it is safe (Kumar &

Newman 1999, Ekeberg et al 2009), easy to use and cost-effective (Dacre et al 1989, Croft 1998).

According to Saunders & Longworth (2012), in the UK injection therapy is the most widely used treatment option in rheumatological disease of the joints and soft tissues. Traditionally, rheumatologists, doctors in orthopaedics, musculoskeletal and sports medicine, and pain management delivered injection therapy (Saunders & Longworth 2012). A UK survey has found that GPs also perform joint and soft tissue injections, particularly those of knees, shoulders and elbows (Liddel et al 2005). However, most of the injections carried out locally are done by only 5-15% of GPs (Gormley et al 2003). Lack of confidence with injection techniques, inadequate training, and lack of maintenance of injection skills have been suggested as some of the hindrances to performing these injections (Liddel et al 2005).

In practice, subacromial injection is the most common in musculoskeletal conditions. This is consistent with a study that reported that 1 in 5 injections to the peripheral joints and soft tissue is subacromial injection (Longworth 2004). Similarly, a Dutch study found that steroid injections into the shoulder accounted for 20% of all episodes of shoulder disorders (Van der Heijden et al 1996).

2.6.4.4 Delivery of Injection Therapy by Extended Scope Practitioners

Since 1995, ESPs in the UK were given permission to train and perform soft tissue and joint injections (Saunders & Longworth 2012). These injections, for example cortisone injections, are administered to the intra-articular, extra-articular tissues and joints spaces such as the shoulder joint and subacromial space. The primary aims of these injections are to relieve pain and inflammation; and improve joint functions such as elevation. However, injection therapy can be used as an adjunct to manual therapy (Saunders & Longworth 2012). The general effects of these injections are to suppress inflammation in joints and soft tissue, and to break up the cycle of inflammatory response in low-grade re-injury of soft tissue (Saunders & Longworth 2012). The reported side effects of cortisone injection include post injection pain, tendon rupture, steroid arthropathy, subcutaneous atrophy/skin depigmentation, facial flushing and alteration in glycaemic control (diabetics). However, they rarely occur, their effects are normally mild and temporary (Kumar & Newman 1999, Saunders & Longworth 2012). For example, only 2 - 10 in every 100 patients having cortisone injection will experience post injection flare of pain; and only 1:17000 - 77000 patients will report joint sepsis (Kumar & Newman 1999).

There are several types of cortisone injection such as Triamcinolone acetonide (Kenalog), Methylprednisolone acetate (Depo-Medrone) and Hydrocortisone acetate. The choice of cortisone injection is often based on the clinician's knowledge with a certain compound and their experience of its effectiveness

(ACPOMIT 1999). Local anaesthetic such as Lidocaine is commonly used in combination with cortisone injections for the management of shoulder pain (Nelson et al 1995). The therapeutic effects of the Lidocaine are to provide immediate inflammatory pain inhibition and increase the volume of the cortisone (Nelson et al 1995).

Cortisone injections are carried out under the Patient Group Directions (PGDs) to ensure standardisation of the volume, dose and strength of steroid and local anaesthetic used during subacromial injections (Saunders & Longworth 2012). PGDs are written instructions for ESPs to inject patients with local inflammatory joint or soft tissue conditions in a musculoskeletal clinic without the presence of a medical colleague and to enable professional autonomy (ACPOMIT 1999). This is a supply and administration frame, and not a prescribing tool for the ESP. A doctor and a pharmacist must define in writing the named medicine to be supplied and/or administered. The PGD must be written in a specific manner in order to be legally acceptable.

Injection therapy by ESPs has been demonstrated to improve pain in patients with musculoskeletal and orthopaedic conditions such as SAIS (Hattam 1999). Several authors (Daker-White et al 1999) have reported that as well as generating lower initial direct hospital costs, ESPs have been shown to provide effective injection therapy that is comparable to orthopaedic surgeons. A recent randomised control and economic analysis trial found that corticosteroid injection

for shoulder pain, provided by a trained and experienced physiotherapist is not only clinically effective and less expensive, but also comparable with those delivered by an orthopaedic surgeon (Mark et al 2016). The study involved 64 participants who were randomised to two groups (physiotherapist 33, orthopaedic surgeon 31). At 6 and 12 weeks follow-up there were no statistically significant differences between groups on SPADI outcomes, perceived improvement, adverse events, satisfaction, quality of life and costs. The authors suggested that policy makers and service providers should consider implementing this model of care. This study compares favourably with Chambers et al (2005) who in a retrospective study that compared the accuracy and efficiency of subacromial injection through an anterior approach by a consultant, registrar and a specialist physiotherapist, found that the injections of the specialist physiotherapist (ESP) were comparable to those of the consultant and generally better than the registrar's. Similarly, Dogu et al (2012) reported that blind subacromial injections performed by experienced clinicians in patients with SAIS not only produced improvements in shoulder pain and function but were applicable to routine clinical practice.

2.6.5 Critical Appraisal of Evidence Use of Cortisone Injections in Subacromial Impingement Syndrome

From the quantitative literature review seven systematic reviews (Van der Heijden GJ et al (1996), Johansson et al 2002, Buchbinder et al 2003, Arroll & Goodyear-Smith 2005, Koester et al 2007, Gaujoux-Viala et al 2009, Mohamadi et al 2016), were identified that evaluated the effects of cortisone injection in the

treatment of SAIS. Seven RCTs (Adebajo 1990, Blair 1996, Winter et al 1997, Plafki et al 2000, Akgun et al 2004, Penning et al 2012, Min et al 2013) were identified that evaluated the effects of cortisone injection in the treatment of SAIS.

Cortisone injection is common in the treatment of shoulder pain due to SAIS (National Institute for Clinical Excellence [NICE] 2015, Ellegaard et al 2016). Although the reports of some studies (Goupille & Sibilia 1996, Van der Heijden et al 1996) on the efficacy of subacromial corticosteroid injections were inconclusive, with passage of time several authors have confirmed its effectiveness and recommended its use for SAIS (Hanchard et al 2004, Dorrestijn et al 2009, Hanchard et al 2013, Diercks 2014, NICE 2015).

Three separate RCTs (Adebayo 1990, Blair 1996, Plafki 2000) investigating the effects of subacromial injection to non-steroidal anti-inflammatory medication (NSAID) or placebo for rotator cuff disease, have reported that cortisone injection was more beneficial in improving clinical outcomes of shoulder pain and function. However, Blair et al (1996) found no statically significant difference between the cortisone and placebo group with regards to daily activities. Although the study was double blind, the analysis and loss to follow-up were questionable (Buchbinder 2003). The Adebajo (1990) trial was double-blind (participants and outcome assessment), no loss to follow-up was reported and an intention to treat analysis (that is participants were analysed in the group they were originally

randomised to) was performed. Compared to the Adebayo 1990, where the follow-up period was over a 4 weeks' period; in the Blair 1996 study it was up to 28 – 33 weeks, while in the Plafki et al (2000) study participants were followed up after six months. The different up-follow periods in these 3 studies could limit the possibility of pooling their result findings for a meta-analysis. Although the Plafki study was double blinded, treatment was stopped in the placebo group after first the 10 participants failed to improve, and four of them had worsening symptoms. In this study, the fact that group 1 (the placebo arm) only had 10 participants while the other intervention groups had 20 participants each warrant cautious interpretation of the study.

In a RCT that respectively compared intra-articular and subacromial injections to manipulative and non-manipulative physiotherapy for shoulder complaints, Winters et al (1997) reported that an average of 1.8 injections of triamcinolone acetonide produced a statistically significant better outcome of pain relief of up to 11 weeks compared to the physiotherapy groups. This compares favourably with Akgun et al (2004) who, in a randomised controlled study, investigated whether cortisone injection would provide additional benefit when combined with previous medication and exercise regime. They found that subacromial cortisone injection produced added benefit by relieving pain which affected sleep as well as day time activities.

Penning et al (2012) in a RCT of 159 patients with subacromial impingement found corticosteroid injections were more effective in reducing shoulder pain than hyaluronic acid injections and placebo in the first 3 to 12 weeks post treatment. At 26 weeks, although the cortisone group showed better reduction in shoulder pain compared to the hyaluronic acid group, it was found to be no more effective than the placebo group. According to Van der Windt et al (1996) 50% of patients referred to primary care with new episodes of shoulder pain would experience complete resolution at 6 months rising to only 60% after a year (Van der Windt et al 1996). Penning et al (2012) found no significant adverse effects (such as tendon rupture) in their study, therefore they recommended the use of cortisone injection for fast initial pain relief in the treatment of patients with SAIS.

Min et al (2013) in a double-blind RCT compared the effects of subacromial injection using corticosteroid versus NSAID in patients with shoulder impingement syndrome. The study had 32 participants and the steroid group received an injection of 40 mg triamcinolone; and the NSAID group received 60 mg ketorolac. Clinical outcomes were arc of motion, visual analogue scale (VAS) for evaluating pain, and the UCLA (The University of California at Los Angeles) shoulder rating scale at four weeks follow-up. At one month follow-up both groups had increased range of motion and decreased pain ($p=0.03$). At 4 weeks although both groups continued to improve, the NSAID group had greater improvements in the UCLA shoulder rating scale than the steroid group. Due to

the small sample and short follow-up period, it is reasonable to argue that the results of this study should be interpreted with caution.

Van der Heijden GJ et al (1996) in a systematic review that investigated the benefits of steroid injection in shoulder disorders concluded that the evidence for its efficacy was scarce and that there were few studies of adequate methodological quality. Most of the studies had small sample sizes and were not adequately powered. The poor methodological issues were due to incomparability of co-interventions, lack of information about randomization, outcome measures included, poor blinding of therapist, patients and outcome measurement. Similarly, Koester et al (2007) in a systematic review compared subacromial corticosteroid injection with placebo in patients with rotator cuff disease. The review which included nine RCTs concluded that the evidence to support the efficacy of subacromial corticosteroid in managing rotator cuff disease was scarce.

On the contrary Johansson et al (2002) in a systematic review that investigated the interventions for subacromial pain found that corticosteroid injection was superior over NSAIDs, acupuncture, ice, heat and exercise. The review had 17 studies on subacromial pain and although the health benefits such as reducing pain and improving function were short-term, the results were supported by large effect sizes, which are defined by (Coe 2002, Ken & Kristopher 2012) as strength of the mean difference between two groups.

Based on a systematic review to evaluate the evidence for corticosteroid injections for shoulder pain, Buchbinder et al (2003) pooled the results of three RCTs. They concluded that steroid injection into the subacromial area was more beneficial compared to placebo. However, they argued that the effect may be small and may not be more substantial compared to patients who took NSAIDs. In practice, however, patients might consider cortisone injections for SAIS not only because of its fewer repetitions, but also because it has less gastrointestinal side effects compared to oral NSAIDs. All NSAIDs including ibuprofen, naproxen, and diclofenac are primarily associated with damage to the gastrointestinal tract (GIT) such as severe abdominal (GIT) bleeding and ulceration (Ciccone 2007).

Contrary to this a more recent systematic review of seven RCTs by Arroll & Goodyear-Smith (2005) found that the relative risks for intra-articular steroid injection for rotator cuff tendonitis was low. They found cortisone injections were more effective in reducing pain compared to placebo, with an improvement of up to 9 months. Based on the review of three RCTS that investigated the effectiveness of cortisone injection versus NSAIDs for patients with rotator cuff tendonitis, the authors favoured the use of cortisone injection over NSAIDs for rotator cuff tendonitis (also called SAIS). Subsequently a meta-analysis of RCTs by Gaujoux-Viala et al (2009) was undertaken to assess the efficacy and safety of steroid injections for shoulder and elbow tendonitis. The authors found that although the effects of steroid injections were comparable to NSAIDs, they were more effective than pooled other treatments in shoulder tendonitis and are well

tolerated, with rare and minor side effects such as transient post injection pain and skin modification. The study involved 20 RCTs (744 patients treated by injections and 987 patients treated by controls; 618 shoulders and 1113 elbows).

Similarly, Mohamadi et al (2016) in a recent systematic review and meta-analysis of 11 RCTs compared cortisone injections with injection of local anaesthesia or placebo in adults with rotator cuff tendinosis. The review identified 11 RCTs and it involved 726 adults. All the trials included in the review used VAS scale to measure pain at 1, 2 and 3 months after the injections. The review showed that cortisone injections provided moderate pain relief for patients with rotator cuff disorders up to two months after the injection, but the effect wore off after three months. The authors however, cautioned about the varying methodological quality, interventions and heterogeneity of populations in the trials. Given the short term health benefits of cortisone injection from this review, it might be necessary to consider other treatments such as physiotherapy along with a steroid injection particularly where SAIS secondary to instability is concerned (Kamkar et al 1993).

Hanchard et al (2004) undertook a comprehensive systematic review that investigated the effectiveness of physiotherapy interventions used in the management of shoulder impingement syndrome. They recommended the use of steroid injection to facilitate the management of SAIS particularly in cases were pain is the most limiting factor. This is supported by the recent NICE (2015)

guidelines on the management of SAIS. For example, in practice, corticosteroid injection is indicative where symptoms prevent patients with SAIS from participating in physiotherapy. There are instances where patients with SAIS have received a cortisone injection and subsequently they are then referred to physiotherapy for strengthening of the affected area. However, this is not standard practice, as there are patients that may not be routinely referred for physiotherapy after subacromial injection rather they are advised on exercises to do at home.

Furthermore, a recent Dutch review for the diagnosis and treatment of subacromial pain by Diercks et al (2014) concluded that corticosteroid injections are more effective than placebo injections, physiotherapy, or no treatment in reducing pain and improving shoulder function. However, in the short term they found that cortisone injections were not superior to NSAIDs in reducing pain.

2.6.6 Issue of Needle Placement in Subacromial Injections

Subacromial injections can be performed using the anterior (front), lateral (side) and posterior (back) approaches (Sardelli & Burks 2008, Saunders 2010, Bloom et al 2012, Marder et al 2012, Saunders & Longworth 2012). It has been reported that some practitioners support either a lateral (Saunders 2010) or a posterior (Marder et al 2012, Saunders & Longworth 2012) approach to the subacromial injection. However, anecdotal evidence suggests that in practice, clinicians, including ESPs, commonly use the lateral and/or posterior approaches, with

most using the latter method. Whereas a lateral route to subacromial injection involves placing the needle underneath mid-way between the anterior and posterior margin of the acromion, in a posterior route, the needle is placed 1cm directly below the posterior lateral margin of the acromion (Kang et al 2008). From an anatomical view point, the posterior approach provides easier access particularly in patients with humeral heads anteriorly translated. However, a longer needle may be needed to access the subacromial bursa (Innes 2012). Although the choice of needle placement is based on preference, experience or anatomy, the evidence establishing superiority of one method over the other in normal practice is not only scarce, but is still controversial.

2.6.7 Evidence on Needle Placement in Subacromial Injections

From the quantitative literature search, three non-RCTs (Eustace 1997, Yamakado 2002, Esenyel 2003), evaluated the effect of one approach of cortisone injection in treatment of SAIS. Four RCTs (Henkus et al 2006, Kang et al 2008, Goel et al 2012 and Marder et al 2012) and one non RCT (Sardelli & Burks 2008) directly evaluated the effects of different approaches of cortisone injection in treatment of SAIS.

Several studies, cadaveric and clinical have been published that investigate needle placement in subacromial injections with mixed results, using different or single injection approach.

2.6.8 Critical Appraisal of Evidence on Different Approaches to Needle Placement in Subacromial Injections

From the quantitative literature search, four RCTs (Henkus et al 2006, Kang et al 2008, Goel et al 2012 and Marder et al 2012) and one non RCT (Sardelli & Burks 2008) directly evaluated the effects of different approaches of cortisone injection in treatment of SAIS using magnetic or radiographic reference.

Henkus et al (2006) examined 33 subacromial injections using MRI evaluation, with participants randomly allocated to posterior and anteriomedial routes of injection. An orthopaedic surgeon carried out the injections. Injection outcomes were measured immediately after the injection and 6 weeks after using the Constant Murley and VAS scores. The VAS has been explained in point 2.5.7.2. The Constant Murley Score (CMS) is a measure of shoulder pain, function and range of movement (Constant & Murley 1987). Although the score is easy to use and applicable to patients with SAIS, the objective component of the scale that measures range of shoulder movement is not applicable to shoulder studies that measure patient's outcome subjectively over the telephone or by post. Henkus et al (2006) reported that 13 out of 17 (76%) of the injections got into the subacromial bursa with a posterior route and 10 out 16 (69%) with an anteriomedial approach. They found no significant statistical differences between the two approaches in terms of accuracy. However, injections that reached the subacromial bursa produced significant reduction in pain ($P = 0.004$) and improvement in shoulder function over those that target other structures such as

the subdeltoid bursa. A limitation of this study was the small sample size and the sample size calculation was not discussed therefore it is difficult to comment on how they arrived at the number of patients in the study. Since one orthopaedic surgeon carried out the injections, the possibility of intra-rater reliability bias (consistency of a single examiner in the application of an instrument over time) could not be eliminated.

Kang et al (2008) in a study that used radiographic contrast dye to investigate 58 patients with impingement syndrome, found no significant statistical difference using an anterior, lateral or posterior approach of subacromial injection. The authors found no significant difference in outcomes of pain, function and patient satisfaction at three months with accurate injections. However, the accuracy rate of needle placement was 70% among the three different approaches. This is consistent with Henkus et al (2006) that compared posterior and anteriomedial routes of subacromial injection, and reported no significant statistical difference, yet accuracy rates were 70%. Although participants in the Kang et al study were properly randomised to the injection site and the treating surgeon was blinded to the results of injection accuracy, the use of a single experienced radiologist to review the films might have introduced assessment bias - limiting intra-rater reliability. The authors reported the use of composite interventions of NSAIDs, physical therapy and cortisone injection/local anaesthetic on each patient. Although this is common in normal clinical practice, however, from the study's findings it was difficult to single out the contributions of the additional effects of

cortisone injection alone. They reported that the major variable under investigation was injection accuracy. In clinical practice, clinicians, including ESPs, provide subacromial cortisone injections with or without a local anesthetic as a treatment choice, with many stipulating exercise after a period of relative rest (a week or more) following the injection. However, these exercise prescriptions are not routine and standardised (Innes 2012). To avoid potential tendon damage, it has been recommended that resisted exercise should be avoided 2 weeks after shoulder cortisone injection (Hanchard et al 2004).

Sardelli & Burks (2008) in a study of 30 shoulders, measured the distances to the subacromial bursa of injection placement from anterior, lateral and posterior routes using arthroscopy. They found that the average distance for anterior approach was 2.9 +/-0.6cm, lateral route was 2.9 +/- 0.7cm and posterior route was 5.2+/- 1.1cm. This demonstrated that needle placement from the posterior approach to the subacromial bursa was almost twice as much as those of anterior and lateral routes. They reported that the distances from both the anterior and lateral approaches to the subacromial bursa were almost the same and within the zone of a standard 22- or 25-gauge needle. However, needle placement from the posterior approach using a 22- or 25-gauge needle may not reach the subacromial bursa. Therefore, Sardelli & Burks (2008) recommended that practitioners using the posterior portal to the subacromial bursa should apply a longer needle to enhance the accuracy of placement. They concluded that standard-length needles would demonstrate accuracy from the anterior and

lateral portals. However, in practice clinicians, including ESPs use standard length needles of 21-gauge, for the posterior, as well as lateral and anterior approaches (Saunders & Longworth 2012). This is to enhance standardisation of injection procedures using PGD (Saunders & Longworth 2012). The result of the Sardelli & Burk's (2008) study should be interpreted with care given the small sample number. The study used an arthroscopic model to evaluate needle accuracy to the subacromial, therefore its findings are limited in demonstrating clinical efficacy of needle placement in SAIS. Nevertheless, the study's finding should provide some motivation for conducting the appropriate and necessary RCTs for investigating the effectiveness of needle placement in SAIS patients using anterior, lateral or posterior approaches of subacromial injection. Participants in the study were not randomised to the injection site this might have introduced allocation or measurement bias. The use of a single experienced orthopaedic consultant to complete the arthroscopic evaluation of the needle distance might have introduced assessment bias - limiting intra-rater reliability.

Goel et al (2012) undertook a prospective RCT to investigate the accuracy of posterior and anteriolateral approaches of subacromial injection in patients with SAIS. The study involved 50 patients (23 women and 27 men) with an average age of 64.5 years and the authors used VAS and the CMS to assess shoulder pain and function respectively. Randomisation to the two study groups occurred after patients had given informed consent to participate in the study. Random allocation was by sealed envelopes. A consultant Radiologist blinded to the

method of the injection carried out the evaluation of needle accuracy and effectiveness of the 2 groups. Both the VAS and CMS were measured at baseline and 30 minutes post injection. The authors found a statistically significant difference ($p < 0.05$) in favour of the posterior group 78% compared to the anterolateral approach 63.6%. Although the study used concealed random allocation and the treating consultant or registrar was blinded to the results of injection accuracy, the use of a single experienced clinician to review the films might have introduced experiment or treatment bias - limiting intra-rater reliability. The finding of this study is in contrast with some previous authors (Partington et al 1998, Esenyel et al 2003, Yamakado 2002) who favoured lateral approach with similar percentage margins with the Goel et al (2012) study. For example, while Yamakado (2002) demonstrated a 70% success, Partington et al (1998) and Esenyel et al (2003) have both reported accuracy rates of 83% and 87%, respectively through anteriolateral route.

Marder et al (2012) investigated 75 patients with rotator cuff syndrome to compare the accuracy of anterior, lateral and posterior approaches of subacromial injections to the bursa area using radiopaque contrast. An orthopaedic surgeon performed the injections. The authors reported different degrees of accuracy using the three approaches. The lateral route was 92% ($p = 0.006$), the anterior route was 84% and the posterior route was least with 56%. At one hour, injections that reached the bursae (intrabursal) produced significantly greater pain relief in patients than in those whose injections were

extrabursal. They concluded that the anterior and lateral approaches of injections into the subacromial area were more accurate in women, but not in men, compared to the posterior approach. However, the authors reported that the accuracy of injection was approximately 90% irrespective of whether the injection was from an anterior, lateral or posterior approach. A limitation of the Marder et al study is that a single orthopaedic consultant (who traditionally had used the posterior approach) performed all injections (Brett 2012).

Similarly, Yamakado (2002) in a study of accuracy of subacromial injection into the shoulder demonstrated a 70% success rate in targeting the subacromial bursa in 53 patients through lateral approach. Partington et al (1998) and Esenyel et al (2003) have both reported accuracy rates of 83% and 87%, respectively through anteriolateral route. However, the Partington et al study used cadaveric shoulders. Although the Esenyel et al study did not compare the anteriolateral route with posterior approach, the percentage of improvement of the anteriolateral route was significant to prove its efficacy. The question therefore is why do clinicians traditionally adopt the posterior approach if it has least accuracy. Marder et al (2012) showed that sample size was adequately powered based on sample calculations of previous studies (Yamakado 2002, Kang et al 2008). However, in the Marder et al (2012) study post injection outcomes for measures of accuracy and level of pain were measured at 10 minutes and between 30 minutes to one hour respectively by a radiologist. This

follow-up regime is in contrast with normal MSK or GP clinical practice where follow-up periods are much longer that is 4 - 12 weeks.

In concluding this section of the evidence of needle placements in subacromial injections, four studies (Henkus et al 2006, Kang et al 2008, Sardelli & Burks et al 2008, and Marder et al 2012) investigated needle placements in patients with SAIS. They did so by assessing the accuracy of anterior, lateral and posterior approaches of subacromial injections in patients with SAIS either by using a MRI (Henkus et al 2006), radiographic contrast dye (Kang et al 2008), arthroscopy (Sardelli & Burks 2008) or radiopaque contrast (Marder et al 2012) as a reference. Although the injections were performed by experienced clinician, they were done with the aid of a diagnostic evaluation, however, in normal practice, clinicians such as ESPs and GPs do not inject the shoulder using an imaging reference. In all four studies, a single orthopaedic surgeon performed all the injections. The lack of inter-rater measures in these studies, could compromise their intra-rater reliability. The results of two of the studies (Henkus et al 2006, Kang et al 2008) indicate that there is no evidence supporting the use of either anterior, lateral or posterior approaches over each other. In contrast, the Goel et al (2012) study favoured lateral approach compared to posterior route. Further still, Marder et al (2012) have demonstrated that subacromial injection using anterior and lateral routes were more accurate in women compared to the posterior route. Sardelli & Burks (2008) have recommended that compared to lateral and anterior approaches a longer needle length is necessary to enhance

the accuracy of from the posterior because it had least accuracy. Therefore, the results of the four studies that were critically evaluated indicate that there is no consensus regarding the evidence establishing superiority of any one method of injection approach over the other in clinical practice.

2.7 Discussion of the Qualitative Literature Review Findings

This section focuses on the qualitative literature review on shoulder pain and SAIS. It discusses the importance of investigating the experiences of patients with SAIS receiving subacromial injection from a qualitative perspective. The benefits of qualitative study in musculoskeletal conditions, the ontological and epistemological positions of using semi-structured interview methods as a means of exploring the lived experiences of patients with SAIS being treated with either posterior or lateral route of subacromial injection are also discussed.

Generally, SAIS has been treated conservatively with a focus on improving clinical outcomes of pain, function and disability. However, the experiences, perceptions, and preferences of SAIS patients are often neglected, and this can have a profound influence on treatment outcomes (Australia Physiotherapy Association 2003, Walker & Sofaer 2003). Currently there is increased pressure on healthcare practitioners, including ESPs, to demonstrate that their practice is evidence-based. The emphasis to document improvements in a patient's health status helps in justifying funding needs, hence the necessity for research that focuses on the holistic model of patient care cannot be overemphasised.

Therefore, clinicians such as ESPS have to adopt an approach that moves away from focusing solely on measuring pain, muscle function and disability toward a greater emphasis on assessment of the individuals' experiences before, during and after treatment (Copeland et al 2008 and Shaw et al 2010).

Conservative management of SAIS is multifactorial and consists of rest, NSAIDs, corticosteroid injections, acupuncture, manual and exercise therapy. While several authors have demonstrated short-term benefits of cortisone injection in the treatment of SAIS, the research literature demonstrates paucity in the subjective experience of SAIS patients receiving subacromial injections either through a lateral or a posterior approach. A systematic review commissioned by the UK department of Health that searched for studies on patient's experience of conservative treatment found none (Maund et al 2012).

2.7.1 Patient Experience on Subacromial Cortisone Injection

The results of the qualitative literature search (from 1980 to 2016) found just one study (Nyman et al 2012) that investigated the experiences of patients with supraspinatus tendinitis who had received either physiotherapy and cortisone injection or had undergone open or arthroscopic shoulder surgery. The study involved 26 participants aged 43-63 and interviews were through focus groups. However, only three of the participants received cortisone injection. The interviews occurred between 2005 and 2007, and participants were divided into six focus groups: three before and three after treatments. The groups were also

chosen according to the type of treatment the respondents had received. Data analysis was through a thematic method. The main themes that emerged from the interviews were in two categories the before and after intervention themes. The pre-intervention themes consist of patients concern with pain disturbing their sleep, daily activities, reaction of their work colleagues to their condition and lack of understanding of their problem. The post intervention experiences of the participants were professionalism of physiotherapists, the therapeutic relationship they enjoyed during treatment, time taken before they were treated, treatment expectations and the environment of their treatment. The findings of the study compare favourably with other shoulder studies (Jones et al 2013, Chester et al 2016) that reported that patient expectations and experiences of their treatment and care contributed to their overall clinical outcomes.

Although this study provides information on patients' experiences of shoulder problems before and after intervention using focus groups interviews, only three out of the 26 participants who were interviewed were treated with cortisone injection after having physiotherapy. While the study's findings are generalisable to patients with supraspinatus tendonitis receiving physiotherapy or surgical interview, they are not generalisable to SAIS patients receiving cortisone injection because of the small number (3 out of 26) of those involved in the study. However, the study provides a good platform to conduct future qualitative interviews regarding SAIS patients' experiences of receiving subacromial injection. This view is supported the Department of Health (DOH 2009)

document that recommends patient centred treatment. This was the motivation as to why I undertook this current research.

The Department of Health (DOH 2009) in its report of reforms of “NHS 2010-2015: from good to great” (DOH 2009) specifies that NHS services must be more productive, patient centred and closer to people’s home. The document acknowledges that there are shortcomings in musculoskeletal service’s pathways due to inappropriate referral down a less effective route and/or delayed referral to more appropriate care and seeks to address these by ensuring more patient and public involvement – taking into account their views and experiences (DOH 2009). This is to ensure that decisions made regarding resource allocation are patient-led rather than provider and/or bureaucracy-led, one that is prompt and equitable, cost effective and a rational service for all (DOH 2009). This includes referrals to clinical specialists such as ESPs who can provide treatment options including cortisone injection to patients in a timely fashion and closer to their homes.

Currently, specialist musculoskeletal services are commissioned by GPs mainly to enhance patient experience by reducing waiting times. This is because previously patients, including those with shoulder pain, have had to wait longer periods to access these services (including provision of injection therapy) – leading to delayed referral along the specialist musculoskeletal pathway. Such delay can negatively influence the overall experience of patients, as well as

leading to patients developing chronic symptoms thereby reducing the effectiveness of future interventions such as cortisone injection (DOH 2009). However, a prompt referral to an appropriate clinical pathway such as extended scope musculoskeletal service, could achieve better clinical outcomes in improving the patient's condition by arresting progression of painful symptoms – leading to a better patient experience. Therefore, it is necessary to examine the impact that the current referral pathway would have on patient experience in relation to cortisone injection.

In conclusion, since SAIS is so common and causes so much cost and disability, it is therefore important it be treated effectively. Research evidence also suggests that generally, the lateral and posterior approaches are used by ESPs for subacromial injection. However, the posterior approach is most commonly used. In normal practice, the evidence establishing superiority of the lateral approach over the posterior route in subacromial injection is still controversial. Therefore, it is uncertain if a lateral approach to subacromial injection is more effective over a posterior route in improving outcomes of pain and function in SAIS. The evidence in the subjective experience of SAIS patients receiving subacromial injections is very scare. To my knowledge and despite extensive literature search, no study has both compared the effectiveness of the lateral versus the posterior approach in subacromial cortisone injection in normal clinical situations and the experiences of the patients receiving these treatments. This study will therefore address these issues.

2.8 The Research Question

To address the gap in the current knowledge on which of the needle approaches whether lateral or posterior to subacromial injection is more effective in the treatment of SAIS patients and their experiences of receiving these injections the following research questions were formulated.

1. Is lateral approach to subacromial injection more effective at improving shoulder pain and function in patients with SAIS compared to a posterior approach?
2. What are the experiences of patients with SAIS receiving these subacromial injections?

2.9 Null Hypothesis of the Study

There is no significant difference in the effectiveness of lateral approach compared with posterior approach to subacromial injection at improving shoulder pain and function in patients with SAIS.

2.10 Alternative Hypothesis of the Study

Lateral approach to subacromial injection is more effective at improving shoulder pain and function in patients with SAIS compared to a posterior approach.

2.11 Aims of the Study

2.11.1 Primary Aims

1. To determine the effectiveness of lateral approach to subacromial injection compared to posterior approach for the treatment of SAIS
2. To establish the experiences of patients with SAIS receiving these subacromial injections

2.12 Chapter Summary

This review has critically appraised the current literature on SAIS and its clinical presentation, classification, aetiology, diagnostic difficulties and clinical assessment. The current trend in National Health Service (NHS) musculoskeletal practice, the role of Extended Scope Practitioner (ESP) in musculoskeletal practice, current treatment for SAIS, and the issue of needle placement in subacromial injections have been presented. The review also critiqued the evidence regarding needle placements in subacromial injections in patients with SAIS and the experience of those receiving these treatments. There was lack of clear evidence establishing superiority of the lateral approach over the posterior route in subacromial injection in normal practice with paucity of literature investigating the experiences of these patients. Therefore, answering questions about the effectiveness of these approaches and the patients' perspective of these treatments are relevant to both patients and clinicians, as this may inform and transform practice.

The next chapter describes the methodology of the research including the aims of research, the research hypothesis and design, study setting and selection criteria for both the quantitative and qualitative study, clinicians involvement in the study, recruitment of participants, sample size calculation, process of randomisation, concealed allocation and blinding. I also provide a discussion on the study groups, interventions, treatment procedure, baseline comparability, data collection methods and analysis for both arms of the study. Finally, a discussion of ethical considerations and input of service users to the research is considered.

CHAPTER 3 METHODOLOGY

3.1 Introduction

In the previous chapter, a review of SAIS, the evidence relating to needle placement in subacromial injection with adults with SAIS and the knowledge gap regarding which approach of subacromial injections is more effective and the experiences of those receiving these injections are provided. This chapter will describe the methodology used to address these gaps in knowledge. The chapter is organised around the research design for both the quantitative and qualitative aspects of this research, data collection methods and analysis. The chapter concludes with a discussion of ethical considerations and input of service users to the research.

3.2 Research Design

This study used a mixed methods approach that combines both a quantitative and a qualitative approach as the research design.

3.3 Mixed Method Design

A research paradigm that combines both qualitative and quantitative methods, that is centred on optimizing treatment outcomes and integrating patient's perception and preferences is better suited to answer the above research questions. Several authors have suggested that combining qualitative research with quantitative methods greatly enhances the understanding patients provide

to treatment interventions (such as injection therapy), and the expectation they have concerning treatment outcomes such as pain relief (Verhoef et al 2002, Copeland et al 2008, Rowell & Polipnick 2008, Shaw et al 2010). This is in tandem with the current Department of Health drive to include patient's expectations and their experiences in the design and evaluation of healthcare research and services (DOH 2010). A systematic review of qualitative and quantitative studies on patients' expectations of treatment of musculoskeletal pain concluded that patients should be more involved in the decision-making process of their treatment (Verbeek et al 2004). This is because patients' involvement would enhance shared decision making and improve the quality of treatment they receive. The authors however, expressed some concerns with the mixed method research; for example, the lack of generally accepted quality criteria for evaluating mixed methods research (Creswell & Piano Clark 2007). However, the Priority-Sequence approach suggested by Morgan (1993) provides an acceptable quality approach for evaluating both qualitative and quantitative research methods. The approach by Morgan (1993) allows different but complementary information to be obtained in a mixed method research design. Furthermore, researchers with different areas of methodological expertise can provide potential innovation for guidance and quality criteria to enhance both qualitative and quantitative methods (Rauscher & Greenfield 2009, Shaw et al 2010).

The priority-sequence model by Morgan (1993) attempts to address the complementary needs aspects of different research methodologies. The author proposes that the first research design decision is to decide on which approach, either quantitative or the qualitative will be the principal data collection method. The next step is for the researcher to select a contrasting complementary method that adds additional sets of values to the research design's overall ability to meet the project goals. The second research design decision is to determine the sequence or order of the two methods. Combining this two-step decision making led Morgan to develop four major research designs which include:

a) A qualitative preliminary study that contributes to a principal quantitative study (qual-QUANT),
b) A quantitative preliminary study to enhance a principal qualitative study (quant-QUAL),
c) A qualitative method that complements a principal quantitative approach (QUANT-qual) and
d) A complementary quantitative study that serves as follow-up to a principal qualitative study (QUAL-quant)

Since this study aims to determine which injection approach is superior to the other for SAIS treatment and to establish the experiences of the patients receiving these injections, the third design Quant-qual (Morgan 1993) was used because it allowed for exploration of the study's objectives from two perspectives. The adoption of a complementary design approach enabled the demarcation of the data each method generated and ensured analyses were

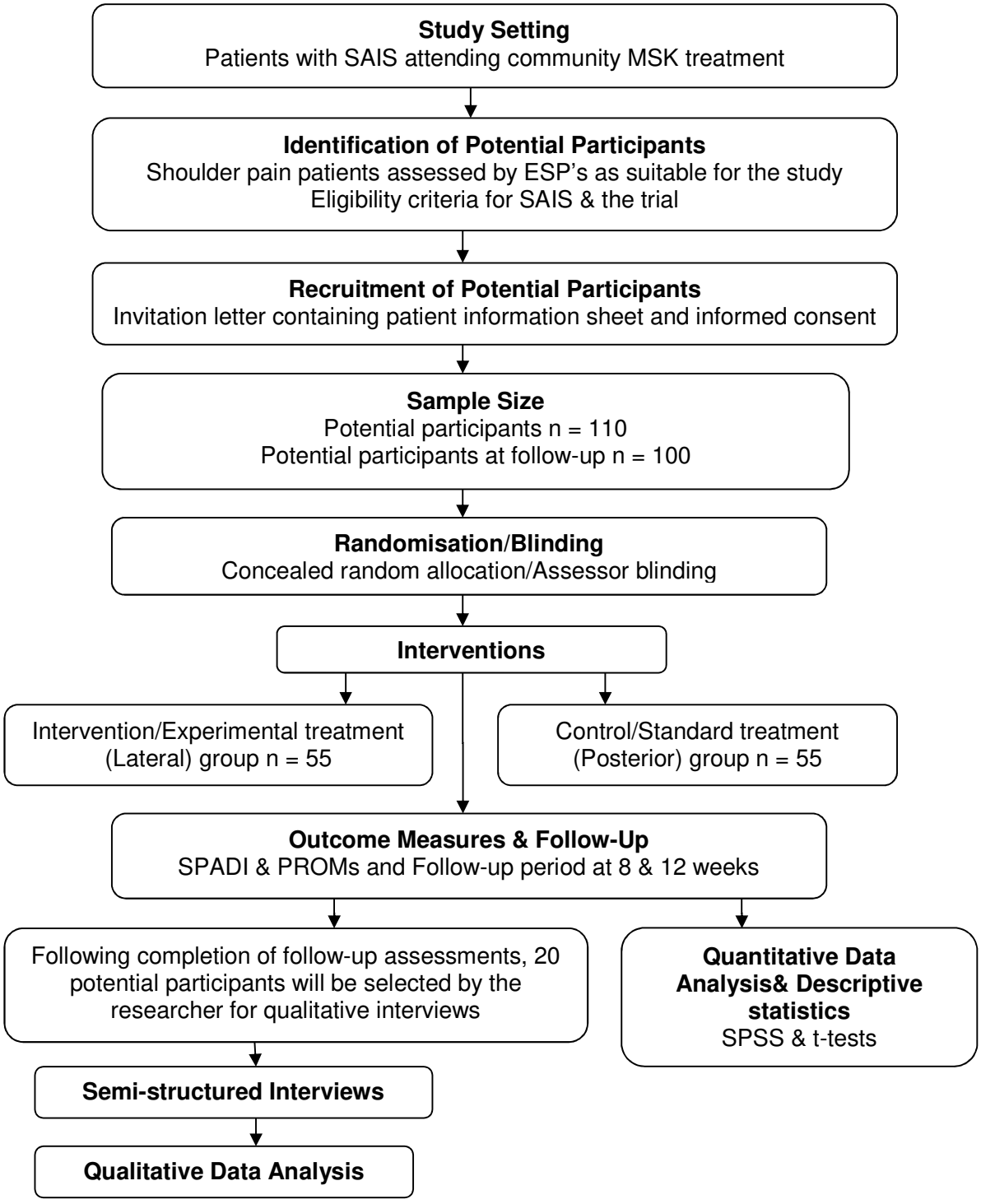
separate. A pragmatic RCT approach was used as the quantitative approach. The objective of using the pragmatic RCT design is to provide a valid and reliable set of clinically relevant data that is capable of detecting clinically important outcomes (such as shoulder pain, function and disability) for patients with SAIS (Walker & Sofaer 2003). Using the Priority-Sequence approach suggested by Morgan (1993), a qualitative study using semi structured qualitative interviews that complements a principally quantitative approach was used as the research methodology. Qualitative interviews using semi-structured questions were used as the qualitative design. This is to enhance the gathering of in-depth, rich data concerning the patient's experiences of subacromial injection. The qualitative method served as a follow-up to the quantitative approach. The desired objective of using the mix-method for this study is for the qualitative method to provide in depth interpretative data for understanding and describing the meanings patients with SAIS ascribe to subacromial cortisone injection.

3.4 Stages of the Research

The study has two phases. Phase 1 involves a randomised control trial and phase 2 is a qualitative study using semi structured interview. The flow charts for the research design are summarised in Figure 5.

In this chapter, I will outline the RCT first and then go on to outline the qualitative aspects of the study.

Figure 5: The Flow Chart for the Research Design



3.5 Phase 1

3.6 Methods

3.6.1 Design: Quantitative – Pragmatic Randomised Controlled Trial

The study is a two-arm, single blind, pragmatic randomised controlled design as defined by Hicks (1999), where the effects on dependent variables (shoulder pain and function) were measured by manipulating a single independent variable subacromial injection with two conditions (lateral and posterior approaches to subacromial injection).

There are many different research designs ranging from a single observational case study, a cohort or case controlled design, to experimental studies such as non-randomised and randomised controlled trials (RCTs). Each design has its own strengths and weaknesses. The choice of methodology may be influenced by factors such as the research question, ethical issues, sample size and funding (Hicks 1999). Although case studies are likely to demonstrate clinically significant improvement in outcomes of pain and function in the individuals, it must not be forgotten that they cannot rule out the effect of natural resolution, bias and other confounders such as the cause of improvement (Ainsworth & Lewis 2007). However, single case studies should provide some motivation for conducting the appropriate and necessary trials such as non-RCTs and RCTs (Egger et al 2007). Non-RCTs can detect associations between an intervention and an outcome, however they cannot rule out the possibility that the association was caused by a third factor linked to both intervention and outcome (Sibbald &

Roland 1998). RCTs are widely considered as the gold standard for assessing the effectiveness of different interventions such as shoulder injections, because they allow us to be confident that a difference in outcome can be directly attributed to a difference in the treatments, rather than some other confounding factors (age and gender) (McGovern 2001, Aveyard 2007). However, other factors, such as patient's clinical experience of the intervention, have been suggested to play a role in determining treatment outcomes (Black 1996). Therefore, a study that combines both aspects by investigating the effectiveness of the interventions as well as exploring the experiences of patients concerning the interventions is important. To achieve this, this study investigated the effectiveness of two interventions (lateral versus posterior approach) to subacromial injections in SAIS patients was well as the experiences of those receiving these injections.

RCTs help to reduce the risks of bias (threats to interval validity), mostly selection bias, and are thus best suited for research designs about the effectiveness of different interventions (Treweek & Zwarenstein 2009). However, it is the opinion of Cochrane, that randomisation does not, of itself, enhance the applicability of the results of a trial (external validity) to situations other than the exact one in which it was conducted (Cochrane 1972). It is possible for a trial to be free of bias but lacking in its application beyond the immediate clinical environment in which it was conducted (Treweek & Zwarenstein 2009). This view was strongly re-echoed by Rothwell (2005) which it stated: “Lack of

consideration of external validity is the most frequent criticism by clinicians of RCTs, systematic reviews, and clinical guidelines" (Rothwell, 2005:8). To resolve this problem Treweek & Zwarenstein (2009) has suggested the use of well-designed trials that adopt a pragmatic approach. In this study, a pragmatic RCT approach was adopted and the study was undertaken in a normal clinical environment within the community where most people with shoulder pain are diagnosed and treated (Hanchard et al 2013) to enhance its generalisation.

3.6.2 Pragmatic Versus Explanatory Randomised Controlled Trial

Schwartz & Lellouch (1967) describe two different types of RCT, explanatory and pragmatic. They proposed a distinction between explanatory and pragmatic trials. It is their view that many trials (such as explanatory trials) were limited in their applicability beyond the artificial, laboratory environment. Explanatory trials are aimed at validating a physiological hypothesis by specifically proving a causal relationship between administration of a treatment (a drug) and a physiological outcome (such as inflammation) (Schwartz & Lellouch 1967). Although pragmatic trials provide an explanation between interventions and treatment outcomes, they are also intended to inform healthcare decision-making, with this decision involving the choice between two or more treatments and real life outcomes (such as pain, function, and disability). On the other hand, explanatory trials provide knowledge about the effects of precisely defined interventions applied to selected groups under highly controlled conditions; however, they are not applicable in normal clinical situations that lack such highly

controlled environments. Pragmatic trials have been offered as a solution in that they retain the rigour of randomisation but are still applicable to normal clinical practice (Relton et al 2010). It is for these reasons that this study adopted a pragmatic approach and took place within a normal clinical environment in the community.

The differences between the two approaches are also highlighted in the use of efficacy and effectiveness (MacRae 1989, Sheikh et al 2002). Explanatory trials deal with efficacy as these studies assess differences in effect between two or more conditions under ideal, highly controlled conditions (Alford 2007). Although the tight controls of explanatory trials result in maximal internal validity, external validity could be lost (Alford 2007) because replicating them under normal clinical practice is difficult. Explanatory trials are thought to be well suited to medical drug trials, which are usually double or triple blinded, and involve the use of a placebo control group (Alford 2007). Pragmatic RCTs utilise effectiveness, which assesses differences in effect between two or more conditions in normal clinical circumstances, thus retaining internal validity and enhancing external validity (Alford 2007). It is the opinion of Alford (2007) that pragmatic RCTs are generally more suited to assessing musculoskeletal interventions such as needle approach to subacromial injections. Explanatory trials are usually more expensive, take more time and involve more personnel, unlike pragmatic trials. These difficulties are the reasons why a pragmatic approach was adopted in this research. To

achieve this, no extra costs or personnel was involved in the study. For example, the study took place within normal clinical hours with the usual staff involved.

3.6.3 Pragmatic Randomised Controlled Trial – Why it is Important

This study used a pragmatic RCT design to compare the effectiveness of posterior or standard approach versus lateral or experimental approach of subacromial injections in SAIS patients in a normal community practice where most people with shoulder pain are diagnosed and managed (Hanchard et al 2013). A pragmatic RCT is aimed at determining the effectiveness of two or more interventions under the usual conditions or real life settings in which they are applied (Califf & Sugarman 2015). Pragmatic trials including RCT are aimed at ensuring that the care delivered in the setting in which trials are conducted matches the care delivered in the setting to which its results are applied (Loudon et al 2015). Pragmatic RCTs are generally linked with clinical practice and they incorporate clinical outcomes that are relevant to inform decision makers such as patients, clinicians, health commissioners and policy makers about interventions that are applicable to a wide range of clinical settings (Califf & Sugarman 2015). These trials adopt minimal exclusion criteria in order for the patients to reflect those receiving care within the normal population (Califf & Sugarman 2015). This study used a pragmatic RCT design to compare both aspects of subacromial injections (posterior or lateral) to determine which of them will produce better clinically important outcomes (such as shoulder pain and function) for patients with SAIS. This is so that decision making by both the patients and healthcare

providers regarding subacromial injections for patients with SAIS could be enhanced. The study included participants with SAIS drawn from a population of patients attending a community (MSK) service and were representative of the general population. To enhance the study credibility, the nine dimensions for assessing the level of pragmatism in a trial, as proposed in the pragmatic-explanatory continuum indicator summary 2 (PRECIS-2) tool was adopted (Loudon et al 2015). See Table 7 for detailed description.

With the current economic climate and given the pressure to improve healthcare delivery within the community, pragmatic RCTs have received wide spread support and acceptance from clinicians, researchers and policy makers (Whicher et al 2015). Healthcare commissioners and policy makers are very interested in pragmatic trials because they are designed to answer important questions relevant to them, which is comparative effectiveness of interventions in the normal clinical practice (Patsopoulos 2011, McCully 2015). The service where this study took place was commissioned by the local Clinical Commissioning Group (CCG) to provide cortisone injection as part of the management of patients with shoulder pain and they were interested in knowing the clinical outcomes. Therefore, they were keen in promoting high quality health research which provides the evidence needed to improve healthcare and treatment. Consequently, during the planning stages of this study, the local CCG and GPs were informed and involved in the study and they supported it.

Table 6: The nine dimensions for assessing the level of pragmatism in a trial, as proposed in the pragmatic-explanatory continuum indicator summary 2 (PRECIS-2) tool

Dimension	Assessment of Pragmatism – PRECIS-2 Tool	What this study did using the PRECIS-2 Tool
Eligibility	To what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care?	This study participants were patients that have been referred to the service by their GP with shoulder pain who usually could be treated with subacromial injection either via a posterior or a lateral approach.
Recruitment	How much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients?	The service where thus study took place receives referrals from 33 GP practices in the area. Therefore, prior to the study, presentations were made to the GP's in the area via the clinical commissioning group (CCG) and to the ESPs and the Physiotherapists at the researcher's place of work to inform them of the study and enhance recruitment of participants.
Setting	How different are the settings of the trial from the usual care setting?	All the participants recruited to the study were from a population of patients attending a community (MSK) service.
Organisation	How different are the resources, provider expertise, and the organisation of care delivery in the intervention arm of the trial from those available in usual care?	No extra cost or personnel was involved in this study. The clinicians involved in this study and the treatment they provided were similar to the care they would normally provide in their clinical practice.
Flexibility in delivery	How different is the flexibility in how the intervention is delivered and the flexibility anticipated in usual care?	The flexibility applied to the intervention in this study was similar to the usual care.
Flexibility in adherence	How different is the flexibility in how participants are monitored and encouraged to adhere to the intervention from the flexibility anticipated in usual care?	In this study standard after care and post-injection information were provided verbally and in the form of information leaflet based usual care.
Follow-up	How different is the intensity of measurement and follow-up of participants in the trial from the typical follow-up in usual care?	Participants in this study were assessed three times during the study period, at 0 (baseline), 8 and 12 weeks. The 0 and 8 weeks' timeframe is common in normal clinical practice and previous authors (Akgun et al 2004) have used the 12 weeks' follow-up period. At follow-up, the outcomes of the injection were evaluated via a telephone call similar to normal clinical practice.
Primary outcome	To what extent is the trial's primary outcome directly relevant to participants?	The primary outcome – SPADI and the PROMs that were used in this are patient reported outcome measures that are used in normal clinical practice.
Primary analysis	To what extent are all data included in the analysis of the primary outcome?	In this study, all data were included in the analysis of the primary outcome. Once a participant is randomised to an arm of treatment, they should be analysed in the group to which they were allocated to after randomisation.

Adopted from Loudon et al (2015)

This is consistent with the suggestion by Patsopoulos (2011) that decision makers such healthcare providers and policy makers should be included in the design of pragmatic trials.

In a recent review literature, Drazen et al (2016) advocate that in pragmatic trials, the intervention should be delivered as in normal clinical practice by experienced, skilled and trained clinicians. This is consistent with the pragmatic RCT approach that this study used. It involved experienced, trained and skilled ESPs working in the community with no extra costs or personnel for the research. Pragmatic trials not only compare a new treatment with an existing one, but they can also compare existing treatments with alternatives (Zwarenstein 2016). This is exactly what took place in this study where a posterior (the usual or standard) approach to subacromial injection was compared with a lateral (alternative or experimental) approach to determine which of them is more effective in the treatment of SAIS.

3.6.4 Study Setting

The study setting was at a large Community Musculoskeletal (MSK) service. Prior to the study, presentations were made to the GP's in the area via the clinical commissioning group (CCG) and to the ESPs and the Physiotherapists at the researcher's place of work to inform them of the study. They were provided with details regarding the rationale behind the study and the participants. All the participants recruited to the study were from a population of patients attending a community (MSK) service. This service receives referrals from 33 GP practices in the area.

3.6.5 Sample Criteria

Eligibility of participants is a crucial feature and central to the topic of inferential statistics, this is because the sample chosen should be representative of the population that the results are likely to be applicable to (Hicks 1999). Research predictions are better made if the sample is largely homogeneous to the population that it is trying to represent; otherwise the results are only generalisable to a small subgroup of participants (Hicks 1999). Since restrictive inclusion and exclusion criteria lead to a more homogeneous group of patients, pragmatic trials frequently utilize less restrictive criteria (Godwin et al 2003, Alford 2007). This improves the external validity (generalisability) as patients with the disorder of interest commonly exhibit co-morbidities such as previous injury and diabetes. This maximisation of external validity often occurs at the expense of internal validity (Alford 2007). In balancing these two competing demands, the SAIS criterions when selecting patients with SAIS (Lewis et al 2005) and the study suitability criteria for subacromial injection (Saunders & Longworth 2012) were adopted from previous studies which have successfully used them. Tables 3 and 4 are respectively the participants' diagnosis and study's suitability criteria.

3.6.6 Identification of Participants

Participants were patients that have been referred to the service by their GP with shoulder pain. The term SAIS is reflective of a spectrum of soft tissue pathologies rather than a diagnostic label relating to specific pathology (Lewis 2008). However, in practice a diagnosis of SAIS is still based on findings of a clinical examination for a majority of patients (Dinnes et al 2003). At first

appointment, a trained ESP identifies them through a face-to-face assessment to determine if they have a diagnosis of SAIS and would benefit from a cortisone injection. A diagnosis of SAIS was made by the assessing ESP according to the inclusion and exclusion criteria in Table 7.

Table 7: Diagnosis Criteria for SAIS

Inclusion Criteria	*Exclusion Criteria*
Patients aged 18 and above *Shoulder pain localised to the acromion* *Pain with active arm elevation* *Positive painful arc between 60° and 120° of abduction* *Positive impingement test-Neer's sign or Hawkins Kennedy* *No evidence of referred pain from cervical spine*	*Patients below 18 years of age* *History of:* • *Current Pregnancy* • *Spinal or shoulder surgery (last 6 months) or joint replacement* • *Current Spinal or upper limb fracture* • *Previous hydrocortisone injection in the last 4 weeks* • *Shoulder dislocation/ instability* • *Current Frozen shoulder* • *Acromioclavicular joint arthritis* • *Os acromiale* • *Bony metastases* *Clinical findings of presence of positive:* • *External rotation lag sign* • *load and shift test* • *Sulcus sign* • *Active compression labral test* *Reproduction of shoulder symptoms during active cervical movements* *Reproduction of shoulder symptoms on movements of the cervical or thoracic spine rather than shoulder movement* *Radiographic evidence of calcific periarthritis*

3.6.7 Suitability Criteria for the Study

Once SAIS criteria had been met, a further selection was made using all of the inclusion and exclusion criteria listed in Table 8 below to select patients for the study.

Table 8: Inclusion and Exclusion Criteria for the Study

Inclusion Criteria	*Exclusion Criteria*
Patients 18 years and above *They fulfil the eligibility criteria for SAIS* *Able to give informed consent* *Eligible for lateral and posterior routes of subacromial injection* *Patients with no contraindication to cortisone injection such as:* • *sepsis, fracture sites, prosthetic joint and uncontrolled blood glucose levels*	*Patients under 18 years of age* *Did not fulfil the eligibility criteria for SAIS* *Failure to consent* *Not eligible for lateral and posterior routes of subacromial injection* *Patients with contraindication to cortisone injection such as:* • *sepsis, fracture sites, prosthetic joint and uncontrolled blood glucose levels*

3.6.8 Clinicians Involvement in the Study

The researcher as Chief Investigator and two Extended Scope Practitioners (ESPs 1 & 2) were involved in this study. Both ESPs (1 & 2) were involved in consenting, assessing and injecting patients. The Chief Investigator, who was not involved in the patient's initial assessment and therefore blinded to the baseline measurement, was involved in the follow-up assessments at 8 and 12 weeks. Information about the eligibility criteria was provided to both ESPs to aid diagnosis and they, as well as the administrative staff involved in the randomisation, received training on the study protocol. For the ESPs the training included the selection criteria, consenting of participants and adequate documentation of none identifiable participant's information. The

administrative staff were trained on the participant information sheet, patient recruitment and randomisation procedure. A standard operating procedure (Appendix 1) was developed for this purpose and everyone involved in administering the study followed it.

3.6.9 Recruitment of Potential Participants

When the first musculoskeletal appointment was posted to the patient, a separate envelope containing a letter of invitation (Appendix 2) to take part in the study was also sent. The invitation pack contained a letter of invitation with a Patient Information Sheet (PIS) (Appendix 3) and two consent forms (for the quantitative part and the qualitative interview) (Appendix 4). In the PIS, it was clearly stated that involvement in the study was voluntary and that participants were free to withdraw from the study at any time. Participants who were interested in taking part in the study but had further questions were encouraged to contact the researcher via a study mobile number or postal address. Participants were asked to read the PIS before attending their first musculoskeletal appointment if they wished to participate. On attending their appointment they had an opportunity to ask questions and were asked to sign the consent forms. Potential participants who fulfilled the eligibility criteria following screening by the assessing ESP and provided written informed consent were then recruited into the study.

3.6.10 Sample Size Calculation

The primary aim of the study is to detect whether there is a clinically important difference between a lateral and posterior approach to subacromial injection. Sample size calculation is an important step in the design of a clinical trial;

however, the amount of literature that addresses such an important issue is scarce (Kieser & Friede 2000). Miaoulis & Michener (1976) in relation to determining appropriate sample size have specified three key areas: level of precision, level of confidence or risk and degree of variability of the attributes in the population. In general the more heterogeneous the population, the larger the sample required to obtain the desired level of precision and conversely the more homogeneous the population the smaller the required sample (Israel 1992, Claver 2009). Sample size also has an economic viewpoint with underestimated sample size not having the capacity to produce meaningful findings and therefore can be a waste of resources (Claver 2009). However, an oversized sample uses more resources than are necessary (Claver 2009). In today's current healthcare climate where there are limited resources it is important to have a sample size that is large enough to produce a significant result yet still within available budgets and resources (Claver 2009). When the sample size is small RCTs are subject to type II errors (Keirse & Hanssens 2000, Hicks 2009). These refer to the probability of concluding that no difference between the treatment groups exists when, in fact, a difference does exist i.e. false negatives (Lochner et al 2001, Hicks 2009) In this situation, the null hypothesis is false, but erroneously fails to be rejected (Lochner et al 2001, Hicks 2009). One way of reducing type II error is increasing the sample size (Hicks 2009), which ultimately increases the power of the study, defined by Bigby & Gadenne (1996) as the ability of a trial to detect a difference in treatments if one exists. The power of a study could also be influenced by the statistical significance level (usually set at 5%) and knowledge of the minimum clinically important difference (MCID) of the primary outcome measure, which can be based on previous studies or expert

opinion (Claver 2009). A power level of 80% - 90% is usually considered adequate (Murray 1991); this implies that if the clinically important difference in treatment truly exists, 4 - 4.5 out of 5 treatments with the specified number of patients in the treatment groups will show a statistically significant difference (Claver 2009). A large sample size has another advantage in that it increases the likelihood of the sample being representative of the population being studied (Hicks 1999). According to Alford (2007), pragmatic clinical trials generally require larger sample sizes due to the heterogeneity of the sample population. In SAIS where the attributes of the population are diverse and the prognostic factors not well established, a larger sample offers the possibility of achieving the desired level of precision and ensuring that the study is sufficiently powered (Claver 2009). Sample size calculations are frequently performed using formulas and figures or with the aid of computer software. In this study, the former was adopted.

The sample size calculations were based on work by Roach et al (1991) who estimated the MCID for the Shoulder Pain and Disability Index (SPADI) to be a change in score of 13 points at 90% power level. Identification of a MCID between treatments groups is important in deciding the treatment effect-size and therefore the sample size (Samsa & Matchar 2001). SPADI is one of the primary outcome measures to be used in this study. It is a self-report questionnaire designed to measure pain and disability specifically associated with shoulder pain of musculoskeletal origin (Roach et al 1991).

Based on data from a previous shoulder study (Ekeberg et al 2009) that estimated the standard deviation of change in SPADI to be 20 points, the

power level was set at 90% and statistical significance at 5% to detect a MCID of 13 points. Using these figures, a sample size of 100 is estimated. To account for a 10% rate of loss at follow-up the study included 110 participants. This value was achieved using formula and figures listed in Bland (2000 p, 338 – 339) as shown in Table 9.

Table 9: Sample size calculation using formula and figures listed in Bland (2000 p, 338 – 339)

According to Bland (2000), for comparison of two means for equal sized groups, $n_1 = n_2 = n$, the equation becomes:
$(\mu1 - \mu2)^2 = f(\alpha, P)\, 2\sigma^2/n$
Using the Bland (2000) table, if power P = 0.90 = 90%, α = 0.05 =5%, the conventional values of f (α, P) is 10.5.
P = power of the test = 90%
α = significance level = 5%
n = the sample size in each of the groups
μ1 = population mean in treatment Group 1 – Lateral Group
μ2 = population mean in treatment Group 2 – Posterior Group
μ1 – μ2 = d =13
d = the difference the researcher wishes to detect (clinically important difference)
σ = population variance standard deviation (SD) = 20
Since $d = \mu_1 - \mu_2 = 13$, $f(\alpha,P) = 10.5$, $\sigma = 20$
$(\mu1 - \mu2)^2 = f(\alpha, P)\, 2\sigma^2/n$ becomes $13^2 = 10.5 \times [2 \times 20^2]/n$
which gives $n = 10.5 \times [2 \times 20^2]/13^2 = 49.70$
Hence, the researcher needs 50 patients in each group. Therefore, the researcher needs 100 patients. To account for a 10% rate of loss at follow-up, this study will include 110 participants.

3.6.11 Randomisation & Allocation Concealment

After recruitment into the study the participants were randomly assigned to the two study groups: the experimental group was treated with cortisone injections via the lateral approach; and the control group received cortisone injections via the posterior route. The use of random allocation to assign participants to the treatment groups has numerous advantages. These include, for example, even distribution of random errors i.e. factors that obscure the results in a random or unpredictable way (Hicks 1999), even distribution of intrinsic prognostic factors among the groups and control of selection and evaluation bias (Bigby & Gadenne 1996). The success in splitting the major confounders and prognostic variables will be judged using baseline characteristics. Further measures of restricted randomisation such as blocking were considered. In block randomisation, participants are randomised into treatment groups that result in equal distribution of sample sizes (Suresh 2011). This approach is simple, easy to apply and ensures a balance in sample size across groups over time; and the block size is determined by the researcher and they are in multiple of the treatment groups (for example, with two treatment groups, block size could be 4, 6, 8, 12, 16, ...30 etc) (Suresh 2011). In this study the researcher used a block size of 30 generating equal numbers of participants in each group (lateral or posterior).

The use of randomisation to allocate subjects to either group helps to minimise systematic differences between the groups that may potentially distort the results, balancing both known and unknown prognostic factors such as age, sex, race (Sibbald & Roland 1998). Alford (2007) suggests that random allocation of participants to groups is an important feature of RCTs

that helps to reduce allocation bias. However, it is not always practicable to investigate healthcare interventions using random allocation (McKee et al 1999). Furthermore, simply by having a random allocation sequence the risk of selection bias is not completely removed (Sibbald & Roland 1998). If participants or clinicians are aware of the order of the allocation sequence, then they can allocate participants to one group or another by deciding whether to recruit them into the trial. However, this can be prevented by ensuring allocation concealment thus reducing selection bias (Sibbald & Roland 1998).

An administrative staff member who was blinded to the hypothesis of the study carried out the randomisation process. This took place after the participant has agreed to participant in the study using sealed opaque envelopes thus achieving concealed random allocation.

3.6.12 Blinding

In traditional explanatory RCTs such has pharmaceutical trials, blinding of participants and therapists (double blinding) is an important aspect (Alford 2007). It refers to concealment of the allocated treatment group after the participant has entered into the trial and it helps to reduce measurement bias (Verhagen et al 1998). Unlike explanatory trials, in pragmatic trials it is often impractical to blind participants to the nature of the treatment they are receiving or therapists to the treatment they are administering. However, it may be possible for the assessor to be blinded. Ethical considerations may prevent the inclusion of a “no treatment” group (Alford 2007). Comparison of different treatment approaches, such as standard treatment (posterior

approach) versus experimental treatment (lateral approach) is the preference (MacPherson 2004). In pragmatic trials the non-blinding of both patients and therapists to treatment approach can be accepted (Roland & Torgerson 1998) as this reflects what happens in normal clinical settings, where treatment effect may be influenced by the expectations of the patient and the therapist (Alford 2007). However, Herbert et al (2005) and Hotopf (2002) argued that to minimise the risk of selection or measurement bias by researchers, concealed randomisation and blinding of the assessor to outcome is imperative.

In this current study, a pragmatic approach was adopted because it was well suited to situations where it was difficult or impossible to blind both participants and therapists (Helms 2002). The injecting clinicians were therefore blinded to participant allocation in order to minimise experimenter bias as defined by Hicks (1999), as expectations of outcome may influence what you perceive and how you behave and the assessor was blinded to the baseline measures.

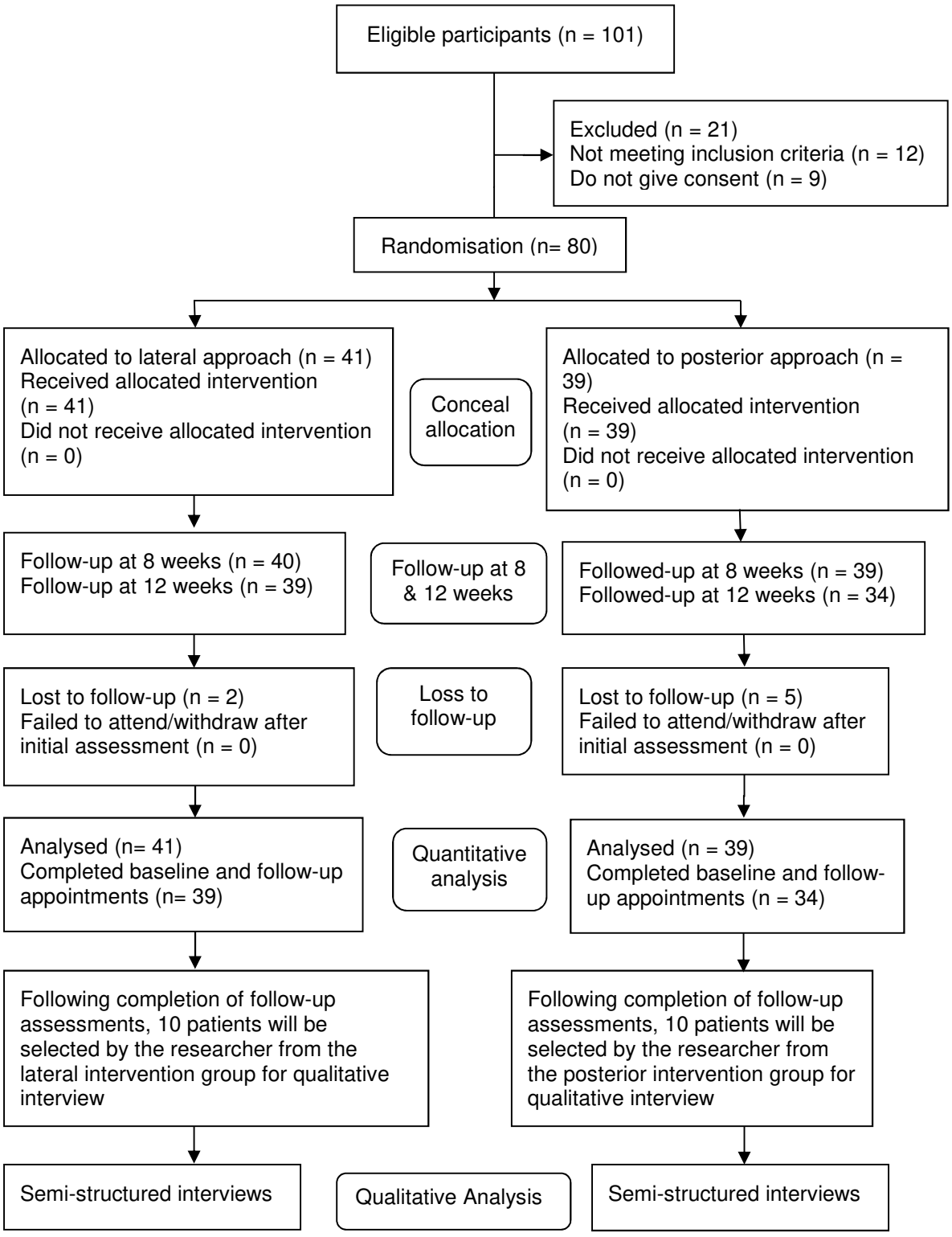
3.6.13 Randomisation and Blinding Process

Randomisation was based on concealed random allocation using sealed opaque envelopes. Allocation concealment ensures that participants and clinicians cannot know or predict what the next patient's treatment allocation will be (Viera & Bangdiwala 2007). After obtaining consent from the patient, the assessing and injecting ESPs immediately telephoned administrative staff who performed the randomisation process. Assignment was made by sequentially numbered, otherwise identical, sealed envelopes. Envelopes were opaque and lined inside with aluminium foil. Each envelope contained

an approximately 2-inch by 2-inch paper with a written code L or P designating intervention/experimental (lateral approach) or control/standard group (posterior approach) respectively. Following the opening of each envelope, the administrative staff assigned the patient to either the intervention or control group using the label L or P on the sealed envelope. Following the notification of the randomisation result by the administrative staff, the injecting ESP injected the patients using either lateral approach if the envelope was labelled L or posterior approach if it was labelled P. This process corresponded to the concealed random allocation design. Through such a process, every participant had an equal opportunity of being allocated in the intervention or control group. It ensured that there was no order or time effect thus minimising systematic bias. Although subacromial injections are routinely performed using a posterior approach they can also be given via a lateral route because the injecting clinicians have been trained in both methods. A detail of participant flow through the study is in figure 6.

Patients in the study had their follow-up outcomes assessed by the Chief Investigator. The patient's study number and their contact details were used by the Chief Investigator who was blinded to the baseline measurement to contact the patient during follow-up assessment at 8 and 12 weeks. The 8 weeks' timeframe is normal clinical practice and the further 4 weeks is to look for any additional differences. The 12 weeks' follow-up period is consistent with previous authors (Akgun et al 2004, Kang et al 2008).

Figure 6: Flow chart showing movements of patient through the trial



The success of the randomisation process in splitting the major confounders such as previous clinical experience was judged by whether the baseline characteristics of the study groups were similar. Potential participants were partially blinded to the treatment allocation. Although they might know from experience whether they are receiving lateral or posterior subacromial injection, they did not know however, whether they were receiving the experimental or standard treatment. Therefore, they were partially blinded to the treatment they received. It is impossible for the injecting ESP to be blinded to treatment allocation with this design because they already know what the experimental and standard treatment is. However, they do not control which patient they inject because of the concealed random allocation of potential participants.

3.6.14 The Study Groups

The research has two-arms; the standard group received a cortisone injection through the posterior shoulder and the experimental group via the lateral approach. Both arms of the study injections had similar physiological drug (cortisone) properties therefore any difference in outcomes should be due to the injection approach. To reduce performance bias clinical factors such as the volume, dose and strength of steroid and local anaesthetic used during subacromial injections were standardised. Subacromial cortisone injections were carried out under the Patient Group Directions (PGDs) to ensure standardisation of the volume, dose and strength of steroid and local anesthetic used (Saunders & Longworth 2012).

3.6.15 Interventions

Intervention (experimental) group: These received a single subacromial injection with a 21 gauge (1.5 – 2 inches) Green needle with 40 mg/ml of Kenalog (triamcinolonacetonide) and 4 ml of 1% Lidocaine through a lateral approach (Figure 5a shows the lateral approach). This is the experimental treatment. The procedure includes needle gauge and the injection volume, dose and strength of the steroid and local anaesthetic that are standardised using recommended values by the PGDs for subacromial injections (Saunders & Longworth 2012). This was delivered by a trained and qualified ESP during the patient's outpatient musculoskeletal appointment.

Control (standard) group: These received an identical treatment except for the location, which was by a posterior approach (Figure 7b shows the posterior approach). This is the routine treatment.

Figure 7: Diagram to illustrate the difference between the posterior and lateral approach of subacromial injection.

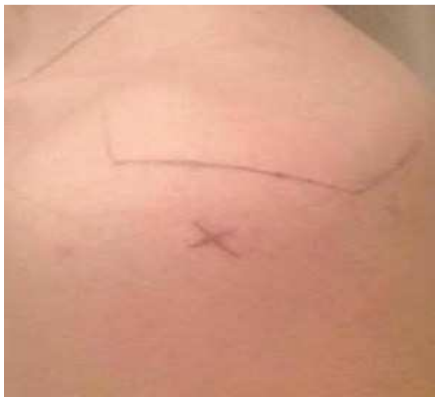


Figure 7a

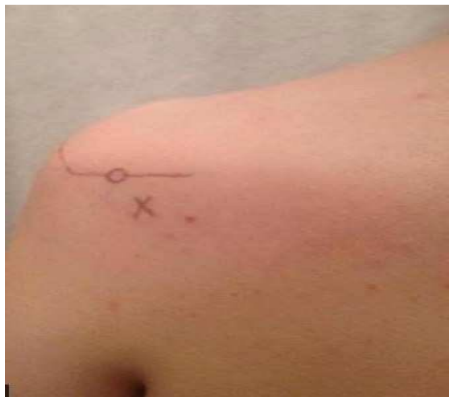


Figure 7b

7a External view of left shoulder showing the location of the lateral shoulder injection portal, 7b External view of left shoulder showing the location of the posterior shoulder injection portal (Reproduced with permission from Wickramasinghe et al 2012).

3.6.16 Treatment Procedure

After obtaining consent from the participants, a routine clinical examination was carried out by the injecting ESP before the injection procedure. After a diagnosis of SAIS was confirmed and suitability assessment for the trial was achieved, the injecting ESP injected each patient by either a lateral or a posterior approach according to the label L or P on the sealed envelope. The label L or P on the sealed envelope represented the administration of their route of injection. The patient's study entry number and contact details were then used by the Chief Investigator to contact the patient at 8 and 12 weeks follow-up assessment.

Standard after care and post-injection information were provided verbally and in the form of an information leaflet based on published recommendations (ACPOMIT 1999, Saunders & Longworth 2012). These included rest from strenuous activities such as heavy lifting for a period of 1 – 2 weeks and a gradual return to normal activities of daily living (Coombes et al 2009). Participants were informed of potential post injection side effects such as minor bleeding or bruising, post injection flare of pain and skin depigmentation/subcutaneous atrophy. They were advised to inform their GP in the event of any adverse reactions such as joint infection. All side effects were managed by normal clinical procedure by the service manager and the service clinical lead. Both groups received either a posterior or a lateral subacromial injection and were permitted to continue with their current pain medication regime such as paracetamol or ibuprofen. Other forms of conservative intervention characteristic in the management of SAIS including shoulder stretching and strengthening exercises were allowed. This is

reflective of “real life” practice where patients receiving physiotherapy for shoulder pain rarely receive a single treatment or intervention in isolation (Green et al 2003, Hanchard et al 2004).

3.6.17 Baseline Comparability

In a controlled trial, random allocation ensures that allocation of patients to treatments is left purely to chance (Altman 1985, Trowman et al 2007). It is the opinion of Burgess et al (2003) that well-balanced baseline data improves the quality of a trial by enhancing its internal and external validity. The authors also suggest that the success of randomisation can be measured with baseline characteristics of patients. This is because if randomisation is properly executed, groups will be similar in baseline characteristics (Burgess et al 2003). Where the baseline characteristics of patients that may influence outcome are well distributed between the intervention and the control groups, any difference in outcome can be assumed to be due to the intervention (Hicks 1999, Roberts & Torgerson 1999). In this study, the difference could be attributed to the lateral or posterior route of cortisone injection. However, imbalance between groups in baseline characteristics that may influence outcome (such as age or sex) can bias statistical tests, leading to what is sometimes referred to as chance bias (Roberts & Torgerson 1999). Although the practice of statistical testing of baseline variables to assess the effect of imbalance is common (Alman & Dore 1990), it has been challenged (Altman 1985). Roberts & Torgerson (1999) argue that baseline tests of imbalance are unsuitable unless the researchers suspect that there are problems with the randomisation. In RCTs, in order to describe the population in the trial adequately, baseline data should include demographic variables such as

potential confounders (age, gender). These are known and unknown factors that are likely to influence the outcome (including medications being taken by participants), modify any benefit of treatment, and those that may predict adverse reactions (Burgess et al 2003). In this study, restricted randomisation such as blocking was used to help to reduce the chance of imbalance (Burgess et al 2003).

3.6.18 Outcome Measures and Follow up

3.6.18.1 Baseline Assessment

Baseline characteristics include age, gender, duration of symptoms, dominant side affected, previous cortisone treatment, current treatment analgesia and current treatment NSAIDS. It also includes the initial SPADI and PROMs scores (Table 10 is the breakdown of baseline characteristics).

Table 10: Baseline Characteristics table

	Lateral Group A No or mean or %	Posterior Group B No or mean or %
Age Gender Duration of symptoms Manual occupation Initial SPADI Score Initial PROMs Score Dominant side affected Previous cortisone treatment Current treatment analgesia Current treatment NSAIDS		

3.6.18.2 Primary Outcomes

When assessing the outcome from shoulder interventions such as cortisone injection various measurement tools such as SPADI and NPS can be considered because previous shoulder studies have used them (Roy et al 2009, Bennell et al 2010, Rhon et al 2014). Rhon et al (2014) in a pragmatic

RCT that involved 104 patients with shoulder impingement syndrome compared the effectiveness of corticosteroid injection with manual physical therapy using both SPADI and NPS scores as outcome measures. A physical therapy outcome measure is a test or scale administered and interpreted by physical therapists that has been shown to measure accurately a particular attribute of interest to the patients and therapists and is expected to be influence by intervention (Mayo 1994). The primary outcome measures in this study were the Shoulder Pain and Disability Index (SPADI) and Patient Reported Outcome Measures (PROMs) (Appendix 5 and 6). Both measures are routinely used for cortisone injections for patients with shoulder pain as baseline and outcome measures. The participants' shoulder pain and function were evaluated using SPADI and PROMs (NPS and shoulder function) during their first musculoskeletal appointment. In the PROMs scale, NPS was used to measure daytime and night time pain at baseline and at follow-up. Prior to the injection therapy, these measures were administered and recorded as baseline measures by the injecting ESPs. The Chief Investigator at follow-up used them as outcome measures by using the patient's study number that was allocated to them at baseline.

3.6.18.3 Shoulder Pain and Disability Index

The participants' shoulder pain and function were evaluated with the shoulder pain and disability index (SPADI) score. SPADI is a self-report questionnaire designed to measure pain and disability specifically associated with shoulder pain of musculoskeletal origin (Roach et al 1991). Thirteen items, covering two domains (pain and disability) are scored on a numerical rating scale between zero (no pain/difficulty) and ten (worst pain imaginable/so difficult it

requires help). The pain dimension consists of five questions concerning the severity of a patient's pain. Functional activities are measured with eight questions designed to assess the degree of difficulty a patient has with different activities of daily living (Roach et al 1991). Each domain carries equal weighting in the overall score that is expressed as a percentage where zero represents no pain or disability and 100% represents maximum pain and disability. A minimally important clinical difference for the SPADI is 8-13% (Roy et al 2009). In practice, it is easy to administer and requires minimal time for a patient to complete (Breckenridge & McAuley 2011) and Roy et al (2009) reports that it is not only very reliable, but a valid region-specific measure for the shoulder.

3.6.18.4 Patient Reported Outcome Measures (PROMs)

The PROMs contain a numeric pain scale (NPS) (Appendix 5) that was used to measure day time and night time pain and this is applicable in clinical practice. The NPS is a single 11-point numeric scale (with 0 as "no pain" and 10 as the "worse imaginable pain") used to measure pain intensity in adults (Hawker et al 2011). It allows patients to measure their level of pain accordingly using a whole number (0-10 integers) that corresponds to their pain intensity (Rodriguez 2001). The major advantages of the NPS over the visual analogue scale are that it can be administered verbally by telephone or by self-completion through the post (Jensen et al 1986). The scale is considered reliable (accurate and consistent), responsive (able to detect clinically significant changes) and valid (actually measures what it sets out to) (Hawker et al 2011). The NPS is relatively easy to understand and to apply, especially by patients with musculoskeletal disorders (Hawker et al 2011).

The PROMs contains a single 11-point NPS that measures day time and night time pain in the participants. Since night pain is commonly associated with SAIS (Zuckerman et al 1991), it is important to measure it. This is consistent with (Akgun et al 2004) who in a RCT that evaluated the effects of subacromial injections in SAIS patients used a similar pain scale to measure shoulder pain at day time and night time. The PROMs also measure how much of specific shoulder function such as lifting is affected using a 6-point percentage scale with 0% as full function and 100% as complete loss of function. This was considered adequate following expert statistician opinion and agreement with my supervisor.

3.6.18.5 Outcome Assessment

Participants were assessed three times during the study period, at 0 (baseline), 8 and 12 weeks. This allowed inferences to be drawn about immediate and short-term effects. The 8 weeks' timeframe is common in normal clinical practice and previous authors (Akgun et al 2004, Kang et al 2008) have used the 12 weeks' follow-up period. At 8 and 12 weeks, the outcomes of the injection were evaluated via a telephone call. The Chief Investigator (who was not involved in the patient's initial assessment and therefore blinded to the baseline measurement) contacted participants during these periods using the participant's study number and their contact details. The Chief Investigator left a voice message with a reminder for the patient to call back if they were not contactable. The response rate was facilitated through a reminder by post to patients using a self-addressed envelope that contained the outcome measures.

3.6.18.6 Loss to Follow-up

This study lasted for 12 months therefore, at 4 months a review of the rate of loss to follow-up was undertaken to ensure that this does not affect the findings of the study. At 4 months, the rate of loss to follow-up was not much higher in one group compared with the other. Patients who were lost to follow-up, data collected up to that point were included in the analysis based on intention to treat (ITT).

3.6.19 Non-Response and Intention to Treat Analysis

Intention to treat analysis (ITT) is widely accepted as the gold standard for evaluating the results of clinical trials particularly if the trial uses a pragmatic design. This is consistent with a systematic review by Armigo-Olivo et al (2009) that investigated compliance, drop-outs and loss of follow-up data and recommended the use of ITT analysis for evaluation of the results of pragmatic studies. This is because pragmatic studies (such as the one undertaken by this research) examine the effectiveness of a specific treatment in a real-life situation (clinical setting). ITT analysis takes into account all randomised patients in the groups to which they were randomly assigned, regardless of their adherence with the entry criteria, treatment they actually received, and subsequent withdrawal from treatment or deviation from the study protocol (Fisher et al 1990). Similarly, it means that once a participant is randomised to an arm of treatment, they should be analysed in the group to which they were allocated to after randomisation notwithstanding noncompliance, protocol deviations, and anything that happens after randomisation (Kruse et al 2002). ITT analysis therefore helps to prevent two major issues such as noncompliance and missing data that are associated

with RCT (Gupta 2011). In actual clinical practice where participants are likely to be non-compliant and deviate from study protocols, ITT analysis prevents over estimation of the efficacy of an intervention by including these in its analysis instead of removing them (Wertz 1995, Heritier et al 2003). This will further enhance prognostic balance generated from the original random treatment allocation giving rise to equitable estimate of treatment effect (Wertz 1995, Heritier et al 2003). Other benefits of ITT analysis include preservation of the sample size and statistical power, because if non-respondents and drop outs are excluded from the final analysis, the sample size and consequently the statistical power might be significantly reduced (Wertz 1995, Heritier et al 2003). Fergusson et al (2002) argues that because ITT analysis is cautious in its approach and it enhances greater generalisation that it reduces a type 1 error, which is regarded as the probability of concluding that a difference between the treatment groups exists when, in fact, no difference exists i.e. false positives (Hicks 2009). In this situation, the null hypothesis would be falsely accepted.

Although ITT is widely accepted by clinicians and healthcare researchers for analysing the results of clinical trials, it has some limitations. For example, opponents of ITT analysis (Sommer & Zeger 1991, Rubin 1998) have argued that it can be too cautious and thus prone to a type II error (which is the probability of concluding that no difference between the treatment groups exists when, in fact, a difference exists i.e. false negatives). ITT limitations also include difficulty in analysing the data if the number of losses to follow-up or non-compliance is significant. However, some practical solutions have been suggested for overcoming these challenges. According to Pocock

(1983) informing study participants about the study objectives, treatment protocol and follow-up schedules will improve their cooperation and thereby reduce non-compliance and minimise loss to follow-up. Maintaining a tight follow-up regime by contacting patients at the agreed date and time will reinforce compliance and avoid drop outs. In this study, to enhance compliance and improve follow-up rate, participants were contacted at an agreed date and a more convenient time by telephone. And those that could not be reached by this method had the follow-up measures sent to them by post with a self addressed envelope included for them to complete and then return to the researcher. The use of these approaches significantly minimised loss to follow-up, and only one participant dropped out of the study after randomisation at both 8 and 12 weeks follow-up despite being contacted by phone and being sent a self addressed envelope to their address.

In practice a patient is generally allowed a maximum of 3 sessions of cortisone injection in a year (Haslock et al 1995, Saunders & Longworth 2012). Therefore, in this study where a patient has had a failed injection, such a patient was allowed a repeat dose, but the treatment data was not included in the analysis. However, data collected up to this point was recorded as part of the study analysis using ITT analysis. Participants who withdrew from the study after being randomised were included in the analysis based on ITT.

3.6.20 Plan of Analysis

All analyses will be undertaken on an intention to treat basis. The results of both outcome measures will give a difference in scores from the baseline to 8 and 12 weeks. Both the SPADI and PROMs measures are considered

continuous scales. Therefore, the data is likely to assume normality; that is the mean, median and mode will converge. It is likely they will have a unimodal, bell shape, which means skewness and kurtosis will approach zero, and 95% of the data will be accounted for within 2 standard deviations. Data was therefore analysed using an independent t-test (Field 2009). Normality was checked using the Sharipo-Wilk test since the sample size was 110. Independent t-test gives a p value indicating whether there is a statistically significant difference between the two groups for outcome measures at the pre-specified timescales (Field 2009). Statistical significance was set at 5% to detect a minimal clinically important difference of 13 points between the groups receiving lateral or posterior approach to subacromial injection. Confidence intervals were set at 95% to give an indication of the direction of clinical significance. Descriptive statistics such as mean age, gender and manual occupation were used to describe patient's baseline characteristics

3.7 Phase 2

3.8 Design: Qualitative Semi-structured Approach

Traditionally qualitative research methods derive their approach from social science and they are usually conducted in a natural setting using data from interviews, fieldnotes, audiotapes or videos (Ritchie & Lewis 2003). The emphasis on qualitative research is on capturing detail and in-depth meaning that people provide about a 'lived' experience (the real-life situation) regarding a phenomenon. The ontological position of this study was based on the premise that SAIS patients who have received subacromial injection were perceived as being competent and capable of reflecting on their situation and

providing meaningful interpretations of their experiences. The study's epistemological stance was on the premise that qualitative investigations assume that patients are active constructors of knowledge about an event or experience, therefore they have their own individual interpretation of it (Ritchie & Lewis 2003). A qualitative research approach seeks to explore the meaning (ontological position) that patients construct (epistemological) about an individual reality of a phenomenon (cortisone injection) through their lived experience (Marshall & Rossman 1999, Denzin & Lincoln 2005, Creswell 2007).

A number of qualitative methods could have been used to explore the experiences of participants with SAIS receiving subacromial injections, such as focus groups, one-to-one in-depth interviews and semi-structured interviews. Each method has its own strengths and weaknesses. While in-depth interviews and focus groups are suited to investigating perceptions and experiences of patients receiving an intervention, they require more time and resources compared to a semi-structured interview (Irvine et al 2012). Semi-structured interviews allow individuals to speak freely (Mason 2002), unrestrained by the views of others, unlike a focus group where issues such as conflict, power struggles and status difference may become a militating factor (Hollander 2004, Rubin & Rubin 2005). Unlike, the other methods, semi-structured interviews are based on a semi-structured interview guide, which is an organised presentation of questions or topics that relates to the subject matter of the interview (Dicicco-Bloom & Crabtree 2006). The choice to use a semi-structured interview was therefore based on consideration of the research objectives, the strengths of the semi-structured interview method

and the strengths and weakness of the previously mentioned techniques. Semi-structured interviews are widely accepted as the most common interview method in qualitative research (Horton et al 2004, DiCicco-Bloom & Crabtree 2006). A semi-structured interview approach is best suited to answer a research question that seeks to understand a lived experience and the sense patients make of it (Reid et al 2005). In this study, a semi-structured interview method was used because it is suited to obtaining data by telephone and it fits with normal clinical practice and pragmatic RCT. This approach led to obtaining data that enhanced the understanding of experiences of participants about their symptom relief and patient care after a subacromial injection (Mason 2002, Coombes et al 2009).

In normal practice, patients who have had shoulder injections are contacted by telephone at follow-up times to evaluate its outcomes. The qualitative telephone interviews took place after participants had participated in the quantitative study and they were linked to normal practice follow-up times. Here the focus is to gain an in-depth and interpreted understanding of individuals' experiences concerning shoulder injection in a normal clinical setting.

3.8.1 Sampling Method and Participant Selection

In qualitative research, there is flexibility in the rules regarding the size of sample needed and sample size is generally small compared to quantitative research (Morse 2000, Mason 2002). However, a number of factors can affect the number of interviews needed to achieve saturation, which is the point where very little new evidence is obtained from each individual field unit or

when nothing new is being added (Morse 2000, Mason 2002). These include the purpose of the study, the research question, the nature and scope of the researcher, number of interviews per participant, sampling procedures, and practical constraints of time and cost (Morse 2000, Mason 2002). Purposive, convenience sampling as suggested by Patton (2002) was used to identify participants from those that have participated in phase 1 of the quantitative study and have agreed to being contacted for interview. This sampling strategy is flexible and hence a positive feature of qualitative study that allows research to develop as the data is collected and analysed simultaneously (Patton 2002, Tongco 2007). Twenty potential participants, ten each from the experimental and standard treatment group were recruited by the Chief Investigator. Participants with different gender, ages and socio-economic backgrounds including negative responders to subacromial injections were selected to offer a broad understanding of the topic being studied (Patton 2002, Tongco 2007, Ritchie & Lewis 2003) and allowed maximum variation in the data that was collected (Mason 2002).

3.8.2 Recruitment Process

The recruitment process took place over a year between August 2014 and August 2015. The participants were identified from those who participated in the RCT study and who gave consent to be contacted to participate in the qualitative study. They were selected from the list of those who had complete pain relief and those who had residual symptoms after the cortisone injection. The Chief Investigator identified 10 participants from each group of the subacromial injection routes. They were contacted by telephone by the Chief Investigator to first check they were still willing to participate in an interview. If

they were, they were re-consented verbally and a date and time for the semi-structured interview concerning their experiences of the subacromial injections was arranged.

3.8.3 Data Collection Methods

In normal practice, patients who have had injection therapy are sometimes contacted by telephone to evaluate its outcomes. A semi-structured interview was used as a method of gathering data. This took the form of open-ended questions. The interview date, time and convenience were mutually agreed by the researcher and the respondents prior to the interview. The researcher conducted interviews after participants took part in the quantitative research. All interviews were conducted by telephone conversation and were centred on symptom relief, aggravation and patient care following an experience of subacromial injection (Appendix 7 for the interview guide questions). Interviewees were allowed the opportunity to give detailed accounts of their experiences with individual interviews lasting approximately 20 - 30 minutes. Interviews were Dictaphone-recorded with the consent of the interviewee and field notes were taken by the Chief Investigator following the interviews to contextualise the data (Ritchie & Spencer 1994, Mason 2000, Ritchie & Lewis 2013). All data were transcribed verbatim.

3.8.4 Development of Interview Guide and the Process

To facilitate the interview process, an interview guide was developed and the questions were centred about the research questions to ensure that important and relevant areas of the aims of the study were covered during the interview. The interview guide was used to remind the interviewer about important bits

of information to relay to the interviewee such as the purpose of the interview, what will happen to the information obtained, and any confidentiality concerns. The guide was used to assist with data generation and to allow for conversational style of discussion between the researcher and the interviewee.

The topic of discussion (that is the experiences of patients that have received the subacromial injections) was introduced by the Chief Investigator to allow for clarification and further explanation. Interviews were guided using open-ended questions to allow participants to talk interactively and freely with the interviewer (Mason 2002, Patton 2002, DiCicco-Bloom & Crabtree 2006).

3.8.5 Plan of Analysis

Data analysis took the form of the Framework Method reported by Ritchie and Lewis (2003). Data collected from qualitative methods is generally large and consists of unstructured accounts of people's experiences or the meaning they give to a particular phenomenon. In order for the researcher to provide some consistency and structure to qualitative data (interview transcripts/field notes) and yet retain the original accounts and observations of the data, the Framework approach was used (Ritchie & Lewis 2003). The choice of the framework approach was because it allows the researchers' interpretations of participants' experiences to be explicit and therefore easily accessible for clinicians, health care policy makers and funding providers (Ritchie & Lewis 2003). Furthermore, the framework method enables systematic and comprehensive coverage of the data set, and it allows flexibility of new ideas and refinements to occur at almost any stage of the qualitative analysis

(Ritchie & Lewis 2003). Although the approach involves a systematic and well-defined process of sifting, indexing and coding material according to main issues and themes, it has five stages that are interlinked (Ritchie & Spencer 1994, Ritchie & Lewis 2003). The key stages involved in framework are:

3.8.5.1 Familiarisation

This is an important foundational step in qualitative data analysis, upon which the other stages of the analysis build on (Ritchie & Lewis 2003). This process involves being up to date with the data and it entails listening to interview audio recordings, reading transcripts of interviews and studying field notes to gain an oversight of the richness, depth and diversity of the data (Ritchie & Spencer 1994, Ritchie & Lewis 2003). In my study, data (transcribed interviews) were initially analysed using a computer software package MAXQDA. The software enabled the researcher to manage, shape and make sense of unstructured information quickly and easily (Saillard 2011). During the familiarisation phase of this study, I not only listened to the audio recordings and read the interview transcripts, but also listed key issues, concepts and recurrent themes (such as pain relief, treatment efficacy and exercise prescription) that emerged as being important to the research participants. The captured data reflected the phenomena under investigation and the aims and objectives of the thesis as stated in Chapter 2.

3.8.5.2 Identifying a Conceptual Framework or Indexing

In this stage, the researcher come back to the reviewed material (notes taken during the familiarisation stage) and tries to identify the key issues and

emerging themes that enable the data to be further examined and then referenced (Ritchie & Spencer 1994). The key issues and the emerging themes expressed by the participants then form the basis of a thematic framework that is used to sift and sort the data (Ritchie & Spencer 1994). Although the researcher may have a set of priori issues, Ritchie & Lewis (2003) suggest that it is important at this stage of the analysis for key issues and emerging themes from the data to be described in language and meanings that reflect the participants' expressions. The researcher allows themes to develop from the data collected (bottom-up approach) rather than trying to fit data under already formulated core themes (top-bottom approach) (Miles & Huberman 1994). In this study, this phase involved identifying relevant portions of the data that relate to a particular theme and then numbering them systematically. This applies to all the transcripts of interview (textual) data and Ritcher & Spencer (1994) suggest that the numbering systems for the indexing references are annotated in the margin beside the text. In this study, MAXQDA was used to facilitate the indexing of the textual data.

3.8.5.3 Labelling or Tagging the Data by Themes and Subthemes

This stage involves the construction of the initial conceptual framework or indexed data by applying the indexed data to the appropriate sentences or paragraphs in the interview transcripts (raw data). The process shows which theme or concept is being mentioned or referred to within a particular section of the interview transcript. In this study, the researcher ensured that pieces of data that were lifted from their context were still clearly linked to the respondent they came from (Ritchie & Spencer 1994, Ritchie & Lewis 2003).

3.8.5.4 Creating Thematic Charts

This stage of the analytical data abstraction involves identifying common concepts or patterns across the participants' interview transcripts and grouping them into categories and charts using the thematic charts (Ritchie & Lewis 2003). This involves the building up of specific pieces of the indexed data as a whole. Data are lifted from their original textual content and placed in charts that consist of headings and subheadings that are drawn from the thematic framework (see Table 21) or from a priori research question (Ritchie & Spencer 1994:186).

3.8.5.5 Descriptive and Classification Analysis - Identifying Elements and Dimensions, Refining Categories, Classifying Data

This stage of the analysis involved unpacking, refining and categorising the contents and nature of the key themes (Ritchie & Lewis 2003). It also involved identification of a particular theme, refining of categories and assigning groups of categories to 'classes' usually at a higher level of abstraction (Ritchie & Lewis 2003).

3.8.5.6 Dimensions and Explanatory Accounts

After investigating the descriptive list, identification of specific conceptual labels or a number of associated features took place. This stage leads to the creation of new or key dimensions and themes under certain typologies. At this stage the researcher is familiar with the objectives of qualitative analysis which are "defining ideas, creating and refining categories, finding associations, creating typologies, providing explanations and developing strategies" (Ritchie & Spencer 1994:186). Following the coding of data, definition of concepts, finding associations/patterns and providing

explanations to core themes were achieved based on the research questions stated in Chapter 2 (Ritchie & Spencer 1994).

3.9 Ethical Considerations

Ethical approval to conduct the study was obtained from the National Research Ethics Committee (Ref No: 14/LO/0406 - Appendix 11). Since the study involved NHS patients in a non-NHS setting, ethical approval was also sought from the non-NHS Research Consortium (14/LO/0849 - Appendix 12).

My academic supervisor, a statistician, a steering group for the research project (Senior physiotherapists, ESPs and Administrative staff) and a Patient Participation Group (from a local GP practice) were involved in the development of the research proposal. The National Lead (a more senior clinician) of the Community Musculoskeletal Service also peer reviewed the research proposal.

The three principles, described by Ford and Reutter (1990), namely autonomy, benefits of the research and potential risks of participation were adopted for this study. Also the current NHS Research Ethics Committee Guidelines (Integrated Research Application System [IRAS 2013]) were used.

3.9.1 Inclusion / Exclusion Criteria

The inclusion criteria for the study involved adults 18 years and above, who fulfilled the eligibility criteria for subacromial impingement syndrome, who gave consent and are eligible for shoulder injection. The exclusion criteria will

be contrary - vice versa. The criteria did not discriminate against any particular groups of individuals.

3.9.2 Recruitment

When the first musculoskeletal appointment was posted to the patient, a separate envelope containing a letter of invitation to take part in the study was also sent. The invitation pack contained a letter of invitation with a Patient Information Sheet and two consent forms (for the quantitative part and qualitative interview) (Appendix 3 and 4). The invitation pack was posted at least 48 hours before they were due to attend their first musculoskeletal appointment to allow participants to decide whether or not to take part in the study. Participants who were interested in taking part in the study but had further questions were encouraged to contact the researcher through a study mobile number or postal address. These contact details were provided in the patient information sheet. On arriving for their first musculoskeletal appointment, participants who provided written informed consent and fulfilled the eligibility criteria for the study after being screened by the assessing ESP were recruited into the study.

3.9.3 Consent

Participants were given the opportunity to determine if they want to participate in the study or not. The letter of invitation with a PIS and the consent forms (for the quantitative part and qualitative interview) were provided before the research to allow participants adequate time to reflect on their content, prior to giving consent. The PIS stated clearly the purpose and nature of the research along with any potential risks and benefits and that participation is

voluntary. In the PIS, it is clearly stated that participants were free to withdraw from the study at any time. When participants attended their first musculoskeletal appointment and if they agreed to participate in the study, consent was obtained by ESPs 1 & 2. They were informed through the PIS that they would be contacted by telephone by the Chief Investigator for the qualitative interview. This was to first check that they were still willing i.e. re-consent them verbally and to arrange a date and time for the semi-structured interview.

Participants had the capacity to give informed consent based on the Mental Capacity Act (2005). It was made clear at the consent interview that failure to provide consent or withdrawal of consent without giving a reason will not affect the treatment that they will receive. Participants were informed that should they withdraw from the trial prior to its completion; the data collected up to that point would be used in the analysis. The patient's GP was informed via a letter of their patient's participation in the study, after obtaining consent from the participant to do this (Appendix 13).

Participants were asked to read the PIS before attending their first musculoskeletal appointment when they had the opportunity to ask questions if they wished to participate and they were then asked to sign the consent forms. Participants who were interested in taking part in the study but had further questions were encouraged to contact the Chief Investigator. A variety of contact methods were provided on the patient information sheet including a study mobile number or postal address. The injecting ESP checked that the consent forms had been accurately completed by the

participants and were valid before accepting them to the study. This information was later scanned into the patient's medical records.

3.9.4 Risks, Burdens and Benefits

There are no additional risks involved besides those that could routinely possibly be related to the treatment, such as minor bleeding, pain and changes in skin colour. The ethics committees were informed that all side effects would be managed by normal clinical procedure by the service manager, the service clinical lead and the local clinical governance group.

Participants were informed prior to the study, through the information sheet, that serious side effects are not commonly reported with subacromial injections, however, when they do occur, their effects are normally mild and temporary (Kumar & Newman 1999, Penning et al 2012). For example, only 2 - 10 in every 100 patients having cortisone injection will experience post injection flare of pain; and only 1:17000 - 77000 patients will report joint sepsis (Kumar & Newman 1999). Other rare side effects include skin depigmentation, erythema, bruising and tendon rupture.

Participants were informed that their GP would be informed of their participation in the study and after obtaining consent from them to do so, the patient's GP was informed via a letter of their patient's participation in the study. If a participant is feeling distressed or uncomfortable during the trial, they were advised to consult their GP and were excluded from the study, but any data collected up to that point was included in the analysis.

Participants were informed that there are not any direct personal benefits to them taking part in this study. However, the information derived from the study would help clinicians to know which of the two shoulder injection methods (from either the side or the back) is better in treating patients with shoulder pain in the future. Participants were informed that they will be offered shoulder injection from either the side or back of their shoulder.

3.9.5 Participants Rights, Safety and Well-being

Participants were informed prior to the study, through the information sheet, that serious side effects are not commonly reported with subacromial injections, however, when they do occur, their effects are normally mild and temporary (Kumar & Newman 1999, Penning et al 2012). In this study, no major adverse event occurred, besides those that could routinely possibly be related to the treatment, such as minor bleeding, pain and changes in skin colour.

3.9.6 Confidentiality

Participants' records were stored and handled in accordance with the Data Protection Act (1998) and all the information collected about participants as part of this study was handled in confidence. Only those involved in their care knew if they participated in the study. Anonymised aggregated findings from both aspects of the research were made available to my academic supervisor – but they did not contain any personal details that would identify participants, for example, name and home address. All participant details, as well as their comments, were kept secured and confidential in a locked cabinet (with controlled access) and on a password protected computer to which only the

researcher had access. Any information provided to the Chief Investigator was anonymised using pseudonyms and unique identifying numbers so that it was not possible to identify the patient. Dictaphone recordings of interviews were destroyed once they had been transcribed and transcripts were stored in a locked cabinet (with controlled access) and on a password protected computer.

3.9.7 Conflict of Interest

This area was considered and there was no conflict of interest. A summary of the research findings would be made available to any participants who requested one.

3.10 Input of Service Users to the Research

The involvement of patients and members of the public in research has been shown to lead to better research, clearer outcomes, and faster uptake of new evidence (National Institute for Health Research (2013). During the planning stage of this study, services users, administrative staff and ESPs were involved as part of the project steering group to look at ways to improve the study. Service users were identified through the local public participation group linked to the GP practice located at the service where the study took place. Engagement with service users was through their coordinator located at the GP practice. They were provided with copies of the patient information sheet, consent forms and a sample of the qualitative interview questions and were asked to make suggestions on ways to improve these documents, including their format and details. Following this, some changes were made to

the wording of these documents including re-phrasing of the interview questions.

3.11 Chapter Summary

This chapter has described the methodology used for this research including the research objectives and hypothesis, design of both the quantitative and qualitative aspects, methods of data collection and analysis. In chapter 4, the results of both the quantitative and qualitative study are presented.

CHAPTER 4 RESULTS

4.1 Introduction

This chapter will present the results of the quantitative analysis and the semi-structured interviews. The quantitative aspect will present the sample size, normality testing, statistical tests, effect size, the flow of participants through the study, and results from the completed primary outcome measures namely the PROMs and SPADI. Depending on whether these outcomes were normally distributed or not, they were analysed using either a parametric test such as a t-test or a non parametric test such as a Mann Whitney test. The results include the between group baseline analysis, time change of between group differences and the graphs of their means, change over time of within and between group differences. Finally an explorative multiple regression test was used to evaluate the contribution of the participant's baseline data to the outcome measures.

In section 1, the results of the quantitative analysis will be reported and section 2 will concentrate on the results of the qualitative semi-structured interviews. The qualitative phase will discuss the results of the semi-structured interviews which were conducted with participants who participated in phase 1 of the quantitative study and agreed to be interviewed. This section will include the demographics of the participants and the interview themes.

4.2 Section 1: Quantitative Analysis

4.2.1 Sample Size Calculation

Sample size was estimated based on a previous shoulder pain study (Ekeberg et al 2009) that estimated the standard deviation (SD) of change in SPADI to be 20 points, the power level was set at 90% and statistical significance at 5% to detect a minimum clinically important difference (MCID) of 13 points. Using these figures a sample size of 100 was estimated. To account for a 10% rate of loss at follow-up 110 participants was needed for the study. However, only 80 participants were actually recruited into this study because of some difficulties such as shortage of staff with the service and English language barriers to ethnic minorities. By recruiting 80 participants with the statistical significance set at 5% to detect a MCID at 13 points, with SD of 20 points, a power of 87% was achieved by this study. This shows that a sample of 80 participants, with only 1 lost to follow-up was adequately powered (87%) to show a statistically significant difference because a power of 80% - 90% is usually considered adequate (Murray 1991) and previous shoulder studies (Mclnerney et al 2003, Ekeberg et al 2009) have used a similar figure.

4.2.2 Tests of Normality

The variables PROMs and SPADI scores were continuous data, however not all of them were normally distributed. Normality was checked using measures of central tendency and dispersion (such as the mean, median, mode, and standard deviation [SD]), histograms, PP plots, and estimates of kurtosis and skewness. Normality was also checked using the Sharipo-Wilk test because the sample size was 80. Both measures of central tendency and dispersion of

the PROMs and SPADI scores were checked if they closely converged and their estimates of kurtosis and skewness approached zero and they had a low standard deviation. The PP plots of both measures were checked if they showed similar variance above and below the diagonal line suggesting that these data could be normally distributed or approaching normality. Also the histograms of these measures were examined if they did 'fit' into a bell shape curve. The results of the Shapiro Wilk test were examined and if the measures were not statistically significantly different from a normal distribution at 0.05, this could indicate that the variables were normally distributed. On balance of probability after using all the above assumptions of parametric tests, I concluded that the all the baseline variables were "reasonably normally" distributed as parametric statistics are reasonably robust to minor deviations from normality. The baseline mean duration of symptom variable was not normally distributed therefore it was tested using a Mann Whitney test. The PROMs and SPADI scores both at 8 and 12 weeks were not normally distributed and were analysed using Mann-Whitney tests. The change over time of the outcomes from week 0 to 8, week 0 to 12 and week 8 to 12 were normally distributed, therefore they were analysed using independent t-tests. See Appendices 14 – 17 for details of how normality was decided. Chi square (χ^2) was used for dichotomous and nominal variables such as groups of age, gender, symptom duration, manual occupation, dominant side affected, previous cortisone treatment and current treatment.

4.2.3 Statistical Tests

Data were analysed according to the principle of intention to treat using last observation carried forward and the hypothesis test was two tailed with a level

of significance set at 5%. The reasonably normally distributed variables were all analysed using independent t-tests. The independent t-test gives a p value indicating whether there is a statistically significant difference between the two groups (lateral and posterior approaches) for outcome measures at the pre specified timescales (0, 8 and 12 weeks). A paired t-test for paired samples was used to check the within group difference for each of the groups (lateral and posterior) for change in scores. Conversely those variables that were not normally distributed such as symptom of duration at baseline, the PROMs and SPADI scores both at 8 and 12 weeks were analysed with Mann-Whitney test for 2 independent samples (Field 2009). The Mann-Whitney test gives a p value indicating whether there is a statistically significant difference between the two groups (lateral and posterior approaches) for outcome measures at the pre specified timescales (0, 8 and 12 weeks) (Field 2009).

4.2.4 Effect Size

Effect size (symbol = r) tells us the strength of the mean difference between two groups (Coe 2002, Ken & Kristopher 2012) for example the mean difference of PROMs day time pain of the lateral and posterior groups. Effect size is important in estimating and reporting the effectiveness of an intervention against the control, hence it is a measure of clinical significance (Ken & Kristopher 2012. A statistic called Eta-squared (η^2) is one means of calculating effect size (Hicks 2009). Cohen (1992) defines eta squared value of 0.01 as indicating a small clinical effect, a value of 0.06 as a moderate clinical effect and a value of 0.14 as a large effect. This means that the strength is larger as it approaches the value 1. In this study, the eta squared for independent t test of the change over time of the within and between

groups difference of the lateral and posterior groups from week 0 to 8, week 0 to 12 and week 8 to 12 are reported. Within groups, eta squared for paired t test compares the means of the same group on two occasions - between time 1 and time 2 (Coe 2002).

4.2.5 Study Participants – Flow through the Study

Participants were recruited into this study between September 2014 and August 2015. Eighty participants who had a diagnosis of SAIS and fulfilled the study's eligibility criteria were recruited into this study, 41 (51.2%) to the lateral group and 39 (48.8%) to the posterior group (see Table 11). However, 101 participants with shoulder pain were approached for the study, but 21 were excluded. Among those excluded from the study, 10 did not have a diagnosis of SAIS, 2 did not fulfill the injection eligibility criteria and 9 refused to participate in the study. Therefore a total of 80 participants were recruited into the study.

Table 11: Number of Patients Recruited into the Study

Participants	Lateral Group	Posterior Group	Totals
Male	20	19	39
Female	21	20	41
Totals	41	39	80

One participant was lost to follow up at 8 and 12 weeks because they could not be reached by phone and postal communication. Two participants were lost to follow up at 12 weeks because they could not be reached by phone and postal communication. However, the data were analysed based on intention to treat analysis using last observation carried forward. Two participants were referred to secondary care after 8 weeks' follow-up

assessment because of failed injection and worsening of their symptoms. Three participants were further investigated with MRI scan and then referred to secondary care after 8 weeks' follow-up assessment because the cortisone injection and other conservative treatments such as physiotherapy were unsuccessful. Figure 8 in the next shows the flow of participants through the study.

Baseline demographics included age, gender, duration of symptoms, manual occupation, dominant side affected, previous cortisone treatment, current treatment. The main outcome measures were the PROMs and SPADI. Both measures were administered at baseline and at 8 and 12 weeks' follow-ups. Participants recorded their responses on each item on the basis of current symptoms. Day time pain and night time pain were measured using the PROMs. Table 12 shows the baseline characteristics of the study sample. From Table 12 (in page 154), the lateral and posterior groups at baseline were similar with respect to age, gender, duration of symptoms, manual occupation, dominant side affected, previous cortisone treatment and current drug treatment. Both groups were also similar for initial SPADI and PROMs at baseline. There was no statistically significant difference between the means of both groups at baseline which meant they were similar at baseline and the process of randomisation was robust.

Figure 8: Flow Diagram Showing Flow of the Patient through the Trial

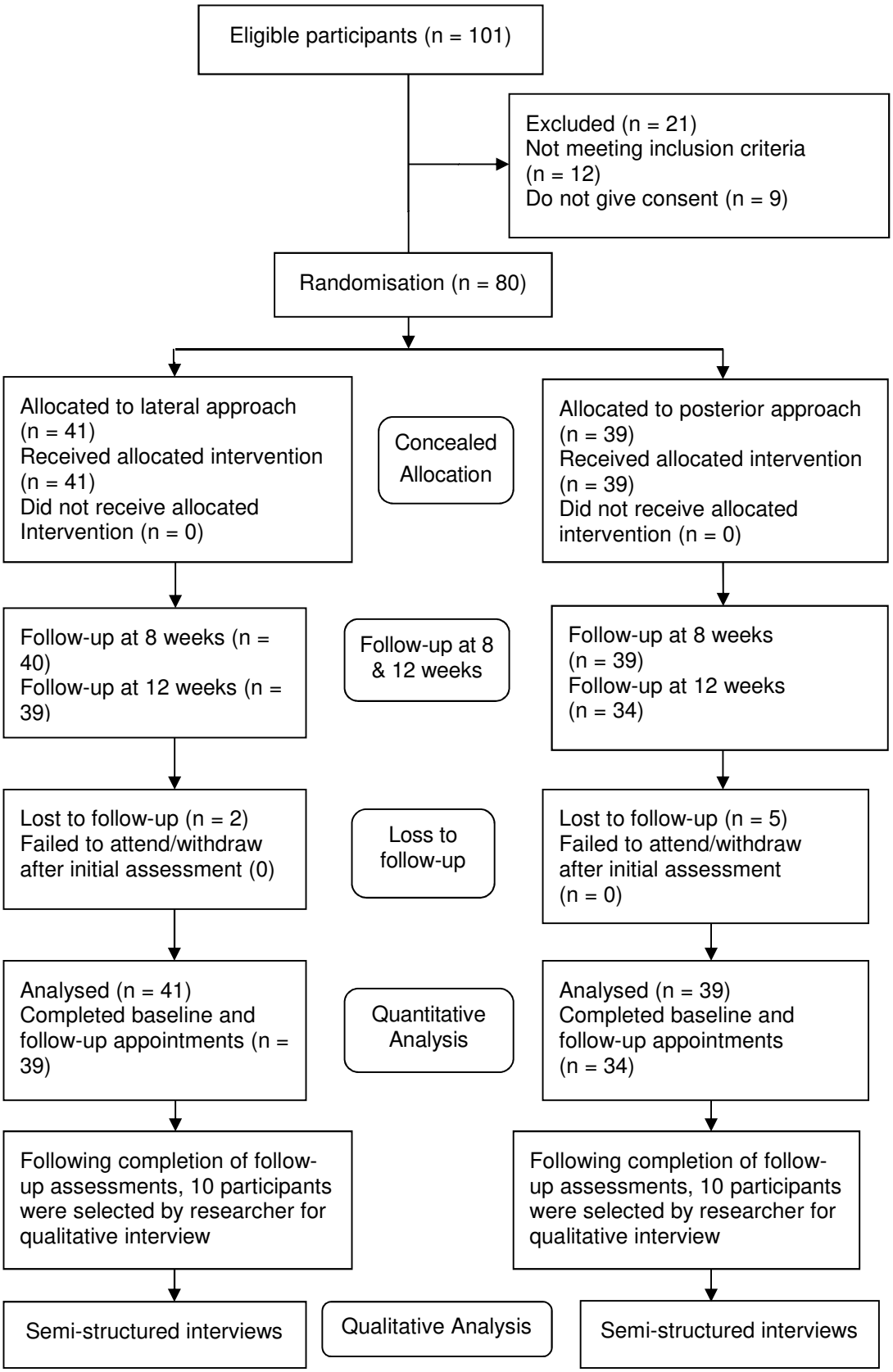


Table 12: Baseline Characteristics according to Groups

Values are numbers (percentages) unless stated otherwise

Characteristic	Lateral Group (n= 41)	Posterior Group (n = 39)	P value
Mean (SD) Age (years)	54.6 (12.6)	56.2 (11.7)	0.578
18 - 40[a]	6 (14.6)	5 (12.8)	0.743
41 - 65[a]	24 (58.5)	26 (66.7)	
65+[a]	11 (26.8)	8 (20.5)	
Gender (*a*)			
Male	20 (48.8)	19 (48.7)	0.996
Female	21 (51.2)	20 (51.3)	
Mean (SD) Symptom duration (weeks) ([b])	40.9 (61.6)	36.4 (40.2)	0.429
0 - 12([a])	13 (31.8)	10 (25.7)	0.366
13 - 26([a])	15 (36.5)	11 (28.2)	
26+([a])	13 (31.7)	18 (46.2)	
Manual occupation ([a])			
Yes	16 (31.0)	18 (46.2)	0.519
No	25 (69.0)	21 (53.8)	
Dominant side affected([a])			
Yes	25 (69.0)	23 (59.0)	0.855
No	16 (31.0)	16 (41.0)	
Previous cortisone treatment([a])			
Yes	10 (24.4)	15 (38.5)	0.175
No	31 (75.6)	24 (61.5)	
Current treatment([a])			
Analgesia	25 (61.0)	27 (69.2)	0.263
NSAIDs	10 (24.4)	8 (20.5)	
None	6 (14.6)	4 (10.3)	
Mean (SD) Initial PROMs Score			
Day time pain (SD)	7.1 (2.1)	6.2 (2.0)	0.059
Night time pain (SD)	6.8 (2.4)	6.3 (2.5)	0.345
Function affected (SD)	2.8 (1.1)	2.7 (1.1)	0.732
Mean (SD) Initial SPADI Score	81.6 (25.1)	80.3 (27.6)	0.829

Keys: a = p values of Chi square χ^2tests; b = p value of a Mann-Whitney test; where there is no symbol the number represents a p value of an independent t - test.

4.2.6 Between Group Differences at baseline, week 8 and week 12

4.2.6.1 PROMs SCORES

Day Time Pain

Table 13 shows the results of an independent t-test that compared the mean change scores of day time pain between the lateral (n=41) and posterior groups (n=39).

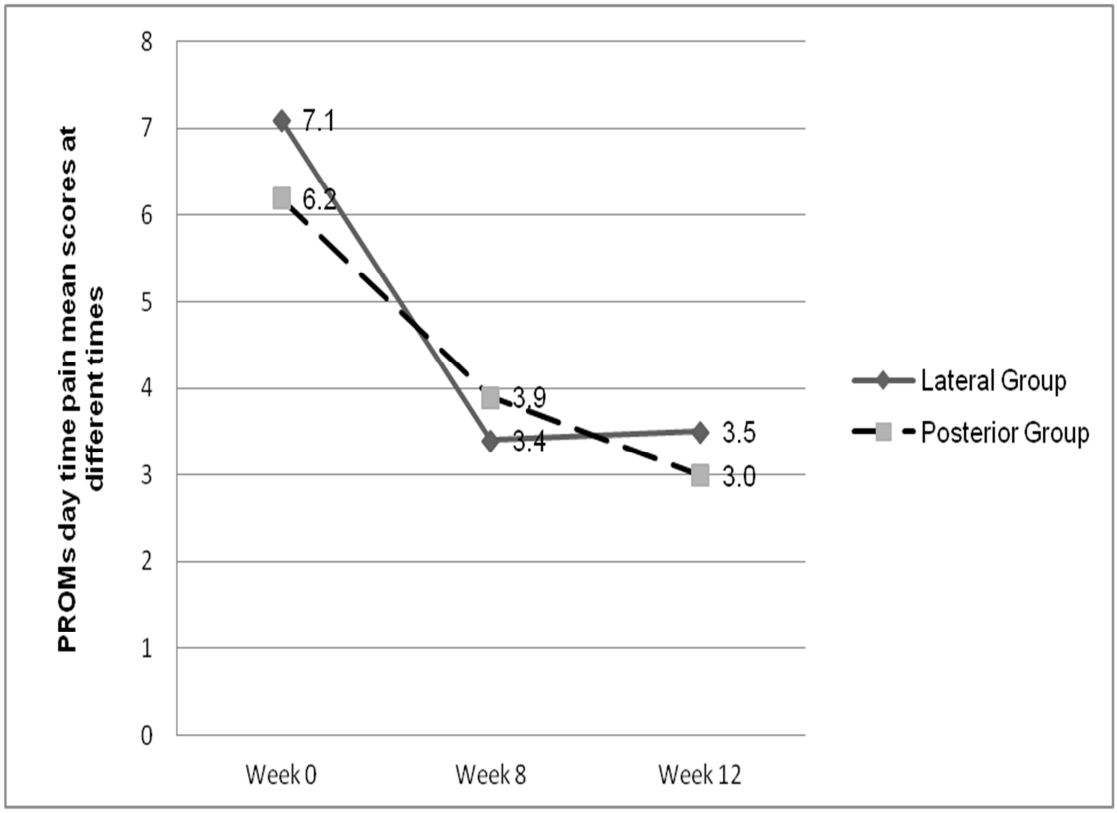
Table 13: Results of PROMs and SPADI Scores of Between Group Differences at Baseline, Week 8 and Week 12

	Lateral Group	**Posterior Group**		
	Mean score	Mean score	Mean difference (95% CI)	Mann-Whitney tests (p - value)
PROMs:				
Day time pain				
Week 0	7.1	6.2	0.9 (-0.0 to 1.8)	0.059[a]
Week 8	3.4	3.9	-0.5 (-1.8 to 0.8)	0.386
Week 12	3.5	3.0	0.5 (-0.9 to 1.8)	0.590
Night time pain				
Week 0	6.8	6.3	0.5 (-0.6 to 1.6)	0.319
Week 8	3.8	4.3	-0.5 (-1.9 to 1.0)	0.470
Week 12	4.1	3.8	0.3 (-1.3 to 2.0)	0.787
Shoulder function				
Week 0	2.8	2.7	0.1 (-0.4 to 0.5)	0.643
Week 8	1.6	1.7	-0.2 (-0.8 to 0.4)	0.497
Week 12	1.8	1.3	0.6 (-0.1 to 1.2)	0.089
SPADI				
Week 0	81.6	80.6	1.3(-10.5 to 13.0)	0.878
Week 8	47.7	49.1	-1.4(-17.4 to 14.6)	0.862
Week 12	50.1	41.1	8.9 (-9.0 to 26.9)	0.324

Key: a = p value of independent t-test

There was no statistically significant difference between the groups at baseline (p = 0.059). Using a Mann-Whitney test there was no statistically significant difference between the groups at week 8 (p = 0.386) and week 12 follow up (p = 0.590). However, both groups demonstrated improvement from baseline of 3.4 (at week 8) and 3.5 (at week 12) for the lateral group and 3.9 (at week 8) and 3.0 (at week 12) for the posterior group. At 12 weeks the posterior group showed better improvement compared with the lateral group, however this was not statistically significant. See Figure 9 for a graphical display of the results.

Figure 9: Line plot of PROMs day time pain mean scores of lateral and posterior group at different times

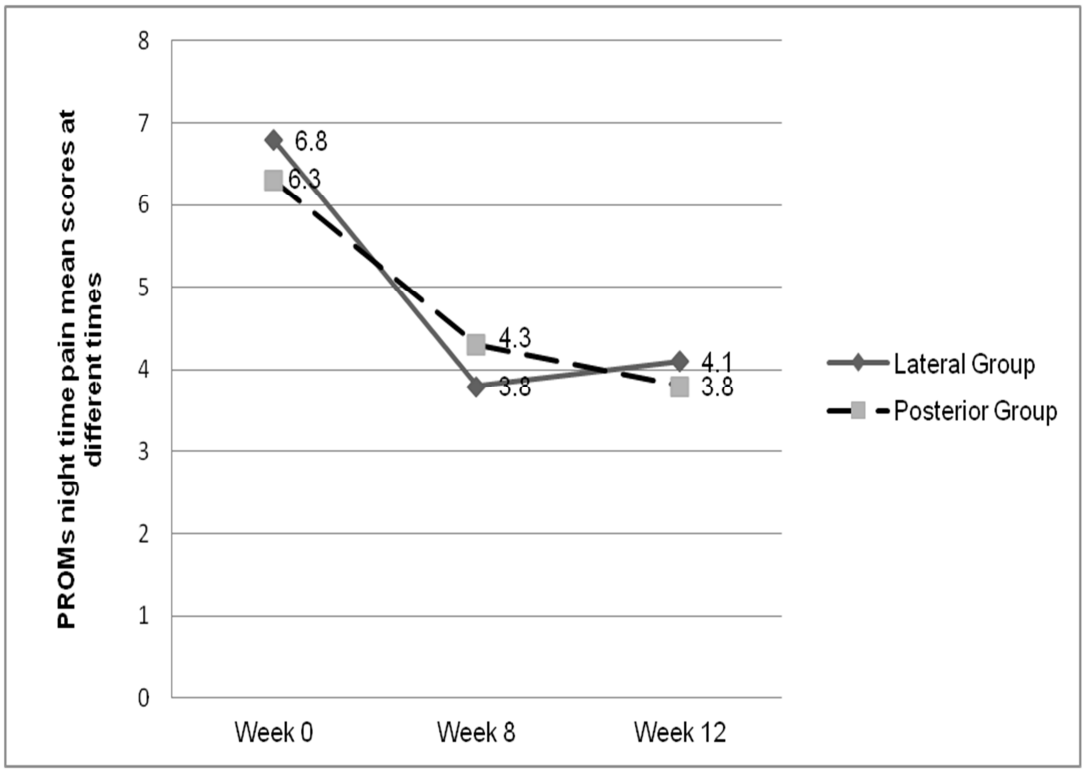


Night Time Pain

Table 13 shows the results of an independent-sample Mann-Whitney U test that compared the mean scores of night pain time between the lateral (n=41)

and posterior groups (n=39) at baseline, 8 and 12 weeks. There was no significant difference between the groups at baseline (p = 0.319), week 8 (p = 0.470) and week 12 (p = 0.787). However, both groups demonstrated improvement from baseline of 3.8 (at week 8) and 4.1 (at week 12) for the lateral group and 4.3 (at week 8) and 3.8 (at week 12) for the posterior group. See Figure 10 for a graphical display of the results.

Figure 10: Line plot of PROMs night time pain mean scores of lateral and posterior group at different times

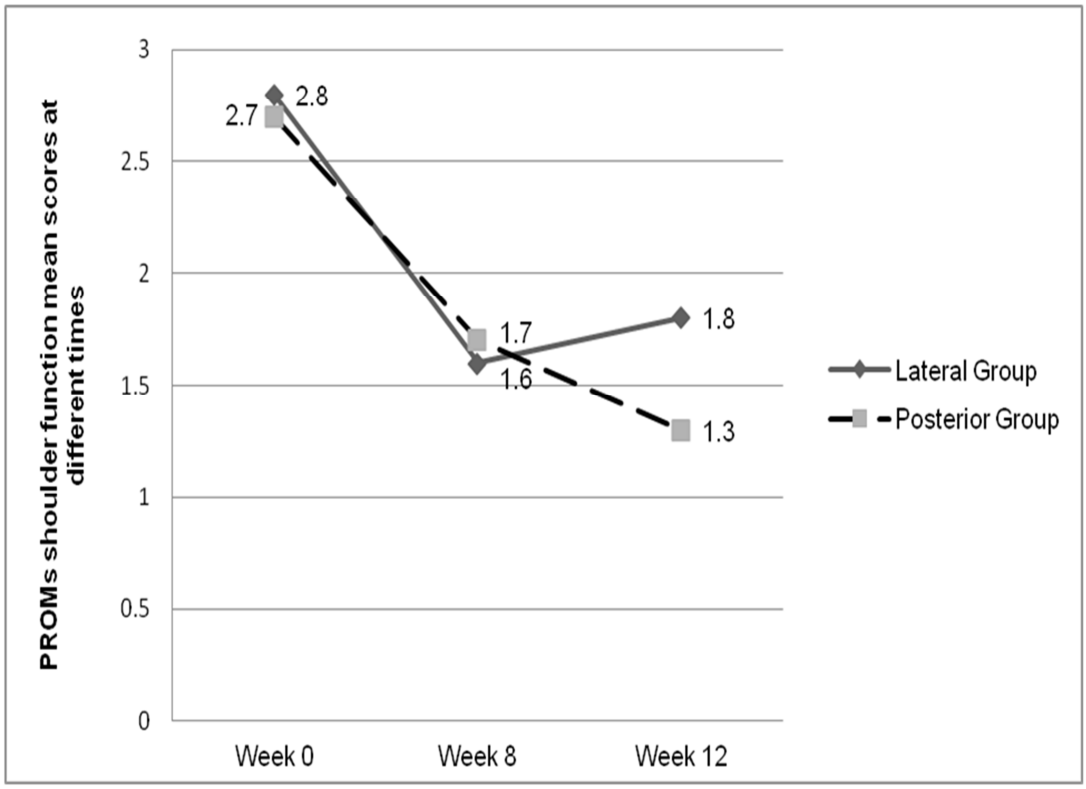


Shoulder function

Table 13 shows the results of an independent-sample Mann-Whitney U test that compared the change scores of shoulder function between the lateral (n=41) and posterior groups (n=39) at baseline, 8 and 12 weeks. There was no significant difference between the groups at baseline (p = 0.643), week 8 (p = 0.497) and week 12 (p = 0.089), although both groups demonstrated improvement from baseline of 1.6 (at week 8) and 1.8 (at week 12) for the

lateral group and 1.7 (at week 8) and 1.3 (at week 12) for the posterior group. The posterior group improved better at 12 weeks compared to the lateral group, but it was not statistically significant. See Figure 11 for a graphical display of the results.

Figure 11: Line plot of PROMs shoulder function mean scores of lateral and posterior group at different times

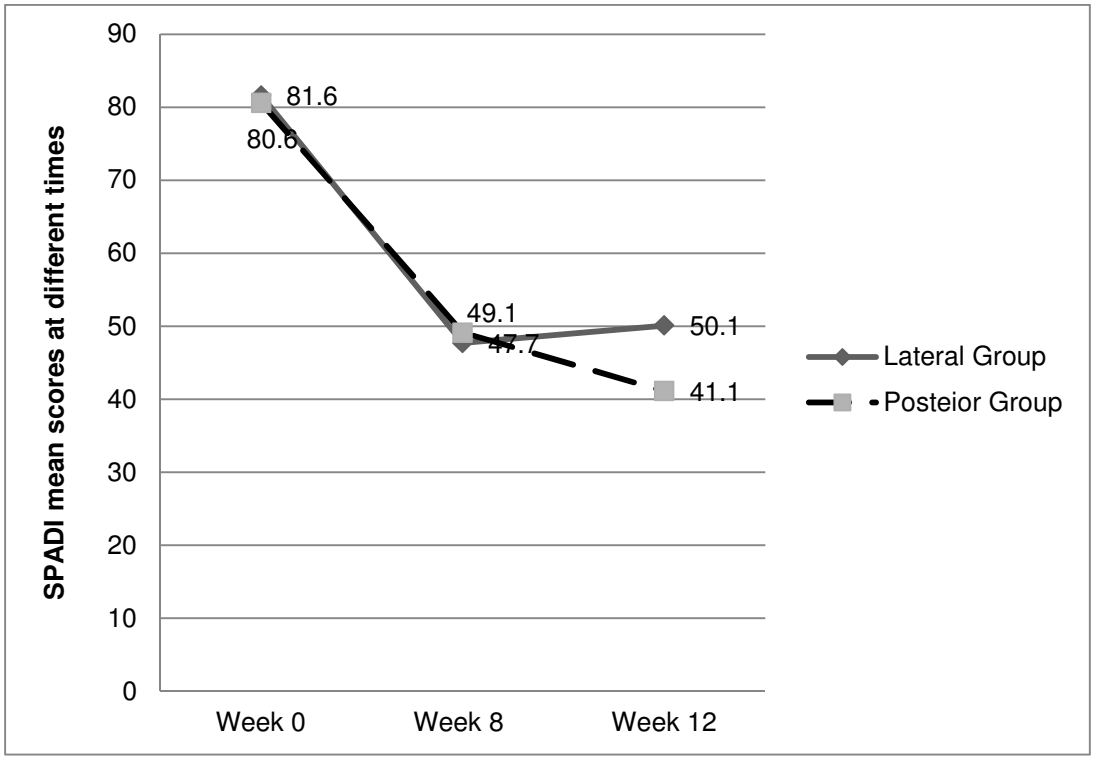


4.2.6.2 SPADI SCORES

Table 13 shows the results of an independent-sample Mann-Whitney U test that compared the SPADI change scores between the lateral (n=41) and posterior groups (n=39) at baseline, 8 and 12 weeks. There was no significant difference between the groups at baseline (p = 0.878), week 8 (p = 0.862) and week 12 (p = 0.324), although both groups demonstrated improvement from baseline of 47.7 (at week 8) and 50.2 (at week 12) for the

lateral group and 49.1 (at week 8) and 41.1 (at week 12) for the posterior group. See Figure 12 for a graphical display of the results.

Figure 12: Line plot of SPADI mean scores of lateral and posterior group at different times



4.2.7 Within Group Difference of Change over Time from week 0 to 8, week 0 to 12 and week 8 to 12

4.2.7.1 PROMs SCORES

Day Time Pain

Table 14 presents the results of a paired t-test that compared the change over time of day time pain scores within the lateral (n=41) and posterior groups (n=39) between 0 to 8 weeks, 0 to 12 weeks and 8 to 12 weeks. Within the lateral group, there was a statistically significant difference in day time pain between week 0 to 8 (mean difference = 3.7, SD = 2.6, p = 0.000, eta squared = 0.675) and week 0 to 12 (mean difference = 3.6, SD = 3.2, p = 0.000, eta squared = 0.567). The effect sizes of the differences in the means

between week 0 to 8 (mean difference = 3.7, 95% CI: 2.9 to 4.5) and week 0 to 12 (mean difference = 3.6, 95% CI: 2.6 to 4.7) were large (eta squared = 0.675 and 0.567) respectively.

Within the posterior group, there was a statistically significant difference in day time pain between week 0 to 8 (mean difference = 2.3, SD = 2.6, p = 0.000, eta squared = 0.441) and week 0 to 12 (mean difference = 3.0, SD = 2.9, p = 0.000, eta squared = 0.535). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 2.3, 95% CI: 1.5 to 3.2) and week 0 to 12 (mean difference = 3.0, 95% CI: 2.0 to 4.0) were large (eta squared = 0.441 and 0.535) respectively.

There was no statistically significant difference within the lateral (mean difference = - 0.2, SD = 2.3, p = 0.626, eta squared = 0.006 and posterior groups (mean difference = 0.6, SD = 2.5, p = 0.135, eta squared = 0.441) between week 8 to 12.

Table 14: Results of PROMs and SPADI Within Group Change over Time between 0 - 8 weeks, 0 - 12 weeks and 8 - 12 weeks using Paired t-test

	Lateral Group (n = 41)				Posterior Group (n =39)			
Measure	Mean change (SD)	(95% CI)	Eta squared	p - value	Mean change (SD)	(95% CI)	Eta squared	p - value
PROMs:								
Day time pain								
0 - 8 weeks	3.7(2.6)	(2.9 to 4.5)	0.675	0.000	2.3 (2.6)	(1.5 to 3.2)	0.441	0.000[a]
0 - 12 weeks	3.6 (3.2)	(2.6 to 4.7)	0.567	0.000	3.0 (2.9)	(2.0 to 4.0)	0.535	0.000[a]
8 - 12 weeks	-0.1 (2.3)	(-0.9 to 0.6)	0.006	0.626	0.9 (2.5)	(-0.2 to 1.5)	0.063	0.135
Night time pain								
0 - 8 weeks	3.1 (3.5)	(2.0 to 4.2)	0.443	0.000	2.1 (3.1)	(1.0 to 3.1)	0.306	0.000[a]
0 - 12 weeks	2.7 (4.0)	(1.5 to 4.0)	0.329	0.000	2.7 (3.7)	(1.4 to 4.0)	0.350	0.000[a]
8 - 12 weeks	-0.4 (2.4)	(-1.2 to 0.3)	0.031	0.267	0.2 (2.0)	(-0.5 to 0.9)	0.009	0.561
Shoulder function								
0 - 8 weeks	1.3 (1.3)	(0.9 to 1.7)	0.512	0.000	1.0 (1.3)	(0.6 to 1.4)	0.367	0.000[a]
0 - 12 weeks	1.0 (1.5)	(0.5 to 1.5)	0.321	0.000	1.4 (1.4)	(0.9 to 1.9)	0.484	0.000[a]
8 - 12 weeks	-0.2 (0.1)	(-0.6 to 0.1)	0.063	0.130	0.4 (0.8)	(0.1 to 0.7)	0.160	0.016[a]
SPADI								
0 - 8 weeks	34.0 (31.3)	(24.0 to 44.0)	0.580	0.000	31.3 (30.8)	(21.2 to 41.0)	0.506	0.000[a]
0 - 12 weeks	30.6 (34.7)	(19.3 to 41.2)	0.448	0.000	41.3 (35.4)	(28.7 to 53.9)	0.583	0.000[a]
8 - 12 weeks	-3.8 (22.7)	(-11.2 to 3.5)	0.025	0.299	6.3 (22.3)	(-1.6 to 14.2)	0.074	0.115

Key: a = $p < 0.05$

Night Time Pain

Table 14 presents the results of a paired t-test that compared the change over time of night time pain scores within the lateral (n=41) and posterior groups (n=39) between 0 to 8 weeks, 0 to 12 weeks and 8 to 12 weeks.

Within the lateral group, there was a statistically significant difference in night time pain between week 0 to 8 (mean difference = 3.1, SD = 3.5, p = 0.000, eta squared = 0.443) and week 0 to 12 (mean difference = 2.7, SD = 4.0, p = 0.000, eta squared = 0.329). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 3.1, 95% CI: 2.0 to 4.2) and week 0 to 12 (mean difference = 2.7, 95% CI: 1.5 to 4.0) were large (eta squared = 0.443 and 0.329) respectively.

Within the posterior group, there was a statistically significant difference in night time pain between week 0 to 8 (mean difference = 2.1, SD = 3.1, p = 0.000, eta squared = 0.306) and week 0 to 12 (mean difference = 2.7, SD = 3.7, p = 0.000, eta squared = 0.350). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 2.1, 95% CI: 1.0 to 3.1) and week 0 to 12 (mean difference = 2.7, 95% CI: 1.4 to 4.0) were large (eta squared = 0.306 and 0.350) respectively.

There was no statistically significant difference within the lateral (mean difference = - 0.4, SD = 2.4, p = 0.267, eta squared = 0.031 and posterior groups (mean difference = 0.2, SD = 2.0, p = 0.561, eta squared = 0.009) from week 8 to 12.

Shoulder function

Table 14 presents the results of a paired t-test that compared the change over time of shoulder function scores within the lateral (n=41) and posterior groups (n=39) between 0 to 8 weeks, 0 to 12 weeks and 8 to 12 weeks.

Within the lateral group, there was a statistically significant difference in shoulder function between week 0 to 8 (mean difference = 1.3, SD = 1.3, p = 0.000, eta squared = 0.512) and week 0 to 12 (mean difference = 1.0, SD = 1.5, p = 0.000, eta squared = 0.321). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 1.3, 95% CI: 0.9 to 1.7) and week 0 to 12 (mean difference = 1.0, 95% CI: 0.5 to 1.5) were large (eta squared = 0.512 and 0.321) respectively. Between week 8 to 12, there was no statistically significant difference (mean difference = - 0.2, SD = 0.1, p = 0.130, eta squared = 0.063.

Within the posterior group, there was a statistically significant difference in shoulder function between week 0 to 8 (mean difference = 1.0, SD = 1.3, p = 0.000, eta squared = 0.367) and week 0 to 12 (mean difference = 1.4, SD = 1.4, p = 0.000, eta squared = 0.484). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 1.0, 95% CI: 0.6 to 1.4) and week 0 to 12 (mean difference = 1.4, 95% CI: 0.9 to 1.9) were large (eta squared = 0.367 and 0.484) respectively. Between week 8 and 12, there was also a statistically significant difference in shoulder function (mean difference = 0.4, SD = 0.8, p = 0.016, eta squared = 0.160). The effect of the differences in the means (mean difference = 0.4, 95% CI: 0.1 to 0.7) was moderate (eta squared = 0.160).

4.2.7.2 SPADI SCORES

Table 14 presents the results of a paired t-test that compared the change over time of SPADI scores within the lateral (n=41) and posterior groups (n=39) between 0 to 8 weeks, 0 to 12 weeks and 8 to 12 weeks.

Within the lateral group, there was a statistically significant difference in the SPADI scores between week 0 to 8 (mean difference = 34.0, SD = 31.1, p = 0.000, eta squared = 0.580) and week 0 to 12 (mean difference = 30.6, SD = 34.7, p = 0.000, eta squared = 0.448). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 34.0, 95% CI: 24.0 to 44.0) and week 0 to 12 (mean difference = 30.6, 95% CI: 19.3 to 41.2) were large (eta squared = 0.580 and 0.448) respectively.

Within the posterior group, there was a statistically significant difference in the SPADI score between week 0 to 8 (mean difference = 31.3, SD = 30.8, p = 0.000, eta squared = 0.506) and week 0 to 12 (mean difference = 41.3, SD = 35.4, p = 0.000, eta squared = 0.583). The effect sizes of the differences in the means between week 0 to 8 (mean difference = 31.3, 95% CI: 21.2 to 41.0) and week 0 to 12 (mean difference = 41.3, 95% CI: 28.7 to 53.9) were large (eta squared = 0.506 and 0.583) respectively.

There was no statistically significant difference within the lateral (mean difference = - 3.8, SD = 22.7, p = 0.299, eta squared = 0.025 and posterior groups (mean difference = 6.3, SD = 22.3, p = 0.115, eta squared = 0.074) between week 8 to 12.

4.2.8 Between Group Differences in Change over Time from week 0 to 8, week 0 to 12 and week 8 to 12 using an Independent t-tests on Change Scores

4.2.8.1 PROMs SCORES

Day Time Pain

Table 15 shows the results of an independent t-test that compared the mean change scores of day time pain between the lateral (n=41) and posterior groups (n=39) between week 0 to 8, week 0 to 12 and week 8 to 12. Since Levene's test was not significant ($p > 0.05$) the first row of the independent t-test output was used. At baseline and 8 week follow up there was a statistically significant difference in day time pain score in favour of the lateral group, with the lateral group showing an improvement of (mean = 3.7) compared with the improvement in the posterior group of (mean = 2.3). The mean difference between the groups for the improvement in day time pain score was 1.4 points (95% CI 0.3 to 2.6, $p = 0.018$) with a medium effect size of 0.071. There was no statistically significant difference between the two groups from week 0 to 12 ($p = 0.415$) and week 8 to 12 ($p = 0.141$) (see Table 15).

Night Time Pain

There was no statistically significant difference between the two groups between week 0 to 8 ($p = 0.174$), week 0 to 12 ($p = 0.914$) and week 8 to 12 ($p = 0.228$) (Table 15).

Table 15: Results of PROMs and SPADI Between Group Differences in Change over Time between 0 - 8 weeks, 0 - 12 weeks and 8 - 12 weeks using an Independent t-test on Change Scores

	Lateral Group	**Posterior Group**			
Measure	Mean change	Mean change	Mean Difference (95% CI)	Eta squared	p - value
PROMs:					
Day time pain					
0 - 8 weeks	3.7	2.3	1.4(0.3 to 2.6)	0.071	0.018[a]
0 - 12 weeks	3.6	3.0	0.6(-0.8 to 2.0)	0.009	0.415
8 - 12 weeks	0.2	0.6	-0.6(-1.9 to 0.3)	0.027	0.141
Night time pain					
0 - 8 weeks	3.1	2.0	1.0(-0.5 to 2.5)	0.021	0.174
0 - 12 weeks	2.7	2.7	0.1(-1.7 to 1.9)	0.000	0.941
8 - 12 weeks	-0.4	0.2	-0.6(-1.7 to 0.4)	0.020	0.228
Shoulder function					
0 - 8 weeks	1.3	1.0	0.3(-0.3 to 0.9)	0.011	0.346
0 - 12 weeks	1.0	1.4	-0.4(-1.1 to 0.3)	0.018	0.289
8 - 12 weeks	-0.2	0.4	-0.6(-1.1 to -0.2)	0.105	0.005
SPADI					
0 - 8 weeks	34.0	31.3	2.7(-11.2 to 16.6)	0.002	0.696
0 - 12 weeks	30.6	41.3	-10.7(-27.2 to 5.9)	0.023	0.202
8 - 12 weeks	-3.8	6.3	-10.1(-20.7 to 0.5)	0.049	0.061

Key: a = $p < 0.05$

Shoulder function between week 0 to 8, week 0 to 12 and week 8 to 12

There was no statistically significant difference between the two groups in the shoulder function scores between week 0 to 8 (p = 0.346), week 0 to 12 (p = 0.289), however from week 8 to 12 there a statistically significant difference in shoulder function in favour of the lateral group -6 (95% CI, -1.1 to -0.2, p = 0.005).

4.2.8.2 SPADI SCORES

SPADI scores between week 0 to 8, week 0 to 12 and week 8 to 12

There was no statistically significant difference between the two groups in the SPADI scores between week 0 to 8 (p = 0.696), week 0 to 12 (p = 0.202) and week 8 to 12 (p = 0.061) (Table 15).

4.2.9 Exploratory Multiple Regression Analysis to Investigate the Contribution of the Independent Baseline Variables on the PROMs and SPADI Outcomes

A one layer multiple regression was used to evaluate the contribution of participant's baseline characteristics such as age, gender, symptom duration, manual occupation, dominant side affected, previous cortisone injection and current treatment on the PROMs and SPADI scores between baseline to 8, week 0 to 12 and week 8 to 12. The model was inspected to ensure that the assumptions of normality, multicollinearity and homoscedasticity were not violated. The results of the multiple regression showed that the individual p values (> 0.05) were greater than 0.05, which means that each individual variable was not a significant predictor of the outcome measures. This implies that the participant's baseline variables were not a statistically significant contributor in predicting the outcomes. For example, see Tables 16 to 19.

Table 16: Coefficients for PROMs Day Time Pain Scores from Baseline

Coefficients for PROMs Day Time Pain Scores									
	0 - 8 weeks			0 - 12 weeks			8 - 12 weeks		
	B	Beta	P	B	Beta	P	B	Beta	P
Constant	4.471		0.036	4.243		0.099	-0.461		0.816
Patient's age in years	-0.013	-0.059	0.640	0.012	0.036	0.739	0.032	0.152	0.249
Patient's gender	-0.216	-0.041	0.740	-0.622	0.765	0.419	-0.619	-0.130	0.304
Duration of symptoms in weeks	0.005	-0.093	0.463	-0.005	0.008	0.509	0.001	0.025	0.850
Manual occupation: No = 0; Yes = 1	0.039	0.007	0.955	-0.317	0.805	0.695	-0.300	-0.063	0.635
Dominant side affected: No = 0; Yes = 1	0.380	0.070	0.580	0.307	0.815	0.707	0.018	0.004	0.978
Previous cortisone injection: No = 0; Yes = 1	0.085	0.015	0.908	-0.329	0.860	0.704	-0.671	-0.132	0.321
Current treatment analgesia = 1; NSAIDS = 2	-0.274	-0.111	0.365	-0.241	0.367	0.514	0.021	0.009	0.943
R Square		0.032			0.036			0.047	

Keys: B - (Unstandardised Coefficients); Beta (Standardised Coefficients)

Table 17: Coefficients for PROMs Night Time Pain Scores from Baseline

Coefficients for PROMs Night Time Pain Scores									
	0 - 8 weeks			0 - 12 weeks			8 - 12 weeks		
	B	Beta	P	B	Beta	P	B	Beta	P
Constant	1.827		0.476	0.098		0.975	-1.964		0.285
Patient's age in years	0.019	0.069	0.581	0.005	0.162	0.209	0.049	0.242	0.060
Patient's gender	0.368	0.056	0.643	0.181	0.024	0.847	-0.655	-0.146	0.238
Duration of symptoms in weeks	0.000	0.005	0.967	-0.001	-0.008	0.950	0.003	0.065	0.617
Manual occupation: No = 0; Yes = 1	0.847	0.127	0.311	1.326	0.174	0.183	0.566	0.126	0.331
Dominant side affected: No = 0; Yes = 1	-0.274	-0.041	0.743	-0.651	-0.085	0.516	-0.432	-0.095	0.463
Previous cortisone injection: No = 0; Yes = 1	0.618	0.087	0.489	0.883	-0.108	0.405	-0.266	-0.055	0.668
Current treatment analgesia = 1; NSAIDS = 2	-0.764	-0.248	0.041	-0.647	-0.180	0.155	-0.005	-0.003	0.984
R Square		0.074			0.081			0.098	

Keys: B - (Unstandardised Coefficients); Beta (Standardised Coefficients)

Table 18: Coefficients for PROMs Shoulder Function Scores from Baseline

Coefficients for PROMs Shoulder Function Scores									
	0 - 8 weeks			0 - 12 weeks			8 - 12 weeks		
	B	Beta	P	B	Beta	P	B	Beta	P
Constant	2.306		0.017	0.887		0.470	-1.393		0.081
Patient's age in years	-0.001	-0.006	0.960	0.018	0.134	0.302	0.018	0.211	0.103
Patient's gender	-0.313	-0.122	0.287	-0.246	-0.065	0.501	0.080	0.043	0.732
Duration of symptoms in weeks	-0.003	-0.119	0.315	0.001	0.046	0.728	0.005	0.263	0.047
Manual occupation: No = 0; Yes = 1	-0.026	0.049	0.682	0.391	0.134	0.321	0.356	0.188	0.162
Dominant side affected: No = 0; Yes = 1	0.062	0.024	0.841	0.063	0.021	0.873	-0.028	-0.014	0.913
Previous cortisone injection: No = 0; Yes = 1	0.272	0.099	0.411	0.257	0.083	0.525	-0.155	-0.077	0.550
Current treatment analgesia = 1; NSAIDS = 2	-0.428	-0.359	0.002	-0.416	-0.310	0.514	0.015	0.017	0.895
R Square		0.156			0.117			0.139	

Keys: B - (Unstandardised Coefficients); Beta (Standardised Coefficients)

Table 19: Coefficients for SPADI Scores from Baseline

Coefficients for SPADI Scores									
	0 - 8 weeks			0 - 12 weeks			8 - 12 weeks		
	B	Beta	P	B	Beta	P	B	Beta	P
Constant	46.197		0.050	25.962		0.380	-22.436		0.209
Patient's age in years	0.040	0.015	0.899	0.300	0.096	0.467	0.337	0.165	0.178
Patient's gender	-3.019	-0.049	0.675	-5.119	-0.073	0.568	-4.103	-0.090	0.448
Duration of symptoms in weeks	-0.063	-0.106	0.383	0.003	0.005	0.972	0.094	-0.222	0.077
Manual occupation: No = 0; Yes = 1	-1.644	-0.027	0.828	5.524	0.079	0.588	9.016	0.197	0.115
Dominant side affected: No = 0; Yes = 1	-2.021	-0.032	0.790	2.757	0.039	0.771	4.950	0.107	0.387
Previous cortisone injection: No = 0; Yes = 1	15.416	0.234	0.060	8.583	0.113	0.398	-11.520	-0.233	0.062
Current treatment analgesia = 1; NSAIDS = 2	-6.964	-0.244	0.040	-4.219	-0.127	0.328	1.730	0.080	0.505
R Square		0.025			0.046			0.183	

Keys: B - (Unstandardised Coefficients); Beta (Standardised Coefficients)

4.2.10 Summary of Quantitative Results

At baseline, the lateral and posterior groups were similar with respect to the baseline demographics and outcome measures.

The results of an independent t-test showed that there was no statistically significant difference between the group's day time pain mean change scores at baseline ($p = 0.059$). Similarly, a Mann-Whitney test found no statistically significant difference between the groups at week 8 ($p = 0.386$) and week 12 follow up ($p = 0.590$).

The results of an independent Mann-Whitney test showed that there was no significant difference between the group's night time pain mean change scores at baseline ($p = 0.319$), week 8 ($p = 0.470$) and week 12 ($p = 0.787$). Similarly, there was no significant difference between the groups for shoulder function mean change scores at baseline ($p = 0.643$), week 8 ($p = 0.497$) and week 12 ($p = 0.089$). Also, no significant difference was demonstrated between the groups for the SPADI mean change scores at baseline ($p = 0.878$), week 8 ($p = 0.862$) and week 12 ($p = 0.324$).

Within both groups, a paired t test found that there was a statistically and clinically significant difference in day time pain between week 0 to 8 and week 8 to 12. Within the lateral group, the improvement was 3.7 points ($p = 0.000$, eta squared = 0.675) between week 0 to 8 and 3.6 points ($p = 0.000$, eta squared = 0.567) between week 0 to 12. Within the posterior group, it was 2.3 points ($p = 0.000$, eta squared = 0.441) between week 0 to 8 and 3.0 points ($p = 0.000$, eta squared = 0.535) between week 0 to 12. However,

within both groups (lateral group p = 0.626; posterior group p = 0.135) no statistically significant difference was demonstrated between week 8 to 12.

Within both groups, a paired t test found that there was a statistically and clinically significant difference in night time pain between week 0 to 8 and week 8 to 12. Within the lateral group, the improvement was 3.1 points (p = 0.000, eta squared = 0.443) between week 0 to 8 and 2.7 points (p = 0.000, eta squared = 0.329) between week 0 to 12. Within the posterior group, it was 2.1 points (p = 0.000, eta squared = 0.306) between week 0 to 8 and 2.7 points (p = 0.000, eta squared = 0.350) between week 0 to 12. However, within both groups (lateral group p = 0.267; posterior group p = 0.561) no statistically significant difference was found between week 8 to 12.

Within both groups, a paired t test found that there was a statistically and clinically significant difference in shoulder function between week 0 to 8 and week 8 to 12. Within the lateral group, the improvement was 1.3 points (p = 0.000, eta squared = 0.512) between week 0 to 8 and 1.0 points (p = 0.000; eta squared = 0.321) between week 0 to 12. Within the posterior group, it was 1.0 points (p = 0.000, eta squared = 0.367) between week 0 to 8 and 1.4 points (p = 0.000, eta squared = 0.484) between week 0 to 12. However, within both groups (lateral group p = 0.267; posterior group p = 0.561) no statistically significant difference was found between week 8 to 12. Within the lateral group, between week 8 to 12, there was no statistically significant difference reported (mean difference = - 0.2, p = 0.130, eta squared = 0.063). Whereas, within the posterior there was (mean difference = 0.4; p = 0.016, eta squared = 0.160).

Within both groups, a paired t test found that there was a statistically and clinically significant difference in the SPADI scores between week 0 to 8 and week 8 to 12. Within the lateral group, the improvement was 34.0 points (p = 0.000, eta squared = 0.580) between week 0 to 8 and 34.7 points (p = 0.000, eta squared = 0.448) between week 0 to 12. Within the posterior group, it was 31.3 points (p = 0.000, eta squared = 0.506) between week 0 to 8 and 35.4 points (p = 0.000, eta squared = 0.583) between week 0 to 12. However, within both groups (lateral group p = 0.299; posterior group p = 0.115) no statistically significant difference was found between week 8 to 12.

The results of an independent t-test between the lateral and posterior groups demonstrated a statistically and a moderate clinically significant difference in day time pain (mean change score) in favour of the lateral group (mean = 3.7) compared with the posterior group of (mean = 2.3) between week 0 to 8 (1.4 points [95% CI 0.3 to 2.6, p = 0.018]). However, there was no statistically significant difference between the two groups from week 0 to 12 (p = 0.415) and week 8 to 12 (p = 0.141).

Using an independent t-test, there was no statistically significant difference in night time pain between the groups between week 0 to 8 (p = 0.174), week 0 to 12 (p = 0.914) and week 8 to 12 (p = 0.228). Also, no statistically significant difference was found in shoulder function scores between the two groups between week 0 to 8 (p = 0.346), week 0 to 12 (p = 0.289). However, between week 8 to 12 there was a statistically significant difference in favour of the lateral group -0.6 (95% CI, -1.1 to -0.2, p = 0.005). There was no statistically significant difference between the groups in the SPADI scores

between week 0 to 8 (p = 0.696), week 0 to 12 (p = 0.202) and week 8 to 12 (p = 0.061).

The results of a one layer multiple regression that was used to evaluate the contribution of participants' baseline characteristics on the PROMs and SPADI scores between baseline to 8, week 0 to 12 and week 8 to 12 found that the participant's baseline variables were not a statistically significant contributor in predicting the outcomes.

4.3 Section 2: Qualitative Analysis

4.3.1 Introduction

This section will present the results of the semi-structured interviews which were conducted with participants who have participated in phase1 of the quantitative study and agreed be interviewed. From the interviews conducted, five major themes associated with experiencing subacromial injection by the participants with SAIS were identified from the analysis. They included expectation of treatment, treatment outcome, procedure, patient education and access to treatment.

4.3.2 Sample Demographic

Data collection occurred between March 2015 and June 2015. Eighty participants completed phase 1 of the quantitative study. A purposive sample of 20 was chosen from the above sample, to participate in a semi-structured interview. They included 9 males and 11 females aged between 18 to 65 years and above (n = 20). Twelve had a lateral approach and 8 had a posterior approach of subacromial injection. Ten were those with complete

pain relief and ten were those that improved, but still had residual pain to the injection outcomes or no improvement (See Table 20).

Table 20: Description of Interview Participants

Characteristic	Number
Injection Location	
Lateral	11
Posterior	9
Gender	
Male	10
Female	10
Age (years)	
18 - 40	3
41 - 65	14
Above 65	3
Responders	
Complete pain resolution	10
Improved, but with residual pain/No improvement	10

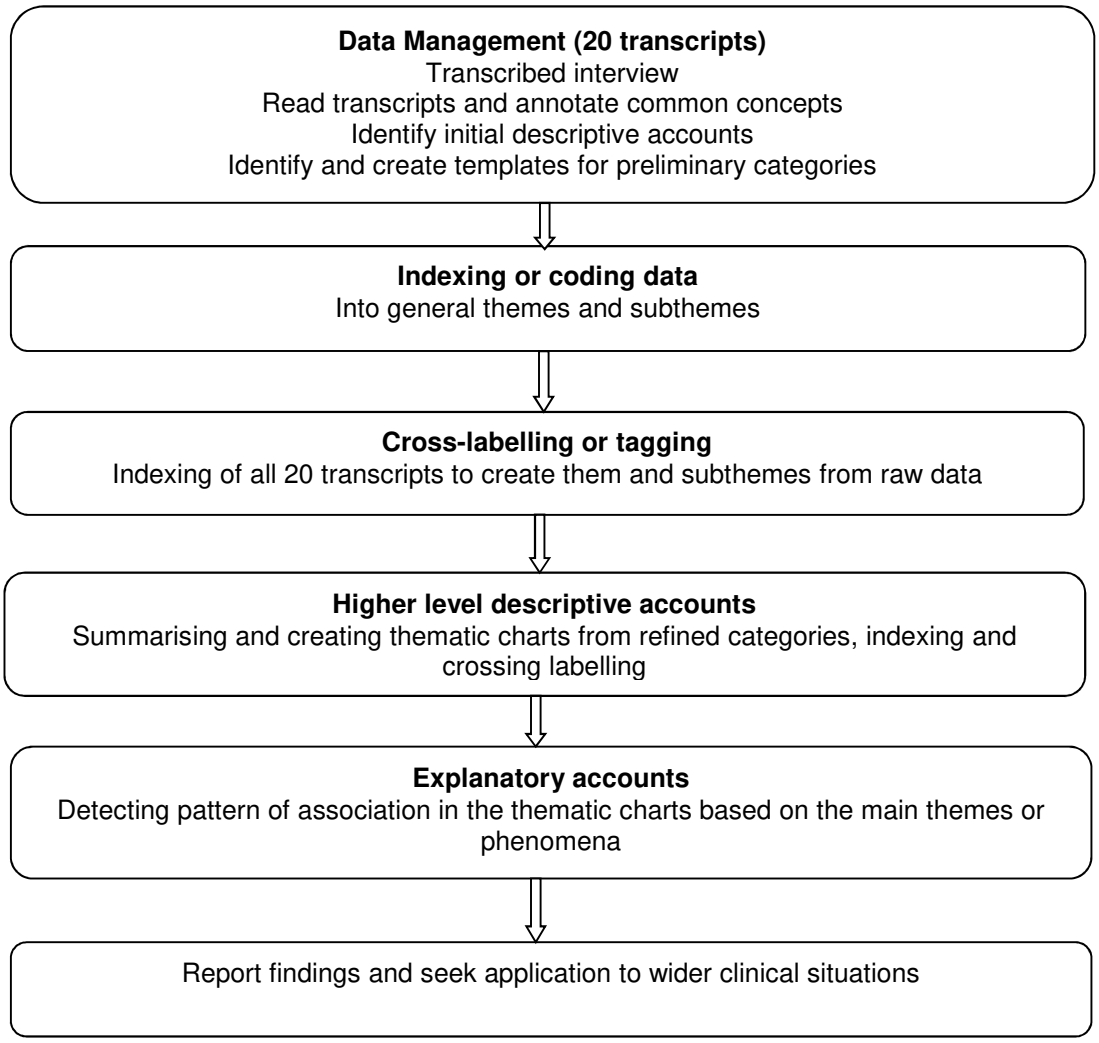
Table 21: Characteristics of the Participants

Participant ID	Participant Gender	Age in years	Group	Duration of symptoms (weeks)	Responders
002L	Male	43	Lateral	12	Improved, but with residual pain
007L	Female	64	Lateral	36	No improvement
0014P	Male	47	Posterior	52	Complete pain resolution
0025P	Female	31	Posterior	12	Complete pain resolution
0027L	Female	58	Lateral	52	Complete pain resolution
0028L	Female	71	Lateral	208	Improved, but with residual pain
0029L	Male	70	Lateral	12	Improved, but with residual pain
0031P	Female	54	Posterior	26	Complete pain resolution
0032L	Male	55	Lateral	26	No improvement
0034P	Female	55	Posterior	20	Complete pain resolution
0035P	Female	49	Posterior	208	Improved, but with residual pain
0038P	Male	54	Posterior	16	No improvement
0039L	Female	67	Lateral	26	Complete pain resolution
0045L	Male	55	Lateral	20	Improved, but with residual pain
0047L	Female	64	Lateral	16	Complete pain resolution
0049P	Male	38	Posterior	20	Complete pain resolution
0052P	Male	43	Posterior	54	Improved, but with residual pain
0055L	Female	51	Posterior	13	No improvement
0056P	Male	51	Posterior	5	Complete pain resolution
0058L	Male	36	Lateral	78	Complete pain resolution

4.3.3 Data Analysis

The 20 interviews were tape recorded and transcribed verbatim. Using MAXQDA as the data management tool the 20-textual data or transcripts were organised and categorised using general comments from the interview. This study adopted the hierarchical framework analysis (bottom-up approach) by Ritchie & Lewis (2003) to guide the data analysis. This is to ensure that the data analysis was strategic, systematic and robust. Ritchie & Lewis (2003) described some strategic steps based on the framework analytical model, these were adopted by this study and are shown in Figure 13.

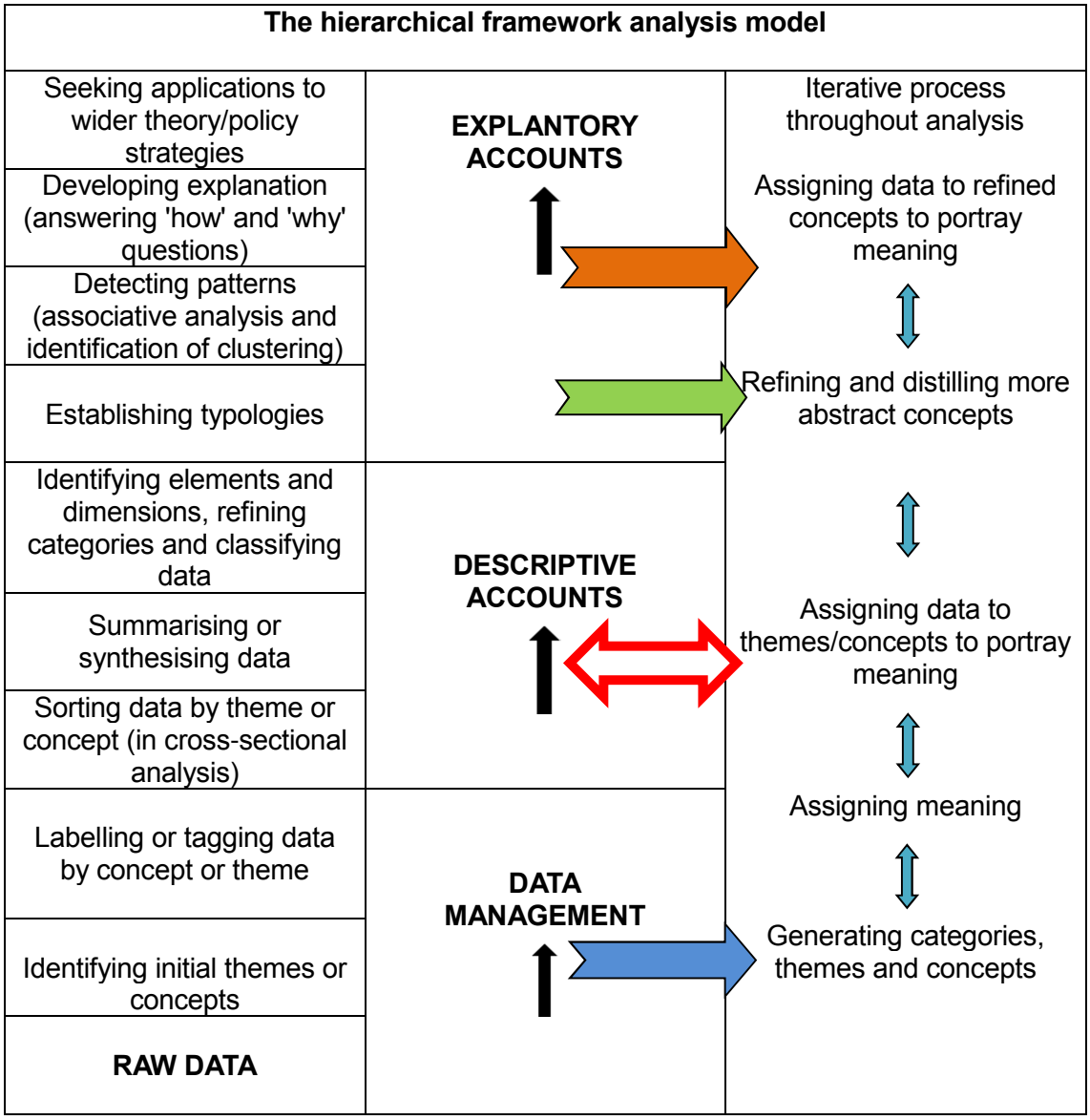
Figure 13: An illustration of the iterative and hierarchical process of qualitative data analysis adopted for this study



4.3.4 Hierarchical Framework Analysis Approach (Ritchie & Lewis 2003)

The concept of the framework not only enabled me to gain an overview and make sense of the data, but to also manage, synthesise and interpret the data in a structured and systematic manner using descriptive and illustrative accounts. Figure 14 shows a diagrammatic representation of the hierarchical framework analysis model proposed by Ritchie & Lewis (2003), used to guide the analysis in this study.

Figure 14: A diagrammatic representation of the hierarchical framework analysis model used to guide the data analysis



(Adapted from Ritchie and Lewis 2003: 212)

The framework model also allows for a systematic formulation of preliminary identification of emerging ideas, concepts and patterns with the focus on the content of the interview transcripts (Ritchie & Lewis 2003). Data accuracy was enhanced by returning the transcribed text to participants for re-validation.

4.3.5 Familiarisation Stage (Identifying Initial Themes and Concepts)

From Figures 13 and 14, this process of the data management was enhanced by the data management tool – MAXQDA and led to data extraction of some descriptive accounts and common concepts that participants used in the data set. According to Ritchie & Lewis (2003) this is the first and essential point to qualitative data analysis stage. During the familiarisation stage of this study, the researcher listened to the audio recording of the interviews, read through the interview transcripts and observation notes and then made notes (memos) of important issues and recurrent themes (such as improvements) that were mentioned by the research participants. The researcher ensured that initial codes that were identified reflected similarities or differences in participants' views about specific issues related to both the aims and objectives of the research as well as the research question. From the interviews, the descriptive phrases were then categorised using broader terms to describe the emerging patterns. The categories of phrases were then reviewed so that those with similar themes were grouped together. Examples of initial descriptive items used by the participants to express their experiences of receiving subacromial injections are shown in Appendix 8.

4.3.6 Identifying Conceptual Framework or Indexing

This stage involved indexing of the phrases and identifying links between categories, grouping them thematically and then sorting them according to different levels of main and subthemes. This process was informed by the methods shown in Figures 13 and 14. The key issues and emerging themes that were expressed by the participants formed the basis of the thematic framework, which was then utilised to filter and classify the data (Ritchie & Spencer 1994, Ritchie & Lewis 2003). The researcher ensured that the key themes and emerging themes from the data mirrored the participant's language and concepts, as well as the research objectives (Braun & Clarke 2006). In this study, the overall index contained 68 subthemes or categories that were grouped under just 10 main substantive themes or headings. The key themes and subthemes were then systematically numbered with the help of MAXQDA to produce an indexing reference (see Figure 15).

Figure 15: Indexing - major themes and subthemes identified during the interview

1. **Expectation of treatment**
   - **1.1** Pain relief
   - **1.2** Better shoulder movement
   - **1.3** A complete cure or pain relief
   - **1.4** Expectation not met
   - **1.5** Self-healing – natural resolution
   - **1.6** Not sure what treatment they were going to receive
   - **1.7** Other issues – physiotherapy or cortisone injection

2. **Information and advice from the clinicians**
   - **2.1** Explanation of every aspect of the treatment and care
   - **2.2** Not knowing what was going in the shoulder
   - **2.3** Explaining what was going on the shoulder and what to do about it
   - **2.4** Been listened to and involved in the treatment
   - **2.5** Exercise information
   - **2.6** General treatment information
   - **2.7** Explanation of treatment procedure
   - **2.8** Other issues

3. **Participants perception of the injecting ESP and the injection procedure**
   - **3.1** Politeness and how knowledgeable the clinician was
   - **3.2** Caring and helpful attitude of the clinician

3.3 Treated as an individual
3.4 Injection technique
3.5 Professionalism of the injecting clinician
3.6 Other issues

4. Description of pain and associated factors
4.1 Duration of pain – 2 weeks, 18-24 months
4.2 Onset of pain – gradual
4.3 Nature of pain – constant
4.4 Pattern of pain – 24 months
4.5 Complete resolution of pain or residual or on-going symptoms
4.6 Location of the pain
4.7 Inflammation of the shoulder
4.8 Stiffness of the shoulder
4.9 Pain on movement of the shoulder at work and during sports
4.10 Sleep disturbance due to night time pain
4.11 Other issues - frustration

5. Understanding of where pain is coming from
5.1 Not sure where the problem is coming from
5.2 Not knowing what was going in the shoulder
5.3 Query diagnosis -? impingement or tendonitis or full tear
5.4 Researching where the pain is coming from
5.5 Self-diagnosis – frozen shoulder
5.6 Other issues – related to elbow

6. Access to treatment
6.1 Easy parking
6.2 Near distance and within walking distance
6.3 Referral system
6.4 Quick appointment and seen sooner
6.5 Location and environment
6.6 The ease and convenience
6.7 Phone call received about appointment
6.8 Other issues – seeking partner's opinion on what to do

7. Outcome perceived after receiving treatment
7.1 Improvement – gradual or immediate
7.2 Better because of the cortisone effect
7.3 Effect on movement – better or same
7.4 Better within few weeks or months
7.5 Not been treated as just another candidate
7.6 The injection helped after 2 weeks
7.7 The way the injection was performed
7.8 Satisfaction/Efficient treatment/Service recommendation
7.9 Referred to another specialism
7.10 Other issues – it did not hurt, I did not feel pain

8. Going to the doctor – seeking help from the GP
8.1 GP took about 3-4 weeks to do the referral
8.2 Got appointment 2 weeks after GP referred
8.3 GP's expectation – patient to have cortisone, or surgery or a scan
8.4 GP's diagnosis – agreement / disagreement

9. Physiotherapy/cortisone referral suggested
9.1 GP initiated physiotherapy
9.2 Family and friend suggested physiotherapy
9.3 Other issues – injection suggested by some friends including GP

10. Service delivery
10.1 Prompt and friendly service
10.2 Good customer service

10.3 Not kept waiting for an appointment or before been treated

4.3.7 Labelling or Tagging the Data by Themes and Subthemes

After constructing the initial conceptual framework or indexed data, this stage involved applying the indexed data in Figure 15 to the appropriate sentences or paragraphs in the interview transcripts (raw data). The process shows which theme or concept is being mentioned or referred to within a particular section of the interview transcript. Figure 16 is an example of labelling or tagging of the indexed themes and subthemes. In this example, the text is a small excerpt of the participant's transcript (0014P) that was cross-labelled and indexed.

Figure 16: An Example of Labelling or Tagging of the Indexed Themes and Subthemes of part of an Interview Transcript of a Participant

The text that follows is small excerpt of an interview with participant 0014P	
Interviewer*: Has there been any improvement since having the injection?*	**Index**
Participant – 0014P *"There was improvement, it was a turning point, until then I was at the peak of the pain, the pain not going any further.*	**7.1**
The pain started gradually, and pain in the shoulder sort of gradually improved. I had constant pain initially and did not know where I was heading for and when I had the injection it brought down the pain level to 7/10 but it did not go up any further since then but is sort of came down gradually. At the same time, I had the psychology that this was going to heal itself with time. Until then I was not getting anywhere and the pain was going up week by week. Myself been a Nurse I was researching about the condition quite a lot and I knew that the pattern of pain was about 24 months. However, no matter what you know about it, not been able to sleep at night because of constant pain can be annoying. It was quite a relief that the pain has decreased. I will recommend this to anyone, while it is does not give instant cure it brings down the pain gradually. The time factor of 18-24 months important, you never know whether it will take the whole time".	**4.2** **4.3/2.2** **7.1** **1.5** **5.4** **4.4** **4.10/4.11** **7.8** **4.2** **4.4**

In the above example, participant 0014P reported that since receiving the cortisone injection there has been an improvement (index 7.1). He talked about how the onset of his shoulder pain has been gradual (index 4.2), and that the pain was constant at the beginning (index 4.3), but he did not know the cause of it (index 2.2). He went on to say that while the injection reduced his pain in a gradual fashion (index 7.1), he thought it would get better with the passage of time (index 1.5). He referred to his Nursing career which enabled him to investigate about his shoulder problem (index 5.4) and how long it might last for (index 4.4). He felt that the knowledge of the problem in itself is not sufficient, because the pain was not only disturbing his sleep at night time (index 4.10), but also frustrating (index 4.11). He admitted he will recommend the treatment to other people because of the benefits he derived from it (index 7.8).

4.3.8 Creating Thematic Charts

This stage of the analytical data abstraction involves identifying common concepts or patterns across the participants' interview transcripts and grouping them into categories and charts using the thematic charts (Ritchie & Lewis 2003). MAXQDA was used to generate the thematic matrices or charts for some key themes and subthemes, which were displayed in a single spreadsheet or code matrix browser in Appendix 9. Six themes and 44 subthemes are contained in the matrix. The first column of the thematic chart consists of each participant's identification code number and the rows consist of the main themes and subthemes that correspond to each participant's code number. Each of the main themes has subthemes with column numbers that ranged from 1 to 14 columns depending on the number of subthemes

associated with it. An example of the layout of the thematic chart taken from Appendix 9 is shown in Table 22. This example represents two participants, 0047L and 0031P. Excerpts from the analysis of their interview transcripts are shown under each subtheme in rows 2.1 to 2.5. They include the exact accounts that the participants gave about their injection experience.

Table 22: Example of a Thematic Chart Showing the Views of two Participants during Interview

THEMATIC CHART 2: PATIENT INFORMATION AND ADVICE	2.1	2.2	2.3	2.4	2.5
Participant ID, Gender, Age, Treatment Group	**Explanation about treatment and care**	**Not knowing about the shoulder problem**	**Explanation of shoulder problem**	**Patient involvement in their treatment**	**Exercise information**
0047L, Female 64, lateral group	I think it is just been explained to, just the general explanation and feeling at ease	Actually, I was scared initially, I knew nothing about the problem before I went. It was less alarming after you got the experience of explaining what it all about.	Why they thought I was having the problem and feeling I know all about the problem because actually I knew nothing about the problem before I went and generally feeling comfortable with the treatment because it seemed the right way to go.	The whole experience you know was very easy and I wasn't at all concerned after it was all explained me.	Been talked through certain movements I do and why it is not working
0031P, Female 54, posterior group	Everything was great, the injection, the way he performed it, the knowledge I got, the exercises	Know what is going on in the shoulder and what I need to do.	You know with you and the other Doctor that did the injection actually listened and you explained. You know you felt like you were a patient and you are being listened to.	When I come there everything you said made me feel like you are being listened to. In the hospital, they do not seem to do that.	I think where I had the injection and I followed the exercises he gave me. I think the combination of it all improved the shoulder itself

4.3.9 Descriptive and Classification Analysis - Identifying Elements and Dimensions, Refining Categories, Classifying Data

This stage of the analysis involved unpacking, refining and categorising the contents and nature of the key themes (Ritchie & Lewis 2003). It also involved identification of a particular theme, refining of categories and assigning groups of categories to 'classes' usually at a higher level of abstraction (Ritchie & Lewis 2003). Appendix 10 is an excerpt from participant's 0052P transcript and is an example of using the Framework approach for descriptive and classification analysis.

Table 23 is an example of the descriptive and classification process performed for the subthemes. Column A is the participant unique identification number, column B contains the original quotes from the transcripts, while column C is a close description of the participant's original quotes, but now contains mainly the relevant elements of the initial quotes. Column D is a higher level of categorisation where elements detected have been interpreted in a more conceptual manner to provide a new meaning. For example, in column C "unsure about the pain" from (participant 0014P) and "Lack of knowledge about the problem" from (participant 0047L) were both categorised in column D as uncertainty about the cause of pain.

Table 23: Example of using Framework for Descriptive and Classification Analysis

Participant ID, Gender, Age, Treatment Group	**Column B Data charted in column 2.2: Not knowing about the shoulder problem**	**Column C Elements/Dimensions identified**	**Column D Categories/classes**
0014P, Male, 47, Posterior group	The pain started gradually, and pain in the shoulder sort of gradually improved. I had constant pain initially and not sure of the pain and when I had the injection it brought down the pain level to 7/10 but it did not go up any further since then but is sort of came down gradually. At the same time, I had the psychology that this was going to heal itself with time. Until then I was not getting anywhere and the pain was going up week by week. Myself been a Nurse I was researching about the condition quite a lot and I knew that the pattern of pain was about 24 months. However, no matter what you know about it, not been able to sleep at night because of constant pain can be annoying. I was quite relief that the pain has decreased. I will recommend this to anyone, while it is does not give instant cure it bring down the pain gradually. The time factor of 18-20 months important, you never know whether it will take the whole time".	Pain started and improved slowly Pain was continuous at first Unsure of the pain Injection slowly improved the pain Felt he will get better with passage of time Took advantage of his profession to investigate the problem Pain lasting up to 24 months Night pain affecting his sleep Expression of pain irritation Happy pain improved Pain slowly improved Could not guarantee complete pain resolution with the injection Relevance of time to pain	Gradual onset of pain Constant nature of pain Uncertainty about the cause of pain Gradual improvement of pain Natural resolution of pain Felt motivated to investigate the cause of pain Prognosis of the problem Affected sleep Sense of frustration with pain Positive outcome Gradual improvement of pain Uncertainty about complete pain resolution Importance of prognosis
0047L, Female 64, Lateral group	Actually, I was scared initially, I knew nothing about the problem before I went. It was less alarming after you got the experience of explaining what it all about.	Fear of what was going on Lack of knowledge about the problem Less frightening following information about the problem	Anxiety about the problem Uncertainty about the cause of pain Sense of reassurance following education

Finally, after application of the above process of analysis in Table 23 to all the main thematic charts and reviewing the descriptive items in column D above, a descriptive list of discovered items that represent new categories were compiled. They represent the participants' concepts regarding their experiences of receiving subacromial injections from injecting ESP's working in normal community practice. Examples of descriptive items include:

- Anxiety about the problem
- Uncertainty about the cause of pain
- Sense of reassurance following education
- Gradual onset of pain
- Constant nature of pain
- Gradual improvement of pain
- Natural resolution of pain
- Felt motivated to investigate the cause of pain
- Prognosis of the problem
- Affected movement and sleep
- Sense of frustration with pain
- Positive outcome
- Uncertainty about complete pain resolution
- Importance of prognosis
- Expectation of pain relief
- Self- efficacy
- Injection efficacy
- Satisfaction with treatment and care received
- Clinician's skill, knowledge and experience

- Receiving clear information about the problem, treatment and care
- Good system with treatment appointment
- Good treatment location with parking arrangements
- Lack of trust in GP injection
- Professionalism of the injecting clinicians

4.3.10 Dimensions and Explanatory Accounts

After investigating the descriptive list, identification of specific conceptual labels or a number of associated features took place. This resulted in the creation of eight new or key dimensions and themes which consist of:

1. **Shoulder pain issues**: This relates to participants' conceptualisation of shoulder pain and factors associated with it - anxiety and uncertainty about the shoulder problem, onset of pain been gradual and constant in nature, frustration about the persistent nature of pain and pain interfering with movement and sleep.
2. **Diagnosis and Prognosis of the problem**: These aspects relate to participants' views about what they think and what they were told by the injecting clinicians was the cause of their problem, whether they will improve or not and when the problem will be resolved.
3. **Interaction with the injecting clinicians**: This dimension represents the participants' experiences of their involvement and encounters with the injecting clinicians. This includes their views and opinions of the assessment and treatment they received as well as the clinician's knowledge, skills and experience.
4. **Information received**: This dimension involves the communication participants received about their problem, treatment procedure, before

and after care. It also relates to information about preventing aggravation of symptoms, exercise, daily activities and work.

5. **Participant's expectation**: This dimension represents participant's anticipation of immediate pain relief following cortisone injection. Some expected it to be gradual. Few thought they were coming to receive physiotherapy not knowing cortisone injection was a possibility.
6. **Treatment Location**: This relates to participants' accounts or experiences of receiving treatment within the community. They include access and facilities.
7. **Referral system**: This dimension represents participants' journey experience from when they were referred by their GP for treatment up till the point when they were being treated. They include expectation of receiving early appointment, treated on time, good and friendly service. It also includes delay getting in appointment.
8. **Outcome of Treatment**: This represented participants' opinion and conclusion about outcome of the treatment they received – many being positive, with few disappointments.

The eight dimensions conceptualise the overall account of the participants' experiences of receiving subacromial injection. These main categories were then re-sorted and revised generating five main final themes. They include: expectation of treatment, treatment outcome, procedure, patient education and access to treatment. Finally, explanation of the core themes was achieved using the theoretical framework of the research to tell the story that participants with SAIS gave about their experiences of receiving subacromial injection performed by ESPs working in a community setting. This is discussed in the next section.

4.3.11 MAIN THEMES

4.3.11.1 Expectation of Treatment

Participants that were interviewed said that the onset of shoulder pain could be gradual or sudden and was either constant or intermittent. The participants mentioned that the reason why they had cortisone injection was mainly because they were in pain but also because they had limited shoulder movement. This is consistent with a shoulder study that found that reduction in shoulder pain and an increase in shoulder function were the most important reasons why patients with symptoms of shoulder pathology sought help from their doctor (Ainsworth et al 2009). The International Association for the Study of Pain defines pain as being "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" (Bonica, 1979: 278). Shoulder pain is one of the most common musculoskeletal reasons why patients visit their GP for help in the community (Roquelaure et al 2006). Pain relief was a key expectation of the participants because they confirmed that after they had received the subacromial cortisone injection they expected their shoulder pain to subside or resolve completely. This is to enable them to use their shoulder better and without much pain so they could perform their normal everyday activities more easily such as lifting a kettle, changing gear and opening a door. Most of the participants interviewed said their expectation of complete pain relief was achieved after receiving the injection into their shoulder while for very few people it was only partial (that is they still had some residual pain). For example two patients commented:

> *"I think actually, I believe my shoulder was quite inflamed and I had it for quite a long time and it probably restricted my movement quite a lot and the injection just improved all of that". (0047L, 64 year old female)*

> *"I thought it was going to clear it, but my arm still aches and there is still a bit of pain when I use it in different directions if you know what I mean, it jerks then it really hurts". (0029L 70 year old male)*

This study has highlighted the importance for clinicians and researchers to understand that the key expectation of patients with SAIS who have received subacromial cortisone injection is that they expect to see their shoulder symptoms improved or completely resolved so that they function more effectively. This is particularly relevant in cases where physiotherapy and other conservative treatments such as cold or hot therapy have failed to improve symptoms of SAIS. This is consistent with previous recommendations that subacromial injection should be the treatment choice for SAIS patients who have failed physiotherapy or where pain is limiting them from performing shoulder exercise (Hanchard et al 2004, Lewis 2011).

Few of the participants who had ongoing symptoms asked if they have some physiotherapy and were been offered, while others were given the option of physiotherapy and they accepted. Very few who did not improve following the injected were further investigated with MRI or ultrasound scan and referred onward for surgical considerations.

4.3.11.2 Treatment Outcome

A key theme from the interviews was the outcome of the cortisone injection. In this study some of the participants who said their pain got better after the injection said that it was certainly due to the efficacy of the cortisone injection. One of the participants who had the injection via lateral route said:

"Yes definitely. It's been about 98% okay because of the cortisone injection" (0058L 36 year old male).

Most of the participants said that the cortisone injection provided complete and immediate pain relief, while some mentioned it was a gradual process. Those who said it was a gradual process also mentioned that their shoulder movement improved in a gradual fashion as well. In this study it was discovered that those who had immediate and complete pain relief did not request physiotherapy and also declined the option of physiotherapy because they would rather self-manage at home with exercises. This highlights the importance of the therapeutic effect of subacromial injection in improving pain and function in patients with SAIS thereby reducing clinical dependency and improving self efficacy. However, some of the participants who said their improvement was gradual wanted some physiotherapy and were therefore offered it. For participants who improved (either through a lateral or posterior route of subacromial injection), the effectiveness of the cortisone injection in reducing pain meant their shoulder movement improved also. For example two participants who received the injection via lateral route commented:

"Because after you've had the injection you are back to completely normal again, you are free from pain and you are free from everything" (0039L 67 year old female).

"Yes, definitely, it gave me more movement the pain is still there, still throbbing, but now not as severe and it has at least given me 30-40% more movement in the last 5 or 6 weeks. (0045L 55 year old male)

4.3.11.3 Procedure

Phrases like "it was brilliant!", "very professional", "1st class!", "very good indeed" and "10 out 10" were used to describe how participants felt about the injection technique. These comments involved both groups of the study and included those who had complete pain relief and those who had residual pain. In this study all the injections were performed by two injecting clinicians who were trained and had adequate experience and skills. All injections followed the recommended PGD guidelines and were performed after obtaining both verbal and written informed consent from the participants. The primary objectives for any shoulder injection procedure are for the needle to be inserted correctly at the selected site in the shoulder with minimal pain and discomfort without introducing infection or causing any adverse effect. These objectives were important not only for the clinicians who performed the injections but also for the participants who received them. Most participants confirmed that the injecting clinicians were knowledgeable of the injection procedure and delivered it in a way that was intended to ensure no pain or discomfort. For example, two participants said:

> *"It seems fine where I had it and no trouble at all. I thought the guy was very professional he knew what he was doing. When I had it before the GP did not really know what he was doing. He stuck the needle in my shoulder and started wiggling it round. But this Doctor numb it first and use the same needle to inject the steroid that was really good" (0052P 43 year old male).*

> *"I did enjoy it and I did not feel it, I did not feel any pain or discomfort when I had the injection" (0039L 67 year old female).*

Very few participants said the outcome of the cortisone injection was not very successful, despite that, they still maintained that the way that the injections were performed was very professional. For example, one participant said:

> *"Your man who did the injection was polite and he knows what he was doing and everything else except this, I do not think the injection made any difference" (002L 43 year old male).*

Participants were asked about their preference of the injection site, whether they would have preferred it either from the side or the back of their shoulder. Most of them (from both injection groups) said they did not have a specific preference for the injection site; rather what they wanted was for the injection to improve their pain and shoulder function. A few of the participants that did not have a very good successful outcome after the injection said they were not exactly sure if the outcome would have been any different if they had received it from a different site. However, when they were given the option of a repeat injection and they had the option of a second injection site and took it. For example, if a posterior route was initially unsuccessful then the repeat injection was performed via a lateral approach.

4.3.11.4 Patient Education

In this study shoulder pain and how the injection works were explained to participants before the treatment. They were also informed about the potential

risks and benefits of the treatment and were they provided with before and aftercare advice about the injection. Although this study is only investigating the effectiveness of subacromial injection through a lateral or posterior approach, cortisone injection was not given as a stand-alone treatment. Rather participants were given exercise information both in verbal and written form to enhance their shoulder function as this is the recommended clinical practice. However, the exercises were not standardised. Most participants said that before the injections, they had anxiety about the reason for their shoulder pain because they lacked understanding of what was causing it. However, after their appointment with the injecting ESP, the participants said they were provided with good information and received full explanations and advice on their care and treatment. They said that this gave them a better understanding of their condition, the effects of the cortisone injection and what to do after the treatment. This further put their mind at ease and gave them the confidence to better use their shoulder without fear of causing more harm. They also expressed their appreciation of the way and manner things were explained to them, which ultimately enhanced their overall improvement. For example, one participant said that she will definitely recommend the service to others because she found her shoulder pain was less alarming after she was given appropriate information regarding her condition and treatment. This highlights the significance of patient education, including aftercare advice and exercise information both in verbal and written forms, to shoulder pain patients receiving subacromial injection. This was echoed by one of the participants:

> *"Yes there has been improvement. Hmm because everything was explained thoroughly to me and everyone was very*

helpful, so wasn't left wondering what was going to happen. Everything was explained to me and straight away I knew exactly what was going to happen and the staff were absolutely fantastic and the overall result has been very good so I would not say anything negative" (0027L 58 year old female).

Participants attributed their improvement in shoulder function not only to cortisone injection but also to the exercises that they were given by the injecting clinician. Providing exercise information meant that participants understood what to do, how to do them, when to do them and how many times to do them. Two participants said:

"The way the exercises was explained and I have been doing it regularly. I have been doing it every day for past 3 weeks" (0034P 55 year old female).

"Everything was great, the injection, the way he performed it, the knowledge I got, the exercises, the understanding of what was going on. I sort of push myself. Knowing what is going on in the shoulder and what I need to do, and like I say I was treated really well by everyone. I will sing the praise to everybody and I will go all day. I am trying to push my husband to have his done. I am glad it really improved it, I really am" (0031P 54 year old female).

4.3.11.5 Access to Treatment

Quick and easy access to a community musculoskeletal service is essential for the management of patients with shoulder pain in order to enhance treatment outcomes. Most of the participants said they were pleased at being treated in a community service because it was more local, easier and quicker

to access and parking was easier compared to the acute hospital. Although a few participants felt their appointment should have been sooner, most participants expressed their satisfaction for having a quicker appointment. They were also complimentary about the clinicians who treated them because they were not kept waiting for long periods of time before they were treated. These comments included those that improved completely and those that had ongoing shoulder symptoms. Some participants spoke about their previous experience of going to the acute hospital for treatment. They said they had to travel a longer distance to get to the acute hospital and that they were kept waiting for long periods before being treated by the injecting ESP. For example when two participants were asked if they would have preferred their treatment in the community or the acute hospital and they had this to say:

> *"In the community I think the hospital it so far, so long and you have to wait in the waiting room for hours and hours. Yours was really well, really fast, it was fast and really worked well. I thought I was coming for check-up and suddenly I had the treatment, I was very impressed with it". (0055L 51 year old female).*

> *Oh no, in the community it was good. I got the appointment fairly quick and was seen so fairly quickly. I did not have to wait for too long. The location is fine because of the car park (0034P 55 year old female).*

Some participants also mentioned that they received a very good customer service and the phone calls for their appointments were polite and prompt. For example, one participant said:

> *"The experience regarding appointment time, phone call all very good. Very professional, 10 out 10 really for you because you've given out all the instructions of what to do (0056P 51 year old male)".*

However, there were a few participants who said they had difficulty contacting the service by telephone and could not speak to someone directly and that parking had been an issue.

All the comments above highlight the importance of locating a musculoskeletal service, such as the one where this study took place, within a central location in the community with easy access, parking availability and good customer service. There were very few participants who did not mind where they received their treatment; rather what was more important to them was improvement of their shoulder symptoms.

4.4 Summary of Qualitative Results

From the semi-structured interviews the five major themes which emerged are expectation of treatment, treatment outcome, procedure, patient education and access to treatment. Participants felt that their shoulder symptoms improved not only because of the effect of the cortisone injection, but also because of other factors such as education about their treatment, exercise information, the experience and skills of the injecting clinicians, access to treatment as well as good customer service. Participants of both groups of the study including those who had complete pain relief and those who still had some residual pain expressed these views. Even though very few participants felt the outcome of the cortisone injection was not entirely

successful, they still said that the clinicians who performed the injections were professional and they had received a good service. They did not attribute the lack of success to anything in particular.

4.5 Chapter Summary

In conclusion, this chapter has presented the results of the quantitative study and qualitative semi-structured interviews. The next chapter will build on previous chapters and provide a more in-depth discussion on relevant aspects including some personal perspectives on key issues such as strength and weakness of the study, implication of this research in clinical practice and recommendation for further research.

CHAPTER 5 DISCUSSION

5.1 Introduction

The study findings demonstrated that in normal musculoskeletal practice, subacromial injections performed using anatomical land-marks provided significant clinical improvements in day time pain, night time pain, shoulder function and disability in participants with SAIS. They also indicated that clinical outcomes, such as the pain relief of participants receiving subacromial injection were influenced by their experiences of these injections. These experiences included their expectation of treatment, treatment outcomes, the information they received before and after the injections, the way the injections were performed and access to treatment.

This chapter discusses the issues in normal musculoskeletal practice regarding needle placement in subacromial injection with patients with SAIS, and discusses the research questions: Is lateral approach to subacromial injection more effective at improving shoulder pain and function in patients with SAIS compared to a posterior approach? What are the experiences of patients with SAIS receiving lateral versus posterior approach to subacromial injections?

5.2 Clinical Improvements

A pain free shoulder is vital for shoulder function which is necessary for performing everyday tasks such as washing, dressing and lifting. Therefore, even small improvements in pain reduction can facilitate activities of daily living. The most important expectation of a patient with shoulder pain is pain

reduction and the ability to live a comfortable life (Fashanu 2014). The current study has demonstrated that cortisone injection, when provided by experienced and trained ESPs, gave early pain relief and improved shoulder function. Although the precise mechanism of action is not well understood, its therapeutic value has been reported to include reducing pain and inflammation, reflex muscle spasm, and influencing tissue metabolism (Neustadt 1991). Paavola et al (2002) in a study of the role of cortisone injections in tendon pathologies reported that corticosteroids can suppress inflammation by changing the release of noxious chemicals that are produced by degenerate tendons. They reported that the other effects of cortisone injections are inhibition of collagen production and granulation tissue and prevention of fibrosis.

Although the benefits of the injection in this study were short term it did enable participants to carry on with their normal everyday tasks, such as washing, and dressing and they therefore, did not require further treatment thus improving self efficacy and reducing clinical dependency (Ainsworth et al 2009). Because these participants did not require further consultations, more appointment spaces were available to other patients who needed them, thereby reducing the waiting times for them to see a clinician. This view was reflected by participants in the qualitative aspect of this current study. For example participants who improved after the injection therapy did not request further treatment or physiotherapy. In fact, those that were given the option of physiotherapy or self management said they would rather self manage with home exercises because they had improved and did not see the need for physiotherapy. In a recent qualitative semi-structured interview study,

Fashanu (2014) reported that some of the participants observed that having a cortisone injection was what actually improved their pain and it was only then that they were able to do the exercises they had been given. This highlights the importance of the therapeutic effect of subacromial injection in SAIS in improving pain and function and thus reducing clinical dependency and hospital admissions. It is widely reported that corticosteroids are important anti-inflammatory and pain relieving medications, which act at both local and systemic levels (Akgun et al 2004, Ekeberg et al 2009).

There were a few participants who said that their improvement was gradual or that they had residual pain. They took up the offer of physiotherapy treatment and were able to comply with the treatment following better pain control. Very few participants had either a repeat injection and or were referred for diagnostic imaging (ultrasound or MRI scan) and then referred onward to secondary care for surgical opinion or intervention. This was because their symptoms had not improved with the cortisone injection and/or with physiotherapy. The evidence suggests that surgery is usually considered as the last option when conservative treatments such as physiotherapy and cortisone injection have been unsuccessful (Lewis 2010, Hanchard et al 2013).

Most of the participants in this study had experienced shoulder problems for a considerable period of time with an average of over 6 month's duration of symptoms. Despite the long duration of symptoms, participants experienced an overall improvement in pain and function regardless of which group they were randomised into. This is consistent with the one layer multiple

regression that was used to evaluate the contribution of participant's baseline characteristics such as symptom duration and the PROMs and SPADI scores between baseline to 8 weeks, week 0 to 12 and week 8 to 12. The results of the multiple regression showed that duration of symptoms was not a significant predictor of the outcome measures. This is consistent with Ainsworth et al (2009) who reported that despite the long durations of symptoms, their cohort of 60 people with rotator cuff tears still showed significant improvement in the clinical outcomes of shoulder pain and function irrespective of the group they were randomised to. However, it contrasts with the findings of Ekeberg et al (2009) who, after a study of ultrasound guided corticosteroid injection versus systematic steroid injection in rotator cuff patients, suggest that the duration of rotator cuff pathology might influence the outcome of cortisone injection treatment. The authors believe that longstanding chronic symptoms have a negative impact on treatment outcomes. In this study, the fact that both groups improved may be a reflection of the combined effects of efficacy of cortisone injection and the experience of the ESPs who managed the whole procedure and gave these injections. This view was supported by the comments of the participants in the semi-structured interview. They felt that they improved not only because of the effect of the cortisone injection but also because the ESPs who performed the injections were very confident in what they were doing and behaved in a very professional manner**.**

5.2.1 Within Group Difference

There was a statistically and clinically significant difference ($p = < 0.05$) within the groups at improving day time pain, night time pain, shoulder function and

SPADI scores both from 0 to 8 weeks and 0 to 12 weeks follow up. The findings suggest that both routes of cortisone injection produced similar clinically important reductions in shoulder pain and improvement in shoulder function and disability. Similarly, participants in the semi-structured interviews which were conducted 12 weeks after the treatment confirmed that after they received the subacromial injection it improved their shoulder pain, function and disability. This highlights the importance of the therapeutic efficacy of cortisone injection in controlling pain and improving shoulder joint and muscle function. This could lead therefore, to reduced clinical dependency on repeat cortisone injection and consequently free up more appointment slots for other patients that need them most and ultimately reduce the waiting times. This could equate to cost savings for both the patients who could be becoming over dependent on pain medication and/or the healthcare service.

The findings of this study are also consistent with several clinical guidelines that have recommended the use of subacromial injection in the treatment of SAIS particularly in cases were pain is the most limiting factor (Hanchard et al 2004, Diercks et al 2014, NICE 2015). It is also consistent with systematic reviews that found significant benefits with cortisone injections in the treatment of patients with shoulder pain (Johansson et al 2002, Buchbinder et al 2003 and Arrol & Goodyear-Smith 2005, Gaujoux-Viala et al 2009). The result of this study also compares favourably with Akgun et al (2004) who, in a randomised controlled study, investigated whether cortisone injection would provide additional benefit when combined with previous medication and exercise regime. They found that subacromial cortisone injection produced added benefit by relieving pain which affected sleep as well as day time

activities. Gaujoux-Viala et al (2009) in a meta-analysis of RCTs involving 618 shoulders found that although the effects of steroid injections were comparable to NSAIDs, they were more favourable in improving shoulder pain and shoulder function compared to other treatments. The authors concluded that cortisone injection was well tolerated, with rare and minor side effects such as transient post injection pain and skin modification. Similarly, Mohamadi et al (2016) in a recent systematic review and meta-analysis of 11 RCTs found that cortisone injections provided moderate pain relief for patients with rotator cuff disorders up to two months after the injection, but the effect was not sustained after three months. However, two systematic reviews (Van der Heijden GJ et al 1996, Koester et al 2007) have reported that the evidence establishing the efficacy of subacromial cortisone injection in shoulder pathologies is unequivocal. The reviews consisted of few studies that lacked adequate methodological quality and most of them had small sample sizes and were not adequately powered.

5.2.2 Between Group Findings

There was a moderate clinically and statistically significant improvement in day time pain score between 0 to 8 weeks follow up in favour of the participants treated by lateral route subacromial injection compared to the posterior group. Because previous shoulder studies (Sardelli & Burks 2008, Marder et al 2012) have both demonstrated that a lateral route subacromial injection was more accurate compared to a posterior route, it was expected that the lateral group would show a statistically significant better improvement compared with the posterior group in all the outcomes. However, this current study was unable to demonstrate a statistically significant difference between

the groups in night time pain, shoulder function and SPADI scores from week 0 to 12 and week 8 to 12.

No previous research has reported improvement in day time pain in favour of the lateral route of subacromial injection compared with the posterior between weeks 0 to 8 using anatomical landmarks. In clinical practice, the standard follow up period for evaluating the success of a shoulder injection outcome is usually between 6 to 8 weeks. Since the lateral route subacromial injection was more effective in reducing day time pain between 0 to 8 weeks, it should therefore be recommended as the standard procedure for subacromial injection. This is particularly so for SAIS patients who only suffer day time pain, with no night symptoms. From my personal clinical experience a patient with an improved day time shoulder pain at 8 weeks follow-up, will be considered for a further injection if they have significant night time pain or other on-going symptoms. Therefore, if the patient's night time pain is not significant and the cortisone injection has resulted in improvement of their day time activities, instead of having a repeat injection the patient could be discharged with advice on self management and a home exercise programme.

The patient could be advised to pace their activities and avoid activities that could strain the shoulder and cause aggravation of the night time pain. But if a lateral cortisone injection has improved a patient's day time pain and they still have ongoing night time pain they should be provided with the option of being referred to their GP for prescription of pain medication and/or sleeping tablets to use at night. They should also be given the option of having

physiotherapy. These options when applied are much cheaper compared to surgical interventions hence reducing hospital admissions. They are easy to access and could potentially reduce the number of repeat cortisone injections and save costs for the GPs and commissioners of community musculoskeletal practice.

Three previous studies (Yamakado 2002, Sardelli & Burks 2008 and Marder et al 2012) have supported the use of lateral approach of subacromial injections with patients with SAIS compared to the posterior route. However, they did so by investigating the accuracy in placing these injections into the bursa using either arthroscopy or radiographic reference. Therefore, these studies represent an arthroscopic rather than a clinical model and they do not represent what happens in normal ESP musculoskeletal practice. In contrast, this current study evaluated the effectiveness of needle placement using anatomical landmarks (blind) which is common clinical practice. Dogu et al (2012) reported that blind subacromial injections performed by experienced clinicians in patients with SAIS not only produced improvements in shoulder pain and function but were applicable to routine clinical practice.

5.2.3 Cortisone Injection and Advice

Besides the positive effect of the cortisone injection in reducing pain and improving function in the participants with SAIS, most of the participants that were interviewed acknowledged the importance of patient education and exercise advice as contributors to their improvements. The post injection information advised rest from strenuous activities such as heavy lifting for a period of 1 – 2 weeks while keeping active within pain limits and a gradual

return to normal everyday tasks. Participants said they were provided with information and received full explanations and advice about their care and treatment which they thought ultimately contributed to their overall improvement. Participants attributed their improvement in shoulder function not only to the cortisone injection but also to the exercises that they were given by the injecting clinician.

Cranshaw et al (2010) in a large pragmatic randomised study involving 235 participants with moderate to severe shoulder pain investigated the effect of cortisone injection plus exercise versus exercise only. They reported that by 12 weeks the majority of patients treated with cortisone injection and shoulder exercise had greater pain relief and improved muscle function compared with the exercise group. There were some participants who were referred from physiotherapy for cortisone injection because pain was preventing them from exercising. Following a successful outcome of the cortisone injection most of them then continued with their physiotherapy and exercise regime. Fashanu (2014) found that exercise prescription to patients with severe shoulder pain was counterproductive to the initial outcome of pain relief. Some of the participants in the study observed that having a cortisone injection was what actually improved their pain and only then they were able to do the exercises they were given.

Although the patient education and exercise information were found to be of additional benefit, the exercise prescriptions were not standardised amongst the participants. However, it has been suggested that exercises prescribed by clinicians should be from a patient-focused perspective (Epstein 2010). The

injection information and consent form were standardised. The lack of standard exercise information could present a weakness in this study and a gap in the evidence. Therefore, further research on a review of the exercises prescribed from a patient-focused perspective (Epstein 2010) or a standard format is suggested.

5.2.4 Follow-up Periods

The timeframes (week 0 to 8 and week 0 to12) used in this study for follow-up were not only longer than some previous studies but also consistent with current musculoskeletal practice and both the posterior and lateral groups improved during these periods. In contrast, previous studies have used shorter study timeframes. For example, Adebajo et al (1990) and Petri et al (1987) in two separate trials found that subacromial cortisone injection in patients with rotator cuff disease reduced pain and improved shoulder function compared with placebo, but the follow up period in both studies was only 4 weeks.

Compared with this study, Blair et al (1996) used a longer follow-up period to evaluate the effectiveness of subacromial injection. The authors reported that a combination of cortisone injection and Lidocaine (Kenalog) produced better pain relief and an increased range of shoulder movements when compared with Lidocaine only. However, the post injection outcomes for the cortisone group and placebo group were assessed at different times, with the cortisone group being followed up at 33 weeks and the placebo group at 28 weeks. The difference in the follow-up periods between the groups makes the findings of this study difficult to apply to normal clinical practice and the pooling of the

results difficult for meta-analysis. This is in agreement with a Cochrane review (Buchbinder et al 2003) that investigated the benefits of subacromial injections for shoulder pain, but had difficulties in pooling the result of the Blair et al (1996) study for a meta-analysis (Buchbinder et al 2003). In this study, the consistencies of the follow-up periods are not only applicable to routine clinical practice but they also have the benefit of contributing to systematic review and meta-analysis.

5.3 Safety and Adverse Effects

There were no safety concerns or adverse effects reported in this study and this could be attributed to the injection technique, experience and skills of the injecting clinicians (McInerney et al 2003). This was reconfirmed by the views expressed by participants in the semi-structured interview. They said that the injecting clinicians were knowledgeable about the injection procedure and that the injections were delivered in a very safe and professional manner. They did not express any concern or report any adverse effects from the injections. This highlights the importance of subacromial injections being performed by trained and experienced ESPs who were also following the PGDs. Subacromial cortisone injections are relatively very safe (Saunders & Longworth 2012) however, some authors have suggested that they may have some adverse local effects such as skin discoloration and tendon rupture (Akgun et al 2004). This is in contrast with this study and also McInerney et al (2003) study that reported no adverse effects of subacromial cortisone injection in their cohort of 98 patients with post-traumatic shoulder impingement. Other studies (Dickson 1995, Kumar & Newman 1999, Penning

et al 2012) however, have reported minor adverse effects such as post injection flare of pain.

5.4 Ultrasound Guided Injections versus Anatomical Landmarks (Blind)

This study has demonstrated that the use of anatomical landmarks (blind) for placing subacromial injections by ESPs has the effect of improving clinical outcomes of reducing shoulder pain and improving shoulder function and disability. This study has also shown that standard shoulder injections (blind) not only produce good clinical outcomes but they are also safe, involve less time and a lower cost compared to previous studies that have used either ultrasound guided or MRI scan guided injections, both of which come at a much higher cost (Sage et al 2013). This compares favourably with several other authors who have demonstrated that there are no statistically and clinically significant differences between USG and blind shoulder injections in the management of SAIS (Lee et al 2009, Panditaratne et al 2010, Dogu et al 2012, Zufferey et al 2012). However, previous shoulder studies (Naredo et al 2004, Chen et al 2006) found that patients who received USG injections showed a significant improvement in shoulder pain and function compared with the non-USG (blind) group. Notwithstanding, more recent studies are in agreement with the findings of my study. For example, in a recent UK study Roddy et al (2016) conducted a RCT using a 2x2 factorial design to compare physiotherapy-led exercise programme versus standard exercise leaflet and USG injection versus blind subacromial injection for SAIS patients. The study involved 256 patients. SPADI was the primary outcome and was measured at 6 weeks, 6 and 12 months. The authors concluded that USG subacromial

injection did not produce better clinical outcomes compared to blind or unguided subacromial injection. Furthermore, a Dutch study by Brandi et al (2016), that involved a cohort of 56 patients with SAIS found no significant differences in the clinical outcomes between the USG subacromial injections and blind subacromial injections.

This study successfully used anatomical landmarks for the placing of the injections and this could be attributed to the training, knowledge, skills and clinical experience of the two ESPs who performed these injections. This assertion was supported by the feedback received from participants in the semi-structured interview. Most of the participants said that they thought that the effectiveness of their treatment and care was because the clinicians who performed the injections were knowledgeable about the injection procedure and confident about the outcomes. Similarly, a study by Stanhope et al (2012) found that injections performed by the ESPs working in orthopaedic outpatients improved the patients' health outcomes because they were properly trained and had adequate experience. It has also been shown that standard shoulder injections (blind) performed by experienced clinicians were reliably accurate and very effective in improving shoulder pain and function in SAIS patients during the short-term follow-up. They are also applicable to daily clinical practice (Dogu et al 2012). Chambers et al (2005) in a retrospective study that compared the accuracy and efficiency of subacromial injection through an anterior approach by a consultant, registrar and a specialist physiotherapist, found that the injections of the specialist physiotherapist (ESP) were comparable to those of the consultant and generally better than the registrar's.

In summary, the findings of the above studies suggest that currently the use of USG subacromial injections does not provide greater clinical benefit when compared with standard shoulder injections (blind) that are much cheaper and readily available within the community MSK service. The current study has clearly demonstrated that having a single blind cortisone injection either through a lateral or a posterior route for SAIS patients provided significant pain relief, both at day and night time and also improved shoulder function and disability. This is comparable with current evidence that subacromial injection is effective in shoulder pain and function. In practice, most CCG service specifications for community MSK services recommend the provision of cortisone injection using shoulder landmarks (blind) which is the usual practice. This study's finding not only supports this proposal but it also equates to cost savings for services as there is no need to invest heavily in expensive diagnostic ultrasound machines, which come with additional training costs for the clinicians who will use them. However, there are instances where the use of ultrasound guided injections is useful. For example, in Barbotage procedure for patients with calcific tendinosis (Diercks et al 2014) as well as painful small joints such as carpometacarpal joint of the thumb where blind injections might prove difficult to achieve.

5.5 Methodological Issues

The inclusion of participants in trials on strict clinical criteria alone has been suggested to limit the number of participants that could potentially be recruited into a trial (Ekeberg et al 2009). In this study, the inclusion criteria for diagnosis of SAIS were therefore based not only on the use of clinical presentation and tests, but also on clinical examination. This is based on the

work of Lewis et al (2005) who found that the use of clinical presentation and tests increased the accuracy of a clinical diagnosis of SAIS. The current study combined the presence of a positive impingement sign, such as Neer's or Hawkins Kennedy, painful arc sign and shoulder pain localised to the acromion, as some of its criteria for diagnosing SAIS (Kuhn 2009). This is not only consistent with Lewis et al's study, but also with several authors who found that using composite tests increased the post-test probability of the diagnosis of SAIS (Murrell & Walton 2001, Park et al 2005, Michener et al 2009). For example, Park et al (2005) achieved a post test probability of 95% (proportion of patients with that particular test result who have the target disorder) of impingement with similar inclusion criteria to that which were adopted for this study. The comparability of this study to previous shoulder trials therefore, makes it readily applicable to normal clinical practice and future shoulder research. The less restrictive strict inclusion criteria adopted for this study could mean that a less homogeneous group of patients were recruited into the study. However, this is acceptable because pragmatic trials often utilize less restrictive criteria (Godwin et al 2003, Alford 2007) to improve the external validity (generalisability).

Compared to previous studies (Henkus et al 2006, Kang et al 2008, Sardelli & Burks et al 2008, and Marder et al 2012) where needle placements were performed by one clinician, in this current study all the injections were performed by 2 qualified and experienced ESPs. This could therefore enhance intra-rater reliability and reduce potential treatment bias that could have resulted from a single practitioner giving these injections. However, intra-rater reliability was not measured in this current study because it was not

part of the study objectives. Although each of the injecting ESPs injected by both lateral and posterior routes, they could not pre-determine which injection site to inject because they were blinded to the participant's treatment allocation. Since the participants were randomised the possibility of treatment bias should have been reduced.

In this study, participants were randomised by the selection of an opaque envelope prior to treatment. The result of statistical analysis showed that there was no statistically significant difference between the means (SPADI and PROMs) of both groups at baseline, which means that they were not only similar at baseline, but that the process of randomisation was adequate.

In summary, the findings of the quantitative aspect of this study have shown that cortisone injection is beneficial to patients with SAIS in the short term; however, it did not explicitly prove the hypothesis that a lateral approach is clinically more beneficial to a posterior approach for subacromial injection.

5.6 Patients' Experiences

To my knowledge no study has investigated the experiences of patients with SAIS receiving subacromial injection either through a lateral or a posterior approach. Currently, this study is the first to explore the experiences of patients with SAIS who have received a cortisone injection from either the side or the back of the shoulder. This section discusses the real life experiences of the participants regarding cortisone injection.

5.6.1 The Importance of Patients' Education

Participants that were interviewed confirmed that they were given adequate information and good explanations about their care and treatment by the injecting clinicians. According to the participants, patient education involved being listened to and being involved with decision making about their treatment, understanding the possible outcome of the treatment and being given exercise advice. They said they felt involved in the discussions and decision-making process regarding their care and treatment. Some of the participants said that initially they had had anxiety about their condition and the treatment but that they were reassured after being listened to by the injecting ESP who thoroughly explained their condition to them in manner they could easily understand. This highlights the contribution that patient education makes in enhancing the overall experience of treatment for shoulder patients and consequently improving their clinical outcomes. This is consistent with a recent qualitative shoulder study by Fashanu (2014) who explored patients' expectations and experiences of physiotherapy and shoulder pain. He concluded that some shoulder pain patients lacked awareness of the possible causes of their pain and what was wrong with their shoulder (Fashanu 2014). Fashanu (2014) suggested that providing patients with information concerning their shoulder pain, its possible causes and diagnosis could ultimately prevent further deterioration and so enhance their improvement and self-efficacy. The participants were advised regarding a home exercise programme, to pace themselves and to avoid strenuous activities such as awkward or heavy lifting that could compromise their improvements. It has been reported that lifting heavy loads, working in

awkward postures and engaging in repetitive movements aggravates shoulder pain (Van der Windt et al 2000).

Participants felt that patient education as well as the therapeutic effect of the cortisone injection contributed to their overall experience and improvement of shoulder pain. The importance of patient education as a key factor in improving pain of musculoskeletal origin is consistent with other studies that have investigated the experiences and/or perceptions of patients with musculoskeletal conditions regarding physiotherapy treatment. Cooper et al (2008) in a qualitative study explored the perceptions of patients with chronic low back pain and physiotherapy treatment. They found that patients considered the discussions about their care and the exercise information they were given by the physiotherapist as very important aspects in meeting their individual needs and treatment outcomes. Similarly, a report by the Department of Health (DoH 2008) found that patients who received individual advice and education about their problem not only improved but also went on to live a more independent life. Furthermore, Jones et al (2013) in a qualitative study that explored the experiences and perceptions of people living with primary frozen shoulder found that the participants were more interested in understanding and finding a solution to the cause of the shoulder pain than in resolving it. Harrison & Williams (2000) reported that a lack of adequate information and involvement of physiotherapy patients in their treatment were some of the reasons why patients were not satisfied with their care. This highlights the importance of involving patients with musculoskeletal problems in all aspects of their care and treatment in order to enhance their overall experience and improve treatment outcomes. In this current study,

participants confirmed that their shoulder pain improved not only because the cortisone injection worked but also because the injecting ESPs involved them in the decision making processes of their care and management and any questions they had about their care were thoroughly explained to them.

There are also other aspects of the patient information, which the participants thought contributed to their overall experience. In general, they said that the information they received about their appointment together with access to the service, including the parking arrangements, also enhanced their experience. Some of the participants said that they felt that having quicker appointment times and not being kept waiting for too long by the injecting clinician as well as receiving very good customer care contributed to their overall improvement. However, a few participants felt that the information about their appointment was not clear enough and that they could have been seen sooner. Several authors (Holdworths et al 2008, Webster et al 2008) including the Department of Health (2008) have reported that if patients with chronic musculoskeletal conditions are given faster and quicker access to treatment they are more likely to manage their condition better and be more independent thus avoiding unplanned hospital admissions and improving self-efficacy.

In summary, the qualitative study revealed that the benefits of having cortisone injection either through a lateral or posterior approach are enhanced by other factors such as education about the treatment, exercise information, the experience and skills of the injecting clinicians, access to treatment as well as good customer service.

5.7 Chapter Summary

This chapter has discussed both the quantitative and qualitative study's findings and the issues in normal musculoskeletal practice regarding shoulder injections in SAIS patients. It also identified that the blind subacromial injections performed by trained and experienced ESPs were not only safe (no adverse reaction reported) and produced good clinical outcomes but were comparable to USS or MRI scan guided injections. It also discussed the contributions that patient education made in enhancing the overall experience and treatment outcomes for patients with SAIS.

CHAPTER 6 CONCLUSION

This study set out to determine the effectiveness of a lateral compared to a posterior approach to a subacromial injection used for the treatment of SAIS and to evaluate the experiences of the patients receiving the injections. It has complied with the nine dimensions for assessing the level of pragmatism in a trial, as proposed in the pragmatic-explanatory continuum indicator summary 2 (PRECIS-2) (Loudon et al 2015).

This study has demonstrated that there is strong evidence supporting the effectiveness of both lateral and posterior routes of subacromial cortisone injection in improving shoulder pain, function and disability in patients with SAIS at 8 weeks and 12 weeks. This supports the null hypothesis, which states that 'there is no significant difference in the effectiveness of lateral approach compared with posterior approach to subacromial injection at improving shoulder pain and function in patients with SAIS'. It has also demonstrated that the lateral route of subacromial injection is more effective when compared to the posterior route in improving day time pain in the short term. However, it did not demonstrate that the lateral group compared to the posterior approach was better at improving night time pain, shoulder function and the SPADI score. Therefore, it is difficult to state that this study has completely proved that the alternate hypothesis which states 'lateral approach to subacromial injection is more effective at improving shoulder pain and function in patients with SAIS compared to a posterior approach' is correct.

The study has confirmed that cortisone injections performed by trained and experienced ESPs using anatomical landmarks are not only safe (no adverse reaction reported) and are comparable to USG injections, but they are also effective, cheaper and easier to administer. These findings were also supported by the comments of the participants in the semi-structured interviews.

This study has shown that either posterior or lateral routes of subacromial injections should be considered in patients with SAIS where pain is present that is limiting daily life activities, and where physiotherapy has not helped. It has also shown that either route of subacromial injection is not only effective but is also necessary in cases where exercise or physiotherapy is aggravating the patient's symptoms. However, where shoulder pain is reduced or completely resolved after receiving a subacromial injection, but where there is still poor muscle control, clinicians should consider recommending physiotherapy to strengthen and improve muscle function. This will ultimately prevent the patient from having a recurrence of their symptoms which may lead to loss of working hours and life style changes. It will also reduce dependence on pain medication which comes with potential side effects such as abdominal irritation and constipation. By applying the recommendations that the researcher will make later in this chapter to clinical practice, clinical effectiveness will improve, the patients' treatment journey will be enhanced, and healthcare providers will potentially be saved the extra cost of patients having too many treatments.

This study found that participants did not have a preference for either posterior or lateral routes of subacromial injection. Since a maximum of three treatment sessions for injections are normally recommended within timescales of varying length, if one approach of injection does not improve the patient's symptom, a repeat injection could be considered using a different route. This highlights the importance for musculoskeletal services to ensure that clinicians, such as ESPs, who work in them are trained and experienced in performing injections using both routes and that they should keep their skills up to date by attending relevant revision courses.

From the themes discussed in the semi-structured interviews, this study has demonstrated that participants with SAIS felt that their shoulder pain and function improved not only because of the effect of the cortisone injection, but also because of other factors. These include the education they received about their treatment, exercise information, the experience and skills of the ESPs who performed the injections and because they were very professional**.** The study has clearly shown that involving patients in the decision making processes of their care and treatment and trying to answer any questions they had about their ongoing care contributed to their understanding of shoulder pain and therefore enhanced their recovery. The study also revealed that having a quicker and easier access to treatment not only addressed their individual needs but also contributed to their overall experience and therefore to their improvement. It is therefore clear from this study that there are multifactorial influences in the understanding of the therapeutic role of subacromial injection in SAIS and the overall experience of patients receiving the injections. These include the biological effect of cortisone injection, patient

education about SAIS and subacromial injection, exercise information, the experience and skills of those performing the injections. Others include the way and manner in which the injections were performed, the professionalism of the injecting clinicians, access to treatment as well as good customer service.

To my knowledge, this is the first study that has used a mixed methods research design that combines both a pragmatic RCT to investigate to investigate the effectiveness of lateral versus posterior approach to subacromial injection together with semi structured qualitative interviews to explore the experiences of the patients receiving the injections. This study has demonstrated that a pragmatic RCT combined with semi-structured interviews provides a better understanding of the clinical outcomes of cortisone injections in SAIS patients and the meaning they provide about their experiences of receiving the injections. This finding is consistent with previous authors (Shaw et al 2010, Rowell & Polipnick 2008) who have supported the use of mixed methods research design in evaluating treatment interventions and the experience of those patients receiving such treatments. Future research should therefore consider the use of a mixed methods approach that combines both a quantitative and a qualitative approach when investigating shoulder pathologies.

6.1 Limitations of the Study

In this study, the injections were performed by two injecting ESPs who were trained and had adequate experience and skills. However, before the study there was no agreement on the number of injections that each of the ESPs

would perform. It was difficult therefore to determine whether one of the ESPs performed more injections in comparison to the other or whether they used one approach more than the other. The lack of an equal amount of injections provided by each of the clinicians could limit inter-rater reliability of the interventions. However, since the participants were adequately randomised and the injecting clinicians were trained and knowledgeable about the injection techniques, the outcomes of the interventions should still be reliable.

The injecting clinicians provided verbal after care advice and written exercise information, but the exercises were not standardised for all the participants because they were intended to meet the specific needs of each patient. This is the usual practice. The lack of standardised exercise information could constitute a weakness in the study. However, my study was mainly investigating the effectiveness of two routes of subacromial injections and not the effect of patient education or specific exercise prescription on SAIS patients. The written consent information that was provided to the participants before the injections and the after-care information they received were however, similar.

The limitations due to the inclusion criteria adopted for this study, whereby some patients that could have been recruited into the study may have been missed, are hard to eliminate. Another weakness in this study could be the fact that the inclusion criteria were based mainly on clinical grounds; this could mean that specific pathology located in the subacromial space might have been missed (Henkus et al 2006). As with many pragmatic trials (Ainsworth et al 2009), one of the weaknesses of this study was the lack of

blinding of the injecting ESPs to the injection approaches, which may have introduced a bias. However, the ESPs were blinded to participant treatment allocation in order to minimise experimenter bias and the assessor was blinded to the baseline measures to reduce assessment bias. According to Gøtzsche (2006), assessment error is defined as error in the assessment of clinical outcomes.

The method of data collection in the qualitative study could be another weakness in this study. The semi-structured interview period was short and there were few variations in the amount of time spent on the interviews, with some participants having more time than others. This could have reduced my ability to probe for more in-depth responses which are necessary for obtaining richer data (Patton 1990). However, I did make an effort to try to ensure that enough information was gathered from the participants during the interviews. I also used respondent re-validation by sending the transcript back to the participants to ensure that its contents matched what had been said. I used a semi-structured interview design to guide the process of the interview. This meant that interview questions were more focused around key issues of the patients' experiences of cortisone injection, thus ensuring that data relevant to the key issues was collected from all participants.

6.2 Reflection on my Current Practice

This study has reinforced my clinical experience that providing subacromial injections using the standard anatomical landmarks method (blind) does not only produce good clinical outcomes, but is also safe because no adverse reaction or significant side effect was reported. This study has also shown

that the successful use of anatomical landmark injections could be attributed to the years of training, knowledge, skills and clinical experience of the injecting ESPs. Therefore, as the Clinical Lead of my service, I will continue to encourage and support the training of potential ESPs in injection therapy to enhance the overall needs of the service and improve clinical outcomes.

This research has highlighted to me the significant benefit of including patient experiences as part of a quantitative research study. As an Extended Scope Physiotherapist, my training and clinical experience has its root in a medical or biomedical model of assessing and treating patients with musculoskeletal pathologies such has SAIS. Over the years, I have adopted some biopsychosocial approaches by taking into consideration patients' expectations and experiences of the treatment they receive as part of my management strategy. Now the role of the psychosocial aspects (experiences) of a patient's recovery is even more evident to me since undertaking this research. This study has shown that the experiences of patients' regarding subacromial injection were significant contributors to the outcomes of their treatment. For example, providing patients with adequate information about their treatment further puts their mind at ease and gives them the confidence to use their shoulder better without fear of causing more harm. This fact has led me to be more patient focused in my subjective questioning and treatment using a more psychosocial approach. This is consistent with a recent systematic review that recommended the use of a psychosocial approach in the management of subacromial pain syndrome (Shanahan & Sladek 2011).

Participants in my study were of the opinion that not being kept waiting for too long by the injecting clinician as well as receiving very good customer care also contributed to their overall improvement. Although in my practice, I make it a point of duty to treat my patients on time, however, on a personal level, I am now even more determined to try not to keep them waiting for too long before being seen.

6.3 Implications of the Study and Recommendations for Practice

6.3.1 To Provide Subacromial Cortisone Injection for SAIS Patients

This study has demonstrated that subacromial injection improves shoulder pain, function and range of movement in the short-term in adult patients with SAIS; therefore, I would recommend that it should be considered as an early intervention for patients with shoulder pain. The study also agrees with previous authors that subacromial injection should be considered where physiotherapy has failed to improve symptoms of SAIS or the shoulder is acutely painful. It should also be used as an adjunct to physiotherapy, to enhance and reduce the number of physiotherapy sessions substantially (Hanchard et al 2004, NICE 2015).

6.3.2 To Refer Shoulder Injection Patients for Physiotherapy

In agreement with previous studies, this study has shown that participants' shoulder function improved not only with a cortisone injection but also from the exercises that they were given by the injecting ESP. I would recommend that clinicians such as GPs, rheumatologists and orthopaedic consultants should consider referring patients with shoulder pain to physiotherapy for

exercise advice after they have received shoulder injections particularly where the patients have residual poor muscle control/strength.

6.3.3 To Provide Lateral Route of Cortisone Injection

This study has showed that the lateral route of subacromial injection produced better day time pain relief when compared to the posterior approach. I would therefore recommend that the lateral route of injection should be considered in the first instance for patients who only suffer day time pain and who have no night symptoms as this may be more beneficial for them.

6.3.4 To Train more ESPs to Provide Cortisone Injection

This study has also confirmed that subacromial injections in combination with patient education and exercise information are effective in patients with SAIS and should therefore be used in their treatment. This study did not report any adverse effects with the subacromial injections given, therefore, clinicians such as ESPs and GPs should be encouraged to provide it as the treatment of choice, particularly in shoulder patients were pain is the main limiting factor. This would suggest that if ESPs working in community or outpatient musculoskeletal practice were trained to perform these injections this could potentially reduce the number of unplanned hospital visits by patients with shoulder pain thus reducing costs for the CCG and NHS. Therefore, more ESPs working in community or outpatient musculoskeletal practice should be trained to perform these injections.

6.3.5 To Involve Shoulder Injection Patients in Their Treatment

This study has highlighted the importance of providing good information and knowledge to patients with shoulder pain receiving subacromial injection. Participants felt that being involved with discussion and decision making about their care and treatment enhanced their understanding, expectations and ultimately the success of their treatment outcome. This suggests that clinicians such as GPs and Rheumatologists who also provide shoulder injections should be aware of the contributions that good patient information and knowledge can add to both the patients experience and treatment outcomes. Therefore, ESPs as well as other clinicians such as GPs and Rheumatologist should ensure that they involve patients in care and treatment plan and also provide them with adequate information to improve their treatment outcomes and experience.

6.3.6 To Encourage Clinicians and Services to be Professional

This study has shown the benefit how the professionalism of the injecting clinicians, access to treatment as well as good customer service contributed to the overall experience of the patients. This implies that MSK physiotherapists should be aware of how their professionalism and therapeutic relationship with the patients they treat contributes to the overall patient experience and clinical outcomes. It also follows that the Administrative staff who provide patients with treatment appointments over the telephone should consider how their rapport with them could influence the patients' treatment experiences and outcomes. This learning should be reinforced and applied to other areas of musculoskeletal practice such as back pain patients.

6.3.7 To Set Up Musculoskeletal Service within the Community

This study has highlighted the importance of setting up a musculoskeletal practice within a central location in the community with easy access and good customer service. It is important therefore for commissioners, GP groups and service providers to work closely together to address these issues before commissioning a community musculoskeletal practice. It is equally vital to seek the opinions of service users during the commissioning phase of such a project. Those who manage such services should to endeavor to make available treatment appointments so that patients are seen sooner, thereby avoid long waiting list. Clinicians working in such a service should ensure they do not keep patients waiting for long before being treated because this could impact on their overall experience and treatment outcomes.

6.4 Recommendations for Future Research

This was a pragmatic single centre RCT with participants from several GP practices from across the area, therefore future research could consider the use of a multicentre RCT to further enhance the geographical spread of the study and therefore the generalisation of the findings. In this study, the exercise information was not standardised but was provided to the patients based on their individual needs. Future studies could therefore compare the use of exercises prescribed from a patient-focused perspective or from a standardised format in order to establish the contribution of different approaches to exercise to subacromial injection outcomes.

The results of the study have shown that both lateral and posterior routes of subacromial injection are effective in treating patients with SAIS in the short

term, further work is therefore necessary to establish long term effectiveness of these treatments. However, this may be difficult to assess due to 8 and 12 weeks' loss to follow-up. The follow-up periods in this study were consistent with some previous studies, therefore, if future research investigating subacromial injections were to adopt similar follow-up periods this would enhance the possibility of systematic review and meta-analysis in this area.

This study has shown that a mixed methods research design that combines RCT and semi-structured interviews to investigate subacromial injections in patients with SAIS provides a better understanding of the factors that contribute to the patients' overall experiences and clinical outcomes. In view of these benefits, future studies could therefore consider the use of both a quantitative and qualitative research method in the investigation of musculoskeletal conditions such as shoulder conditions.

Finally, this study has clearly shown the benefits of using a mixed methods research design to investigate the effectiveness of lateral versus posterior approach to subacromial injection and also the experiences of the patients receiving the injections in normal musculoskeletal practice. Although there were no real significant differences in the treatments, this study has clearly demonstrated that subacromial injections performed using anatomical land-marks by ESPs provided significant clinical improvements in day time pain, night time pain, shoulder function and disability in participants with SAIS. It has also shown that these benefits were not due to the effects of the cortisone injection only but also because of other factors such as patient education and their involvement in the treatment, exercise information, the

professionalism, experience and skills of the injecting clinicians, access to treatment as well as good customer service.

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APPENDICES

Appendix 1: Standard Operating Procedure for the Research

Standard Operating Procedure (SOP) for the Research titled: Needle Placements in Patients with Subacromial Impingement Syndrome: A Comparison of Two Approaches
Service and Premises to Which SOP applies: • The (name of service) Community Musculoskeletal (MSK) Service (place of service) **Version Control** **Date:** v1 21st July 2014 **Date:** v2 14th August 2014
Objectives/Purpose: The purpose of this document is to enable the service, particularly all those involved in the research, to be aware of what their involvement and roles are.
Scope: This procedure document applies to the Extended Scope Practitioners participating in the study working in the service and the Service centre and Administrative staff at Hastings who might be involved.
Responsibilities: • The Chief Investigator - the Clinical Lead is to ensure that all aspects of patients' participation in the research including data collection and recording are met. • It is the responsibility of the Extended Scope Physiotherapists involved in the research to be aware of their roles. • It is the responsibility of the Administrative staff involved in the research to be aware of their roles.
Related Guidelines and Standard Operational Procedures (SOP) to be read in conjunction with this SOP: • CSP Code of Members' Professional Values and Behaviour (2012);
Introduction: The (name of service) MSK Service aims to provide the highest form of quality care and in doing so set clear guidelines regarding aspects of the service, such as staff participation in research.

Definitions

1.0

0.1. **ESP –**Extended Scope Physiotherapist
0.2. **CSP –**Chartered Society of Physiotherapy
0.3. **SPADI –**Shoulder Disability Index

0.4. PROMS –Patient Reported Outcome Measures

2.0 Health & Safety

2.1 There are no Health & Safety implications associated with the implementation of this procedure regarding normal procedures to minimise risk of needle stick injury

2.2. All the ESPs involved in the study must ensure they have adequate training, experience and skills required. While the Administrative staff involve will receive guidance necessary for their involvement

3.0 Procedure

3.1 Participant Identification

3.1.1 Patients referred by their GP with shoulder pain and associated pathologies and then triaged to participating ESPs for possible injection

3.1.2 Patients referred by GP with shoulder pain, with specific request for cortisone injection and then triaged to participating ESPs for possible injection

3.1.3 Patients referred by Physiotherapists with shoulder pain to ESPs for review

3.1.4 Patients referred by Physiotherapists with shoulder pain to ESPs for possible cortisone injection

3.2 Participant Recruitment

3.2.1 When the first musculoskeletal appointment is posted to the patient, a separate envelope containing the letter of invitation to take part in the study will be sent also. This will include patients with first shoulders appointments and all new shoulder injection appointments

3.2.2 The invitation pack will contain a letter of invitation with a Patient Information Sheet (Patient Information Sheet) and two consent forms (for the quantitative part and qualitative interview) (consent forms)

3.2.3 Participants are to bring the consent forms with them to their first appointment with the ESP

3.2.4 Those who forget to bring consent forms will be provided with copies upon arrival for their appointment

3.3 Clinicians Involvement

3.3.1 Injecting ESPs will be directly involved in this study.

3.3.2 The injecting ESPs will be involved in consenting, assessing and injecting patients

3.3.3 Both injecting ESPs to complete the study's screening log that include date, hospital no, eligible, not eligible and why not, name of screener and signature

3.3.4 Both injecting ESPs will be involved in recording the baseline Shoulder Pain Disability Index (SPADI) and PROMS measures including the study no

3.3.5 Both injecting ESPs are to provide the Reception on duty with the baseline SPADI and PROMS sheet after every clinic

3.3.6 Chief Investigator will be involved in the follow-up assessments at 8 and 12 weeks

3.3.7 Chief Investigator to provide Reception Staff on duty with records of follow-up assessments at 8 and 12 weeks

3.3.8 Chief Investigator to undertake data cleaning after completion of follow-ups

3.3.9 Chief Investigator will be involved with telephone interview of the patients after the quantitative study

3.4 Service Centre Involvement

3.4.1 When the first musculoskeletal appointment is posted, to provide all shoulder patients that have been triaged to ESP clinic with the Participant Information Sheet (PIS), letter of invitation and consent forms

3.4.2 To book appointment with injecting ESP's only when they are working at (place of service)

3.5 Administrative/Reception Staff

3.5.1 When patients with shoulder pain are referred from physiotherapists to ESP, to provide them with the study's letter of invitation, PIS and consent forms along with their appointment letters

3.5.2 After an eligible patient has given consent to participant in the study, Reception staff should open the serially numbered sealed envelope and inform injecting ESPs of the allocation by randomisation (injection route) and the patient's study no

3.5.3 Reception staff should record on the envelope the patient's study number and allocation route

3.5.4 Reception staff should record the patient's study number, hospital number, gender, age, initials, allocation date, allocation route, name of investigator in the study allocation sheet and then sign it

3.5.5 Reception staff to provide the Chief Investigator with the patient's name, contact telephone number including mobile number and the patient's study number

3.5.6 Reception staff to enter the following details from:

3.5.6.1 The study allocation sheet – Hospital number,

3.5.6.2 Baseline data – Date, Study number, Age, Gender, Duration of symptoms, Manual occupation (yes or no), Dominant side affected (yes or no), Previous cortisone injection (yes or no), Current treatment Analgesia/NSAIDS, Initial SPADI score, and Initial PROMS score (**Current pain level, how much of night pain is causing sleep disturbance and how of much of function is affected**),

3.5.6.3 SPADI outcome at 8 weeks, PROMs (**Current pain level, how much of night pain is causing sleep disturbance and how much function is affected**) at 8 weeks

3.5.6.4 SPADI outcome at 12 weeks, PROMs (**Current pain level, how much of night pain is causing sleep disturbance and how much function is affected**) at 12 weeks

3.6 Regional operations manager, service manager, service centre manager

3.6.1 Regional operations manager, service manager, service centre manager to please ensure the Service centre staff understand and comply the research SOP

3.6.2 To inform the GP's via the CCG using the Research letter to GP's

3.6.3 To provide individual GP's the research letter to GP's if requested

3.7 Research Coordination

3.7.1 Chief Investigator to coordinate all aspects of the research SOP, with Regional operations manager, service manager, service centre manager and National MSK Lead

3.8 Glossary

3.9 Reception Staff -

3.10 Injecting ESP's -

3.11 Chief Investigator – Clinical Lead - Collins Ogbeivor

3.12 Service Manager –

3.13 Service Manager –

3.14 Regional Operations

3.15 National MSK Lead –

Appendix 2: Letter of Invitation to Participants

Study Title: **Comparison of the Effectiveness of Side versus Back Approach of Shoulder Injections in Patients with Shoulder pain**

Dear Sir/Madam,

My name is Mr Collins Ogbeivor. I am a professional doctorate student in the School of Health and Human Sciences at the University of Essex, Colchester. I am conducting a research study as part of the requirements of my degree in Physiotherapy and I would like to invite you to participate. This study is sponsored by the University of Essex.

I am studying what difference it will make injecting people suffering from shoulder pain from the side or back of the shoulder with cortisone injection. This study is in two parts; the first part is to find out whether people with shoulder pain who are injected from the side of their shoulder would have better pain relief and improved shoulder function compared to those who are injected from the back of the shoulder. The second part is to find out the experiences of patients with shoulder pain who have received a cortisone injection from either the side or the back of the shoulder.

If you decide to participate, you will be asked to you receive a shoulder injection containing cortisone injection and Lidocaine either from the side or back of the shoulder. You will also be asked to participate in an interview discussion about your experience of the shoulder injection. The interview will take place over the telephone at your home or a place convenient at a mutually agreed upon time and place, and should last about 15 - 20 minutes. The interview will be audio taped so that I can accurately reflect on what is discussed. The tapes will only be reviewed by members of the research team who will transcribe and analyze them. They will then be destroyed.

We will be happy to answer any questions you have about the study. You may contact me on (telephone number or email), or my work supervisor, (name), on (telephone number) or (email) if you have study related questions or problems.

Thank you for your consideration. If you would like to participate, please open the invitation pack containing a Patient Information Sheet and two consent forms and read them. When you are done reading them and you wish to participate in the study, please bring these documents along with you during your first musculoskeletal appointment with the Extended Scope Practitioner (Musculoskeletal Clinical Specialists) at (unit address).

With kind regards,

Collins Ogbeivor (MSc, BMr-Physio, MCSP, SRP)
Clinical Lead/Extended Scope Practitioner

Appendix 3: Participant Information Sheet

A Comparison of the Effectiveness of Side versus Back Approach of Shoulder Injections in Patients with Shoulder pain (Subacromial Impingement Syndrome)

You have been invited to take part in this study

My name is Mr Collins Ogbeivor. I am a professional doctorate student in the School of Health and Human Sciences at the University of Essex, Colchester. I am conducting a research study as part of the requirements of my degree in Physiotherapy and I would like to invite you to participate. This study is sponsored by the University of Essex. I would like to invite you to help us with this study and participate in this research. I hope to find out what difference it will make injecting people suffering from shoulder pain from the side or back of the shoulder.

Before you make your mind up, it is necessary for you to understand why the study is being done and what it would involve. I hope you will take time to read this information sheet carefully before you are asked to give your consent to being part of the research. If there is something that you do not understand, please ask me. My contact details are given at the end of this leaflet.

Why have been invited?

You have been invited to participate in this research because you have been referred by your GP to (address of unit) service because you could benefit from injection therapy for treatment of your shoulder pain.

What is the purpose of the study?

- In the UK, the incidence of shoulder pain is very common.
- Whilst a cortisone injection is effective in relieving symptoms of pain and inflammation in people with shoulder pain, we do not know if people are more likely or less likely to benefit if they are injected from the side or the back of the shoulder.
- The purpose of this research is to find out **what difference it will make in terms of better pain relief and improved shoulder function injecting people suffering from shoulder pain from the side or back of the shoulder**

The diagram below illustrates the difference between the lateral (side) and posterior (back) approach of subacromial injection

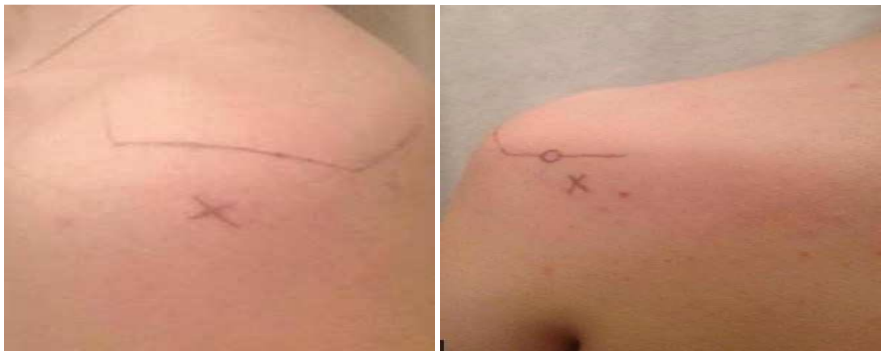


Figure 3a **Figure 3b**

Figure 3: (a) External view of left shoulder showing the location of the lateral shoulder portal (b) External view of left shoulder showing the location of the posterior shoulder portal

- In addition, the study aims to find out the experiences of patients with shoulder pain who have received a cortisone injection from either the side or the back of the shoulder.

Are there any benefits if I take part in this study?

There will not be any direct personal benefit by taking part in this study. However the information we derive from your participation in this study will help us to know how better to treat patients with shoulder pain using shoulder injections in the future.

Do I have to take part?

No, it is up to you to decide. If you agree to participate, you will be given a consent form which you should read in full and sign if you are willing to participate. If you decide not to participate or wish to withdraw from the study later, you may do so at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen if I agree to participate?

- You will be asked to complete the consent form contained inside the enclosed envelope. You will need to bring this with you to your first musculoskeletal appointment.

- **You will be randomised onto the study to either receive a lateral or posterior shoulder injection**

- Your musculoskeletal assessment and treatment will take place as usual.

- Eight and twelve weeks after your first injection therapy a clinician will contact you through telephone to assess your progress.

- Twelve weeks after your injection therapy you may be contacted to part take in a telephone interview about your experiences regarding the treatment you received – if you agreed to this in the consent form.

Are there any possible risks and disadvantages involved in taking part?

There are no additional risks involved besides those that could routinely possibly be related to the treatment, such as minor bleeding, pain, skin colour changes, **seizure (convulsion) and anaphylactic shock**. Please be informed that you will be offered an injection therapy either through the side or back of your shoulder.

Your appointment may take a little longer than if you were not participating in this study.

Will the information collected from me be kept confidential?

Yes, following ethical and legal practice, all the information collected about you as part of this study will be handled in confidence. Only those involved in your care will know if you are participating in the study. The findings from both aspects of the research will be made available to the course supervisor Dr Sheila Black of the Essex University. However, these will not contain any personal details that will identify you, for example your name, home address.

All your details, as well as your comments, will be kept secure and confidential. **Recordings of the interview will be kept anonymously on tape.** Any information you provide to the researcher will be anonymised using pseudonyms and unique identification numbers, so that it will not be possible to identify you.

Will my GP be informed of my participation in the study?

I would like you to provide written informed consent that we have your permission to inform your GP that you are participating in this study. If you are uncomfortable or your pain is getting worse, please contact your GP, who will be happy to help.

What will happen to the results of the research study?

The results of this study will be written up and presented as a research thesis submitted in partial fulfillment of the requirements for a degree of Doctor of Physiotherapy that is being undertaken by the researcher. A copy of the thesis will be deposited in the Albert Sloman Library at the University of Essex. In addition, the results will be shared with the NHS including GP practices. The thesis and results will not contain any names or details that will be identifiable to you personally.

Who is organising and funding the research?

There is no funding for this research. This study is being undertaken as part of a Doctoral thesis by Collins Ogbeivor - Extended Scope Practitioner and Clinical Lead under the supervision of Dr Sheila Black who is a lecturer at the University of Essex, and the clinical supervisor.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study will be reviewed and approved by the National Research Ethics Service London – Chelsea Research Ethics Committee. In addition, because the study will involve NHS patients in non-NHS setting –Community Musculoskeletal Service, it will be reviewed by the NHS Research Consortium and approved by the (address of unit) Research Board.

Who can I speak to if I have more questions or concerns?

If you have any further questions or concerns before, during or after the research, please email us through the details provided below. The researcher will also be happy to talk to you after the research has concluded, if you have any concerns.
Chief Investigator name Collins Ogbeivor Contact details Tel: xxxxxx, Email aocogb@essex.ac.uk

I would like to participate in this study. What happens now?

1. Read the consent form

2. Bring the consent form and the participant information sheet with you to your first orthopaedic appointment. Please do not leave them at the reception desk

3. You will be asked to sign the consent form after you have had an opportunity to ask any questions that you may have.

What if I do not want to participate in the study?

You do not have to do anything more.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the Chief Investigator, Collins Ogbeivor (Tel:xxxxxx) who will do his best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Service Manager at the (address of unit) (Tel xxxxxx)

CONTACT INFORMATION
If you have further questions about the study please contact Collins Ogbeivor

Landline/Answer Machine: (Telxxxxx) There is an answering machine on the landline. Please leave a message and Collins Ogbeivor will return your call.
Study Specific Mobile Number: xxxxxx
Email address: You may also wish to email your questions to **me** at aocogb@essex.ac.uk
Postal Address: Collins Ogbeivor, (address of unit)

Appendix 4: Consent Forms

Section 1 – Quantitative Study

Title of Project: **Comparison of the Effectiveness of Side versus Back Approach of Shoulder Injections in Patients with Shoulder Pain**

Name of Chief Investigator: Collins Ogbeivor

	Please Initial each box separately
1. I confirm that I have read and understand the participant information sheet dated 02/01/2013 (version 1), provided for the above study and have had the opportunity to ask questions	
2. I understand that I will be offered an injection therapy through either the side or back of the shoulder.	
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to give any reason, without my medical care or legal rights being affected	
4. Should I wish to withdraw from the study I am aware that any information already collected can still be used	
5. I understand that my GP may be informed of my participation in the study and I give my consent	
6. I understand that relevant sections of my medical notes and data collected during the study, which is anonymised, may be looked at by individuals from (address of unit), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my anonymised records	
7. I understand that the findings of the above study will be made available to the academic supervisor (Dr Sheila Black of University of Essex) and that, the information I give will be anonymised so I cannot be identified	
8. I agree to take part in the above study	

Name of Patient	Date	Signature
Chief Investigator	Date	Signature

Section 2 – Qualitative Semi-structured Interview Study

Title of Project: **What are the experiences of patients with shoulder pain experiencing side versus back approach to shoulder injections?**

Name of Chief Investigator: Collins Ogbeivor

	Please Initial each box separately
1. I confirm that I have read and understand the participant information sheet 02/01/2013 (version 1), provided for the above study and have had the opportunity to ask questions and will take part in a semi-structured interview	
2. I agree to be contacted to arrange a date and time convenient for the interview	
3. I confirm that I am happy to have the interview taped anonymously	
4. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to give any reason, and without my medical care or legal rights being affected.	
5. Should I wish to withdraw from the study I agree that any information already collected can still be used	
6. If I decide to leave this study I understand that this will not affect my future care	
7. I understand that the findings of the above study will be made available to the academic supervisor (Dr Sheila Black of University of Essex) and that, the information I give will be anonymised so I cannot be identified	
8. I agree to take part in the above study	

Name of Patient	Date	Signature
Chief Investigator	Date	Signature

Appendix 5: Patient Reported Outcome Measures

SHOULDER INJECTION BASELINE MEASURE *NHS*

Study No **Date**

Age **Gender: Male or Female**

Duration of Symptoms in weeks **Manual Occupation: Yes or No, if yes --**

Dominant side affected Yes or No **Previous Cortisone Rx Yes or No**

Current treatment analgesia/NSAIDS (type)

BEFORE THE INJECTION:

Are you able to do your usual work? YES □ NO □ N/A □

Are you able to do your usual sports/hobbies? YES □ NO □ N/A □

On a scale of 0 to 10, If 0 = no pain, 10 = very severe pain? (Please circle correct number)

What is your current shoulder pain level?

0 1 2 3 4 5 6 7 8 9 10

What is the level of shoulder pain at night time causing sleep disturbance on a scale 0 – 10?

0 1 2 3 4 5 6 7 8 9 10

How much is function affected (specify function_____)

0% 20% 40% 60% 80% 100%

Plan at 8/52: (mark appropriate category)

- Consider repeat injection
- Further investigation
- Refer to In-house Consultants or Secondary Care

Comment.....

.....

.....

Thank you Patient signature.....Date ...../..../.....

Appendix 6: Shoulder Pain and Disability Index

Shoulder Pain and Disability Index (SPADI) NHS

Study No **Date**

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

Pain scale

How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

Disability scale

How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

Total Score: /130

Appendix 7: Qualitative Semi-Structured Questions

1. Has there been any improvement since having the injection?
2. If given the choice would have preferred your injection from the side or the back of the shoulder? Why did you answer that way?
3. Now that you have had you treatment, how did you find the experience?
4. What are your experiences concerning your patient care from when your GP referred you to this service?
5. If provided with the opportunity, would you have preferred to have the injection in the acute trust or in the community? Why did you answer that way?
6. Would you recommend this treatment to a friend or relative who had the same problem? Why did you answer that way?

Appendix 8: Examples of Descriptive Items by the Participants

Participants expression of the actual needing experience

- I did not realise it had been done
- No real pain
- I did enjoy it and I did not feel it
- I didn't feel any pain
- The experience as fine
- It is very good, it is not painful at all having the injection
- It's been good, the injection did not hurt

Participants expression of the injection treatment

- From the injection 2 weeks I started to see improvement
- Everything was great, the injection, the way he performed it
- Possibly both the injection and exercises made the difference
- I have 100% improvement, when I had the last injection
- As far as I am concerned the injection was what improved the pain
- Because after you've had the injection you are back to complete
- The injection, I don't really know because it is stiff

The impact of exercise information to treatment

- I think where I had the injection and I followed the exercises
- The way the exercises were explained and I have been doing them
- Everything was great, the injection and the exercise
- I think it is from the exercises I have been given
- Yes, it has not been bad, the exercises I have been given
- The exercises as well to strengthen my muscles

Participants description of factors associated with their shoulder pain

- My shoulder was quite inflamed and painful
- Using my arm at work could have cause the pain
- Not been able to sleep because of the pain
- The time factor of 18-20 months was important
- I played regular Badminton
- I had the psychology that this was going to heal itself with time

Perception of the injection technique and clinician's attitude

- Probably technique as well
- The man who did the injection was polite and knew what he was doing
- He was more than helpful
- The way I was treated, I did not feel I was another candidate
- The guy was professional and he knew what he was doing

Uncertainty and anxiety about the shoulder problem and the treatment

- Actually, I was scared Initially
- I did not know what was going in the shoulder
- Because I play regular Badminton I was not sure if it was impingement or tendonitis or full tear
- I had constant pain initially and did not know where I was heading for
- I did not know much about it
- I don't know I was coming for an injection
- I wasn't sure what the problem was whether it was due to spondylolitis that is coming from the neck or just injury to my shoulder pain.

The impact of patient education

- Because everything was explained thoroughly to me
- Knowing what was going in the shoulder and what I need to do
- I did not know much but I followed the advice
- The way the exercises were explained to me
- I think just been explained to and been talked thorough certainly helped
- Very professional, 10 out of 10 really because you were listened to
- I thought it was explained, he showed me what to do
- The way things were explained to me and how the injection works

Participants expression of satisfaction

- 10 out of 10 definitely
- Very good, yes no problem, no problem at all
- He was so caring, oh yes, he was a wonderful man
- If the other one goes, I will be knocking at your doors
- I will sing the praise of everybody and I will go on all day
- Thank you for giving me my shoulder back it is wonderful
- I couldn't fault it at all
- Everything has been every good everyone looked after me
- My experience was a good one
- All done fine and perfect
- Once I had appointment with you, patient care was wonderful
- It has been brilliant

Participants preference for been treated in a community setting

- I can go down there, I can pack and I can walk
- I will prefer it at the station, it was not hurried
- Oh no in the community was good
- Coming to you was better, the time and it was a bit more friendly
- Anywhere I don't mine, so, it was suitable here, no waiting
- In the community or hospital it makes no difference to me
- In the community, it is fine because it is easy and convenient
- Because it is nearer
- The appointment did not take long
- The experience regarding the time, phone call all very good

Perceptions about cortisone injection

- People do have concerns about steroid, but I would say to them have it
- I will be sending them to you because it works
- It didn't help me, probably it could help someone else
- It took a long time, it took a few months than I thought
- The injection and time. It took more than 2 months to work

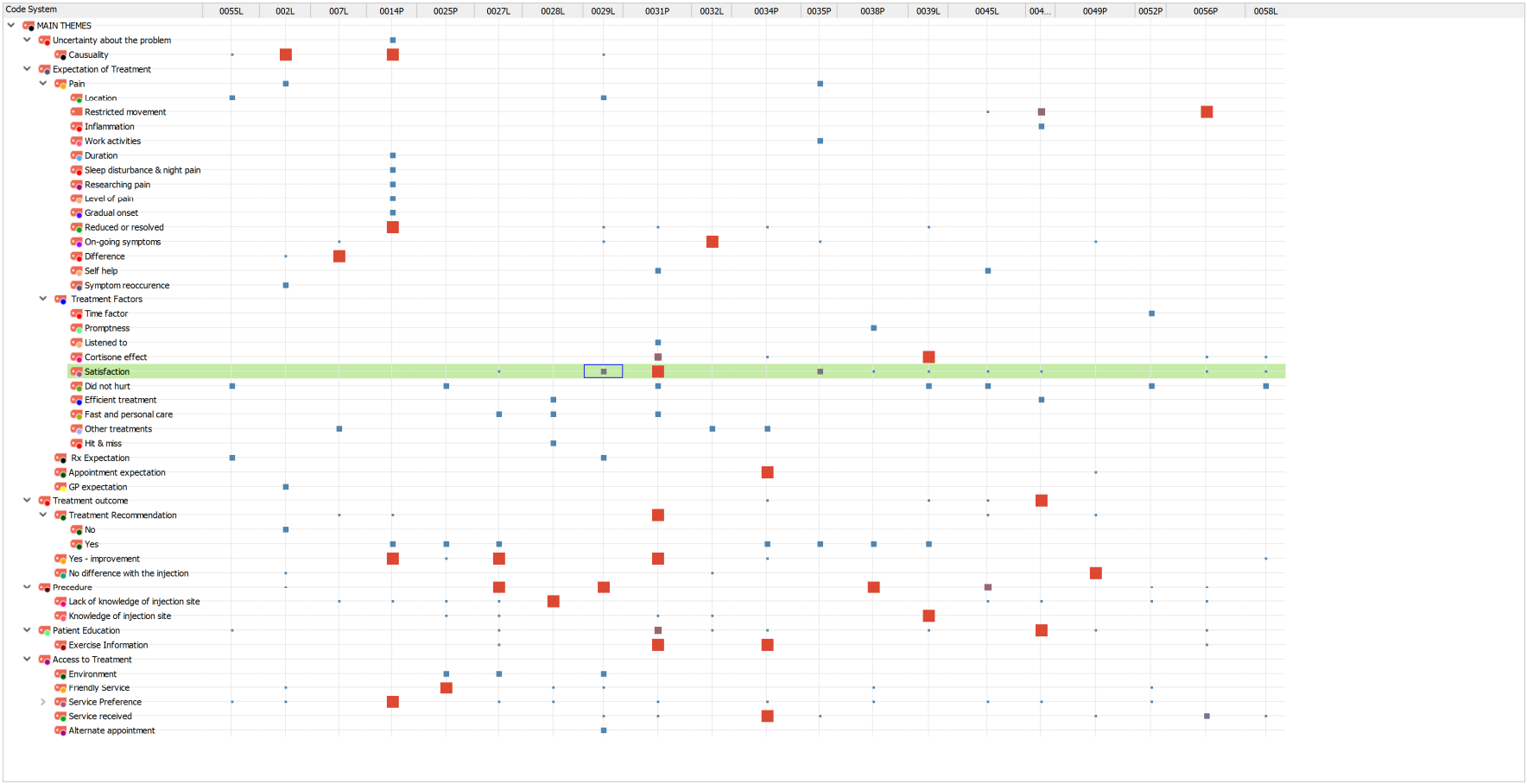
Result after seeing their GP to be referred for treatment

- They said I was not meeting the criteria because I could lift my shoulder
- I had to insist on physiotherapy and have MRI scan
- The GP letter took about 3-4 weeks, but apart from that everything was fine
- I went to the GP, and 2 weeks later I got the appointment
- When I had of the sound of physiotherapy, I could have preferred physio
- Since having the injection I had to go and have MUA

- I had the appointment fairly quickly and was seen so fast
- No problem because my GP retired 6 months ago

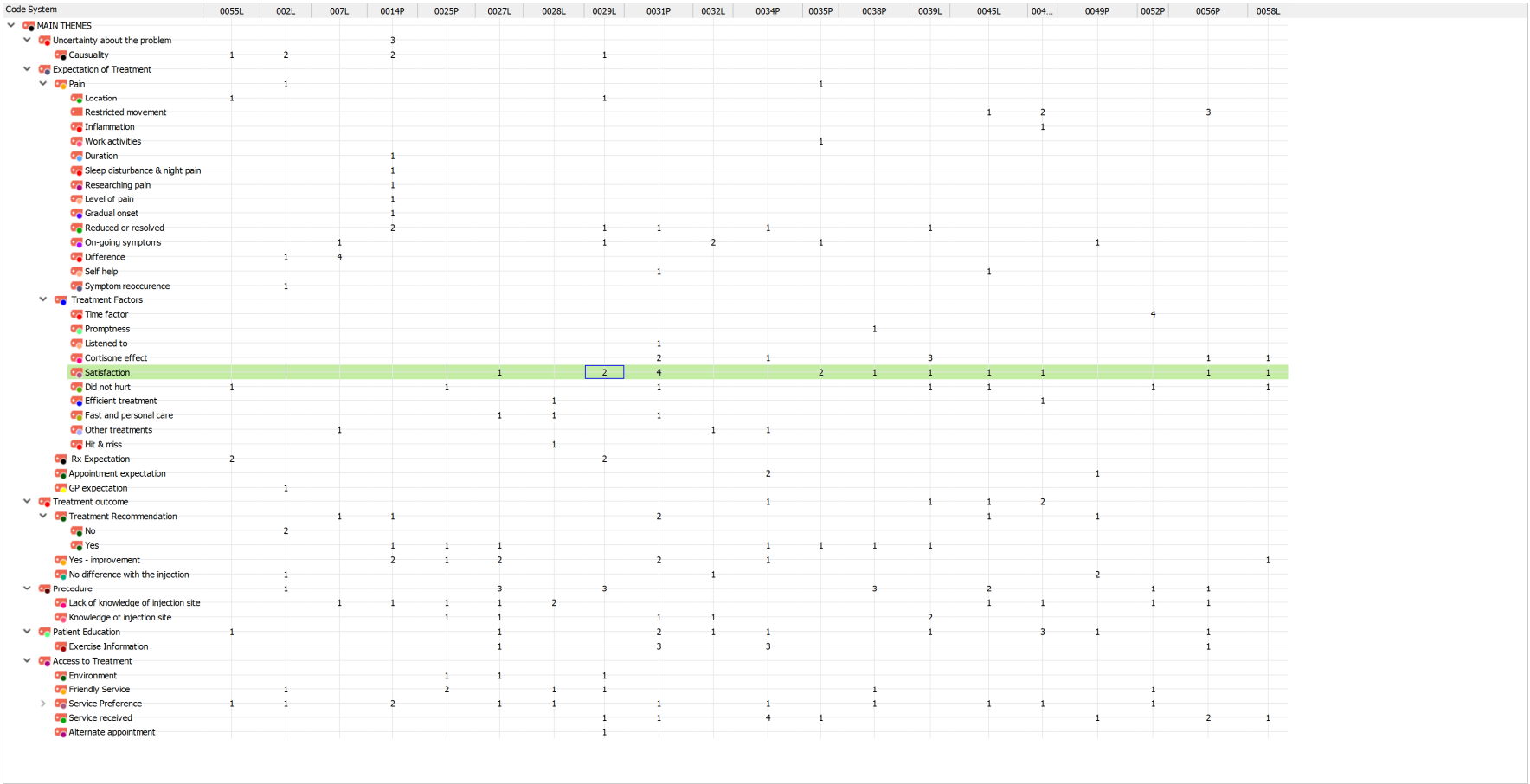
Appendix 9: Code System

A. Charts with boxes



Keys: Boxes represent number of codes

B. Charts with number codes



Code System	0055L	002L	007L	0014P	0025P	0027L	0028L	0029L	0031P	0032L	0034P	0035P	0038P	0039L	0045L	004...	0049P	0052P	0056P	0058L
MAIN THEMES																				
Uncertainty about the problem				3																
Causuality	1	2		2				1												
Expectation of Treatment																				
Pain		1										1								
Location	1							1												
Restricted movement															1	2			3	
Inflammation																1				
Work activities												1								
Duration				1																
Sleep disturbance & night pain				1																
Researching pain				1																
Level of pain				1																
Gradual onset				1																
Reduced or resolved				2				1	1		1			1						
On-going symptoms			1					1		2		1					1			
Difference		1	4																	
Self help									1						1					
Symptom reoccurence		1																		
Treatment Factors																				
Time factor																		4		
Promptness													1							
Listened to									1											
Cortisone effect									2		1			3					1	1
Satisfaction						1		2	4			2	1	1	1	1			1	1
Did not hurt	1				1				1					1	1			1		1
Efficient treatment							1									1				
Fast and personal care						1	1		1											
Other treatments			1							1	1									
Hit & miss							1													
Rx Expectation	2							2												
Appointment expectation											2						1			
GP expectation		1																		
Treatment outcome											1			1	1	2				
Treatment Recommendation			1	1					2						1		1			
No		2																		
Yes				1	1	1					1	1	1	1						
Yes - improvement				2	1	2			2		1									1
No difference with the injection		1								1							2			
Preceedure		1				3		3					3		2			1	1	
Lack of knowledge of injection site			1	1	1	1	2		1	1					1	1		1	1	
Knowledge of injection site					1	1								2						
Patient Education	1					1			2	1	1			1		3	1		1	
Exercise Information						1			3		3								1	
Access to Treatment																				
Environment					1	1		1												
Friendly Service		1			2		1	1					1					1		
Service Preference	1	1		2		1	1		1		1		1		1	1		1		
Service received								1	1		4	1					1		2	1
Alternate appointment								1												

Keys: Numbers represent codes

Appendix 10: Example of using Framework for Descriptive and Classification Analysis

Participant ID, Gender, Age, Treatment Group	Column B Data charted in column 3.5: Professionalism of the injecting clinician	Column C Elements/Dimensions identified	Column D Categories/classes
0052P, Male, 43, Posterior group	It seems fine where I had it and no trouble at all. I thought the guy was very professional he knew what he was doing. When I had it before the GP did not really know what he was doing. He stuck the needle in my shoulder and started wiggling it round. But this Doctor numb it first and use the same needle to inject the steroid, it was really good.	No problem with the injection site Knowledge and skill of the injecting clinician Previous bad GP experience The way the GP did the injection The way the ESP performed the injection Injection outcome	Positive injection experience Professionalism of the injecting ESP Lack of GP's injection experience GP's injection technique ESP's injection technique Successfully experience

Appendix 10 above is an excerpt from participant's 0052P transcript. It is an example of using Framework approach for descriptive and classification analysis. Column A is the participant unique identification number, Column B contains the original quotes from the transcripts, while Column C is a close description of the participant's original quotes, but now contains mainly the relevant elements of the initial quotes. Column D is a higher level of categorisation where elements detected have been interpreted in a more conceptual manner to provide a new meaning. For example, column B is an excerpt from the participant's original transcript that matches item 3.5 in the index on Figure 15 in page 182. In column C "knowledge and skill of the injecting clinician" and "injection outcome" from were both categorised in column D as professionalism of the injecting ESP and successfully injection experience respectively.

Appendix 11: Approval of National Research Ethics Committee (NREC)

Health Research Authority

NRES Committee London - Chelsea
HRA
Research Ethics Committee (REC) London Centre
Ground Floor
80Skipton House
London Road
London
SE1 6LH

Telephone: 02033117294
Facsimile: n/a

14 April 2014

Mr Collins A O Ogbeivor
Clinical Lead/Extended Scope Practitioner of Musculoskeletal Service
(address of unit)

Dear Mr Ogbeivor

Study Title:	**A comparison of the effectiveness of lateral versus posterior approach for cortisone injection in patients with subacromial impingement syndrome**
REC reference:	**14/LO/0406**
IRAS project ID:	**137935**

Thank you for your letter of 09 April 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Gemma Oakes,

nrescommittee.london-chelsea@nhs.net.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.
Ethical review of research sites

NHS sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the

start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.
If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*	
Evidence of insurance or indemnity	(name of insurance company) Heath letter	16 September 2013	
Evidence of insurance or indemnity	Chartered Society of Physiotherapy Insurance Certificate - Mr. Collins Ogbeivor		
GP/Consultant Information Sheets	1	12 February 2014	
Interview Schedules/Topic Guides	Qualitative Semi Structured Interview Questions V1	14 February 2014	
Investigator CV	Mr. Collins Ogbeivor		
Letter from Sponsor	University of Essex letter	19 February 2014	
Letter from Statistician	letter from Sarah Barter-Godfrey (undated)		
Letter of invitation to participant	1	12 February 2014	
Other: Flow chart for research design	1	10 January 2012	
Other: Chartered Society of Physiotherapy Certificate - Mr. Collins Ogbeivor		19 September 2005	
Other: Health Professions Council registration certificate - Mr. Collins Ogbeivor			
Other: Letter from confirming insurance		06 November 2013	
Other: Summary of Product Characteristics - Lidocaine Hydrochloride Injection			
Other: Semi Structured Interview Questions - Guide	1	10 January 2014	
Other: PGD for Lidocaine Hydrochloride			
Other: PGD for Triamcinolone			
Other: CV - (name of investigator)			
Other: CV - (name of investigator)			
Other: CV - Sheila Black			
Other: CV - (name of investigator)			
Other: Non NHS SSI	1	19 February 2014	

Participant Consent Form: Section 2 - Qualitative Semi Structured interview study	1	19 February 2014	
Participant Consent Form: Section 1 - Quantitative Study	1	10 January 2014	
Participant Information Sheet	1	19 February 2014	
Protocol	1	10 January 2014	
Questionnaire: SPADI	1	14 January 2014	
Questionnaire: Patient reported outcome measures - Injection	1	14 January 2014	
Questionnaire: xx			
Questionnaire: Injection Outcome Measure	1	10 January 2014	
REC application	1	19 February 2014	
Referees or other scientific critique report	letter from Mr. (name of referee)	21 February 2014	
Summary/Synopsis	Flow Diagram showing movement of patient through the trial V1	10 February 2011	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
Further information is available at National Research Ethics Service website > After Review

14/LO/0406	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

P.P.

Dr Shelley Dolan
Chair

Email: nrescommittee.london-chelsea@nhs.net

Enclosures: "After ethical review – guidance for researchers" [SL-AR2]

Copy to: Sarah Manning-Press, sarahm@essex.ac.uk

Appendix 12: Approval of Non-NHS Research Consortium

NHS
Health Research Authority

NRES Committee London - Chelsea
Research Ethics Committee (REC) Bristol Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1380

23 May 2014

Mr Collins A O Ogbeivor
Clinical Lead/Extended Scope Practitioner of Musculoskeletal Service
(address of unit)

Dear Mr Ogbeivor

Study Title:	**A comparison of the effectiveness of lateral versus posterior approach for cortisone injection in patients with subacromial impingement syndrome**
REC reference:	**14/LO/0406**
SSA reference:	**14/LO/0849**
IRAS project ID:	**137935**

The REC gave a favourable ethical opinion to this study on the 16 April 2014.

Following site-specific assessment by the committee, I am pleased to confirm that the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research site	*Principal investigator / Local Collaborator*
(name and address of unit)	*Mr Collins A O Ogbeivor*

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

14/LO/0406: Please quote this number on all correspondence

Yours sincerely

Gemma Oakes REC Manager
Email: nrescommittee.london-chelsea@nhs.net

Appendix 13: Letter to GPs

University of Essex	School of Health and Human Sciences T 01206 872754 F 01206 873765 E hhs@essex.ac.uk	Colchester Campus Wivenhoe Park Colchester CO4 3SQ United Kingdom T 01206 873333 F 01206 873598 www.essex.ac.uk

Letter to General Practitioners (GP's)

Dear Doctor …

My name is Mr Collins Ogbeivor. I am a professional doctorate student in the School of Health and Human Sciences at the University of Essex, Colchester. I am conducting a research study as part of the requirements of my degree in Physiotherapy. This study is sponsored by the University of Essex.

This is to inform you that your patient Mr/Mrs Xxxxxxxxxx is taking part in my shoulder injection study. The study is to determine the effectiveness of lateral approach versus posterior approach of subacromial injection for the treatment of subacromial impingement syndrome (SAIS). It also aims to understand the experiences of patients with SAIS experiencing lateral versus posterior approach to subacromial injections.

The patient will be provided with enough information regarding the relevance of the research and reason they have been asked to join via a patient information sheet and will have signed the consent form. They will be allowed to ask questions in any area relating to the research as well as their participation. The patient information sheet will be provided before the research, to allow potential participants adequate time to reflect on their contents, prior to giving consent. They will be informed that their participation in the research in voluntary and it will be made clear that consent could be withdrawn at any stage, without having to give any reason, without their medical care being affected. Participants should have capacity to give informed consent based on the Mental Capacity Act (2005).

Serious side effects are not commonly reported with subacromial injections. Participants will be informed prior to the study, through the information sheet, that if they do occur, their effects are normally mild and temporary. They would be advised to contact their GP if they are feeling distressed or deteriorating rapidly during the trial. Potential participants' records will be stored and handled in accordance with the Data Protection Act (1998). If you have any queries, please contact me on xx or at Collins.Ogbeivor@xxxx.co.uk.

Thank you

Yours Faithfully

Collins Ogbeivor (MSc, BMr-physio, SRP, MCSP)
Clinical Lead/Extended Scope Practitioner

Appendix 14: Baseline Continuous Variables. Is the data normally distributed - deciding with central tendency and Dispersion

Characteristic	Mean	Median	Mode	Skewness	Kurtosis	S.D	Conclusion
Age (years)	55.38	55.00	54.0	- 0.18	- 2.05	12.12	✓
Symptom duration (weeks)	37.00	26.00	23.00	3.12	10.66	52.01	×
Mean (SD) Initial PROMs Score							
Day time pain (SD)	6.79	7.00	8.00	- 0.81	1.03	2.02	✓
Night time pain (SD)	6.58	7.00	7.00	- 0.40	- 0.71	2.45	✓
Function affected (SD)	2.79	3.00	3.00	- 0.65	0.16	1.11	✓
Mean (SD) Initial SPADI Score	80.99	83.00	79.00	- 0.54	- 0.27	26.19	✓

Appendix 15: Baseline Continuous Variables. Is the data normally distributed - deciding with different techniques

Characteristic	Visual inspection	p-p plots	Central tendency and dispersion	Shapiro-Wilk test	Conclusion - normal or not
Age (years)	✓	✓	✓	0.572	Normal
Symptom duration (weeks)	×	×	×	0.000	Not normal
Mean (SD) Initial PROMs Score					
Day time pain (SD)	✓	×	✓	0.000	Normal
Night time pain (SD)	×	✓	✓	0.002	Normal
Function affected (SD)	✓	✓	✓	0.000	Normal
Mean (SD) Initial SPADI Score	×	✓	✓	0.130	Normal

Appendix 16: Outcomes Variable. Is the data normally distributed – Deciding with central tendency, dispersion and distribution

Characteristic	Mean	Median	Mode	Standard Deviation	Skewness	Kurtosis	Conclusion
PROMs Day time pain							
at 8 weeks	3.62	4.0	4.0	2.85	0.40	- 0.69	✓
at 12 weeks	3.25	3.0	0.0	2.94	- 0.52	- 0.74	×
from 0 - 8 weeks	3.02	3.0	1.0	2.67	- 0.13	- 0.30	✓
from 0 - 12 weeks	3.34	3.0	0.0	3.04	- 0.17	- 0.57	✓
from 8 - 12 weeks	0.21	0.0	0.0	2.39	- 0.13	- 0.24	✓
PROMs Night time pain							
at 8 weeks	4.01	4.0	0.0	3.19	0.28	- 1.07	×
at 12 weeks	3.96	4.0	0.0	3.52	0.26	- 1.37	✓
from 0 - 8 weeks	2.57	2.0	0.0	3.33	- 0.45	- 0.55	✓
from 0 - 12 weeks	2.71	3.0	0.0	3.81	- 0.13	- 0.48	✓
from 8 - 12 weeks	-0.13	0.0	0.0	2.26	0.43	1.42	✓
PROMs Function affected							
at 8 weeks	1.65	2.0	0.0	1.33	0.21	- 1.10	×
at 12 weeks	1.57	2.0	0.0	1.38	0.28	- 1.18	×
from 0 - 8 weeks	1.14	1.0	1.0	1.29	- 0.38	- 0.47	✓
from 0 - 12 weeks	1.17	1.0	0.0	1.45	- 0.38	- 0.11	✓
from 8 - 12 weeks	0.04	0.0	0.0	0.95	0.45	1.12	✓
SPADI score:							
at 8 weeks	48.37	51.0	0.0	35.58	0.13	- 1.28	×
at 12 weeks	45.99	43.50	0.0	38.00	0.28	- 1.33	×
from 0 - 8 weeks	32.65	23.00	23.0	30.88	0.60	- 0.38	×
from 0 - 12 weeks	35.53	29.00	18.0	35.19	0.19	- 0.63	×
from 8 - 12 weeks	0.82	0.0	0.0	22.91	- 0.46	1.11	✓

Appendix 17: Outcomes Variable. Is the data normally distributed – Deciding with different techniques

Characteristic	Visual inspection	p-p plots	Central tendency and dispersion	Shapiro -Wilk test	Conclusion -normal or not
PROMs Day time pain					
at 8 weeks	×	×	✓	0.000	Not
at 12 weeks	✓	✓	×	0.000	Not
from 0 - 8 weeks	✓	✓	✓	0.162	Normal
from 0 - 12 weeks	✓	✓	✓	0.145	Normal
from 8 - 12 weeks	✓	✓	✓	0.040	Normal
PROMs Night time pain					
at 8 weeks	×	×	×	0.000	Not
at 12 weeks	×	×	×	0.000	Not
from 0 - 8 weeks	×	✓	✓	0.012	Normal
from 0 - 12 weeks	✓	✓	✓	0.308	Normal
from 8 - 12 weeks	✓	×	✓	0.000	Normal
PROMs Function affected					
at 8 weeks	×	×	×	0.000	Not
at 12 weeks	×	×	×	0.000	Not
from 0 - 8 weeks	✓	✓	✓	0.002	Normal
from 0 - 12 weeks	✓	✓	✓	0.000	Normal
from 8 - 12 weeks	✓	×	✓	0.000	Normal
SPADI score:					
at 8 weeks	×	×	×	0.001	Not
at 12 weeks	×	×	×	0.000	Not
from 0 - 8 weeks	✓	×	×	0.055	Normal
from 0 - 12 weeks	✓	✓	×	0.297	Normal
from 8 - 12 weeks	✓	✓	✓	0.020	Normal