

A RANDOMISED CLINICAL TRIAL
INVESTIGATING THE MOST APPROPRIATE
CONSERVATIVE MANAGEMENT OF
FROZEN SHOULDER

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DECLARATION



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Concurrent registration for two or more academic awards

I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution.

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ABSTRACT

'Frozen Shoulder' is a term which describes a combination of shoulder pain and stiffness that causes sleep disturbance and marked disability, and which runs a prolonged course (Hanchard et al 2011). Physiotherapy has been advocated; however there is no robust evidence on the superiority of any one treatment modality (Callinan et al 2003).

The aim of this study was to evaluate the effect of an exercise class compared to multimodal physiotherapy and a home exercise programme in patients with frozen shoulder. The objectives were to identify that clinical scores were effective at detecting change in the different treatment groups and to provide recommendations for the physiotherapeutic management of frozen shoulder. The study design was a randomised controlled trial with seventy five patients enrolled. The primary outcome measure was the Constant score, secondary outcome measures included the Oxford Shoulder Score (OSS), Hospital Anxiety and Depression Scale (HADS) and the short form 36 item health survey (SF-36). A repeated measures one-way analysis of variance on the outcome data was conducted.

Results from the Constant score and OSS indicate that at six weeks, six months and one year, an Exercise Class was more effective than Multimodal Physiotherapy or Home Exercises. The results from the HADS indicate that the Exercise Class was more effective than Multimodal Physiotherapy or Home Exercises at six weeks and six months. However, at one year Multimodal Physiotherapy was more effective than the Exercise Class and Home Exercises.

This study provides an original contribution to knowledge in frozen shoulder and has important implications for enhancing clinical practice. The findings suggest that a hospital based exercise class produced a rapid recovery with a minimum number of visits to the hospital. Physiotherapy could also be considered to optimise speed of recovery of frozen shoulder. The Constant score, OSS and HADS are recommended in the management of frozen shoulder. Finally, GPs and physiotherapists require training in the clinical diagnostic accuracy of frozen shoulder. The need for further research in this area is emphasized.

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My partner Christopher has encouraged me and provided a welcome glass of wine, which was always a saving grace.

Lastly I wish to dedicate my thesis to my late husband Jonathan Russell without whom I would not have entered this journey.

LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
BP	Bodily Pain
DNA	Did Not Attend
GCT	Gate Control Theory
GH	General Health Perceptions
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HADS-A	Hospital Anxiety and Depression Scale-Anxiety
HADS-D	Hospital Anxiety and Depression Scale-Depression
MH	General Mental Health
OSS	Oxford Shoulder Score
PF	Physical Function
RE	Role Limitations because of Emotional Problems
ROM	Range Of Movement
RP	Role Limitations because of Physical Health Problems
PNF	Proprioceptive Neuromuscular Facilitation
SF	Social Functioning
SF-36	Short form 36 item health survey (SF-36)
TENS	Transcutaneous Electrical Nerve Stimulation
VAS	Visual Analogue Scale
VT	Vitality

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Chapter 1 LITERATURE REVIEW

1.1 SEARCH STRATEGY

Literature searches using the computer based AMED, EMBASE, MEDLINE, CINAHL, Proquest, Biomed Central, Pubmed Central databases in addition to the Cochrane database were undertaken to identify relevant literature surrounding frozen shoulder. There were no limitations on the year of publication for any of the searches. The search strategy was repeated throughout the study and was aimed at retrieving references relating to frozen shoulder. Search terms used included 'frozen shoulder, adhesive capsulitis, physiotherapy, physical therapy, shoulder outcome measures, shoulder pain, exercise classes, stretches, rehabilitation, exercise and compliance'. In addition, the reference lists of articles identified through the above process were also searched to uncover any further relevant literature. Eligibility criterion was set as English language and the title and abstract fields were included in the search. There were 385 hits and 287 articles retrieved. Of the research papers retrieved 50% of references were over ten years old.

1.2 INTRODUCTION

Frozen shoulder, or adhesive capsulitis, was defined in the seminal work of Reeves (1975), as a condition of uncertain aetiology characterised by the spontaneous onset of pain with significant restriction of both active and passive range of movement of the shoulder. Duplay (1872) was credited with the initial description of the painful and restricted shoulder. Codman first introduced the term frozen shoulder in 1934 and described it as "a condition difficult to define, difficult to treat and difficult to explain from the point of view of pathology" (Codman, 1934:254). In 1945, Neviaser coined the term 'adhesive capsulitis' theorising that this pathology results from thickening and eventual contracture of the glenohumeral capsule to reflect his findings at surgery and autopsy, in patients treated for a painful stiff shoulder. Nobuhara (2003) has also reviewed the terminology surrounding frozen shoulder. The condition is known as 50s shoulder in Japan. According to an eighteenth-century source, Rigenshuran, defines 50s shoulder as "pain in the arm and joints which develops at about age

50 at times, but improves after a while without the administration of drugs” (Nobuhara, 2003:161).

Frozen shoulder can be a primary or idiopathic problem or it may secondarily be associated with another systemic illness. Both primary and secondary frozen shoulders have similar clinical presentations but distinct precipitating factors (Stam 1994). Although there is undoubtedly dispute about the diagnostic terminology associated with frozen shoulder, an improved understanding of different pathological processes has led to most authors using similar definitions.

A primary or ‘true’ frozen shoulder occurs where there is no exogenous cause or pre-existing condition. It presents an idiopathic decreased range of movement in which no systemic diagnosis, precipitating shoulder condition or radiographic explanation can be found (Neviaser and Neviaser 1987; Kelly 1993; Stam 1994). Secondary frozen shoulders are defined as those with a known intrinsic or extrinsic precursor, typically causative of shoulder pain and dysfunction that ultimately leads to global stiffness; e.g. diabetes, stroke, hypo or hyper thyroidism, rotator cuff disease, cardiac disease and in association with prolonged immobilisation or trauma (Lundberg 1969; Rizk et al 1983 and Bunker 1997).

This study was investigating ‘primary’ or ‘true’ frozen shoulder.

1.3 AETIOLOGY

Despite considerable research in the last century, the aetiology and pathology of frozen shoulder remain enigmatic (Hannafin and Chiaia 2000). The prevalence is found to be approximately 2-3% of adults in the general population (Binder et al 1984; Hannafin and Chiaia 2000), and is thought to develop between the ages of 40 and 70 (Reeves 1975; Binder et al 1986; Stam 1994). It rarely recurs in the same shoulder unless an injury or disease process predisposes the joint to repeat episodes of stiffness (Binder et al 1986; Di Fabio 1998; Hand et al 2007). It is generally agreed that the non-dominant arm appears more likely to be involved (Kessel 1986; Neviaser and Neviaser 1987;

Fareed and Gallivant 1989). However, Bunker (1998), reports that the condition occurs with equal frequency in the left and right shoulders. With regard to gender, Neviasser and Neviasser 1987; Stam 1994 and Hand et al 2008, found that there is a greater occurrence in women. Bunker (1998) also disputes this reporting that there is equal prevalence between both genders; more recent studies showed a ratio of 1:1 male to female (Bunker 2009).

Frozen shoulder usually presents unilaterally and the incidence of subsequent involvement on the contralateral side is 20% (Lundberg 1969; Hannafin and Chiaia 2000; Hand et al 2008). It affects 20% of people with diabetes and has been described as the most disabling of the common musculoskeletal manifestations of diabetes (Smith et al 2003; Kordella 2002).

1.4 PATHOLOGY

Although the aetiology of frozen shoulder remains elusive, the understanding of its pathogenesis is increasing. Generally, three schools of thought have emerged:

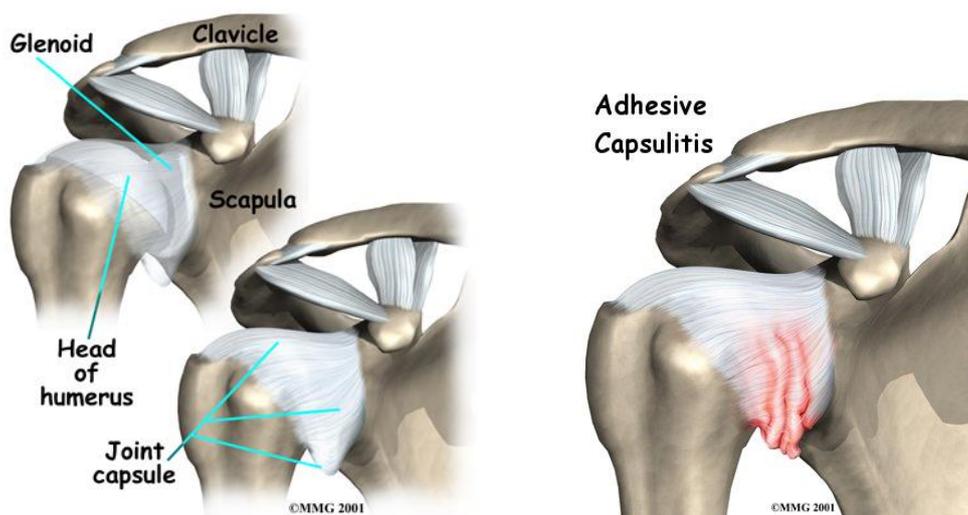
- an inflammatory process (Simmonds 1949; Wiley 1991, Hannafin et al 1994).
- a fibrotic process (Ozaki et al 1989; Bunker and Anthony 1995; Hannafin and Chiaia 2000) and
- an inflammatory process with subsequent reactive capsular fibrosis (Bunker et al 2000).

Duplay (1872) theorized that the pathologic condition of frozen shoulder was found in the subacromial bursa but later Codman (1934) related the disorder to calcific tendonitis. Neviasser (1945) discovered a tight, thickened capsule that adhered to the humeral head. He described an inflammatory reaction that led to adhesions, specifically in the axillary fold and in the attachment of the capsule at the anatomic neck of the humerus. On biopsy and histological examination, he identified perivascular infiltration, capsular thickening, contracture and fibrosis. He proposed that the pathology primarily involved the shoulder capsule, suggesting the term 'adhesive capsulitis' as a better name for the

disease (Figure 1.1). However, Lundberg (1969), Wiley (1991) and Bunker et al (1994), found no adhesions in their arthroscopic studies.

Figure 1.1 Adhesive Capsulitis (A Frozen Shoulder)

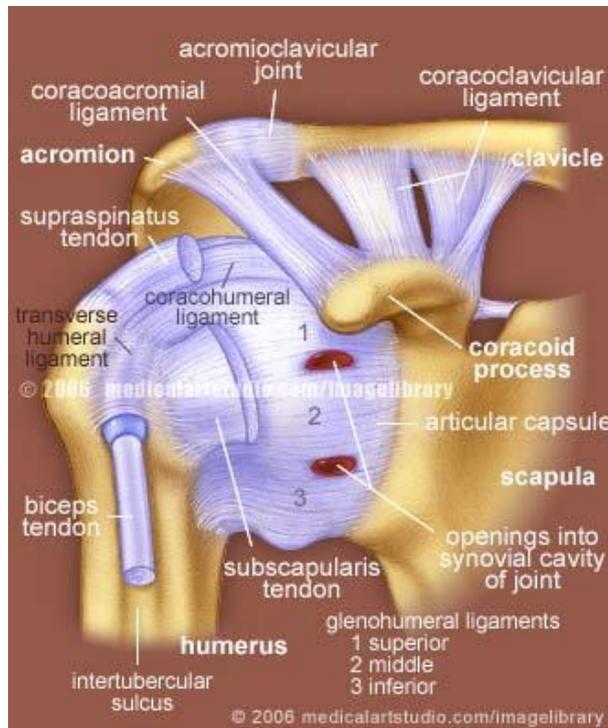
Back in Action (2005)



Simmonds (1949) agreed with Neviaser (1945) and speculated that a loss of motion at the glenohumeral joint was because of degenerative changes and secondary inflammation of the supraspinatus tendon. Lundberg (1969) also observed an inflammation of the capsule as a precursor of the process leading to stiffness, pain and capsular fibrosis but no significant number of inflammatory cells. Significant evidence exists in support of the hypothesis that the underlying pathological changes are synovial inflammation with subsequent reactive capsular fibrosis, making adhesive capsulitis an inflammatory and a fibrosing condition, dependant on the stage of the disease, (Bulgen et al 1982; Grubbs 1993; Carr and Hamilton 2005). Several investigators have proposed an autoimmune basis for frozen shoulder (Bulgen et al 1984; Neviaser and Neviaser 1987). However, specific immunological studies reveal no evidence of any specific auto-immune or arthritic process (Bulgen 1984, Neviaser and Neviaser 1987; Bunker 1998). This fact is used in the differential diagnosis of frozen shoulder. There is general agreement that the pathology affects the glenohumeral capsular tissue and is particularly localised to the coracohumeral

ligament in the rotator interval (Neer et al 1992; Omari and Bunker 2001) (see Figure 1.2).

Figure 1.2 The Shoulder Complex



www.stockmedicalart.com/medicalartlibrary/shoulder-joint-ligaments.html

Neer et al (1992) postulated that the coracohumeral ligament was contracted and Ozaki et al (1989) stated that the release of this ligament was curative and this was confirmed by Bunker et al (1994). Bunker et al (1994) observed that thickening and contracture of the glenohumeral ligament and rotator interval, acts as a check rein which prevents external rotation and causes global loss of active and passive movements. The contracture also causes superior translation of the humeral head leading to impingement and pain (Bunker 1998). Bunker and Anthony (1995) likened the changes of the glenohumeral capsule to Dupuytren's contracture in the palm. They reported that the pathological process is active fibroplastic proliferation, accompanied by some transformation to a smooth muscle phenotype (myofibroblasts). The fibroblasts lay down collagen that appears as a thick nodular band or fleshy mass. They further noted that in the shoulder capsule the inflammatory component was absent or localised to the synovial and subsynovial layers. The tissue observed was highly cellular with cells identified as fibroblasts and myofibroblasts and this has been

confirmed by Killian et al (2001). The findings by Hand et al (2007) confirm these results and support the theory that frozen shoulder is an inflammatory condition that progresses in a continuum to a fibrosing condition. In conclusion, all the histological evidence to date shows that this is a capsular contracture of the shoulder (Bunker 2009). Characteristically, pain precedes stiffness in frozen shoulder which suggests an evolution from inflammation to fibrosis.

1.5 CLINICAL FEATURES

In clinical practice, the tendency is to label any patient with a stiff and painful shoulder as a case of frozen shoulder. For years, much of the literature has referred to frozen shoulder as a self-limiting disease but the duration and severity may vary greatly (Codman 1934; Watson-Jones 1963; Reeves 1975). Even these studies describe the process as lasting a minimum of 12-18 months, before resolution. However there are those who suggest that it can last for as little as 6 months (Rizk and Pinals 1982; Grubbs 1993). Binder et al (1984) described frozen shoulder classically lasting for 18-24 months. Other studies have however challenged this popular belief. Simmonds (1949), Reeves (1975) and Shaffer et al (1992) agree that it can last two to three years, although report significant numbers of people have residual clinical detectable restriction of movement and smaller numbers' have residual disability (at seven years 50% had mild pain, stiffness or both). The clinical picture seen commonly by physiotherapists is characterised by this spontaneous onset of shoulder pain and progressive global stiffness of the gleno-humeral joint, accompanied by decreased function and significant disability (Reeves 1975; Neviasser and Neviasser 1987). The presence of night pain leads to disturbance of sleep and often difficulty lying on the affected shoulder (Shaffer et al 1992; Stam 1994). As the restriction in the motions increases, more difficulties are encountered with activities of daily living (Hannafin and Chiaia 2000). Routine radiographs are typically normal (Binder et al 1984). These are important to rule out serious pathology, abnormalities in the bone, joint or in the local soft tissues e.g. calcific deposit and are a prerequisite to a definitive diagnosis of frozen shoulder (Bunker 2009).

There is general agreement that the condition will pass through three stages (Reeves 1975).

- STAGE I: - involving pain
- STAGE II: - pain and restricted movement and finally
- STAGE III: - painless restriction

Reeves first divided the clinical presentation of frozen shoulder into three stages in 1975, when he studied the natural history of 49 cases over 10 years (Table 1.1).

Table 1.1 Three stages of Classification (Reeves 1975)

<p>Freezing stage 2.5-3 months</p>	<p>The patient reports an insidious onset of diffuse shoulder pain, difficulty lying on the affected side and progressive loss of shoulder motion. Patients often identify pain at night. Ache is unrelated to activity and may be worse at rest.</p>
<p>Frozen stage 4-12 months (approx)</p>	<p>The pain gradually subsides and is described as a dull aching type of sensation and occurs at the extreme of their available movement. Loss of motion plateaus with passive motion equal to active motion or gross reduction of glenohumeral movements, with near total obliteration of external rotation (Capsular pattern).</p>
<p>Thawing stage 12-42 months (approx)</p>	<p>It is characterised by the gradual improvement of shoulder motion and the reduction of pain symptoms, mean duration from onset of frozen shoulder to resolution is over 30 months.</p>

Neviaser and Neviaser (1987) have described an arthroscopic four stage classification (Table 1.2) and stressed the importance of an individual treatment plan based on an understanding of the clinical stages of the disease. More

recently, Hannafin et al (1994) have described a correlation between the arthroscopic stage, the clinical examination and the histological appearance of the tissues.

Table 1.2 Four Stages of Classification (Neviaser and Neviaser 1987)

<p>Stage I 0-3 months</p>	<p>Preadhesive stage. A fibrinous synovial inflammatory reaction is detectable only by arthroscopy. The patients usually present with signs and symptoms of impingement syndrome. The main complaint is pain and minimum deficit in range of motion is detected.</p>
<p>Stage II 4-9 months</p>	<p>Adhesive stage. The acute synovial inflammation is apparent on physical evaluation. Arthroscopic findings demonstrated that the normal spacing between capsular fold, humeral head and biceps tendon, glenoid and humeral head diminish significantly. The patient experiences severe pain and loss of motion. (Neviaser and Neviaser (1987) do not give this stage a name but compared to other classifications it appears to be equivalent to the Adhesive stage).</p>
<p>Stage III 10-15 months</p>	<p>Maturation stage. This stage is evident by the maturation of the inflammatory process. The dependant fold is only half its original size and adherence between various structures are formed.</p>
<p>Stage IV 16-24 months</p>	<p>Chronic stage. Capsular adhesions are fully mature and markedly restricted. Clinically, the shoulder is 'frozen.'</p>

Neviaser and Neviaser (1987) stressed that it is critical to remember that these represent a continuum of disease rather than discrete well-defined stages.

More recently, a survey by Hanchard et al (2011) recommends a simple 'pain-predominant' or 'stiffness-predominant' classification. This is also supported by Cyriax (1982), who suggests that there is a phase of increasing pain and stiffness, whereby pain is the predominant complaint until the pain abates leaving stiffness as the predominant complaint.

The natural history of frozen shoulder is considered benign but because of the long period of pain and disability, many interventions have been considered. Roy and Oldham (1976), state "the bewildering numbers of pathological diagnoses are exceeded in number and confusion only by the different attempts at treatment of the condition" (Roy and Oldham, 1976:1322). Binder et al (1984) feel it is a chronic disorder leading to long-term disability but sometimes a residual stiffness may occur and complete resolution of symptoms remains controversial (Reeves 1975; Simmonds 1979; Shaffer et al 1992). Reeves (1975) in a prospective study of 45 patients with five to ten years follow up demonstrated that the time scales given within this typical presentation vary considerably. 42% had a deficit in their range of motion with 65% having a functional deficit at ten years. Whether a complete resolution actually occurs is disputed by many studies (Reeves 1975; Binder et al 1984; Shaffer et al 1992). Shaffer et al (1992), indicated that one-half of the patient population with frozen shoulder managed non-operatively, remained symptomatic an average of seven years later. They suggested that a minority of patients have a protracted course with ongoing restriction and concluded this made them question whether this is a benign self-resolving condition. These findings were also confirmed by Griggs et al (2000) Smith et al (2001) and more recently by the largest study to date by Hand et al (2008). In this study by Hand et al (2008), 273 patients were followed for up to twenty years and the results demonstrated that 41% of their patients had mild to moderate persistent symptoms at seven years and 6% had severe ongoing symptoms with pain and functional loss.

1.6 MANAGEMENT OF FROZEN SHOULDER

Many studies have attempted to establish the most effective treatment for frozen shoulder but much debate still remains. Currently there is no agreement on the standard management of this condition (Dundar et al 2009). The lack of consensus on diagnostic criteria and concordance in clinical assessment complicates treatment choices. The controversy is due in part to a failure of many authors to precisely define and accurately identify frozen shoulder among other causes of shoulder pain and stiffness (Stam 1994; Green et al 2003; 2009). Orthopaedic and physiotherapy interventions or treatment modalities have been advocated in the management of frozen shoulder in the past thirty years, to alleviate the signs and symptoms and aid recovery.

1.6.1 Orthopaedic Management

There is a considerable body of work devoted to the orthopaedic management of this condition but the aim of this study is to focus on the conservative physiotherapy management. Therefore, only a concise review of orthopaedic management follows. Initially, treatment is directed at pain relief. Non-steroidal anti-inflammatory drugs (NSAID's) are traditionally given but there are no randomised control trials that confirm the effectiveness of these. Oral corticosteroids have been recommended but little evidence exists to support their routine use (Buckbinder et al 2004; Dias et al 2005). Suprascapular nerve block (Dahan et al 2000) and steroid injection have been suggested by some authors (Rizk and Pinals 1982; Bulgen et al 1984; Carette et al 2003). However, this approach alone has not been shown to improve the range of shoulder motion (Lundberg 1969; Lee et al 1973; Rizk and Pinals 1982).

Orthopaedic interventions that have been shown to produce successful outcomes in restoring function include; distension arthrography, manipulation under anaesthetic (MUA) and arthroscopic release.

Distension arthrography was described by Andren and Lundberg as early as 1965 and has been advocated as a means of expanding the contracted capsule. Rizk et al (1994) promoted it as a promising treatment. They performed a study of 16 patients and found that 13 experienced immediate pain

relief and increased shoulder mobility. This was also found by Buchbinder et al (2004) who demonstrated a significantly greater improvement in pain, function and active range of movement (ROM) in the group that received distension at three and six weeks.

Manipulation under anaesthetic (MUA) is the established form of treatment (Snow et al 2009). It results in a rapid return of shoulder motion, although some authors disagree about whether it shortens the disease course (Lundberg 1969; Murnaghan 1990). Bunker and Anthony (1995) showed that 75% of their patients attained a near normal range of movement, 79% were relieved of their pain and 75% returned to normal within nine weeks. Some authors consider manipulation an effective intervention, whereas others claim that it is traumatising and may even exacerbate pain (Kivimaki et al 2007).

Bunker (2005) suggests that arthroscopic release has transformed the management of this disease and recently in 2009 reports that it is still delivering relief of pain, undisturbed sleep and improved function in the majority of people with frozen shoulder. Ogilvie-Harris et al (1995) compared the results of MUA versus arthroscopic release. Although both groups gained the same improvement in ROM, the arthroscopic group had significantly better pain relief and function. Harrymann et al (1997) demonstrated excellent results. The ROM went from 41% of the opposite side to 78% on the first day following surgery and 93% at the end of the study. Berghs et al (2004) demonstrated that 36% of patients experienced pain relief and reduced stiffness after one day following an arthroscopic release and 80% within two weeks.

1.6.2 Physiotherapy Management

Physiotherapy is often the first line of management for shoulder pain, yet its efficacy has not been established (Lynch 2002). The most recent and comprehensive reviews available are the systematic review by Cleland and Durall (2002) and the Cochrane review by Green et al (2003; 2009). In the review conducted by Cleland and Durall (2002) twelve papers met the inclusion criteria and were split into prospective (n=9), retrospective (n=1) and randomised clinical trials (n=2). Their methodological scoring criteria included points for identifying the stage of pathology, whether the frozen shoulder was

primary or secondary, duration of symptoms prior to intervention, and number of treatments. Due to the self-limiting nature of the condition these are important aspects to consider when reviewing the efficacy of treatment and are frequently omitted; this is therefore a strength of their work. However, this study is limited as it only searched two databases and the reviewer was not blinded to the aim of the study and was therefore a threat to the internal validity. They only found two randomised controlled trials (RCT's) and therefore highlighted the need for more prospective RCT's using a standardised outcomes assessment to judge the efficacy of various physiotherapy interventions on frozen shoulder.

The results revealed many inconsistencies. There was considerable variation in intervention strategies, duration of treatment and outcome measures between the studies and lack of rigour and poor standardisation of terminology. This made it difficult to compare relevant published research and determine the effectiveness or economic efficiency of treatments. As most of the studies used complex interventions and combined treatment modalities, they argued that it was difficult to determine which elements of physiotherapy were efficacious.

Green et al (2003; 2009) also highlighted this in their Cochrane review of physiotherapy interventions for shoulder pain. This review has been updated in 2009; however there was no change to the conclusions. They stated that it is unusual for shoulder disorders to receive a single treatment in isolation, demonstrating a conflict between validity and clinical practice. Green et al (2003; 2009) reviewed twenty-six trials that met their inclusion criteria and were concerned by the low number of single modality studies. They identify this as one of the key areas to improve future research, along with larger trials of higher methodological quality, well-defined interventions and a validated inclusion/exclusion criterion. They concluded that there was no evidence that physiotherapy without concurrent interventions, such as corticosteroids, was of benefit for frozen shoulder. They stressed the need for trials of physiotherapy interventions for specific clinical conditions associated with shoulder pain. Four RCT's have been published since Green et al (2003; 2009) published this systematic review: Guler-Uysal and Kozanoglu (2004); Buchbinder et al (2007); Vermeulen et al (2006) and Johnson et al (2007). These authors examined

different types and combinations of treatments over different time periods and used a variety of self-report instruments to assess pain, function and quality of life. It is still unclear from these papers which interventions may be most effective. Both the number and diversity of treatments, which have been recommended, reflect the extremely general nature of the physiotherapy treatment for frozen shoulder. Therefore, there is yet no definitive agreement on the most effective form of treatment (Sun et al 2001).

Physiotherapy management aims to relieve pain, promote healing, reduce muscle spasm, increase joint range of motion and strengthen weakened muscles and ultimately to prevent and treat functional impairment (Green et al 2003; 2009). These include: heat or ice applications; Ultrasound; Interferential therapy; Transcutaneous Electrical Nerve Stimulation (TENS); pulsed electromagnetic field therapy; active and passive ROM exercises; Proprioceptive Neuromuscular Facilitation (PNF) techniques; manual physical therapy and laser therapy.

Green et al (2003; 2009), concluded that vast range of recommended treatment, coupled with a lack of many conclusive studies in this area, means that there is little guidance for today's physiotherapist with patients with a diagnosis of frozen shoulder. Currently there is no robust evidence on the superiority of any one treatment modality compared to another (Callinan et al 2003). Modern literature commonly recommends the use of multiple modalities which precludes the effectiveness of individual treatment (Cleland and Durall 2002).

The Chartered Society of Physiotherapy has completed a project on the management of frozen shoulder (Hanchard et al 2011). Conclusions drawn from these evidence-based clinical guidelines suggest that future researchers should report their physiotherapy interventions in sufficient detail to remove ambiguity consider multi-centre trials and focus on specific stages of frozen shoulder.

1.6.3 Exercise Therapy

Research demonstrates considerable variability in methods of treatment; however, it has been shown for some time that virtually all of them advocate some form of exercise to restore movement (Lee et al 1973; Neviaser and Neviaser 1987; O'Kane et al 1999). In clinical practice, exercises are almost always incorporated into the physiotherapy management of a patient with frozen shoulder. Whilst exercise is undoubtedly an important adjunct to treatment, its effectiveness as a sole treatment for frozen shoulder has not been thoroughly evaluated.

Diercks and Stevens (2004) performed a randomised prospective study of 77 patients with idiopathic frozen shoulder to compare the effect of intensive physical rehabilitation treatment. The patients were divided into two groups. All patients had more than 50% motion restriction for a period of three months or more. One group involved passive stretching and manual mobilisation (stretching group) with supportive therapy and the second with a regime including active and auto-assisted exercises, within the pain limits (supervised neglect group). All patients were followed-up for 24 months after the start of treatment. In the patients treated with supervised neglect, 89% had normal or near-normal painless shoulder function (Constant score >80) at the end of the observation programme 64% reached this result within 12 months. In contrast, in the group receiving intensive physiotherapy treatment, only 63% received a score of 80 or more after 24 months. The authors concluded that supervised neglect yields better outcomes than intensive physiotherapy and passive stretching in patients with frozen shoulder. However, they do not state where or how the sample was obtained, the frequency of treatment sessions or the compliance of patients. The study does not describe the validity or reliability of the measurement tools, who carried out the assessment and whether they were blinded to the intervention the patient received. One of the key findings was that intensive stretching prolonged the course of the disease and increased pain levels. This may be due to stretching into the painful range and could aggravate the symptoms and therefore increase the pain.

Jurgel et al (2005) found that a four week course of physiotherapy treatment resulted in significant improvements in the range of movement (ROM), pain

levels, muscle strength and endurance in 10 patients with idiopathic frozen shoulder, who had pain for two weeks to three months duration. However, they continued to have reduced ROM and strength compared with their unaffected side or controls. Positions were standardised for measuring ROM and muscle strength and endurance. Unfortunately, only endurance in flexion was measured which was performed using a prolonged static posture. This does not relate to many functional activities. Pain was measured using a 10 point visual analogue scale (VAS). However it was unclear if this was at rest or during activity, or over what time period e.g. past day, past week. It was also unclear if pain was measured or whether this was asked pre or post assessment of ROM, muscle strength and endurance. They used a questionnaire to determine difficulties in activities of daily living (ADL). However a standardised validated questionnaire was not used and it was uncertain which activities were assessed. Additionally the ADL questionnaire was not repeated at the final assessment, thus giving no information on whether the improvement in ROM, pain, muscle strength and endurance relate to an improvement in the ability to carry out ADL. The sample was very small therefore affecting the generalisability of the findings to the general population. Moreover, recruitment and the inclusion and exclusion criteria were not stated. No power calculations were mentioned and it is questionable if 10 patients provide enough power to enable robust statistical analysis. Only one physiotherapist assessed muscle strength and endurance, one physiotherapist assessed ROM and one physiotherapist performed the therapeutic interventions. This does reduce error due to inter-rater variability and also reduces the variability in personal interaction between the treating physiotherapist and the patients in the study. However, it is unclear whether the assessing and treating physiotherapists were the same or different people. Though the participants achieved good results in this study it was through quite intensive input of up to an hour per day of mixed therapeutic modalities. A combination of pool and gym exercises, various electrotherapies and massage therapy were used and tailored to each individual participant. Whilst this is how patients tend to be treated in the clinical setting it is difficult to ascertain which intervention was beneficial and as none of the interventions are described it would be difficult to apply this to clinical practice.

There are no clear indications in the literature concerning the optimal treatment frequency and duration, but the trial physiotherapist hypothesised that the regime used would be intensive and long enough to induce changes. Moreover in the absence of scientific evidence regarding the effectiveness of multimodal physiotherapy programmes, this programme was developed in light of results obtained in studies of other groups with musculoskeletal disorders, in animal studies, and from the best available evidence (Grubbs 1993; Stam 1994).

In reviewing the studies presented, it is evident that more research is needed in order to draw conclusions and establish an efficacious and clinically valid treatment method. As identified, this evidence needs to come from robust randomised clinical trials. Such trials need to clearly define the methodological approach used and include sufficient follow up length, with use of clinically valid and reliable outcome measures.

1.7 SUMMARY

In general, the natural history of frozen shoulder is uncertain. It remains controversial with the majority of long term follow up reports performed with evaluation of the patients' response to particular treatments. Difficulty exists in performing these studies owing to the ethical dilemma of assigning patients to an untreated group. Additional randomised, prospective studies are needed.

1.8 AIMS AND OBJECTIVES

The aim of this study was to investigate the clinical effectiveness of common physiotherapy interventions in the treatment of frozen shoulder using the Constant score, the Oxford Shoulder Score (OSS), the Hospital Anxiety and Depression Scale (HADS) and the short form 36 item health survey (SF-36).

The objectives were:

- To determine if there is a difference in effect between the three treatment interventions: an Exercise Class plus home exercises (Exercise Class Group); Physiotherapy plus home exercises (Multimodal Group); home exercises (Home Exercise Group).
- To explore what aspects of the clinical scores used are most affected at detecting change in the different treatment groups.
- To determine if there is any change between the different time intervals at six weeks, six months and one year.
- To provide recommendations for the best practice for the physiotherapeutic management of frozen shoulder.

Chapter 2 METHODS

2.1 QUANTITATIVE EXPERIMENTAL METHODOLOGY

Hypotheses are ideas based on some plausible factual knowledge about a problem (Currier 1990). The review of the literature demonstrates that the research which has investigated the conservative treatment of frozen shoulder is conflicting and unclear. The experimental hypothesis investigated in this thesis is stated as:

Experimental Hypothesis

H1 – The hypothesis is that there will be a significant difference between a home exercise programme alone, a home exercise programme combined with physiotherapy and a home exercise programme combined with an exercise class.

Null Hypothesis

H0 - The null hypothesis in this study is that there will be no significant difference between a home exercise programme alone, a home exercise programme combined with physiotherapy and a home exercise programme combined with an exercise class.

Variables

The independent variable is the one to be manipulated. The variable, which may change as a result of our manipulation of the independent variable, is called the dependent variable. (Clegg 1991; Hicks 2004)

To decrease the risk of error in the results, it is important that the researcher ensures that the measurement tools are valid and reliable (Domholdt 2000). Validity is ensuring that the researcher is measuring what is intended to be measured (Sim and Arnell 1993). Reliability is the ability to reproduce the results. The variables being manipulated in this study are:

Independent Variable

- Treatment: Exercise Class, Multimodal or Home Exercise Group.

Dependent Variables

- Range of shoulder motion
- Pain

Controlled Variables

- Standardised number and duration of treatment sessions, and standardised treatment procedures for patients within each group.
- Standardised assessment protocol and exercise programme for all patients.

2.2 DESIGN OF THE TRIAL

The research design chosen to confirm or negate the study hypothesis and to fulfil the study objectives was a randomised control trial (RCT). This employs a method where patients are randomly allocated to a group and conforms to the CONSORT statement (Altman et al 2001). Randomisation in this way minimises the influence of selection bias on the conclusions of the study and is the most effective method of removing the influence of both known and unknown confounders (Bailey 1997). Thus, clinical studies where randomisation is utilised are often more able to find significant outcomes in the effectiveness of treatments (Hicks 2004).

2.3 SETTING

Patients eligible for the trial were new referrals to the physiotherapy clinics within Ashton Wigan and Leigh Primary Care Trust and Wrightington, Wigan and Leigh NHS Foundation Trust, with a diagnosis of frozen shoulder. The district has a total patient population of 332,221 (2007/2008). There are approximately 6,500 new musculoskeletal physiotherapy referrals per year.

2.4 RECRUITMENT

All GP and Consultant referrals were triaged by the upper limb team. Patients selected for assessment were those with a diagnosis of frozen shoulder on their referral details. The physiotherapists in the team then assessed each potential patient and completed the inclusion sheet (Appendix One). The trial physiotherapist then reviewed each potential patient to ensure that they would be suitable to enter the study. This is shown in the CONSORT flow diagram of patient recruitment (Figure 3.1).

2.5 ETHICAL CONSIDERATIONS

The ethics of the study were considered following guidelines issued by the local National Health Service (NHS) research ethics committee and complied with the principles enunciated in the Declaration of Helsinki (2008). Hicks (2004) recommend that any piece of research must endeavour to protect the rights, dignity, physical and psychological welfare of the patients. Prior to embarking on the study the relevant committees were consulted and informed about the proposed research who subsequently gave the study ethical approval.

In the study, patients in all three groups were given standard clinically accepted treatment to alleviate the signs and symptoms of frozen shoulder as there was no 'non-treatment' control group. This design ensured that no patient entering the study was denied potentially beneficial treatment for their condition. There was minimal risk of complications arising from any of the treatments and to ensure patient safety, all patients entering the study were suitable for exercise therapy. Following completion of the trial all patients were given the option to have continued physiotherapy treatment or to have an orthopaedic consultation should they feel this necessary.

Prior to obtaining patient consent to enter into the study a written patient information sheet (Appendix Two) was provided. All data collected during the study was protected in accordance with the 1998 Data Protection Act.

Approval was sought and gained, through the author's employment trust, for trial data to be stored electronically on a secure NHS computer. Confirmation of registration with the information commissioner was provided by the Information Technology Manager (Health Informatics Department) (www.informationcommissioner.gov.uk).

The original data sheets were stored in locked filing cabinets on secure premises. All coded data, both electronic and hard copies, were securely stored separately from identifiable patient details. Potential patients were assured of the above measures to protect privacy, confidentiality and anonymity prior to consenting to involvement in the study and before collection of any data or personal details.

Confidentiality was maintained at all times with regard to patient information. Following a GP or Consultant referral for physiotherapy, patient records are inputted onto the electronic hospital patient system which is accessed by personal password (changed monthly). Patients cannot be identified on this system as participating in the study. It is only by correspondence with their GP or Consultant can such information be available. Any information for analysis on a home computer was pseudonymised in accordance with Caldicott regulations. Any information for the study was adequate, relevant, accurate and up to date. The use and storage of study information on a home computer was backed by floppy disc and password protected. Patients have the right under Caldicott to view their current written physiotherapy records but this was not requested by any of the patients in the study.

A warning that non-NHS to NHS e-mail is neither secure nor encrypted was explained to all trial patients and therefore that it should not be used in the communication of sensitive personal or identifiable study data. Furthermore, assurance that the trial physiotherapist would not use this means of communication to transfer information was given.

2.6 INFORMED CONSENT

The trial physiotherapist was responsible for gaining informed consent. Patients participated in the study on a voluntary basis and written consent was obtained from the patient prior to commencement (see Appendix Three). The patients received written and verbal explanations of the purposes and procedure of the study. This was in the form of the Patient Information Sheet and provided explanation of the nature of the study and methodology (Appendix Two). This was provided at recruitment a minimum of one week prior to the study. This consultation enabled patients to verbally establish comprehension of the study requirements, clarify individual queries and confirm agreement to enter the study. If no decision was made or a negative response obtained, patients then entered the main stream referrals and standard treatment was offered based upon the initial assessment.

The patient information sheet was developed in accordance with guidelines produced by the Central Office for Research Ethics Committee (2001), (www.corec.gov.uk). The REC reference number is 05/Q1401/86 approved by Stockport Local Research Ethics Committee.

2.7 ELIGIBILITY CRITERIA

The determination of inclusion and exclusion criteria was made not to limit the external validity of the study, as the more stringent the criteria the less likely the sample will be a representative of the population (Currier 1990). A number of previous studies were consulted when determining the inclusion and exclusion criteria. An extensive review of the literature was undertaken to ensure consistency with other studies.

2.7.1 Inclusion Criteria

- Age 40 to 70 years old
- Patients reported local shoulder pain, frequently present over either the anteromedial aspect of the shoulder extending distally into the biceps region, or over the lateral aspect of the shoulder extending into the lateral deltoid region.

- Spontaneous onset of a painful stiff shoulder
- Marked loss of active and passive global shoulder motion, with at least 50% loss of external rotation
- Symptoms present for at least three months. Normal x-rays on anteroposterior and axillary lateral radiographs of the glenohumeral joint (Griggs et al 2000; Wies 2005; Yang 2007)

2.7.2 Exclusion Criteria

- Radiographic pathological findings or glenohumeral osteoarthritis on X-ray
- Clinical evidence of significant cervical spine disease
- History of significant trauma to the shoulder
- Local corticosteroid injection or any physiotherapy intervention to the affected shoulder within the last three months
- Cerebral vascular accident affecting the shoulder
- Inflammatory joint disease affecting the shoulder
- Bilateral frozen shoulder due to possible underlying systemic cause
- Thyroid disease
- Any coronary event, post coronary artery by-pass or catheterisation prior to the clinical appearance of frozen shoulder
- Prior surgery, dislocation or fractures on the affected shoulder
- Active medico legal involvement
(Maricar and Chok 1999; Carette et al 2003; Wies 2005)

Inclusion criteria were representative of the typical features of frozen shoulder (Miller et al 1998). The exclusion criteria served to eliminate patients with an inappropriate diagnosis of frozen shoulder and patients with other inappropriate medical conditions complicating the pathology.

2.8 BASELINE ASSESSMENT

Patients were assessed by the trial physiotherapist and inclusion and exclusion criteria verified. To facilitate this process and to confirm a differential diagnosis of frozen shoulder, patients underwent a standardised subjective and objective

examination, as recommended by Wadsworth (1986) and Bowling et al (1986). Routine radiographs were performed.

Before participating in the study, patients gave written informed consent. Once consent was obtained, assessments of the trial outcome measures using standard assessment forms were undertaken (Appendix Four). After the baseline measurements were carried out, an administrative assistant assigned the patients to the intervention groups according to the randomisation scheme. The baseline record included age, gender, hand dominance, duration of symptoms, manner of onset of pain, precipitating trauma, previous management, history of diabetes and previous history of frozen shoulder. Following baseline evaluation outcome measures were taken at six weeks, six months and at one year. The patients who expressed a desire to withdraw from the trial due to inability to cope with ongoing symptoms were recorded as having failed treatment and offered alternative treatment. Assessment at each time point was performed by the trial physiotherapist who was blinded to treatment allocation. To facilitate control of extraneous variables, all outcome assessments were carried out in a consistent environment, e.g. room temperature, lighting.

2.9 RANDOMISATION

Randomisation took place after written consent was obtained from the study patients and baseline information was gathered. Patients meeting the inclusion criteria and agreeing to participate in the study were then randomly allocated into one of the three treatment groups:

- Group one : Exercise Class plus home exercise (Exercise Class)
- Group two : Physiotherapy plus home exercise (Multimodal)
- Group three : Home Exercise Group

The groups were identified to reflect current clinical practice. Consenting patients were randomly assigned by computer generated permuted block randomisation. The assignment scheme was generated by a statistician independent of the research team using computer-generated random numbers.

A random block length (chosen with equal probability from blocks of length six, nine or 12) was used. The allocation schedule created was provided securely to the Research and Development Department at Wrightington Hospital in April 2006 and staff in department used this to create sequentially numbered, sealed, opaque envelopes each containing a slip indicating which of the three different interventions a patient was to receive. The allocation schedule and envelopes were held by the Research and Development co-ordinator. The patient was then given an envelope with a treatment allocation and this was blinded to the trial physiotherapist. An independent person noted the number and corresponding name of the patient which was then kept in a locked filing cabinet. All the patients' records, questionnaires and post treatment information regarding age, sex, source of referral were recorded by the randomisation number and confidentiality was maintained. The patients were given one week to confirm agreement to enter the study.

2.10 INTERVENTIONS

All the patients were asked to have no other adjuvant therapy during the study except medication such as analgesics including non-steroidal anti-inflammatory drugs. Adherence was monitored via communication with the GP and by interviewing the individuals in the study. They were asked to record if they received any additional treatment. A letter was sent to the GP explaining the trial and the importance of limiting concurrent interventions (Appendix Five). Patients in all groups were given an information booklet (Appendix Six) containing advice on pain, heat, posture and a home exercise programme and were instructed how to perform the home exercise programme. Advice about frequency, intensity and progression of the exercises, was also given to aid compliance with the exercises. These home exercises were demonstrated by the trial physiotherapist. The patients went through the exercises under the supervision of the trial physiotherapist to ensure correct therapeutic exercises were performed. They were instructed when performing their exercises to begin the exercises one to two times per day; gradually build up the number of repetitions and not force through pain (Wies 2005) (Appendix Six). The outcome measures were also assessed at this point for all three groups.

The three groups continued as follows:

Patients randomised into Group Three started their programme immediately, patients randomised into Groups One and Two started their programme approximately one week later depending on the patient's availability. The physiotherapists involved in the treatment programme were all clinical specialists each with in excess of sixteen years of clinical experience and specialisation in the treatment of shoulder disorders for the past nine years. After the six weeks intervention, all patients in all three groups were reviewed by the trial physiotherapist, who remained blind to group allocation and their outcome measures were recorded.

Group One: Exercise Class

This group was assigned to a physiotherapist with 16 years of experience in musculoskeletal physiotherapy, specialisation in the treatment of shoulders for the past nine years. Treatment consisted of group therapy scheduled twice a week for a period of six weeks. Patients performed a 50 minute exercise circuit comprising of 12 stations. Each station exercise was performed for four minutes, comprising of ROM and stretching exercises for all directions of shoulder movement (Appendix Seven). Careful instruction was given by the physiotherapist when demonstrating the exercises (Sun et al 2001). Exercise sheets were given with the name of the exercise, to ensure compliance and aid understanding of the circuit (Appendix Seven). Strengthening exercises were included in week three.

Group Two: Multimodal

This group were assigned to a physiotherapist with 18 years clinical experience in musculoskeletal disorders and specialisation in the treatment of shoulder conditions for the past eleven years. Multimodal physiotherapy consisted of two sessions of individual treatment weekly over a period of six weeks. They were also instructed on the specific shoulder exercises in the home exercise programme and given the information leaflet. The treatment programme was based on local practise and expert opinion in the absence of clear consensus in the literature (Ryans et al 2005). Treatment could be adjusted according to the

severity of symptoms. It included Maitland mobilisations, which were progressed as the condition improved, soft tissue massage, myofascial trigger point release, heat, stretches and the identical home exercise programme as given to each of the other groups.

Group Three: Home Exercise Group

Patients were instructed on the specific shoulder exercises in the home exercise programme and given the information leaflet as described above. They received instruction and advice only and were reviewed in six weeks by the trial physiotherapist.

2.11 STANDARDISATION OF INTERVENTIONS

All patients were given standardised advice and instructed by the trial physiotherapist in an identical home exercise programme (Van der Windt et al 1998). This was reinforced in an information booklet given to each patient. The trial physiotherapist taught the home exercises and gave advice repeated in the information booklet (Appendix Six).

It is rare to find any clinical measurement tool to be 100% reliable as all instruments and measures are fallible. The difference between the true measure and actual measure is known as measurement error (Bruton et al 2000). To enhance the reliability and reduce measurement error, the trial physiotherapist measured all patients ROM using the standardised procedure detailed in Norkin and White (2003)(Appendix Eight).

[See 2.13.1.1 Goniometry].

2.12 BLINDING PROCEDURES

It was impossible to blind patients regarding treatment but patients were instructed not to reveal what group they were in and what intervention they had been given.

The trial physiotherapist was unaware of the treatment allocation and was not working where the treatment was administered.

The Group two physiotherapist only worked with the patients in this group and provided this intervention only. This physiotherapist worked in Ashton, Leigh and Wigan PCT and had no contact with the Group one physiotherapist. The Group one physiotherapist only worked at Wrightington Hospital where the exercise class was held.

The physiotherapists who treated the subjects in conjunction with the trial were not involved in any other aspect of the study. Both physiotherapists and patients never attended the other group or intervened in any of the sessions.

2.13 PRIMARY OUTCOME MEASURE

2.13.1 Constant Score

The primary outcome measure was The Constant-Murley Score (Constant and Murley 1987). Since its introduction in 1987 it has evolved to be the functional score currently recommended by the European Society for Surgery of the Shoulder and the Elbow and by the British Elbow and Shoulder Society (Walton et al 2007). This score reflects shoulder function with accuracy, reliability, and reproducibility (Gazielly et al 1994; Bankes et al 1998; Yian et al 2005). It is easy to use with a high intraobserver reliability and low interobserver error (Conboy et al 1996; Thompson et al 2001). This scoring system combines physical examination tests with subjective evaluations by the patients. The subjective assessment consists of 35 points and the remaining 65 points are assigned for the physical examination assessment. The subjective assessment includes a single item for pain (15 points) and four items for activities of daily living (work four, sport four, sleep two, and positioning the hand in space 10 points). The objective assessment includes: range of motion (forward elevation, 10 points; abduction, 10 points; external rotation, 10 points; internal rotation, 10 points) and power (scoring based on the number of pounds of pull the patient can resist in abduction to a maximum of 25 points). The total possible score is therefore 100 points. Low scores denote significant pain and poor function. The minimal clinically important difference (MCID) is the smallest change in score that patients perceive as meaningful and which would cause clinicians to consider a change in the patients' management (Fayers and Machin 2007). There is no data which clearly state the MCID for the Constant score. However,

in clinical practice we would normally consider a change of approximately 15 points to be clinically important. The publication by Constant and Murley (1987), in which they describe the instrument does not include methodology for how it was developed and more specifically, the rationale for item selection and relative weighting of the items. The strength of the instrument is that the method for administering the tool is quite clearly described, which is an improvement on pre-existing tools (Appendix Four).

2.13.1.1 Goniometry

One component of the Constant score is goniometry. Active ranges of shoulder movement (flexion, lateral rotation and medial rotation) were measured using a universal goniometer. With frozen shoulder however, it was difficult to achieve the recommended 90 degrees abduction starting position in order to measure rotation. The ranges of medial and external rotation were measured at the maximum pain free angle of abduction as recommended by Moore (1949). This angle was recorded during baseline evaluation and subsequently, when the outcome measures reassessed this angle was maintained to ensure comparability of results. Each movement was measured three times and the average taken. Full details of the procedure are given in Appendix Eight. This procedure has been endorsed by Gajdosik and Bohannon (1987). The results from one tester have been shown to be more reliable (Intraclass correlation coefficients of between 0.88-0.93) (MacDermaid et al 1999). The same goniometer was used throughout the testing as some suggest this to be more reliable and necessary when the effect of an intervention is to be assessed (Goodwin et al 1992; MacDermaid et al 1999). Others have suggested that this makes no difference to the reliability (Riddle et al 1987). For repeated measures of the ROM of the shoulder, the best of three readings were chosen. Maricar and Chok (1999) in their study using individuals with frozen shoulder found doing so reflected the maximum ROM achievable in that session. However, averaging more than one reading has been shown to minimally reduce variation among readings (Rothstein et al 1983; Stratford et al 1984) and therefore not essential in stable musculoskeletal conditions of the shoulder (Gajdosik and Bohannon 1987). Goniometry is the most versatile and commonly used assessment tool for measurement of ROM in clinical practice (Gajdosik and Bohannon 1987). From a review of the evidence it appears goniometry has

been proven to be a reliable and valid measure of shoulder movement (MacDermaid et al 1999; Hayes et al 2001). Goniometers are generally accepted to be valid tools, demonstrating good face validity (Gajdosik and Bohannon 1987; Williams and Callaghan 1990).

Measurements were carried out in the same sequence at each attendance and were recorded on a standard data sheet (Appendix Four). Extension was excluded as in all other studies on frozen shoulder, being the least affected movement (Cyriax and Cyriax 1983).

2.13.1.2 Pain (VAS)

Melzack and Wall's Gate Control Theory (GCT) (Melzack and Wall 1982), describes pain as a complex experience comprising sensory, emotional and cognitive dimensions. This model suggests whilst pain can be understood in terms of a stimulus-response pathway this pathway is complex and is mediated by a network of interacting processes leading to an integration of psychological factors into the traditional biomechanical model of pain. An understanding of pain is helpful in the treatment of frozen shoulder. Pain was measured at rest, during functional movement and at night. The patient was asked to identify the worst pain they felt when the shoulder was at rest, with use and at night by marking a visual analogue scale (VAS), at the point that corresponded with this level. The VAS scale is a 10cm line, 0 being no pain; 10 being the worst pain. Scale values are then obtained by measuring the distance from zero to that mark. It is used extensively in Orthopaedics. Revill et al (1976) and Price et al (1983) both conclude that the VAS provides a reliable method for measuring pain and is sufficiently sensitive to detect distinct differences in pain experience. The Price study involved 30 chronic pain patients and 20 health volunteers and assessed VAS responses to experimental pain and to different levels of chronic pain. This study found the VAS reliable for both experimental and chronic pain. It is a simple, easy to use measurement tool that the majority of patients and experimental subjects can easily respond to (Huskisson 1974; Price et al 1983).

2.14 SECONDARY OUTCOME MEASURES

2.14.1 The Oxford Shoulder Score (OSS)

This was developed by Dawson et al (1996). This score is a condition based questionnaire which is completed by patients unaided. It is short, practical, reliable, valid and sensitive to clinically important changes (Dawson et al 1996; Othman and Taylor 2004). The assessment is based on the symptoms experienced in the shoulder during the preceding four weeks and therefore, reflects their condition at the time of completion of the questionnaire. It contains 12 items each of which has five categories of response. There are four items for pain and eight items for activities of daily living (dressing, using a car or bus, using a knife, shopping, carrying a tray, brushing your hair, hanging up clothes and washing yourself). Scores are added to give a single score, with a range from 12 (best) to 60 (worse). The score can also be expressed as a percentage, where 12 points = 100% and 60 points = 0%. It is intended for use as an outcome measure during specialist shoulder treatment and imposes very little burden on the patient (Appendix Four).

2.14.2 Hospital Anxiety and Depression Scale (HADS)

Several measures of depression and depressive symptoms have been developed and used extensively both clinically, in orthopaedics and in the research setting. However, the HADS (Zigmond and Snaith 1983) has proved to be a reliable and valid tool to assess emotional distress in medical populations (Herrmann 1997). More recently it has been suggested that HADS may be suitable for use as a screening tool for use in the rehabilitation settings with musculoskeletal patients (Harter et al 2001; Pallant and Bailey 2005). Moreover, despite its brevity, it also screens for possible anxiety and depressive symptomology similar to more comprehensive clinical measures. HADS consists of 7 depressive items measuring cognitive and emotional aspects of depression (HADS – D) and 7 anxiety items focusing on emotional aspects of anxiety (HADS – A). It was developed for general medical out patients between the ages of 16 to 65 and has been extensively used effectively, primarily with psychiatric and medical patients, as well as the general population, students and non-patients with chronic medical conditions. HADS utilises a four point scale ranging from 0 to three with higher scores indicating greater severity. The

authors recommended cut off scores for the sub-scales which are 0 to seven considered non-case, eight to 10 considered possible case and 11 to 21 considered probable case. The HADS is not a diagnostic tool as it is a poor predictor of making a specific diagnosis (Silverstone 1994). It was designed to identify probable 'cases' of anxiety and depression. Average sensitivities and specificities are >0.80 which is similar to other self-rating screening tools (Herrmann 1997) (Appendix Four).

2.14.3 The Short Form 36 Health Survey (SF-36)

This is a widely used, self administered, 36 item generic indicator used to assess general health (Ware and Sherbourne 1992). It has recently been applied to the evaluation of shoulder disorders (Smith et al 2000). This is a questionnaire designed to assess eight dimensions of health status, which includes physical functioning (10 items), role limitations due to physical health problems (four items), bodily pain (two items), social functioning (two items), mental health (five items), role limitations due to emotional problems (three items), vitality and general health perceptions (five items). Each of the eight subscales is rescaled from 0 (poor health)-100 (good health); with a higher score indicating better health. For norm-based scores, any score above or below 50 can be considered above or below the population average health status for that dimension and each point on the scale is 1/10 of the standard deviation. Population norms are available for the US and the UK. In the UK they are given by age, sex, socioeconomic class and for chronic health conditions (Moncur 2003). It is the most widely used health status measure world wide. Overall, the SF-36 in a review of existing outcome tools struck the best balance between length, reliability, validity, responsiveness and experience in large populations of patients with back pain (Bombardier 2000) (Appendix Four)

2.15 SAMPLE SIZE

Based on the judgement of what constitutes a clinically significant difference on the primary outcome and variability estimates from previous studies, a sample size of 132 (44 per group) was planned (Yang et al 2007). The sample size calculation suggested that, to achieve 80% statistical power using a significance level of 5%, the sample size providing outcome data needed to be at least 39

per group (allowing for 10% dropout), to detect a clinically-significant between-groups difference of 15 points on the Constant score, assuming a standard deviation of 20 points (based on the results of previous studies). We inflated the sample size to 44 in each group to allow for 10% dropout. The calculation was based on three pairwise comparisons and a two-sample t-test. The further use of covariates, such as the baseline value of the Constant score, should further improve the power of the study.

Calculation of adequate sample size was important in order to make sure the sample is representative of the population (Currier 1990) the larger the sample size the less likely the researcher is to obtain negative results or make incorrect inferences about the collected data (Currier 1990). This is often referred to as a Type II error. The experimental hypothesis is rejected in favour of the null hypothesis when the data does, in reality, support the experimental hypothesis. This can be thought of as a 'false negative' finding (Hicks 2004). It is also possible to obtain a significant result and thus reject the null hypothesis, when the null hypothesis is in fact true. This is called a Type I error and may be thought of as a 'false positive' result.

If the sample size is too small, then the results will be unable to be generalised to the population from which the sample was drawn (Hicks 2004). However if the sample size is too large, this could result in a waste of the researcher's resources, as the researcher would have to extend the study. This can also be considered to be unethical as it wastes patients' time who have agreed to take part. It is therefore important that a power calculation is carried out to scientifically determine the correct sample size.

A sample of convenience was used i.e. patients referred for physiotherapy in the Ashton, Leigh and Wigan PCT. Currier (1990), reports that this method is often used in health related research as ethical constraints require that informed consent from subjects is needed prior to participation in the study. However, statisticians have reservations about this method of sampling and it offers no choice of subjects (Currier 1990). As the trial physiotherapist works at Wrightington Hospital and in Ashton, Leigh and Wigan PCT, it is of practical

convenience in regards to travel and costs that the sample is derived from within this population.

2.16 METHOD OF ANALYSIS

Data was analysed within groups to assess the effects of each intervention on the outcome measures and between groups, to compare the effects of the intervention. Descriptive statistics including means and standard deviations on interval/ratio data and frequencies with percentages on categorical data are presented. All data were tested to determine if normally distributed. If normally distributed a repeated measures one-way analysis of variance (RM ANOVA) on the outcome data was conducted. This included prognostic measures using the baseline value of the outcome measure as a covariate. All data were tested using Mauchly's test for sphericity, if this was not significant sphericity was assumed. If Mauchly's test for sphericity was found to be significant then the Greenhouse-Geisser method was used. Pairwise comparisons using the Least Squares Difference were conducted to investigate the differences between the different treatment groups and at the different time intervals following intervention.

The baseline (pre-intervention) measurement is included as a covariate as it will be related to the repeated measurements following introduction of the different interventions rather than being an outcome of the intervention. The effect of the intervention (strictly speaking the average effect of the intervention over time) is then tested via the main effect of intervention group, whether the effect of the intervention varies over time is represented by the interaction between the intervention group and the repeated group and the repeated factor over time. The level of rejection of the null hypothesis was $p < 0.05$ for all measures although the interaction between intervention group and time was tested using $p < 0.10$ as the study was not powered to detect such trends.

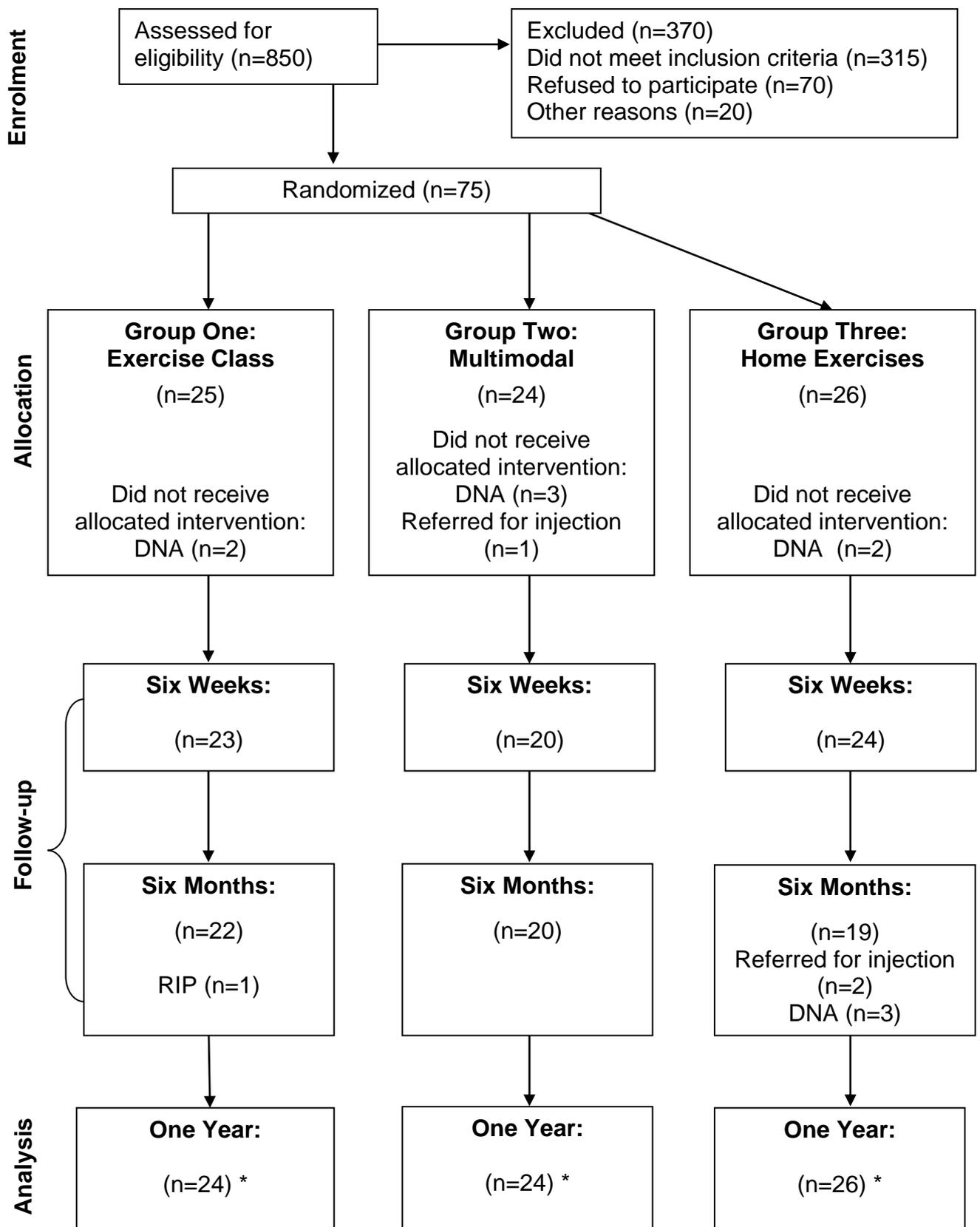
Chapter 3 RESULTS

3.1 RECRUITMENT

A total number of 850 patients were initially recruited during a one year period between September 2006 and September 2007; 370 were excluded; 315 did not fit the inclusion criteria, and 70 refused to participate. The study was stopped due to the time restraints given for the Masters in Research. Thus 75 patients entered the study and were randomly assigned to one of three groups.

A total number of eight patients did not attend (DNA) follow up, despite being contacted and given another appointment. This subsequently led to incomplete data collection up to six months but all patients were reassessed at one year (intention-to-treat). Two patients were from Group one – Exercise Class, three patients were from Group two – Multimodal and three patients from Group three – Home Exercise Group. One patient died from other unrelated causes at six months from Group one – Exercise Class. One of the patients in Group two – Multimodal telephoned at six weeks, and two of the patients in Group three – Home Exercise Group telephoned at six months to say their pain was too much to tolerate and were given an injection. They were reassessed at one year. One patient in Group two asked to see the Consultant but was given no further intervention and again reassessed at one year. At six months, one patient in Group one reported having lower limb problems and two patients in Group two reported having other upper limb problems and cardiac investigations, however they all completed the study. None of the other patients reported receiving any other treatments or interventions (Figure 3.1).

Figure 3.1 Flow diagram to communicate patient flow throughout the study



* = n greater than follow-up section due to intention-to-treat analysis.

3.2 PATIENT CHARACTERISTICS

The mean age of the sample was 51.13 years old (SD 6.84). The ratio of female to male was 1:1.14. The dominant arm was affected in 53 percent of the study population. 73 percent of patients were right-handed. The mean duration of symptoms was 5.79 months (SD 1.48). The primary analysis was intention-to-treat and involved all patients who were randomly assigned. All data was recorded to two decimal points. An independent person checked raw data for accuracy.

Table 3.1 Baseline Characteristics

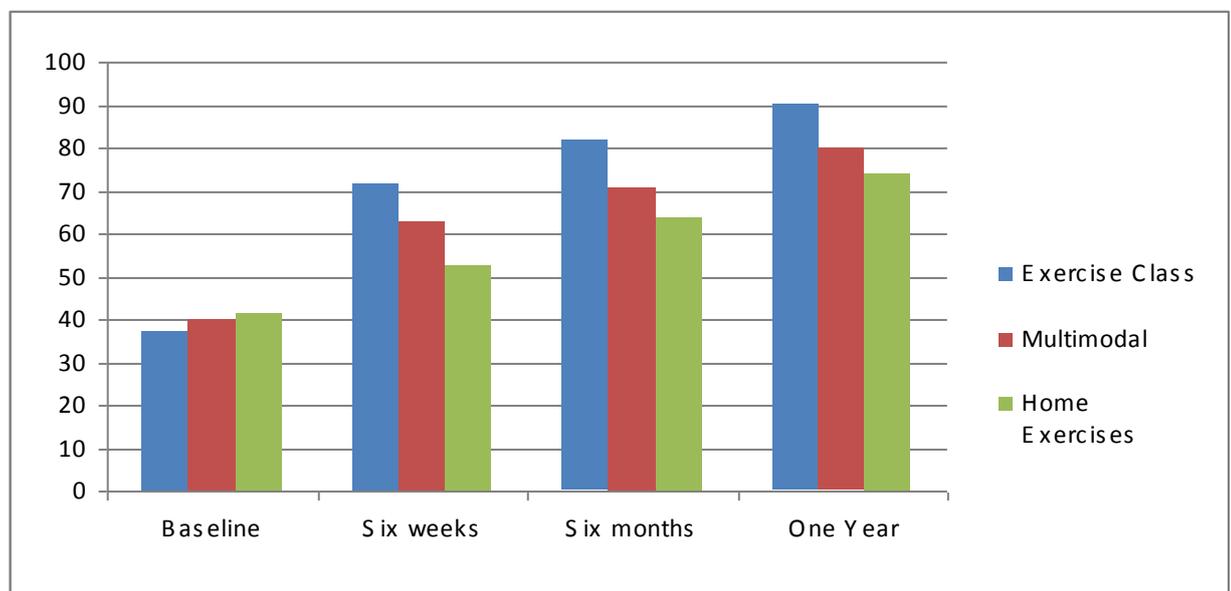
	Group One: Exercise Class	Group Two: Multimodal	Group Three: Home Exercise
Age Mean Range (in years)	51.27 (SD 7.27)	50 (SD 6.06)	52.8 (SD 7.18)
Male Gender n(%)	12(48)	10(42)	13(50)
Female Gender n(%)	13(52)	14(58)	13(50)
Affected Shoulder Right n(%)	11(44)	11(45)	14(54)
Affected Shoulder Left n(%)	14(56)	13(54)	12(46)
Dominant Arm Right n(%)	18(72)	18(75)	19(73)
Dominant Arm Left n(%)	7(28)	6(25)	7(27)
Diabetic n(%)	2(8)	9(37)	2(8)
Mean Duration (in months)	6.12 (SD1.68)	5.36 (SD1.28)	5.84 (SD1.4)

3.3 ANALYSIS OF THE PRIMARY OUTCOME MEASURE (CONSTANT SCORE)

3.3.1 Analysis of the Constant Score between the different time intervals and treatment groups

Figure 3.2 shows the mean values of the Constant score. The Constant score combines subjective and objective measures to produce a 100 point score. This is derived of four parameters – Activities of Daily Living (ADL), Range of Movement (ROM), pain and strength.

Figure 3.2 Mean Constant Score value for each treatment group at six weeks, six months and at one year for the Constant score.



A repeated measures ANOVA did not show a significant difference in the Constant score between treatment groups ($p=0.188$) but did show a significant difference between different time intervals ($p<0.001$). There was no significant difference between the profile of recovery between the three treatment groups ($p=0.188$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better score than the Multimodal and the Home Exercise Groups ($p<0.001$). The Multimodal Group showed a significantly better score than the Home Exercise Group ($p=0.002$)(Table 3.2).

Table 3.2 Pairwise comparison between overall means of the different treatment groups for the Constant Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	10.7	2.871	<0.001
Exercise Class vs. Home Exercises	20.304	2.936	<0.001
Multimodal vs. Home Exercises	9.606	2.970	0.002

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Constant score between six weeks and six months ($p < 0.001$), six weeks and one year ($p < 0.001$) and between six months and one year ($p < 0.001$) (Table 3.3). This shows a continued improvement over time, Figure 3.2.

Table 3.3 Pairwise comparison between the different time intervals for the Constant Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-9.739	-11.527	-7.952	<0.001
six weeks vs. one year	-18.962	-21.063	-16.861	<0.001
six months vs. one year	-9.222	-10.766	-7.679	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.3.2 Analysis of the sub scores of the Constant Score

3.3.2.1 Activities of Daily Living (ADL)

A repeated measures ANOVA did not show a significant difference in the Constant ADL Score between treatment groups ($p = 0.85$) but did show a significant difference between time intervals ($p < 0.001$). There was no significant difference between the profile of recovery between the three treatment groups ($p = 0.85$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better ADL score than the Multimodal and the Home Exercise Groups ($p=0.037$, $p<0.001$) respectively. The Multimodal Group showed a significantly better ADL score than the Home Exercise Group ($p=0.041$)(Table 3.4).

Table 3.4 Pairwise comparison between overall means of the different treatment groups of the Constant ADL Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	1.452	0.680	0.037
Exercise Class vs. Home Exercises	2.840	0.681	<0.001
Multimodal vs. Home Exercises	1.388	0.696	0.041

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Constant ADL Score between six weeks and six months ($p<0.001$), six weeks and one year ($p<0.001$) and between six months and one year ($p<0.001$)(Table 3.5). This shows a continued improvement over time, Figure 3.2.

Table 3.5 Pairwise comparison between the different time intervals of the Constant ADL Score.

Pairwise Comparison	Mean Difference	95%confidence interval for mean difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-1.982	-2.653	-1.312	<0.001
six weeks vs. one year	-3.041	-3.694	-2.388	<0.001
six months vs. one year	-1.059	-1.560	-0.558	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.3.2.2 Range Of Movement (ROM)

A repeated measures ANOVA did not show a significant difference in the Constant ROM Score between treatment groups ($p=0.37$) but did show a significant difference between time intervals ($p<0.001$). There was no significant difference between the profile of recovery between the three treatment groups ($p=0.37$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better Constant ROM Score than the Multimodal and the Home Exercise Groups ($p=0.020$, $p<0.001$) respectively. The Multimodal Group showed a significantly better Constant ROM Score than the Home Exercise Group ($p=0.009$)(Table 3.6).

Table 3.6 Pairwise comparison between overall means of the different treatment groups for the Constant ROM Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	2.131	0.888	0.020
Exercise Class vs. Home Exercises	4.615	0.893	<0.001
Multimodal vs. Home Exercises	2.485	0.917	0.009

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Constant ROM Score between six weeks and six months ($p<0.001$), six weeks and one year ($p<0.001$) and between six months and one year ($p<0.001$)(Table 3.7). This shows a continued improvement over time, Figure 3.2.

Table 3.7 Pairwise comparison between the different time intervals for the Constant ROM Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-1.502	-2.262	-0.742	<0.001
six weeks vs. one year	-3.490	-4.225	-2.755	<0.001
six months vs. one year	-1.988	-2.728	-1.248	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.3.2.3 Pain

A repeated measures ANOVA did not show a significant difference in the Constant Pain Score between treatment groups ($p=0.117$) but did show a significant difference between different time intervals ($p<0.001$). There was no significant difference between the profile of recovery between the three treatment groups ($p=0.117$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better pain score than the Multimodal and the Home Exercise Groups ($p=0.008$, $p<0.001$) respectively. The Multimodal Group did not show a significantly better pain score than the Home Exercise Group ($p=0.075$)(Table 3.8).

Table 3.8 Pairwise comparison between overall means of the different treatment groups for the Constant Pain Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	4.172	1.512	0.008
Exercise Class vs. Home Exercises	7.059	1.568	<0.001
Multimodal vs. Home Exercises	2.887	1.593	0.075

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Constant Pain Score between six weeks and six months ($p < 0.001$), six weeks and one year ($p < 0.001$) and between six months and one year ($p < 0.001$) (Table 3.9). This shows a continued improvement over time, Figure 3.2.

Table 3.9 Pairwise comparison between the different time intervals for the Constant Pain Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-4.007	-5.206	-2.808	<0.001
six weeks vs. one year	-7.750	-9.027	-6.473	<0.001
six months vs. one year	-3.743	-4.685	-2.800	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.3.2.4 Strength

A repeated measures ANOVA showed a significant difference in the Constant Strength Score between treatment groups ($p < 0.001$) and between different time intervals ($p < 0.001$). There was a significant difference between the profile of recovery between the three treatment groups ($p < 0.001$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better Strength score than the Multimodal and the Home Exercise Groups ($p < 0.001$, $p < 0.001$) respectively. The Multimodal Group showed a significantly better Strength score than the Home Exercise Group ($p = 0.006$) (Table 3.10).

Table 3.10 Pairwise comparison between overall means of the different treatment groups for the Constant Strength Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	3.228	0.740	<0.001
Exercise Class vs. Home Exercises	5.391	0.731	<0.001
Multimodal vs. Home Exercises	2.163	0.753	0.006

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Constant Strength Score between six weeks and six months ($p < 0.001$), six weeks and one year ($p < 0.001$) and between six months and one year ($p < 0.001$) (Table 3.11). This shows a continued improvement over time, Figure 3.2.

Table 3.11 Pairwise comparison between the different time intervals for the Constant Strength Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-2.164	-2.845	-1.482	<0.001
six weeks vs. one year	-4.685	-5.502	-3.868	<0.001
six months vs. one year	-2.521	-3.144	-1.899	<0.001

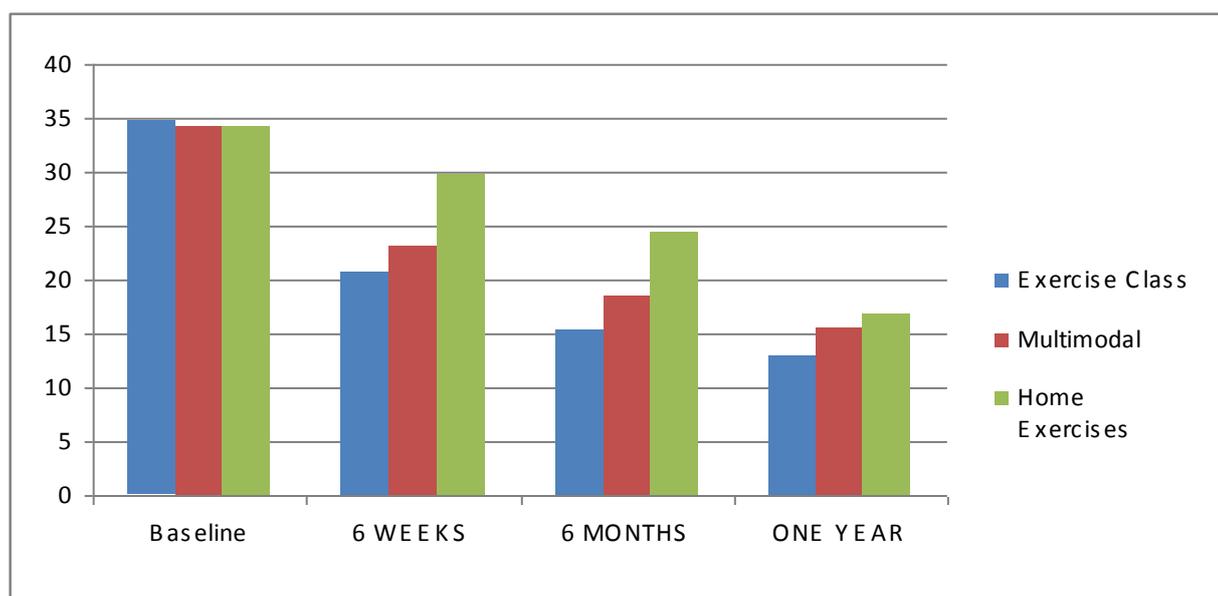
Adjustment for multiple comparisons: Least Significant Difference

3.4 ANALYSIS OF THE OXFORD SHOULDER SCORE (OSS)

3.4.1 Analysis of the Oxford Shoulder Score between the different time intervals and treatment groups

Figure 3.3 shows the mean values of the Oxford Shoulder Score. This is a subjective questionnaire which contains 12 questions. This is derived from two parameters; pain and function. Scores from each of the questions are added to produce a single score with a range from 12 (least difficulties) to 60 (most difficulties).

Figure 3.3 Mean Oxford Shoulder Score value for each treatment group at six weeks, six months and at one year for the Oxford Shoulder Score.



A repeated measures ANOVA showed a significant difference in the Oxford Shoulder Score between treatment groups ($p < 0.001$) and between different time intervals ($P = 0.033$). There was a significant difference between the profile of recovery between the three treatment groups ($p < 0.001$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better Oxford Shoulder Score than the Multimodal and the Home Exercise Groups ($p < 0.037$, $p < 0.001$) respectively. The Multimodal Group showed a significantly better Oxford Shoulder Score than the Home Exercise Group ($p < 0.001$)(Table 3.12).

Table 3.12 Pairwise comparison between overall means of the different treatment groups for the Oxford Shoulder Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	-2.848*	1.332	0.037
Exercise Class vs. Home Exercises	-7.549*	1.316	<0.001
Multimodal vs. Home Exercises	-4.701*	1.347	<0.001

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Oxford Shoulder Score between six weeks and six months ($p < 0.001$), six weeks and one year ($p < 0.001$) and between six months and one year ($p < 0.001$) (Table 3.13). This shows a continued improvement over time, Figure 3.3.

Table 3.13 Pairwise comparison between the different time intervals for the Oxford Shoulder Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	5.162	3.957	6.366	<0.001
six weeks vs. one year	9.504	8.386	10.622	<0.001
six months vs. one year	4.342	3.141	5.544	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.4.2 Analysis of the sub scores of the Oxford Shoulder Score

3.4.2.1 Pain

A repeated measures ANOVA showed a significant difference in the Oxford Pain Score between treatment groups ($p < 0.001$) and between different time intervals ($P = 0.015$). There was a significant difference between the profile of recovery between the three treatment groups ($p < 0.001$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class showed a significantly better Pain score than the Multimodal and the Home Exercise Groups ($p = 0.004$, $p < 0.001$) respectively. The Multimodal Group showed a significantly better Pain score than the Home Exercise Group ($p < 0.001$) (Table 3.14).

Table 3.14 Pairwise comparison between overall means of the different treatment groups for the Oxford Pain Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	-1.825	0.615	0.004
Exercise Class vs. Home Exercises	-4.152	0.606	<0.001
Multimodal vs. Home Exercises	-2.327	0.624	<0.001

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Oxford Pain Score between six weeks and six months ($p < 0.001$), six weeks and one year ($p < 0.001$) and between six months and one year ($p < 0.001$) (Table 3.15). This shows a continued improvement over time, Figure 3.3.

Table 3.15 Pairwise comparison between the different time intervals for the Oxford Pain Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	2.931	2.313	3.550	<0.001
six weeks vs. one year	5.230	4.586	5.875	<0.001
six months vs. one year	2.299	1.746	2.853	<0.001

Adjustment for multiple comparisons: Least Significant Difference

3.4.2.2 Function

A repeated measures ANOVA showed a significant difference in the Oxford Function Score for function between treatment groups ($p = 0.012$) but not between different time intervals ($P = 0.090$). There was a significant difference between the profile of recovery between the three treatment groups ($p = 0.012$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not

show a significantly better Function score than the Multimodal Group ($p=0.360$) but the Exercise Class showed a significantly better Function score than the Home Exercise Group ($p<0.001$). The Multimodal Group showed a significantly better Function score than the Home Exercise Group ($p=0.006$)(Table 3.16).

Table 3.16 Pairwise comparison between overall means of the different treatment groups for the Oxford Function Score.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	-0.796	0.862	0.360
Exercise Class vs. Home Exercises	-3.262	0.851	<0.001
Multimodal vs. Home Exercises	-2.467	0.872	0.006

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison showed a significant difference in the Oxford Function Score between six weeks and six months ($p<0.001$), six weeks and one year ($p<0.001$) and between six months and one year ($p<0.001$)(Table 3.17). This shows a continued improvement over time, Figure 3.3.

Table 3.17 Pairwise comparison between the different time intervals for the Oxford Function Score.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	2.383	1.578	3.188	<0.001
six weeks vs. six year	4.425	3.626	5.228	<0.001
six months vs. one year	2.042	1.229	2.856	<0.001

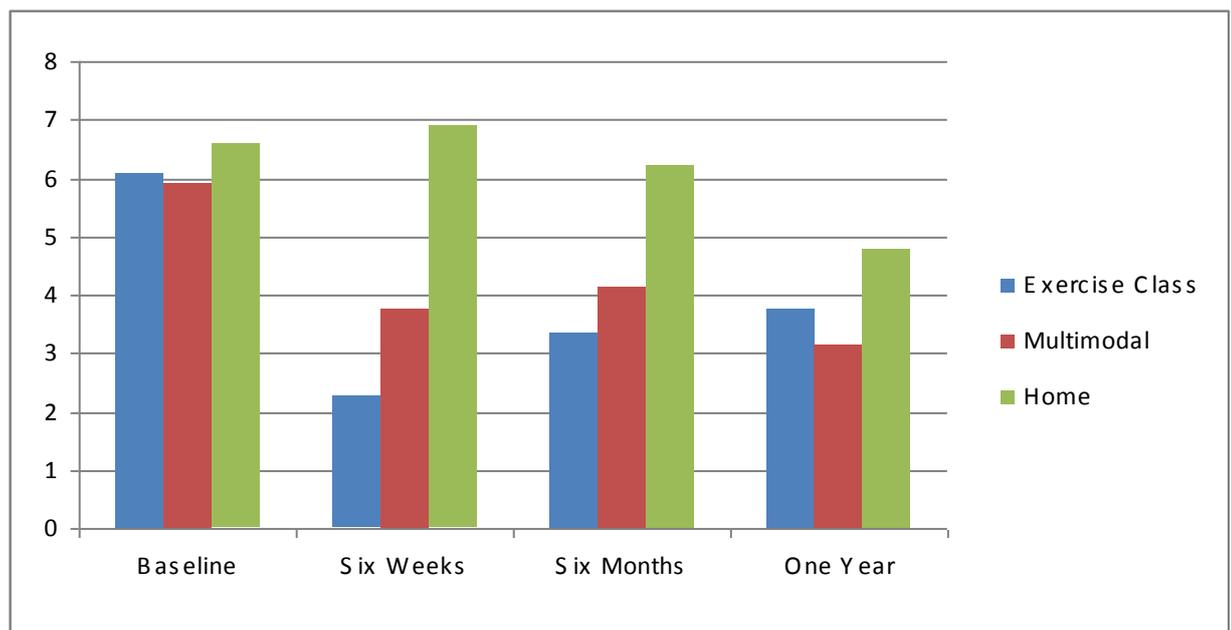
Adjustment for multiple comparisons: Least Significant Difference

3.5 ANALYSIS OF THE HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS)

HADS consists of seven depressive items measuring cognitive and emotional aspects of depression (HADS-D) and seven anxiety items focusing on emotional aspects of anxiety (HADS-A). This score consists of 14 items rated on a four-point scale, ranging from the absence of a symptom or the presence of positive features (scoring 0) to maximal symptomology or the absence of positive features, which score three. Therefore, the higher the score the more severe the disorder, indicating greater severity.

3.5.1 Analysis of the HADS for Anxiety (HADS-A) between the different time intervals and treatment groups

Figure 3.4 Mean HADS-A value for each treatment group at six weeks, six months and at one year for the HADS-A.



A repeated measures ANOVA showed a significant difference in the HADS-A Score between treatment groups ($p < 0.001$) but did not show a significant difference between different time intervals ($p = 0.566$). There was a significant difference between the profile of recovery between the three treatment groups ($p < 0.001$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not show a significantly better HADS-A score than the Multimodal Group ($p=0.288$). However, the Exercise Class showed a significantly better HADS-A score than the Home Exercise Group ($p<0.001$) and the Multimodal Group showed a significantly better HADS-A score than the Home Exercise Group ($p=0.024$)(Table 3.18).

Table 3.18 Pairwise comparison between overall measures of the different treatment groups for the HADS-A.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	-0.686	0.639	0.288
Exercise Class vs. Home exercise	-2.195	0.636	<0.001
Multimodal vs. Home Exercises	-1.509	0.653	0.024

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison did not show a significant difference in the HADS-A Score between six weeks and six months ($p=0.442$), six weeks and one year ($p=0.231$) but did show a significant difference between six months and one year ($p=0.035$)(Table 3.19). This shows a continued improvement over time, Figure 3.4.

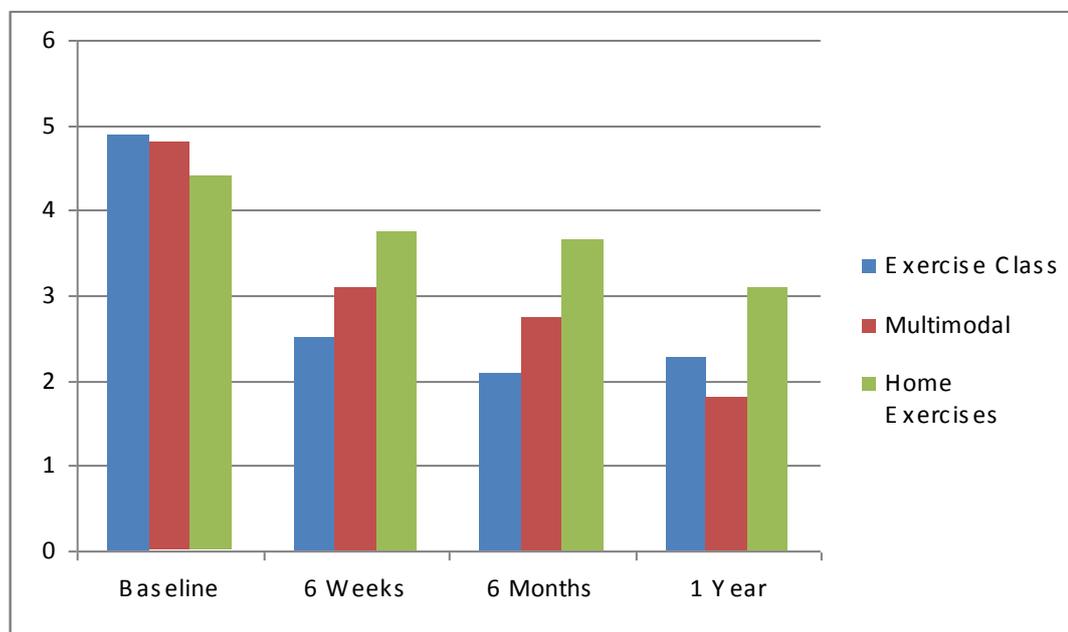
Table 3.19 Pairwise comparison between the different time intervals for the HADS-A.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-0.243	-0.871	0.385	0.442
six weeks vs. one year	0.431	-0.281	1.143	0.231
six months vs. one year	0.674	0.050	1.298	0.035

Adjustment for multiple comparisons: Least Significant Difference

3.5.2 Analysis of the HADS for Depression (HADS-D) between the different time intervals and treatment groups

Figure 3.5 Mean HADS-D value for each treatment group at six weeks, six months and at one year for the HADS-D.



A repeated measures ANOVA did not show a significant difference in the HADS-D between treatment groups ($p=0.359$) or between different time intervals ($p=0.750$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.359$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not show a significantly better HADS-D score than the Multimodal Group ($p=0.704$). However, the Exercise Class showed a significantly better HADS-D score than the Home Exercise Group ($p=0.006$) and the Multimodal Group showed a significantly better HADS-D score than the Home Exercise Group ($p=0.021$)(Table 3.20).

Table 3.20 Pairwise comparison between overall means of the different treatment groups for the HADS-D.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	-0.173	0.453	0.704
Exercise Class vs. Home Exercises	-1.264	0.447	0.006
Multimodal vs. Home Exercises	-1.090	0.458	0.021

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison did not show a significant difference in the HADS-D between six weeks and six months ($p=0.208$) and between six months and one year ($p=0.068$), but did show a significant difference between six weeks and one year ($p=0.014$)(Table 3.21). This shows a continued improvement over time, Figure 3.5.

Table 3.21 Pairwise comparison between the different time intervals for the HADS-D.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	0.285	-0.163	0.732	0.208
six weeks vs. one year	0.731	0.151	1.311	0.014
six months vs. one year	0.446	-0.034	0.927	0.068

Adjustment for multiple comparisons: Least Significant Difference

3.6 ANALYSIS OF THE SHORT FORM 36 (SF-36)

The short form 36 item health survey (SF-36) is a widely used, self administered, 36 item generic indicator of health status which consists of eight subscales representing eight dimensions of quality of life: general health perceptions (GH), physical function (PF), role limitations because of physical health problems (RP), role limitations because of emotional problems (RE), social functioning (SF), bodily pain (BP), vitality (VT) and general mental health

(MH). Each of the eight subscales is rescaled from 0–100; higher scores represent better health.

3.6.1 Analysis of the SF-36 between the different time intervals and treatment groups

3.6.1.1 General Health (GH)

A repeated measures ANOVA did not show a significant difference in the GH between treatment groups ($p=0.937$) or between different time intervals ($p=0.223$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.937$).

3.6.1.2 Physical Function (PF)

A repeated measures ANOVA did not show a significant difference in the PF between treatment groups ($p=0.470$) or between different time intervals ($p=0.674$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.470$).

3.6.1.3 Role limitations because of health problems (RP)

A repeated measures ANOVA did not show a significant difference in the RP between treatment groups ($p=0.354$) or between different time intervals ($p=0.132$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.354$).

3.6.1.4 Role limitations because of emotional problems (RE)

A repeated measures ANOVA did not show a significant difference in the RE between treatment groups ($p=0.843$) or between different time intervals ($p=0.300$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.843$).

3.6.1.5 Social Functioning (SF)

A repeated measures ANOVA did not show a significant difference in the SF between treatment groups ($p=0.335$) but did show a significant difference in the time intervals ($p<0.001$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.335$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not show a significantly better SF score than the Multimodal or the Home Exercise Groups ($p=0.882$, $p=0.227$) respectively. The Multimodal Group did not show a significantly better SF score than the Home Exercise Group ($p=0.306$)(Table 3.22).

Table 3.22 Pairwise comparison between overall means of the different treatment groups for SF.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	0.806	5.397	0.882
Exercise Class vs. Home Exercises	6.539	5.356	0.227
Multimodal vs. Home Exercises	5.733	5.549	0.306

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison did not show a significant difference in the SF between six weeks and six months ($p=0.844$), but did show a significant difference between six weeks and one year ($p=0.045$) and between six months and one year ($p=0.021$)(Table 3.23). This shows a continued improvement over time.

Table 3.23 Pairwise comparison between the different time intervals for SF.

Pairwise Comparison	Mean Difference	95% Confidence Interval for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-0.386	-4.293	3.521	0.844
six weeks vs. one year	7.767	0.161	15.372	0.045
six months vs. one year	8.153	1.249	15.058	0.021

Adjustment for multiple comparisons: Least Significant Difference

3.6.1.6 Bodily Pain (BP)

A repeated measures ANOVA did not show a significant difference in the BP between treatment groups ($p=0.520$) but did show a significant difference between different time intervals ($p=0.011$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.520$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not show a significantly better BP score than the Multimodal Group ($p=0.122$) and the Multimodal Group did not show a significantly better BP score than the Home Exercise Group ($p=0.525$). However, the Exercise Class did show a significantly better BP score than the Home Exercise Group ($p=0.032$)(Table 3.24).

Table 3.24 Pairwise comparison between overall means of the different treatment groups for BP.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	8.310	5.302	0.122
Exercise Class vs. Home Exercises	11.772	5.355	0.032
Multimodal vs. Home Exercises	3.462	5.411	0.525

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison did not show a significant difference in the BP between six weeks and six months ($p=0.938$), but did show a significant difference between six weeks and one year ($p<0.001$) and between six months and one year ($p=0.005$)(Table 3.25). This shows a continued improvement over time.

Table 3.25 Pairwise comparison between the different time intervals for BP.

Pairwise Comparison	Mean Difference	95% Confidence Intervals for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	-0.157	-4.165	3.851	0.938
six weeks vs. one year	-7.189	-11.317	-3.060	<0.001
six months vs. one year	-7.032	11.862	-2.202	0.005

Adjustment for multiple comparisons: Least Significant Difference

3.6.1.7 Vitality (VT)

A repeated measures ANOVA did not show a significant difference in the VT between treatment groups ($p=0.384$) or between different time intervals ($p=0.825$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.384$).

3.6.1.8 Mental Health (MH)

A repeated measures ANOVA did not show a significant difference in the MH between treatment groups ($p=0.075$) but did show a significant difference between different time intervals ($p=0.009$). There was not a significant difference between the profile of recovery between the three treatment groups ($p=0.075$).

However, a further analysis using a pairwise comparison allowed the intercomparison of the individual treatment groups. The Exercise Class did not show a significantly better MH score than the Multimodal or the Home Exercise Groups ($p=0.059$, $p=0.126$) respectively. The Multimodal Group did not show a significantly better MH score than the Home Exercise Group ($p=0.705$)(Table 3.26).

Table 3.26 Pairwise comparison between overall means of the different treatment groups for MH.

Pairwise Comparison	Mean Difference	Standard Error	p value
Exercise Class vs. Multimodal	6.313	3.274	0.059
Exercise Class vs. Home Exercises	5.056	3.256	0.126
Multimodal vs. Home Exercises	-1.257	3.300	0.705

Adjustment for multiple comparisons: Least Significant Difference

A pairwise comparison did not show a significant difference in the MH between six weeks and six months ($p=0.815$), between six weeks and one year ($p=0.164$) and between six months and one year ($p=0.062$)(Table 3.27). This did show a continued improvement over time.

Table 3.27 Pairwise comparison between the different time intervals for MH.

Pairwise Comparison	Mean Difference	95% Confidence Intervals for Mean Difference		p value
		Lower Bound	Upper Bound	
six weeks vs. six months	0.272	-2.041	2.584	0.815
six weeks vs. one year	-2.390	-5.781	1.001	0.164
six months vs. one year	-0.2.662	0.062	-5.457	0.062

Adjustment for multiple comparisons: Least Significant Difference

3.7 SUMMARY OF RESULTS

The following table outlines the final results.

Table 3.28 Summary of Results

	6 WEEKS			6 MONTHS			1 YEAR		
	EC	M	HE	EC	M	HE	EC	M	HE
CONSTANT SCORE	1	2	3	1	2	3	1	2	3
OSS	1	2	3	1	2	3	1	2	3
HADS-A	1	2	3	1	2	3	2	1	3
HADS-D	1	2	3	1	2	3	2	1	3

Key

EC = Exercise Class

M = Multimodal

HE = Home Exercises



Most Effective



Moderately Effective



Least Effective

Chapter 4 DISCUSSION

4.1 INTRODUCTION

This chapter will firstly evaluate and discuss the results obtained in the present study. When possible, comparison with other research trials is considered to demonstrate the similarities and differences in findings. This chapter will then focus on the strengths and limitations in the methods and other relevant issues, in order to highlight factors that may have influenced results. Finally statements about the experimental hypotheses, clinical implications and suggestions for future research will be made.

Despite considerable research and interest in the condition, frozen shoulder remains a controversial and debatable disease. Currently, no standard medical, surgical, or therapy regimen is universally accepted as the most efficacious treatment for restoring motion in patients with frozen shoulder (Loew et al 2005). Goals of treatment are to decrease pain, increase range of movement (ROM) and improve function. Although the literature lacks a consensus on the optimal non-operative approach for the treatment of frozen shoulder, it is still the primary intervention (Lynch 2002). When this fails, operative treatment of manipulation under anaesthetic alone or in combination with arthroscopic release may be reasonable options and appear to produce satisfactory results in most cases (Hannafin and Chiaia 2000; Hannafin and Strickland 2000).

4.2 LIMITATIONS OF THE STUDY

A potential limitation of the study is the sample size. The pre study sample size calculation suggested that 44 patients were required per group to detect a clinically significant difference of 15 points on the Constant score, assuming a standard deviation of 20 points. The significant difference observed in this study was 20 points on the Constant score and the smallest difference of 9.6 points on the Constant score. However, the largest standard deviation observed was 14 points and the smallest standard deviation was 8 points. Based on the results of this study a further power calculation was performed. This indicated that a lower sample size of 31 per group is required to determine a difference.

This reduction in sample size was due to smaller standard deviations that were initially estimated which reduces the chance of type 1 errors. The results show that there were by chance an unequal number of people with diabetes in each group (See Table 3.1). Group two had a considerably greater number than the other two groups (Group two – nine, Group one and Group three - two). It could be reasonable to suggest that the people with diabetes may have a different response to treatment (Smith et al 2003). Unfortunately it would be difficult to postulate the overall effect of this imbalance in numbers although it would be interesting to understand the implications of this in the future.

Physiotherapy interventions were devised and based on the best evidence available and physiotherapists were selected with over sixteen years clinical experience in the treatment of musculoskeletal conditions. They specialised in the treatment of shoulder disorders for the past nine years. It was not possible to standardise all aspects of the physiotherapy intervention in Group two but there were common components that could be reproduced in a variety of clinical settings. The physiotherapist in this group had over 18 year's clinical experience and specialised in the treatment of shoulder disorders for the past eleven years. The content of each physiotherapy session may have varied from one patient to another. It included Maitland mobilisations, which were progressed as the condition improved, soft tissue massage, myofascial trigger point release, heat, stretches and the identical home exercise programme as given to each of the other groups. The scope of generalisability of the results in the study may be limited. Foster et al (2009) reported that RCT's are performed to limit individual variation and optimize prognostic similarity of intervention groups by using homogenous groups of patients. They agree that this limits the generalisability of the findings and obscure a variation of individual responses, with some patients showing dramatic improvement while others hardly respond to the same intervention. While the results cannot be generalised to other types of physiotherapy interventions, they apply to patients meeting the selection criteria and for the actual interventions in the study. Further research is required to verify the effects of various techniques in manual therapy for the treatment of frozen shoulder.

One year follow up was a relatively short period for a study; especially of a disease that many authors suggest has a protracted course and even state can last for as long as seven years (Shaffer et al 1992). Symptom resolution does not always occur but persistent symptoms are most commonly mild (Hand et al 2007). The obvious preference would be to continue the study for a prolonged time period to investigate if significant numbers of people have residual clinical detectable restriction of movement and smaller numbers have residual disability. Foster et al (2009) suggest that there has been insufficient identification of important patient subgroups in previous trials and simply small and often short-term effects have been reported. They recommend that outcome measures should be used to assess common musculoskeletal conditions over a prolonged time period rather than focusing on specified follow-up time points alone. Even though this study is relatively short compared to the course of the condition, the follow up length of one year is impressive in the current state of research in physiotherapy for the treatment of frozen shoulder.

4.3 LIMITATIONS OF THE PRIMARY OUTCOME MEASURE – The Constant Score.

To date, research has not identified a specific outcome tool or specified score range that is optimal for individuals with frozen shoulder (Kelly et al 2009). Even though the Constant score is currently the outcome measure recommended by the European Society for Surgery of the Shoulder and the Elbow and by the British Elbow and Shoulder Society (Walton et al 2007) but none the less, like many outcome measures, it has limitations when applied to frozen shoulder. The Constant score lacked the disability and ROM evaluation required for stage three of frozen shoulder. It appeared to be more widely used in medical papers as a single system of gathering different categories of information. It has a maximum score of 100 points with subject parameter of pain and objective parameter of ROM and strength components in a ratio of 35:65 (Constant and Murley 1987). It uses point systems of different values assigned to pain and active ROM after initial goniometry measurement of elevation and lateral rotation determined by positions relative to anatomical landmarks. The process of assigning score values after goniometry measurement appears unnecessary since goniometry measurement has higher validity and reliability than a scoring

system (Mayerson and Milano 1984). The procedure for measuring shoulder elevation is also vague. Strength is assessed according to the load that can be lifted up to a max score of 25 for each pound lifted. One of the most criticized issues of the Constant score is the relatively high rating of the factor strength on the final results (Brinker et al 2002). The limitation of this strength measurement is that extra points are not given for strength beyond 25 pounds.

The content of the Constant score appears to include all relevant aspects of shoulder outcome, with the exception of whether or not the patient is satisfied with his or her shoulder. However, each item of the scale requires a significant degree of interpretation by the patient. There is only one pain scale in which the patient is asked to rate the most severe pain experienced at rest, during sleep, or with various activities. Clinical experience seems to suggest that patients experience varying degrees of pain with different activities. One pain scale appears to be inadequate to gain a true picture of the patient's pain. There is also concern that report of function is not specific to any particular activity and therefore is left to interpretation by the patient.

The objective assessment of external rotation is also questionable (Gerber 1993). The patient is awarded four points for placing the hand behind the back with the elbow held back, whereas eight points are awarded for hand placement on top of the head with the elbow held back. The difference of shoulder external rotation between these two points is negligible.

4.4 THE EFFECT BETWEEN THE THREE TREATMENTS

4.4.1 Shoulder Scores (Constant Score; Oxford Shoulder Score [OSS])

Both the Constant score and the OSS showed a significant difference between the three groups. The Constant score for the Exercise Class showed a significant difference in improvement compared to the Home Exercise Group and Multimodal Group ($p < 0.001$). There was a difference between the Exercise Class and Home Exercise Group of 33% on the Constant score with the Exercise Class having a more positive outcome. This was also apparent between the Exercise Class and the Multimodal Group with a difference of 15%.

The Multimodal Group also showed an improvement of 15% over the Home Exercise Group ($p=0.002$).

This was also mirrored for the OSS. The Exercise Class showed a significant difference in improvement than the Multimodal and Home Exercise Group ($p=0.037$, $p<0.001$) respectively. There was a difference between the Exercise Class and Home Exercise Group and Multimodal Group of 63% on the OSS with the Exercise Class again having a more positive outcome. Again the Multimodal Group showed an improvement over the Home Exercise Group of 29% ($p<0.001$).

The Constant score and the OSS agree and convincingly demonstrate that patients in the Exercise Class improve more than patients treated with physiotherapy or those doing a home exercise programme. This demonstrates a link between exercises in a controlled environment and it appears that a close therapist/relationship leads to more adherence. This has been supported by Martin et al (1984) and Knapp (1988) who found that in healthy sedentary adults whose compliance is being monitored and who received feedback about their efforts and progress comply better than adults without supervision. Martin et al (1984) concluded that the most reliable measure of adherence was class attendance.

Bird and Thornes (1998) recommended that the venue of the class is non-threatening, that the patients have common agreed goals and collective aspirations. Self-efficacy is likely to be increased if new patients can see other people actually participating and have had a positive experience from the class. Health professionals should give lots of verbal encouragement at the start of a new exercise programme, ensuring that unconditional positive reinforcement is given during the sessions. Exercising with patients who have similar problems can provide peer support, encouragement, reassurance and camaraderie. It is also more economically effective if the physiotherapist is able to supervise several people at once.

Smidt et al (2005) concluded in their systematic review, that there was insufficient evidence to support or refute the effectiveness of therapeutic

exercise for shoulder pain. However, the results of this study contradict this and agree with the findings by Brosseau et al (2004) and Pelland et al (2004) that supervised group exercise programmes were more effective than unsupervised individual exercise programmes in treating osteoarthritis of the knee.

4.4.2 Psychosocial Scores (Hospital Anxiety and Depression Scale [HADS]; Short Form 36 item health survey [SF-36])

HADS-A results further showed that there was a significant difference in improvement between the Exercise Class and Home Exercise Group ($p < 0.001$). The patients in the Exercise Class Group had a lower level of anxiety than those in the Home Exercise Group measured as a 40% difference on the HADS-A. The Multimodal Group showed a significantly better HADS-A score than the Home Exercise Group ($p = 0.024$), with an improvement of 27%. When comparing the Exercise Class Group against the Multimodal Group there was no significant difference, however a mean improvement of 17% was seen ($p = 0.288$) which could be a clinically important difference. Therefore, this could suggest that patients are less anxious when there is an intervention from a physiotherapist, be it from the Exercise Class Group or the Multimodal Group and that the patients have benefited from greater positive psychosocial influences during treatment.

The HADS-D results also show that there was a significant difference in improvement between the Exercise Class and Home Exercise Group ($p = 0.006$). The patients in the Exercise Class also had a lower level of depression than those in the Home Exercise Group measured as a 35% difference on the HADS-D. This is also apparent in the Multimodal Group, showing a 31% improvement than the Home Exercise Group ($p = 0.021$). Therefore both groups with the presence of a physiotherapist appear to suggest they are less depressed than in the Home Exercise Group that have had no intervention. This may be due to the fact that in the Exercise Class and Multimodal Group the patients are receiving continual feedback about their progress. They will have constant reassurance, direction and guidance on the progression of their condition and subsequent treatment. Patients may also feel supported as their condition is being closely monitored by their physiotherapist and therefore any

anxieties that developed may be quickly addressed. There was no significant difference between the Exercise Class Group and Multimodal Group.

This study suggests that the use of HADS has identified that physiotherapy intervention in a group setting in the management of frozen shoulder, can influence the psychological status of a patient in a beneficial way. This is the first time that this has been investigated and is therefore a novel finding from this study. HADS scores have not been used in any form of research appertaining to the treatment of frozen shoulder with this specific form of exercise. It has not been possible to find any other physiotherapy studies that have been used to compare this to date. There appears to be relatively little research into the psychometric properties of the HADS for use in a rehabilitation context. One exception is a study conducted by Harter et al (2001). They assessed the HADS in a number of inpatient rehabilitation clinics as a screening tool with musculoskeletal patients. Based on the findings of their study they recommended that the HADS was an efficient instrument to identify patients with musculoskeletal disease and potential psychiatric morbidity. More recently, Pallant and Bailey (2005) proposed that it is necessary for clinicians who are considering using the HADS as a screening tool to first assess its suitability with their particular patient group. They found high levels of anxiety and depression detected in their sample of 296 patients attending an outpatient musculoskeletal clinic and suggested that screening for psychological co-morbidity is important in musculoskeletal rehabilitation settings.

4.4.3 SF-36

The SF-36 had been used to explain either psychological or physical relationships which may have had an impact on the outcomes from the interventions. Interestingly, out of all components of the SF-36, only the Bodily Pain showed any significant change. The Exercise Class showed a significantly better Bodily Pain score than the Home Exercise Group ($p=0.032$). This is more closely linked to expected physiotherapy outcomes.

Due to the evidence that the Constant score, OSS and HADS scores have shown a definite change and the SF-36 has only demonstrated a minor change in one of the subscales, this may suggest that the SF-36 is not an appropriate

outcome measure for patients with frozen shoulder as shown from these analyses. Interestingly, this is also reported by Carette et al (2003), who found that there were no significant differences between the groups they had analysed in their study comparing the use of corticosteroid injection, a supervised exercise programme and a combination of the two and placebo in the treatment of frozen shoulder. Beaton and Richards (1996) and Griggs et al (2000), concluded that the SF-36 was not sensitive enough to detect the disability experienced by patients with upper extremity problems. Griggs et al (2000) incorporated the SF-36 into a study evaluating the efficacy of a specific four-direction shoulder-stretching exercise programme. They concluded that the SF-36 did not demonstrate significantly lower scores for the satisfied patients compared with the general population. Mossberg and McFarland (1995) were also in agreement discovering that there were lower physical functioning scores in patients with lower-quarter involvement than those with upper-quarter involvement. Buckbinder et al (2004), in a previous trial of oral steroids for frozen shoulder, discovered that only the bodily pain subscale of the SF-36 detected a benefit of prednisolone over placebo at three weeks, despite large clinically significant benefits observed for other outcomes including pain, function and ROM. This finding suggests that generic measures of quality of life such as the SF-36 may not be a useful outcome to measure in clinical trials of interventions for frozen shoulder.

This is in contrast to the paper by Paul et al (2004) who recommended using a core of health measures to enable comparison between studies and data pooling, including a self completed shoulder-specific questionnaire, 10cm VAS scores of pain and a generic health measure. The local clinical practice recommends that the use of the SF-36 is part of the routine outcome assessments in the Upper limb Unit at Wrightington Hospital. However, the results of this study tend to concur that the SF-36 is not a good outcome measure for patients with a diagnosis of frozen shoulder, given that nearly all items in the physical functioning subscale are in some way associated with the use of lower extremities.

4.5 CHANGE BETWEEN TIME INTERVALS

4.5.1 Shoulder Scores (Constant Score; OSS)

The Constant score and OSS show that patients treated in all of the three groups demonstrated improvement at six weeks, with further improvement at six months and still further improvement at one year. This confirms those results reported by Reeves (1975), Binder et al (1984) and Shaffer et al (1992) suggesting the natural history of frozen shoulder is such that most patients improve with time. A similar relationship was seen for all treatments.

4.5.1.1 Constant Score

In the Exercise Class Group there was a 91% improvement from baseline at six weeks, 104% improvement from baseline at six months and 116% improvement at one year. In the Multimodal Group there was only 68% improvement from baseline at six weeks, 76% improvement at six months and 92% at one year. In the Home Exercise Group there was a 41% improvement from baseline at six weeks, 58% improvement from baseline at six months and 78% improvement at one year.

One would expect a significant change in results during the first six weeks due to the impact of treatment intervention. This is indeed reflected in the results of this study. In clinical practice we would normally consider a change (MCID) of approximately 15 points to be clinically important. The improvement of 91% excessively exceeds the MCID, similarly in the Multimodal Group by 68% and doubled in the Home Exercise Group by 41%. This may be due to the benefits of group exercise. Group exercise provides a clinical setting in which patients can discuss their condition with others who are in a similar position. This may reassure patients and provide them with peer support and the motivation they need to continue and progress their rehabilitation.

At six months there is a smaller effect from the intervention at six weeks, which could reflect a gradual improvement due to the natural history of the condition. In the long term follow up of one year the MCID is still apparent. The Exercise Class Group has 116% improvement, the Multimodal Group has an improvement of 92% and the Home Exercise Group has still improved by 78%.

Even though there is an enormous improvement in the patients in the first six weeks there is a continued improvement up until one year.

4.5.1.2 OSS

In the Exercise Class Group there was a 40% improvement from baseline at six weeks, 55% improvement from baseline at six months and 62% improvement at one year. In the Multimodal Group there was only 33% improvement from baseline at six weeks, 46% improvement at six months and 54% at one year. In the Home Exercise Group there was a 14% improvement from baseline at six weeks, 28% improvement from baseline at six months and 51% improvement at one year.

Work is in process to produce MCID estimates for the OSS. Currently there is no MCID guidelines published. This study demonstrated in the results that the Exercise Class Group had a 40% improvement, compared to the Multimodal Group of 33% and consistent with all the previous results in this study the Home Exercise Group only had a minimal improvement of 14%. This dramatic change supports the results of the Constant score with a positive influence after the intervention of a physiotherapist in a class or individual treatment.

Again at six months when the intervention was withdrawn, there was minimal change. However, the change was not a short term improvement but continued up to six months with an improvement of 55% in the Exercise Class Group, 46% in the Multimodal Group and only 28% in the Home Exercise Group. The scores appear to converge over a 12 month period similar to the Constant score, supporting the natural history of frozen shoulder.

Perhaps the reason for the larger improvement of the Constant score rather than the OSS is the use of a purely subjective questionnaire. It has not been resolved whether this discrepancy between the subjective and objective outcome is due to an adaptation to the restriction of ROM or to the fact that the restriction of movement are in planes that are unimportant for the activities of daily living e.g. lateral rotation in neutral. Neer (1990) suggested that the limitation of lateral rotation impacts on the functional demands of the patient.

Older patients, who have fewer functional demands, can tolerate more restriction in any plane of movement.

The study confirms that the improvement gained during the first six weeks of intervention was likely to be due to the intervention itself and not spontaneous recovery. After six weeks and therefore following intervention, if spontaneous recovery was occurring, a greater improvement between the six weeks and six months would have been expected in all three groups. This was not demonstrated in the results and may suggest that initial intervention of a physiotherapist (Exercise Class Group or Multimodal Group) continued to have a positive impact on the patient scores.

Although several authors consider frozen shoulder to be a self-limiting disorder with spontaneous recovery within two years (Lundberg 1969 and Watson-Jones 1963), most recent articles agree that it is not that predictable. Several authors concur that the disability is likely to persist for three or more years (Reeves 1975 and Shaffer et al 1992). It is difficult to compare this study due to the lack of initial investigation for the natural history of frozen shoulder rather than long term follow up. Binder et al (1984) performed a prospective study of 40 patients to determine the long term outcome of frozen shoulder but did establish that at eight month follow up there was significant improvement in all movements of the shoulder, although five patients had shown some deterioration of range during this time. However, when the range was compared with that in the control group significant restriction in range of all movements except shoulder abduction and flexion was still present, suggesting that patients had improved but not to a normal level.

4.5.2 Psychosocial Scores (HADS; SF-36)

4.5.2.1 HADS – A

The results show that there was no significant difference in the scores between the groups initially at six weeks but at six months, a significant difference was apparent. This may suggest that the patients became less anxious at this point and continued up to one year. The postulation may be that the patients' anxiety status improved and could be due to experiencing less pain, improved ROM and function. A possible explanation could be that in accordance with the

natural history of frozen shoulder, as time progresses pain becomes less of a problem than stiffness and therefore pain scores would naturally decrease. This could explain why there was also further pain reduction between six weeks and six months. It could be considered that if one had this condition for a long time and had short term pain relief, (that is in the first six weeks of intervention) one may still be anxious. As time continued and the pain continued to improve as the study showed at six months and one year, anxiety would decrease as one was more confident that the pain would not return.

In the Exercise Class Group there was a 63% improvement from baseline at six weeks, 43% improvement from baseline at six months and no further improvement at one year. In the Multimodal Group there was 38% improvement from baseline at six weeks, 30% improvement at six months and 52% at one year. In the Home Exercise Group there was a 15% improvement from baseline at six weeks, 5% improvement from baseline at six months and 27% improvement at one year.

These results are inconsistent with the other scores in this study but the general pattern of improvement was similar to that seen in the Constant score and the OSS. This study provides strong evidence that the Exercise Class Group provides the optimum effect of intervention across a number of outcome parameters.

4.5.2.2 HADS – D

The results show that there was a significant difference at six weeks compared to one year. This demonstrated a continued improvement over time and suggested that with intervention there was some effect on Depression scores. A decrease in pain could lead to a patient being less depressed immediately at six weeks but it could be quite possible that one would still be anxious until time progressed. This may imply that the value of having a physiotherapist in an exercise class or part of individual treatment has a significant effect on depression (See section 4.2.2). The hypothesis could therefore be that professional guidance and support is a valuable adjunct to treatment.

In the Exercise Class Group there was a 49% improvement from baseline at six weeks, 56% improvement from baseline at six months but at one year there was deterioration in the score back to the level recorded at six weeks (48%). In the Multimodal Group there was a 37% improvement from baseline at six weeks, 43% improvement at six months and 59% at one year. In the Home Exercise Group there was a 23% improvement from baseline at six weeks, 24% improvement from baseline at six months and 30% improvement at one year.

In contrast, HADS-D yielded three different patterns of scores across the three groups with only the Home Exercise Group showing a small consistent improvement. This proposes a question that is difficult to answer due to the fact that no other similar studies have reported on this outcome measure with this population of patients. The physiotherapy intervention provided does not have a direct active component that addresses depression. This may be why this inconsistency is evident. It may suggest that physiotherapists should consider addressing depression prior to treatment and adopt more strategies to impact positively on these scores and consequently lead to greater patient satisfaction. This would support the use of a biopsychological outcome measure in the assessment of patients with a diagnosis of frozen shoulder. Alternatively, the Constant score, OSS and HADS-A have been consistent with the findings of this study and have confirmed that they are important for clinical practice, however these results reveal that the HADS-D score is not appropriate for use in the physiotherapy practice of patients referred with frozen shoulder. Therefore, further research needs to be conducted to identify a suitable tool to measure depression in patients with frozen shoulder.

4.5.2.3 SF-36

The only significant difference with the effect of time was found in the dimensions of Social Functioning and Bodily Pain. They showed a significant improvement between six weeks and one year and between six months and one year. The reasons for this have previously been discussed in section 4.2.3 which highlights the issue of whether the SF-36 is an appropriate outcome measure for the use with a diagnosis of frozen shoulder.

4.6 AGREEMENT BETWEEN THE SCORES

The Constant score ($p=0.004$), Oxford Shoulder Score ($p<0.001$) and HADS-A ($p<0.001$) are all in agreement between the different main effects, except from HADS-D ($p=0.359$) which did not show a significant change between the groups.

The scores show that the patients in the Exercise Class Group are significantly better than those in the Multimodal Group and in the Home Exercise Group. The results also show that the patients in the Multimodal Group demonstrate greater improvement than the Home Exercise Group. This supports the hypothesis that the intervention of a physiotherapist in the Exercise Class Group or in the Multimodal Group was superior to the Home Exercise Group.

This is in contrast to the work by Levine et al (2007) who suggest that patients placed on a therapist directed home exercise programme had the same outcomes at short and long term follow-ups as those treated with other interventions. Kivimaki et al (2007) compared patients treated with a home exercise programme to those with manipulation under anaesthetic and a home exercise programme. Other than a slight increase in ROM, the group performing just a home exercise programme did not differ at any follow up in pain or working ability.

In this current study, exercise within pain limits, as used in the home exercises, was given to all three groups and has previously been shown to be more effective than intensive physiotherapy in frozen shoulder patients (Diercks and Stevens 2004). They presented a series of patients treated with supervised neglect and a control group that received formal physical therapy. Supervised neglect included pendulum and active exercises in the pain-free range and instructions to resume all tolerable activities. After two years from the start of treatment, 89% of patients treated with supervised neglect had normal or near normal shoulder function compared to 63% of patients treated successfully with intensive physiotherapy. However, it is important to note that both treatments were more than 50% effective and that there was no long term evidence of efficacy of either method.

4.7 DISCUSSION OF PATIENT CHARACTERISTICS

The baseline characteristics of the study's population were surprisingly good when compared to the generally accepted aetiology of the condition. Excellent comparability was not expected due to the sample size and time available for this study. However, the results were comparable with the findings of Reeves (1975) and Binder et al (1986) who suggest that frozen shoulder is most common between the ages of 40-70. The results also agree with the findings by Bunker (2009) that the evidence suggesting a ratio of female to male was 1:1. Although, this is in contrast to the findings of Binder et al (1984), who suggest that approximately 70% of patients presenting with frozen shoulder are women.

Kelly et al (2009) have stated that "there is no clear evidence to determine which patients may need formal supervised therapy than simply a home exercise programme" (Kelly, 2009:197). However, the findings of this study support the use of an exercise class in the treatment of the patients with these characteristics and a true diagnosis of frozen shoulder and provide substantial evidence to confirm this.

4.8 METHODOLOGICAL ISSUES

The author encountered difficulties with slow patient recruitment. This has previously been reported in other studies in recruiting patients with frozen shoulder, resulting in trial termination (Carette et al 2003). The study was extended for another year to prevent a relatively small sample size. This was confirmed by Bunker and Anthony (1995) who suggest that frozen shoulder is relatively rare, accounting for only 50 out of 935 shoulder referrals. Patients were recruited from new referrals to the physiotherapy clinics within Ashton Wigan and Leigh Primary Care Trust and Wrightington, Wigan and Leigh NHS Foundation Trust, with a diagnosis of frozen shoulder. 110 patients out of 850 patients assessed for eligibility had shoulder pain attributable to causes other than frozen shoulder, suggesting that general practitioners are poor at recognising this clinical entity. Even more interesting however, was that of these patients seen by the physiotherapists and diagnosed with frozen shoulder, 20

actually had signs more consistent with impingement. This highlighted a need for further training in the physiotherapy service across the trust and how difficult it was to diagnose a 'true' frozen shoulder.

Reeves (1975) documented three phases with which to address the progression of frozen shoulder: the pain phase, the stiffness phase and the recovery phase. The patients were in the second phase with a mean duration of six months. The results of this study therefore cannot be generalized to other patients at various stages of signs or symptoms.

All outcome measures were presented within a booklet. The booklet was printed and not photocopied so that all VAS lines were exactly 10 centimetres long. The outcome measures were completed in the same order to ensure consistency in the methods. The trial physiotherapist also made sure that all questions had been answered at each assessment thus enhancing quality of data and minimising non-completion. The trial physiotherapist also had an established rapport with all patients and was available to answer any questions or concerns. Every care was taken to ensure that nothing was said that could sway patients' responses and that all of the outcome measures were explained in the same manner to each patient, ensuring that they felt it was a true account of how they felt at that particular assessment point.

The study also benefited from the effort to minimise inter-operator inconsistencies with the use of a trial physiotherapist who taught the home exercises to all groups and recorded the outcome measures. The trial physiotherapist made all the calculations, anonymised all data and inputted all data to a password-protected database. This was completed weekly and diligently, ensuring enhanced consistency of data with less error.

Another important issue to consider is the potential of both patient and researcher bias due to lack of blinding in this study. It would be impossible to blind the patients to their treatment with the inclusion of exercise as an intervention. However, this is similar in most studies which investigate the efficacy of physiotherapy intervention (Koes and Hoving 1998).

Potential bias was reduced by not allowing the patient or the trial physiotherapist access to prior results until raw data was analysed at completion of the study. It was also minimised by the strict standardised procedure of measurement of the objective primary outcome measure, the Constant score. The use of a secondary subjective measure, the Oxford Shoulder Score, as previously discussed, limited potential observer bias due to the use of patient recording.

To control the threats of internal validity, the interventions have to be very specific and well defined. By reducing the number of variables one will know exactly which element of treatment had the specific resultant effect. However, in physiotherapy one rarely gives a specific treatment in isolation. One would diagnose and formulate an individual patient specific treatment plan, which incorporated a variety of treatment techniques to address all the component problems of their frozen shoulder. Subsequently, once effects of specific interventions in isolation have been found one needs to consider interventions in combination. An intervention, which may not have been found to be beneficial in isolation, may markedly improve outcome when combined with another intervention. An important point to consider is that by maintaining rigorous experimental control the external validity of the randomised controlled trial is compromised. One can only conclude the effects of a very specific intervention on a very specific population, which may reflect neither the typical presenting population nor the varied treatment received in clinical practice. Only by developing research into the combination of treatment components can one hope to determine the best evidence based practice. This apparent need for scientific studies evaluating combined treatments was highlighted by Green et al (2003; 2009) who appreciated that this is the norm rather than the exception in practice. Foster et al (2009) agree that typically therapies are delivered as part of a package of care, rather than as a single intervention which does indeed complicate the design of trials to test treatment effectiveness. They do therefore, recommend that one should define the various components of the intervention and determine the characteristics of patients that may respond to a multi-modal intervention.

4.9 IMPLICATIONS FOR CLINICAL PRACTICE

This study has confirmed that patients seen in an exercise class and supervised by a physiotherapist had better outcomes and recovered in a shorter time frame than those patients on a home exercise programme. This can influence clinical practice. It may potentially reduce the number of individual physiotherapy treatment sessions which would impact upon both waiting times and budgets. Patients were taught self management of their condition and how to deal with any increase in pain. The trial physiotherapist hypothesised that behavioural changes during the treatment period, relating to improvement of self – management due to the exercise class, would reduce the utilization of health care services during the follow up period and reduce sick leave in patients.

The need for only one physiotherapist to treat a group of patients would increase cost effectiveness and improve care pathways by initiating effective management from initial diagnosis. It would standardise treatment outcomes and impact upon the need for surgical implications.

Clinicians need to be made aware of the psychological issues when treating a patient with frozen shoulder. They should be encouraged to assess changes or problems that occur in a patient's wider context during routine assessment. Such issues as sick leave as a response to disease activity need to be considered. Awareness of these changes could guide interpretation of disease status leading to informed clinical decision-making and instigation of appropriate interventions. The reason for a poor response to treatment or increase in psychological distress could be related to their ability to cope with their condition. The inclusion of a psychosocial screening tool as part of routine care would enable clinicians to see patterns developing in changes with psychological status. The use of HADS in clinical practice as a screening tool for patients with a diagnosis of frozen shoulder could be beneficial in that it can highlight patients who would benefit more from face to face physiotherapy interventions rather than exercising at home. The use of outcome measures should be used to highlight patients who are less likely to respond to this treatment type allowing the most effective course of treatment prescribed. Based on the findings of this study, the assessment and identification of patients with high levels of anxiety and depression should be given high priority,

particularly given their influence on aspects such as quality of life, pain experiences and treatment conformity.

The study highlights a need to educate primary care physicians and those health professionals involved in the diagnosis and management of frozen shoulder. Once identified, referral should be made into secondary care for prompt assessment, rehabilitation, education and instigation of a supervised exercise class. Such treatment pathways would ensure that patients received appropriate treatment and effective management of frozen shoulder and thus reduced the impact of the condition.

4.10 FURTHER WORK

There are several avenues to pursue in future investigations. The usefulness of a home exercise programme was not in question but compliance to a home exercise programme could be an issue with some patients (O'Doherty et al 2007). Wilcox et al (2006) performed a study investigating perceived barriers to exercise in patients with musculoskeletal pain. They identified many factors that affect adherence to a home exercise programme such as pain, psychological barriers such as attitudes and beliefs, lack of time, motivation and enjoyment of exercise. Further study relating to the compliance of a home exercise regime would enhance the physiotherapy programme in the treatment of frozen shoulder. It would also be valuable to investigate the potential long term benefit of physiotherapy in the management of frozen shoulder. Other research could focus on the effect of physiotherapy following surgical intervention in patients with a diagnosis of frozen shoulder e.g. MUA or arthroscopic release.

5.0 CONCLUSION

The efficacy of the treatments of frozen shoulder has rarely been evaluated in randomised controlled trials. It is difficult to draw reliable conclusions about the

efficacy of one treatment versus the other on the current studies. This ambiguity stems from factors that include the design of the studies, the general lack of a control group, the timing of the intervention and the variable natural history of the disorder. The debate on the effectiveness of physiotherapy in the treatment of frozen shoulder continues. The length of physiotherapy intervention and the stage at which it may be appropriate, has not been justified thus far in the research. Based on the limited quality of high grade evidence, it has been concluded that for many patients with frozen shoulder, home exercises will result in major improvements, sparing many patients from more aggressive and higher risk treatments. This study has completed the objectives of developing, implementing and evaluating the efficacy of the most appropriate management of frozen shoulder. The research study considered three interventions commonly used by physiotherapists in the treatment of frozen shoulder. The results suggest that an exercise class is superior in relieving the signs and symptoms of frozen shoulder.

Therefore, it seems reasonable to use a hospital based exercise class aimed at a rapid recovery rate with a minimum number of visits to the hospital after which a follow up period with a home based exercise programme would be recommended.

5.1 KEY RECOMMENDATIONS

- Frozen shoulder should be managed in an exercise class. If this is not possible then physiotherapy is a good alternative to optimise the speed of recovery of frozen shoulder.
- The Constant score, OSS and HADS are useful outcome measures in the management of frozen shoulder. The SF-36 is not a useful outcome measure to assess general health for patients with frozen shoulder.
- Training for GPs and physiotherapists in the clinical diagnostic accuracy of frozen shoulder.

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APPENDIX ONE

Inclusion sheet

INCLUSION TO FROZEN SHOULDER STUDY

Patient's Name Date

Insidious onset Yes No

Intervention in last six weeks Yes No

State

Duration of symptoms (established)

Dominant side Left Right

Affected shoulder Left Right

X-ray clear of gleno-humeral joint OA Yes No

X-ray findings

Past Medical History Significant joint problems

.....

Drug History

Steroid injections Yes No Where?

How many? When?

Diabetic Yes No Type

Smoker Yes No Less than 10 10 or more

Litigation pending Yes No

Social History Occupation

Able to work at normal capacity Yes No

Occupational type -

Heavy manual Moderate manual

Light manual Sedentary

RANGE OF MOVEMENT OF AFFECTED SHOULDER			
		Affected Shoulder	Unaffected Shoulder
Abduction	Active	a ₁	b ₁
	Passive	a ₁	b ₁
Lateral Rotation	Active	a ₂	b ₂
	Passive	a ₂	b ₂

APPENDIX TWO

Patient information sheet

Hand Unit Research Department
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
Lancs
WN6 9EP

01257 256248

PATIENT INFORMATION SHEET

What is the most effective conservative management of the frozen shoulder?

Name of Researcher: Mrs S Russell

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of this study?

You have the condition of frozen shoulder. It is a condition that usually gets better eventually but this can take two to three years. Many different physiotherapy treatments have been tried such as supervised exercise; advise on home exercises and individual treatment from a physiotherapist. It is not known which people will benefit most from these different treatments and this study is designed to compare the results of these different treatments.

What happens to me if I take part?

If you agree to enter this study the treatment you receive will be the same type of treatment as if you were not in the study. We will record information about your problem and check how much you can move it and how strong it is. We will repeat these tests and ask you to complete a questionnaire on occasions when you attend in the future. You will receive either type of physiotherapy. Our assessment of your shoulder indicates that you would be suitable for either treatment. Which treatment you receive will be decided by a method called

randomisation. This means that the decision cannot be influenced by you or any of the research workers. This will decide which treatment you will receive and you must be happy to have either form of physiotherapy.

What do I have to do?

The main part of this study will last about six months. During this time you can take any usual medication you have along with your pain killers or anti inflammatory medication you need to help the pain. You will be asked to fill in a set of questions about your condition at the beginning of the study and then every month when you attend for a treatment session. We would also like you to attend once more in two years time to fill in the questions again. Reimbursement of travelling expenses will be available for this "extra visit"

What does the Exercise Class Involve?

You will be given advice about the condition and appropriate medication. You will then attend the physiotherapy department to be instructed on exercises in a class setting twice per week. Advice sheets will also be issued to assist this. You will be seen and reassessed at intervals. If after 3 months you have not improved you will be given the opportunity to see a surgeon to discuss further treatment.

What does Individual Treatment Involve?

You will be given advice about the condition and appropriate medication. You will then attend the physiotherapy department and receive treatment by a senior physiotherapist twice per week. You will also be instructed on how to exercise at home. Advice sheets will also be issued to assist this. You will be seen and reassessed at intervals. If after 3 months you have not improved you will be given the opportunity to see a surgeon to discuss further treatment.

What does the Home Exercise Programme Involve?

You will be given advice about the condition and appropriate medication. You will then attend the physiotherapy department to be instructed on how to exercise at home. Advice sheets will also be issued to assist this. You will be seen and reassessed at intervals. If after 3 months you have not improved you will be given the opportunity to see a surgeon to discuss further treatment.

What are the possible advantages of taking part?

There are no risks to being part of this study because we are only offering treatments that are in regular use at the present time. Some pain or discomfort would normally be experienced with the treatments anyway and you will be given appropriate advice about medication. The main disadvantage is the need to fill in questionnaires but these are not complicated and will mainly be given to you during a routine attendance.

All people who have been referred to Wrightington, Wigan and Leigh NHS Trust who have frozen shoulder and could be treated by either type of physiotherapy are being considered for this study.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign the appropriate consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. You can be assured that this will not affect any future care you will receive at this hospital.

What are the benefits of taking part?

It may well be that you will not benefit personally from this research, but obviously it will have significant impact on how frozen shoulder is treated in the future.

Whilst there is no payment for your inclusion in this research, you can be assured that the normal compensation arrangements that are applicable to all patients undergoing treatment will apply in your case.

Will my taking part in this study be kept confidential?

All information, which is collected about you during the course of this research will be kept and treated in a strictly confidential manner. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognised from it. If a scientific paper is written about the results your name and address will be removed completely.

Who has reviewed this study?

The Wrightington Wigan and Leigh local research and ethics committee have reviewed this study.

Contact for further information

Sarah Russell:- 01942 822100

Thank you for agreeing to take part in this study

APPENDIX THREE

Patient consent form

Hand Unit Research Department
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
Lancs
WN6 9EP
Tel: 01257 256248

PATIENT CONSENT FORM

Title of Project: What is the most appropriate management of a frozen Shoulder?

Name of Researcher: Mrs Sarah Russell (ESP)

Patient Identification Number:

Version 1. May 2005

Please initial box

I confirm that I have read and understood the information sheet dated

For the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason, without my medical care or legal rights being affected.

I understand that sections of any of my medical notes may be looked at by responsible individuals from Wrightington hospital or from Regulatory authorities where it is relevant to my taking part in the research. I give my permission for these individuals to have access to my records.

I agree to my GP being informed that I am taking part in this study.

I agree to take part in the above study.

Name of Patient

Date

Signature

Name of Person taking consent
(if different from Researcher)

Date

Signature

Researcher

Date

Signature

(Copy to patient, copy to researcher and copy kept with Hospital Notes)

APPENDIX FOUR

Outcome measures

- Constant Score
- Oxford Shoulder Score
- SF-36 Short Form 36
item health survey
- HADS

Patient ID

CONSTANT SCORE

Inclusion
Following Intervention
6 Months
Year

A. Pain **A**

1. Do you have pain in your shoulder (normal activities)?

No Mild pain Moderate Severe or permanent

2. Linear Scale:

If '0' means no pain and '10' is the maximum pain you can experience, please circle where is the level of pain of your shoulder.

Level of Pain

At Rest	0	10
With Use	0	10
At Night	0	10

B. Activities Of Daily Living **B**

1. Is your occupation or daily living limited by your shoulder?

No Moderate limitation Severe limitation

2. Are your leisure and recreational activities limited by your shoulder?

No Moderate limitation Severe limitation

3. Is your night sleep disturbed by your shoulder?

No Sometimes Yes

4. State to what level you can use your arm for painless, reasonable activities.

Waist Lower Chest Neck Head Above Head

C. Range Of Movement leave this for the doctor or physiotherapist **C**

1. **Forward Flexion** _____ 2. **Abduction** _____

3. **External Rotation** _____ 4. **Internal Rotation** (dorsum hand to)

Hand behind head and elbow forward	2	Thigh	0
Hand behind head and elbow back	4	Buttock	2
Hand above head and elbow forward	6	SI joint	4
Hand above head and elbow back	8	Waist	6
Full elevation of arm	10	T12	8
		Between shoulder blades	10

D. Power kg x 2 **D**

Patient ID

Inclusion
Following Intervention
6 Months
Year

OXFORD SHOULDER SCORE

Problems with your shoulder **DURING THE PAST 4 WEEKS**

✓ Tick **one** box for each question

Right

Left

1	How would you describe the <u>worse</u> pain you had from your shoulder? None Mild Moderate Severe Unbearable <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Have you had any trouble dressing yourself because of your shoulder? No trouble at all A little bit of trouble Moderate trouble Extreme difficult Impossible to do <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Have you had any trouble getting in and out of a car or using public transport because of your shoulder? No trouble at all A little bit of trouble Moderate trouble Extreme difficulty Impossible to do <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Have you been able to use a knife and fork - at the same time? Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Could you do the household shopping on your own? Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Could you carry a tray containing a plate of food across a room? Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Could you brush/comb your hair with the affected arm? Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	How would you describe the pain usually had from your shoulder? None Very Mild Mild Moderate Severe <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Could you hang your clothes up in a wardrobe, - using the affected arm? Yes, easily With little difficulty With moderate difficulty With great difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Have you been able to wash and dry yourself under both arms? Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
11	How much has pain from your shoulder interfered with your usual work (including housework)? Not at all A little bit Moderately Greatly Totally <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12	Have you been troubled by pain from your shoulder in bed at night? No night Only 1 or 2 night Some nights Most night Every night <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Patient ID

YOUR HEALTH AND WELL-BEING

Inclusion
Following Intervention
6 Months
Year

The following questions ask for your views about your health and how you feel about life in general. If you are unsure about how to answer any question, try and think about your overall health and give the best answer you can. Do not spend too much time answering as your immediate response is likely to be the most accurate. For each of the following questions please put a **cross** in the box that best describes your answer.

1. In general, would you say your health is:

- Excellent Very good Good
 Fair Poor

2. Compared to 3 months ago, how would you rate your health in general now?

- Much better than 3 months ago Somewhat better than 3 months ago
 About the same Somewhat worse now than 3 months ago
 Much worse now than 3 months ago

3. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Moderate activities , such as moving a table, pushing a vacuum, bowling or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Walking more than a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Walking half a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Walking 100 yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Bathing and dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past 2 weeks, how much time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Were limited in the kind of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Had difficulty performing the work or other activities (eg it took more effort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. During the past 2 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- All of the time
 - Most of the time
 - Some of the time
 - A little of the time
 - None of the time
-

11. How TRUE or FALSE is each of the following statements for you?

- | | Definitely True | Mostly True | Not Sure | Mostly False | Definitely False |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a. I seem to get ill more easily than other people | <input type="checkbox"/> |
| b. I am as healthy as anybody I know | <input type="checkbox"/> |
| c. I expect my health to get worse | <input type="checkbox"/> |
| d. My health is excellent | <input type="checkbox"/> |
-

The Hospital Anxiety and Depression Scale

Name Date

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings, he or she will be able to help you more. This questionnaire is designed to help your clinician know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling **in the past week**.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response. Tick only one box in each section. **Please answer every question.**

(A) I feel tense or wound up:

- 3 Most of the time
- 2 a lot of the time
- 1 Time to time, occasionally
- 0 Not at all

(D) I still enjoy the things I used to enjoy:

- 0 Definitely as much
- 1 Not quite as much
- 2 Only a little
- 3 Hardly at all

(A) I get a sort of frightened feeling as if something awful is about to happen:

- 3 Very definitely and quite badly
- 2 Yes, but not too badly
- 1 A little, but it doesn't worry me
- 0 Not at all

(D) I can laugh and see the funny side of things:

- 0 As much as I always could
- 1 Not quite so much now
- 2 Definitely not so much now
- 3 Not at all

(A) Worrying thoughts go through my mind:

- 3 A great deal of the time
- 2 A lot of the time
- 1 From time to time, but not too often
- 0 Only occasionally

(D) I feel cheerful:

- 3 Not at all
- 2 Not often
- 1 Sometimes
- 0 Most of the time

(A) I can sit at ease and feel relaxed:

- 0 Definitely
- 1 Usually
- 2 Not often
- 3 Not at all

(D) I feel as if I am slowed down:

- 3 Nearly all the time
- 2 Very often
- 1 Sometimes
- 0 Not at all

(A) I get a sort of frightened feeling like "butterflies" in the stomach

- 0 Not at all
- 1 Occasionally
- 2 Quite often
- 3 Very often

(D) I have lost interest in my appearance:

- 3 Definitely
- 2 I don't take as much care as I should
- 1 I may not take quite as much care
- 0 I take just as much care as ever

(A) I feel restless as if I have to be on the move:

- 3 Very much indeed
- 2 Quite a lot
- 1 Not very much
- 0 Not at all

(D) I look forward with enjoyment to things:

- 0 As much as I ever did
- 1 Rather less than I used to
- 2 Definitely less than I used to
- 3 Hardly at all

(A) I get sudden feelings of panic:

- 3 Very often indeed
- 2 Quite often
- 1 Not very much
- 0 Not at all

(D) I can enjoy a good book or radio or TV programme:

- 0 Often
- 1 Sometimes
- 2 Not often
- 3 Very seldom

STAFF SCORING

Totals: Dep = /21; Anx = /21

Interpreting scores:

**Clinical cut-off's in non-chronic pain population
(score out of 21 for each dimension):**

- 0-8 = Normal Range
- 8-10 = Borderline clinical anxious/depressed (ie Mild)
- 11-14 = Moderate
- 15+ = Severe

Zigmond and Snaith, 1983. Acta Scandinavica, 67, p361-70

APPENDIX FIVE

GP letter

RE:

Hand Unit Research Department
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
Lancs
WN6 9EP
Tel: 01257 256248

GP INFORMATION SHEET

Comparison of Conservative Management of the Frozen Shoulder?

Your patient has agreed to enter a trial that is being performed within Wrightington, Wigan and Leigh NHS Trust to compare different types of physiotherapy treatment for a Frozen Shoulder.

There will be three groups receiving either of the treatments after randomisation. They are eligible because they are suitable for either method of treatment. After 3 months the physiotherapy group will be offered surgery if they wish it. All participants will fill in functional scoring questionnaires at intervals for about 6 months and again at 2 years to assess the progress they are making.

Whilst they are in the study there will be no restriction on what analgesic or anti-inflammatory medication they receive. We would ask that they are not prescribed steroids or given steroid injections to the shoulder whilst they are in the study. If you think such treatment is indicated, please contact us and we will arrange a follow up visit as soon as possible. Should they require oral steroids for some other condition then clearly they should be given. This study should not influence how you treat your patient for other conditions they may have. If you have any concerns about the treatment of their frozen shoulder please contact me on 01257256289 or Robert Conlon, Physiotherapist on 01257256533

I enclose a copy of the patient information sheet for your information.

Mrs Sarah Russell
Extended Scope Practitioner

APPENDIX SIX

Patient information booklet



Ashton, Leigh & Wigan
Primary Care Trust

In conjunction with
Wrightington, Wigan & Leigh NHS Trust

PHYSIOTHERAPY SERVICE

***FROZEN SHOULDER/
ADHESIVE CAPSULITIS***

Patient Information Leaflet

PATIENT ADVICE AND LIAISON SERVICE (PALS)

The PALS are able to provide 'on the spot' help and advice to patients, carers, friends and families. We will listen to you and provide you with relevant information and support, to help resolve any concerns or problems you may have that you do not wish to discuss with a member of staff, as quickly and efficiently and confidentially as possible.

If you have a concern, or need help or information, you can contact the PALS and we will do our best to help you. We can be contacted Monday to Friday, 9.00 am to 5.30 pm on 01942 822376 – outside these hours there is an answer phone service available.

Alternatively, we can be contacted by bleep. Just ring the switchboard on the main Leigh Hospital number (01942 672333) and ask them to bleep us on 2376.

If they are unable to allay your concerns and you feel you would like to take your complaint further, you can write to:

**The Complaints Manager
Ashton, Leigh & Wigan PCT
Bryan House
Standishgate
Wigan
WN1 1AH**

WHAT IS FROZEN SHOULDER/ADHESIVE CAPSULITIS?

Frozen shoulder is an extremely painful condition in which the shoulder is completely or partially unmovable. Frozen shoulder often starts without any serious cause but may be triggered by a mild injury to the shoulder. The condition goes through three phases, starting with pain, then stiffness and finally a stage of resolution as the pain eases and most of the movement returns. This process may take an awfully long time, sometimes as long as two or more years.

Three Stages of Development

Typically frozen shoulder develops slowly, and in three stages:

- **Stage One:** Pain increases with movement and is often worse at night. There is a progressive loss of motion with increasing pain. This stage lasts approximately 2 to 9 months.
- **Stage Two:** Pain begins to diminish; however the range of motion is now much more limited, as much as 50% less than in the other arm. This stage may last 4 to 12 months.
- **Stage Three:** The condition may begin to resolve. Most patients experience a gradual restoration of motion over the next 12 to 42 months.

TREATMENT

Many different treatments have been tried varying from surgery to physiotherapy or advice alone. At present it is not known which of these is the most effective.

SELF HELP

Analgesia or Painkillers

Heat

Resting Positions

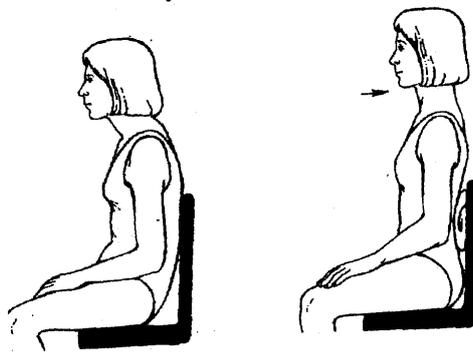
Sleep can be uncomfortable if you try and lie on your affected arm. We would recommend that at first you lie on your back or on the opposite side. If you lie on your back, support your affected arm. Make sure that your elbow is above your shoulder. If you are on your side then a folded pillow supports your affected arm from your elbow to your wrist.



Posture

Poor posture can aggravate your symptoms. It is advisable to:

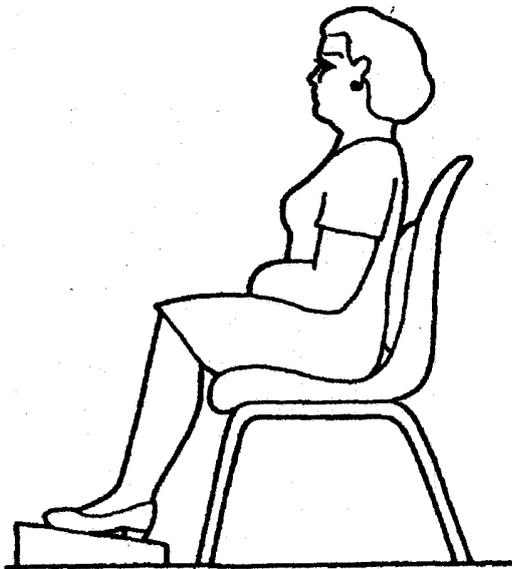
- Always try and maintain an upright position. This applies to standing, walking or sitting.
- Maintain the lumbar lordosis in all positions.
- Change position frequently.
- Avoid slouching.



Sitting

- When sitting, maintain the lumbar lordosis.
- Use a rolled up towel and place in the bottom of your back.
- Use a chair with some lumbar support, if possible.
- Use a straight back, firm chair.
- Use a chair that is not too low.
- When sitting on an easy chair or settee, use your lumbar roll and change position.

- **DO NOT SLOUCH**
- Avoid crossing legs or curling legs underneath.
- Sit straight in a chair, not leaning to one side.
- Do not sit for prolonged periods; get up and move around.
- Take care when getting in and out of a chair.
Stand in front of the chair, bend the knees at the same time and place the hands behind you to rest on the seat or arms of the chair.



TENS MACHINES

Transcutaneous electrical nerve stimulator (TENS) is effective for many people in the reduction of pain.

By passing electrical pulses through the skin which pass up to the brain. TENS can help block the pain gate. It also works by increasing the level of endorphins released.

There are many machines on the market and it is advisable that you try one on loan before purchasing to see if it helps you.

Examples Of Companies

- Physio-Med Services,
7-11 Glossop Brook Industrial Park,
Glossop.
SK13 7AJ
Tel: 01457 860444
- Body Clock Healthcare Ltd.,
108 George Lane,
South Woodford,
London.
E18 1AD
Tel: 0208 5329595

EXERCISES

The following exercises should be done 10-15 repetitions, 4 times a day.

1. Sit or stand with good posture.

Keeping face forward,
tip ear towards shoulder.

Hold for 10 seconds.

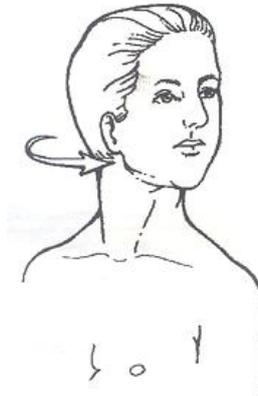
Repeat to other side.



2. Sit or stand with good posture.

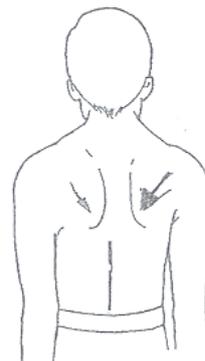
Turn head to one side then the other.

Hold for 10 seconds.



3. Assume upright posture with shoulders relaxed.

Move affected shoulder blade down and towards opposite hip.

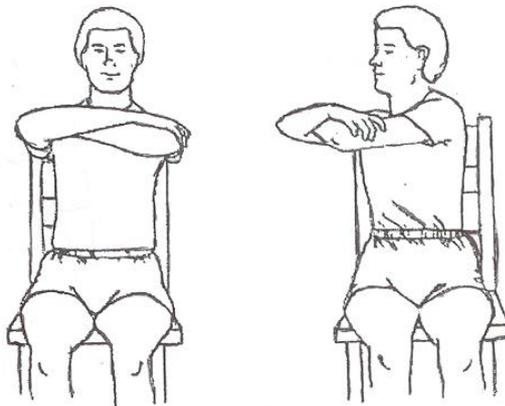


4. Sitting, arms crossed at shoulder height. Turn to right.

Hold for 10 seconds.

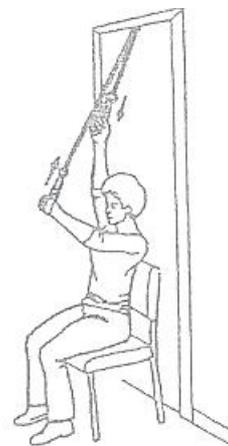
Turn to left and hold.

Repeat 10 times.



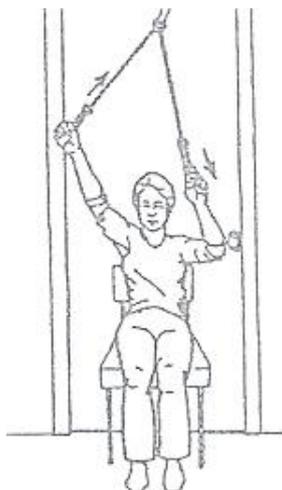
5. Sit in a chair with pulley assembled as shown.

Raise the affected arm overhead pulling down on the pulley with the other hand so that you feel a stretch.



6. Sit in a chair with pulley assembled as shown.

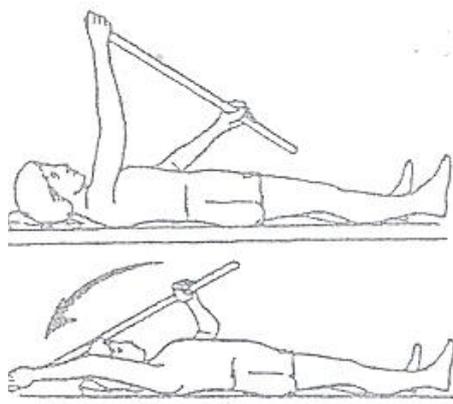
Raise the affected arm out to side and overhead, pulling down on the pulley with the other hand so that you feel a stretch.



7. Lie on back as shown, with affected hand at the top of the stick.

Using the stick for assistance, stretch your arm higher overhead.

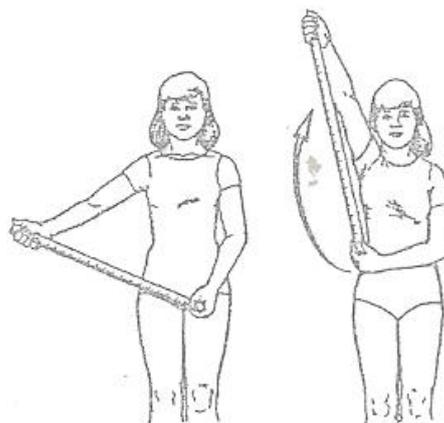
Hold for 10 seconds.



8. Stand holding stick as shown with your affected arm out to the side.

Using the stick for assistance, stretch your arm further out to side and overhead.

Hold for 10 seconds.



9. Stand grasping the elbow with other hand as shown.

Pull the elbow and arm across your chest so that you feel a stretch.

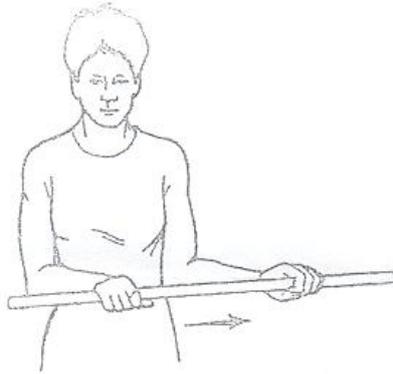
Hold for 10 seconds.



10. Lie on your back or stand with a pillow under your arm.

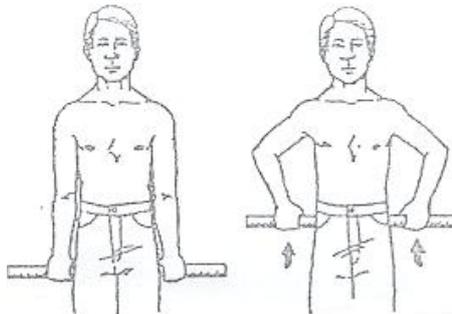
Using stick for assistance, rotate your operation hand and forearm out away from your body. Make sure your elbow stays tucked into your side.

Hold for 10 seconds.



11. Grasp stick behind back as shown.

Slide stick up back so that you feel a stretch.



12. Place a rolled hand towel under the affected arm.

Grasp forearm with other hand and pull behind back and downwards as shown.

Hold for 10 seconds.

APPENDIX SEVEN

Exercise Class recording sheet

APPENDIX EIGHT

Standardised measurement procedure

STANDARD PROCEDURE FOR MEASUREMENT OF SHOULDER JOINT RANGE

(Taken from Norkin & White 2003)

Use a 10" full circle plastic universal goniometer.

□ **FLEXION:**

(Mean shoulder complex flexion 0-190°)

- Testing position: Supine, with knees flexed to flatten the lumbar spine. Position the shoulder in 0° of abduction and rotation. Place the elbow in extension. Position the forearm in 0° of supination so that the palm of the hand faces the body.
- Stabilisation: Stabilise the thorax to prevent extension of the spine and movement of the ribs. The weight of the trunk may assist in stabilisation.
- Testing Motion: Flex the shoulder by lifting humerus off the plinth, bringing hand up and over the subject's head. Maintain the extremity in neutral abduction and adduction during the motion. The end of the ROM occurs when resistance to further motion is felt and attempts to overcome the resistance cause extension of the spine or motion of the ribs.
- Goniometer alignment:
 1. Centre the fulcrum of the goniometer over the lateral aspect of the greater tubercle.
 2. Align the proximal arm parallel to the midaxillary line of the thorax.
 3. Align the distal arm with the lateral midline of the humerus. Depending on how much flexion and MR occur, the lateral epicondyle of the humerus or the olecranon process of the ulnar may be helpful references.

□ **ABDUCTION:**

(Mean shoulder complex abduction is 0-180°)

- Testing position: Supine, with shoulder in LR and 0° of flexion and extension so that the palm of the hand faces anteriorly. The elbow should be extended.
- Stabilisation: Stabilise the thorax to prevent lateral flexion of the spine. The weight of the trunk may assist in stabilisation.
- Testing motion: Abduct the shoulder by moving the humerus laterally away from the subject's trunk. Maintain the upper extremity in LR and neutral flexion and extension during the motion. The end of the ROM occurs when resistance to further motion is felt and attempts to overcome the resistance cause lateral flexion of the spine.
- Goniometer Alignment
 1. Centre the fulcrum of the goniometer close to the anterior aspect of the acromion process.
 2. Align the proximal arm so that it is parallel to the midline of the anterior aspect of the sternum.
 3. Align the distal arm with the anterior of the humerus. Depending on the amount of abduction and LR that has occurred, the medial epicondyle may be a helpful reference.

□ **MEDIAL ROTATION:**

(Mean shoulder complex MR is 0-90°)

- Testing position: Supine, with the arm being tested in 90° of shoulder abduction (or as close to it as possible – document the range of abduction that is tested, if it's less than 90°). Place the forearm perpendicular to the supporting surface and in 0° of supination and pronation so that the palm of the hand faces the feet. Rest the full length of the humerus on the plinth. The elbow is not supported by the plinth. Place a pad under the humerus so that the humerus is level with the acromion process.
- Stabilisation: Stabilisation is often needed at the distal end of the humerus to keep the shoulder in 90° (or maximum) abduction. The thorax may be stabilised by the weight of the subject's trunk or with the examiner's hand to prevent flexion or rotation of the spine.

- Testing Motion: Medially rotate the shoulder by moving the forearm anteriorly, bringing the palm of the hand toward the floor. Maintain the shoulder in 90 degrees (or maximum) and the elbow in 90° of flexion during the motion. The end of ROM occurs when resistance to further motion is felt and attempts to overcome the resistance cause flexion or rotation of the spine.
- Goniometer Alignment:
 1. Centre the fulcrum of the goniometer over the olecranon process.
 2. Align the proximal arm so that it is either perpendicular to or parallel with the floor.
 3. Align the distal arm with the ulna, using the olecranon process and Ulnar styloid for reference.

□ **LATERAL ROTATION**

(Mean LR of the shoulder complex is 0-90°)

- Testing Position: Same as MR.
- Stabilisation: Stabilisation is often needed at the distal end of the humerus to keep the shoulder in 90° of abduction (or its maximum if less than 90°). To prevent extension or rotation of the spine, the thorax may be stabilised by the weight of the subject's trunk or by the examiners hand.
- Testing Motion: Rotate the shoulder laterally by moving the forearm posteriorly, bringing the dorsal surface of the hand toward the floor. Maintain the shoulder in 90 degrees (or maximum available) of abduction and the elbow in 90 degrees of flexion during the motion. The end of ROM occurs when resistance to further motion is felt and attempts to overcome the resistance cause extension or rotation of the spine.
- Goniometer Alignment:
 1. Centre the fulcrum of the goniometer over the olecranon process.
 2. Align the proximal arm so that it is either parallel to or perpendicular to the floor.
 3. Align the distal arm with the ulnar, using the olecranon process and the ulnar styloid for reference.