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PhD Thesis:

Self-managed exercise for rotator cuff tendinopathy

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Summary of PhD thesis

Self-managed exercise for rotator cuff tendinopathy

Shoulder pain is one of the most common musculoskeletal symptoms and the third most common reason for consultation with a physiotherapist. Disorders of the rotator cuff, including tendinopathy, are thought to be the commonest cause of this pain. Despite the commonality and burden of rotator cuff tendinopathy, it is a poorly understood condition with a lack of high quality studies upon which to base practice. Numerous systematic reviews have been undertaken in relation to the various plausible interventions including exercise, corticosteroid injections and surgery, but all identify the insufficiency of the evidence base when attempting to draw conclusions.

Building upon a review of systematic reviews undertaken by the author, this PhD thesis aimed to evaluate the clinical and cost-effectiveness of a self-managed exercise programme for rotator cuff tendinopathy. The mixed methods SELF study comprised a multi-centre pragmatic randomised controlled trial (n = 86) which was conducted in the UK NHS to evaluate clinical effectiveness; an economic analysis was conducted alongside the trial to evaluate cost-effectiveness; and a qualitative study was undertaken to identify some of the barriers and facilitators concerning implementation of the self-managed exercise intervention.

Preceding these studies a further systematic review was undertaken by the author to determine the important component parts of an exercise programme for evaluation. The recommendations from this review were used to evaluate the validity of the proposed self-managed exercise programme. Following a full description of the intervention including consideration of the potential mechanism(s) of action, feasibility work was undertaken in the form of a patient and public involvement event (n = 4), a pilot randomised controlled trial (n = 24) with three month follow-up and a pilot qualitative study (n = 8) that was undertaken to better understand potential barriers to the conduct of the substantive randomised controlled trial.

The messages from this feasibility work facilitated development of the mixed methods SELF study; the results of which suggest short- and mid-term comparability between the self-managed exercise programme and usual physiotherapy treatment in terms of clinical and cost-effectiveness. A platform upon which to develop future research has been developed and understanding of the optimal strategies to manage rotator cuff tendinopathy has been enhanced and hence new knowledge generated.

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Chapter 1: Setting the scene

Summary

This chapter sets the scene for this PhD thesis which aims to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. The rotator cuff and relevant terminology is introduced along with the burden of rotator cuff tendinopathy. The justification for undertaking further work is considered before the aims and objectives of the PhD are presented.

1.0 Introduction

The rotator cuff consists of the tendons of the supraspinatus, infraspinatus, teres minor and subscapularis muscles at the shoulder. This group of tendons create a functional unit which communicates closely with the subacromial bursa and is interwoven with the glenohumeral joint capsule to surround the humeral head at the shoulder (Palastanga et al. 1994). The rotator cuff is thought to contribute to both stability and movement of the shoulder and hence is regarded by many to be integral to the functioning of that joint (Lewis 2009).

The term rotator cuff tendinopathy implies a painful disorder of the shoulder attributable to the rotator cuff tendon, but without implication of specific pathology, for example degeneration (Lewis 2009; Rees et al. 2006). As will be discussed, rotator cuff tendinopathy is a currently a poorly understood disorder. Little is known about what causes the pain associated with tendinopathy, there is only limited evidence relating to risk and prognostic factors (Littlewood et al. 2013a) and hence, understandably, the optimal management strategies are also unclear (Littlewood et al. 2012a; 2012b).

1.1 Burden of rotator cuff tendinopathy

Littlewood et al. (2013a) systematically reviewed the literature in relation to incidence and prevalence of rotator cuff tendinopathy. It was reported that annual incidence was as high as 5.5% in the working-age population with point prevalence estimated at 2.4% to 14.0%

rising to 21.0% when populations older than 70 years were included (Littlewood et al. 2013a).

From a sufferer's perspective, the consequence of this disorder is shoulder pain and, for most, impaired shoulder function which impacts significantly upon activities of daily living, including eating, dressing and working (Bennell et al. 2007). Although a proportion of people might recover within the first few months of onset, significant proportions go on to develop persistent and/or recurrent symptoms (Chard et al. 1988a).

From a financial perspective, it has been estimated that around 1% of adults in the UK consult their GP with a new presentation of shoulder pain each year, incorporating rotator cuff tendinopathy (Murphy & Carr 2009). Based upon 2011 Census data from the Office of National Statistics which indicated that there were approximately 50 million adults living in the UK at that time, this suggests that approximately 500,000 adults might consult with a new episode of shoulder pain each year (Office of National Statistics 2011). Previously, costs in the first six months following primary care contact have been estimated to be €690 (Kuijpers et al. 2006). Hence, recognising the dated nature of this data and the inherent uncertainty, it is estimated that costs attributable to this problem might be in the region of €345 million or £310 million per year. When such figures are considered in the context of rising rates of shoulder surgery (Weber et al. 2002; Ensor et al. 2013), the inference from this data is that rotator cuff tendinopathy is a reasonably common disorder that brings the associated health costs and economic burden, including loss of productivity, associated with other chronic conditions (Bennell et al. 2007). Hence, this is an important problem for patients, clinicians, commissioners and researchers to consider.

1.2 Terminology

Before considering the rationale for the further study that underpins this thesis it is important to highlight the author's perspective upon the use of terminology, particularly the term 'rotator cuff tendinopathy' which, for the purpose of this thesis refers to;

- no/ minimal shoulder pain at rest
- largely preserved range of shoulder motion

- shoulder pain consistently provoked through resisted testing
- no obvious involvement of the cervical spine (Littlewood et al. 2012a).

These basic criteria largely reflect the wider body of evidence but others have added orthopaedic special tests, for example Hawkins-Kennedy Impingement test, or imaging, for example diagnostic ultrasound. However, due to the low specificity of many special orthopaedic tests and as not all structural pathology correlates well with symptoms (Lewis 2009), it was felt that these additions would not be helpful in this context. The limitations of this approach, for example failing to identify useful sub-groups of prognostic significance, and hence the uncertainty of this approach are recognised. But, in the absence of a universally accepted or gold standard method of assessment or diagnosis, for the purpose of clarity, this thesis will adopt the above criteria and take a consistent approach to the use of terminology.

There is much debate, or at least, there is much inconsistency in the terms used to describe the clinical presentation referred to above (Littlewood et al. 2012b). Currently a range of poorly understood, but probably synonymous, terms exist to describe disorders associated with the rotator cuff, for example subacromial impingement syndrome, subacromial pain syndrome, painful arc syndrome, shoulder impingement, subacromial bursitis, rotator cuff tendonitis, supraspinatus tendonitis, rotator cuff tendinopathy, rotator cuff tendinosis, contractile dysfunction. There appears to be significant overlap and replication in terms of what these diagnostic labels are actually referring to which reflects the uncertainty in relation to the origin of shoulder pain of this nature.

As described above, tendinopathy is a term used to describe a tendon disorder but without implication of pathology as opposed to the terms tendinitis or tendinosis which imply tendon pathology of an inflammatory or degenerative nature respectively (Rees et al. 2006). The limited role of inflammation, as understood from a ‘traditional’ perspective, with reference to most tendon disorders has been recognised over recent years and rightfully the term tendinitis is now being used more restrictively. Tendinosis, implying a non-inflammatory degenerative tendon disorder, can only be diagnosed with the use of imaging devices, for example diagnostic ultrasound or magnetic resonance imaging, which limits practical application in most physiotherapy settings. However, because degenerative

pathology in isolation is not strongly correlated with symptomatic presentations the term tendinosis might actually be of limited clinical value anyway. Hence, in this context the use of the term tendinopathy appears appropriate but, again, the uncertainty and potentially restrictive nature of this approach is recognised and stimulus to re-visit the use of this terminology might be forthcoming as knowledge relating to the origin of shoulder pain of this nature advances. Further, largely pragmatic, reasons for use of this terminology at this stage include:

- The terminology is recognised by and familiar to clinicians (Littlewood et al. 2012a).
- The terminology avoids ascribing a specific faulty structure as the source, or stage of pathology as the cause, but still offers a useful basis upon which to facilitate communication with patients (Littlewood et al. 2013b).
- The clinical presentation can be reliably identified by different clinicians (k = 0.83) (May & Ross 2009).

One further consideration in relation to the term rotator cuff tendinopathy, which will be discussed in chapter three, is the role of the central nervous system (CNS). In the context of a thesis that will attempt to highlight the role of the CNS, such specific pathology or impairment terminology might be regarded as a backward step because of their reference to specific peripheral tissue or mechanical mechanisms. However, the use of such term is deliberate, purposeful and felt to be relevant to highlight how current practice models can be interpreted and usefully evaluated in a research context while maintaining relevance to current clinical practice; hence there is further pragmatic value.

1.3 Rationale underpinning further study

Despite the commonality and burden of rotator cuff tendinopathy, in tandem with a limited understanding of pathoaetiology, the optimal management strategies are not clear and a range of interventions might currently be offered to a person complaining of pain attributable to the rotator cuff (Littlewood et al. 2012a). It is in the context of a common, burdensome and poorly understood disorder that this thesis is presented.

As a pre-cursor to developing the study upon which this thesis is based; the SELF study - A mixed-methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders (Littlewood et al. 2012c), Littlewood et al. (2012b) conducted a systematic review. This review concluded that due to a paucity of research and methodological limitations associated with the studies to date including inadequate power, inadequate control groups and inadequate outcome measures, further evaluation of exercise for rotator cuff tendinopathy was indicated. Critically Littlewood et al. (2012b) focused solely upon an evaluation of exercise and did not consider the range of interventions that might be offered. However, it is largely based upon the systematic review by Littlewood et al. (2012b) that the protocol for the SELF study was developed, including the self-managed exercise intervention, prior to commencing this thesis.

1.3.1 Aims and objectives

In the context of a pre-established protocol, the aim of this work is to evaluate a self-managed exercise programme for rotator cuff tendinopathy in terms of both clinical and cost-effectiveness.

Underpinning this aim are several objectives:

i. To systematically review the current evidence base to evaluate the validity of evaluating the effectiveness of an exercise programme in contrast to other commonly prescribed conservative interventions

ii. To systematically review the current evidence base to evaluate the validity of the exercise programme proposed for evaluation within the SELF study

iii. To establish the feasibility of conducting a randomised controlled trial (RCT) within the UK NHS

iv. To understand the barriers which might prevent implementation of the self-managed exercise programme into clinical practice or future research studies

v. To conduct and complete a substantive RCT and report clinical and cost-effectiveness results

vi. To propose future research priorities relating to the management of rotator cuff tendinopathy.

By meeting these objectives it is suggested that knowledge will be developed in terms of the optimal conservative management strategies for rotator cuff tendinopathy.

With this in mind, the next chapter presents two systematic literature reviews to initially establish the validity of undertaking further evaluation of exercise for rotator cuff tendinopathy; and building upon this the second systematic review aims to identify the important component parts of such exercise programmes. These reviews form the foundation upon which the remainder of the thesis is developed. Chapter three describes and justifies the self-managed exercise programme that was evaluated as well as considering its potential mechanism(s) of action. Chapter four justifies the methodological approach underpinning this thesis and introduces the mixed-method research employed. Chapters five, six and seven refer to the work undertaken to develop the research methods and inform feasibility of the substantive study. Chapter five reports the patient and public involvement event (n = 4); chapter six reports the pilot randomised controlled trial (RCT) (n = 24) with three-month follow-up; and chapter seven reports the pilot qualitative study (n = 8) which was undertaken to better understand potential barriers to the conduct of the substantive study. Chapter eight reports the substantive RCT (n = 86) which was conducted with the aim of evaluating clinical effectiveness of the self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. Chapter nine details the economic analysis undertaken alongside the substantive RCT and chapter ten reports the final qualitative study (n = 21) undertaken with patients and physiotherapists involved in the substantive RCT to identify some of the barriers and facilitators concerning implementation of the self-managed exercise intervention. Chapter eleven concludes this thesis with discussion relating to the aims and objectives, and how knowledge has been developed, before ideas for further, related research are presented.

Chapter 2: Literature review

*Based upon Littlewood et al (2013c). A review of systematic reviews of the effectiveness of conservative interventions for rotator cuff tendinopathy. Shoulder & Elbow 5(3), 151-167 (**Appendix 1**)*

Summary

This chapter presents two systematic reviews. Part one is a review of systematic reviews upon which the rationale for evaluating the effectiveness of exercise for rotator cuff tendinopathy is based. The second review looks more closely at the component parts of exercise programmes that have previously been evaluated in the area of rotator cuff tendinopathy with a view to generating evidence-based recommendations to inform the development of future exercise programmes.

Part One: A review of systematic reviews of the effectiveness of conservative interventions for rotator cuff tendinopathy

2.0 Introduction

A range of conservative and surgical interventions are currently used to treat rotator cuff tendinopathy. A recent survey of current practice highlighted that physiotherapists in the UK might offer a variety of conservative interventions and it is evident that clinical practice varies widely (Littlewood et al. 2012a). Over time multiple systematic reviews relating to the effectiveness of interventions for rotator cuff tendinopathy have been published. Due to this expansive secondary evidence base, the objective of this review is to systematically retrieve, appraise and synthesise findings from previous systematic reviews to establish the effectiveness of conservative interventions as a foundation upon which further primary research should be undertaken.

2.1 Methods

2.1.1 Data sources and search strategy

Electronic searches of the Physiotherapy Evidence Database (PEDro), the Cochrane Library and MEDLINE from their inception to September 2012 were undertaken by one reviewer (CL). The search terms used for the MEDLINE search are displayed in table 2.1.

Table 2.1 MEDLINE Search strategy

	Search term	Limited to
1	shoulder pain or shoulder impingement* or shoulder tend* or shoulder burs* or rotator cuff* or subacromial impingement* or subacromial burs* or supraspinatus* or impingement* or contractile dysfunction or painful arc*	Title & abstract
2	Review or systematic review or meta-analysis or synthesis	Title & abstract
3	1 and 2	

The electronic search was complemented by citation searching of the identified systematic reviews followed by hand-searching the reference lists of these systematic reviews.

2.1.2 Study selection

Study selection was undertaken by one reviewer (CL). Systematic reviews including RCTs comprising participants presenting with signs and symptoms suggestive of rotator cuff tendinopathy were included. A range of terms exist that are synonymous with the term rotator cuff tendinopathy and, as suggested in chapter one, there appears to be significant overlap and replication in terms of what these diagnostic labels are actually referring to (Littlewood et al. 2012b). Due to the diverse nature of classification in combination with poor reporting of diagnostic criteria the diagnosis of rotator cuff tendinopathy was operationalized as pain presenting locally at the shoulder with largely maintained range of movement without fracture, instability, calcific tendinitis or post-surgical status. Although not ideal, such a pragmatic approach is in keeping with the approach of others (Braun & Hanchard 2010). For the purpose of this review, systematic reviews that included studies focusing solely upon participants with rotator cuff tears were excluded. Systematic reviews that comprised studies with a mix of diagnoses, for example frozen shoulder and rotator cuff tendinopathy, were included provided that sub-group analysis relating to rotator cuff tendinopathy was offered.

Systematic reviews that evaluated the effectiveness of conservative interventions typically offered by physiotherapists in the UK, including exercise, manual therapy, electrotherapy, acupuncture and corticosteroid injections (Littlewood et al. 2012a), in comparison to no intervention, placebo, other conservative interventions or surgical interventions were

included. For pragmatic reasons, systematic reviews published in languages other than English were excluded.

2.1.3 Data extraction

One reviewer (CL) extracted data relating to the systematic review methods, type and number of studies included, diagnostic criteria, interventions evaluated and main outcomes.

2.1.4 Quality appraisal

Quality appraisal was undertaken by one reviewer (CL). The AMSTAR (assessment of multiple systematic reviews) checklist was utilised to evaluate the methodological quality of the included systematic reviews. AMSTAR consists of 11 items, which are not summed to give an overall quality score, each with a 'yes', 'no', 'can't answer', or 'not applicable' response (Shea et al. 2007). Good content and face validity for measuring the quality of systematic reviews has been reported (Shea et al. 2007).

2.1.5 Data synthesis

Heterogeneity between primary studies evaluating the effectiveness of interventions in this field is well-recognised and has an obvious impact upon the ability to synthesise findings from subsequent systematic reviews. For this reason, a narrative approach was undertaken to synthesise the findings in relation to the various conservative interventions.

2.2 Results

2.2.1 Study selection

Figure 2.1 depicts the study selection process. The electronic search yielded a total of 445 articles and a further five were identified though hand and citation searching. The title and abstracts of 450 articles were screened with 37 potentially relevant reviews identified for full-text review. Only one non-English language systematic review that was potentially relevant was identified, but excluded at this stage. Of these 37 articles, 26 were selected. Ten articles (Albright et al. 2001; Alexander et al. 2010; Bjordal et al. 2001; Brudvig et al. 2011; Camarinos & Marinko 2009; Marinko et al. 2011; Pribicevic et al. 2010; van der Heijden et al. 1996; van der Heijden et al. 1997; Gaujoux-Viala et al. 2009), excluded at the stage of full-text review, did not include participants with rotator cuff tendinopathy and/-or the systematic review authors did not generate a relevant sub-group analysis pertaining to

rotator cuff tendinopathy. One article was excluded because it was not a systematic review (Cardoso de Souza et al. 2009).

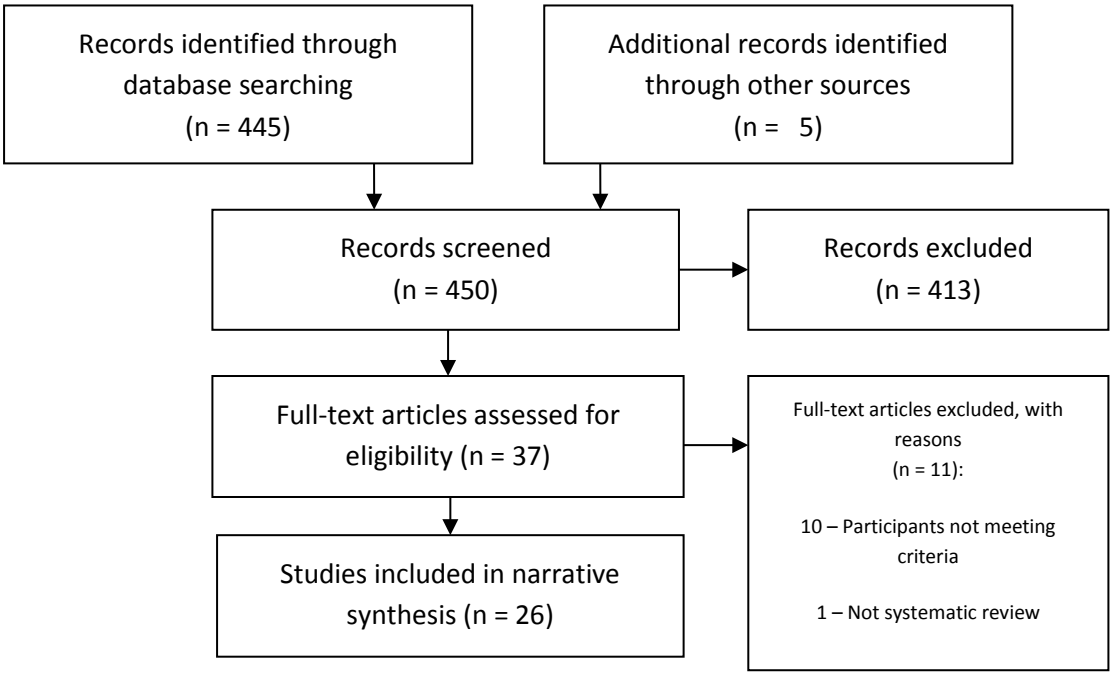


Figure 2.1 Study selection process

2.2.2 Quality appraisal

The results of the AMSTAR quality appraisal are shown in table 2.2. The mean quality score was 6 (range 3 to 9). The most common reason for not meeting an AMSTAR criterion was a failure to assess the likelihood of publication bias (96%), failure to search beyond published literature (88%), failure to include a list of included and excluded studies (85%), failure to undertake a comprehensive literature search (62%) and failure to declare any potential conflicts of interest (62%).

2.2.3 Study characteristics

A summary of the characteristics of the included systematic reviews along with the main outcomes are shown in tables 2.3 to 2.11.

Table 2.2 Results of the AMSTAR quality appraisal

Study	1	2	3	4	5	6	7	8	9	10	11
(Green et al. 1998)	✓	✓	✓	x	✓	✓	✓	✓	✓	x	✓
(Johansson et al. 2002)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Buchbinder et al. 2002)	✓	✓	✓	x	✓	✓	✓	✓	✓	x	✓
(Green et al. 2003)	✓	✓	✓	x	✓	✓	✓	✓	✓	x	✓
(Desmeules et al. 2003)	--	✓	x	x	x	✓	✓	✓	✓	--	x
(Grant et al. 2004)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Michener et al. 2004)	--	✓	✓	✓	x	✓	✓	✓	✓	x	x
(Harniman et al. 2004)	--	✓	--	x	x	✓	✓	✓	✓	x	x
(Green et al. 2005)	✓	✓	✓	x	✓	✓	✓	✓	✓	x	✓
(Arroll & Goodyear-Smith 2005)	✓	✓	x	✓	x	x	✓	✓	✓	✓	✓
(Trampas & Kitsios 2006)	--	✓	✓	x	x	✓	✓	✓	✓	x	x
(Faber et al. 2006)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Woodley et al. 2007)	--	--	x	x	x	✓	✓	✓	NA	x	✓
(Koester et al. 2007)	--	x	x	x	x	✓	✓	✓	✓	x	✓
(Ho et al. 2009)	--	x	✓	x	x	x	✓	x	✓	x	x
(Kuhn 2009)	✓	x	x	x	x	✓	✓	x	✓	x	x
(Greving et al. 2011)	--	✓	✓	x	x	✓	✓	x	✓	x	x
(Kromer et al. 2009)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Nyberg et al. 2010)	--	x	x	x	x	✓	✓	✓	✓	x	x
(Braun & Hanchard 2010)	✓	x	x	x	✓	✓	✓	✓	✓	x	✓
(Tumilty et al. 2010)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Kelly et al. 2010)	--	✓	✓	x	x	✓	✓	✓	✓	x	x
(Huisstede et al. 2011)	--	✓	x	x	x	✓	✓	✓	✓	x	x
(Brantingham et al. 2011)	--	--	x	x	x	✓	✓	✓	x	x	✓
(Littlewood et al. 2012b)	✓	✓	✓	✓	x	✓	✓	✓	✓	x	✓
(Hanratty et al. 2012)	✓	✓	x	x	x	✓	✓	✓	✓	x	x

(✓ = Yes, x = No, - = can't answer, NA = not applicable) (*1. Was an 'a priori' design developed? 2. Was there duplicate study selection & data extraction? 3. Was a comprehensive literature search performed? 4. Was the status of publication used as an inclusion criterion? 5. Was a list of studies (included and excluded) provided? 6. Were the characteristics of the included studies provided? 7. Was the scientific quality of the included studies assessed & documented? 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? 9. Were the methods used to combine the findings of the studies appropriate? 10. Was the likelihood of publication bias assessed? 11. Was the conflict of interest stated?)*

2.2.3.1 Exercise for rotator cuff tendinopathy

Thirteen systematic reviews relating to the effectiveness of exercise for rotator cuff tendinopathy were retrieved from 2003 to 2012 (table 2.3). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). Despite this variability, the reviews consistently supported the superior effectiveness of exercise, in terms of statistical significance, compared to no treatment or placebo. Other active interventions, including multi-modal physiotherapy or surgery, confer no additional benefit over exercise alone. The clinical importance of any treatment effects due to exercise are unclear and only a minority of systematic reviews considered this.

Table 2.3 Systematic reviews relating to the effectiveness of exercise for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Green et al. 2003)	9	Rotator cuff tendinitis	Exercise	Results from one RCT ((Brox et al. 1993; Brox et al. 1999); n = 80): Evidence supportive of short- and long-term effectiveness in terms of improved function compared to placebo	RR of good/ excellent function 2.45 (95% CI 1.24 to 4.86)
(Desmeules et al. 2003)	5	Impingement syndrome, rotator cuff tendinitis or bursitis		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Ginn et al. 1997); n = 146): Evidence supportive of effectiveness compared to placebo or no treatment	NC
(Grant et al. 2004)	5	Rotator cuff pathology		Results from one RCT ((Brox et al. 1993; Brox et al. 1999); n = 80): Evidence supportive of short- and long-term effectiveness in terms of improved function compared to placebo	NC
(Michener et al. 2004)	7	Subacromial impingement syndrome		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Ludewig & Borstad 2003); n = 147): Evidence supportive of effectiveness in the short- and long-term in terms of improved function compared to placebo or no intervention Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Rahme et al. 1998); n = 137): Evidence suggestive of no significant difference in short- and medium-term but conflicting in the long-term when compared to surgery	NC NA
(Trampas & Kitsios 2006)	6	Shoulder impingement		Results from one RCT ((Ludewig & Borstad 2003); n = 67): Evidence supportive of effectiveness compared to no treatment	NC

		syndrome		Results from two RCTs ((Walther et al. 2004; Haahr et al. 2005); n = 150): Evidence suggestive of no significant difference in terms of pain or function compared to multi-modal physiotherapy, functional brace or surgery	NA
(Faber et al. 2006)	5	Shoulder impingement syndrome		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Ludewig & Borstad 2003); n = 147): Evidence supportive of effectiveness in terms of functional limitations or work status compared to placebo or no intervention Results from one RCT ((Brox et al. 1993; Brox et al. 1999); n = 95): Evidence suggestive of no significant difference in terms of functional limitations compared to surgery	NC NA
(Woodley et al. 2007)	4	Rotator cuff tendinopathy		No relevant RCTs retrieved	NA
(Kuhn 2009)	4	Rotator cuff impingement		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Ludewig & Borstad 2003); n = 147) Evidence supportive of effectiveness compared to placebo or no treatment Results from two RCTs ((Walther et al. 2004; Werner et al. 2002); n = 80): Evidence suggestive of no significant difference between home exercise and supervised exercise	Conflicting evidence NA
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Haahr et al. 2005; Haahr & Andersen 2006); n = 179) Evidence suggestive of no significant difference in the short-, medium- or long-term compared to surgery Results from two RCTs ((Walther et al. 2004; Werner et al. 2002); n = 80): Evidence suggestive of no significant difference between home exercise and supervised exercise	NA NA
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Haahr et al. 2005; Haahr & Andersen 2006); n = 179) Evidence suggestive of no significant difference in the short-, medium- or long-term compared to surgery Results from two RCTs ((Ludewig & Borstad 2003; Lombardi et al. 2008); n = 127) Evidence supportive of effectiveness compared to no treatment Results from one RCT ((Engebretsen et al. 2009); n = 104) Evidence supportive of effectiveness in the short- and medium- term compared to extracorporeal shockwave therapy Results from one RCT ((Walther et al. 2004); n = 40): Evidence suggestive of no significant difference between home exercise and supervised	NA NC NC NA

				(physiotherapy) exercise Results from one RCT ((Osteras & Torstensen 2010); n = 80): Evidence supportive of effectiveness of high dose exercise compared to lower dose exercise	NC
(Braun & Hanchard 2010)	7	Impingement-related pain		Results from one RCT ((Giombini et al. 2006); n = 37): Evidence not supportive of effectiveness in the short-term compared to heat application Results from one RCT ((Lombardi et al. 2008); n = 60): Evidence supportive of effectiveness compared to no treatment Results from one RCT ((Haahr & Andersen 2006); n = 84): Evidence suggestive of no significant difference in the long-term compared to surgery	NC NC NA
(Kelly et al. 2010)	6	Subacromial impingement syndrome		Results from two RCTs ((Brox et al. 1993; Brox et al. 1999; Lombardi et al. 2008); n = 140): Evidence supportive of effectiveness compared to placebo or no treatment Results from one RCT ((Walther et al. 2004); n = 60): Evidence suggestive of no significant difference compared with functional brace or physiotherapy Results from three RCTs ((Brox et al. 1993; Brox et al. 1999; Rahme et al. 1998; Haahr et al. 2005); n = 227): Evidence suggestive of no significant difference compared to surgery	NC NA NA
(Littlewood et al. 2012b)	9	Rotator cuff tendinopathy		Results from three RCTs ((Brox et al. 1993; Brox et al. 1999; Ludewig & Borstad 2003; Lombardi et al. 2008); n = 207) Evidence supportive of effectiveness in the short-, medium- and long-term compared to placebo or no intervention Results from one RCT ((Brox et al. 1993; Brox et al. 1999); n = 95) Evidence suggestive of no significant difference in the short-, medium- and long-term compared to surgery Results from one RCT ((Walther et al. 2004); n = 60) Evidence suggestive of no significant difference in the short-term compared to multi-modal physiotherapy or functional brace	Unclear NA NA

(NC = No commentary available; NA = Not applicable; RR = relative risk)

2.2.3.2 Exercise combined with manual therapy for rotator cuff tendinopathy

Eleven systematic reviews relating to the effectiveness of exercise combined with manual therapy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (table 2.4). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 3 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews supported the short-term effectiveness

of exercise combined with manual therapy, in terms of statistical significance, compared with exercise alone based upon the two studies by Conroy & Hayes (1998) and Bang & Deyle (2000). Post-2006, the inclusion of Citaker et al. (2005) and subsequently Senbursa et al. (2007) the evidence became conflicting. However, Citaker et al. (2005) report a significant difference in favour of exercise combined with manual therapy although the between-group results presented in the paper do not support this. Braun & Hanchard (2010) recognise this inconsistency but report in favour of manual therapy whereas Kelly et al. (2010) do not. Kuhn (2009) and Nyberg et al. (2010) do not appear to recognise this inconsistency but this conflict in reporting might only be purely academic in nature because the difference reported by Senbursa et al. (2007) is not regarded as clinically important. Overall, only a minority of systematic reviews considered the clinical importance of any treatment effects attributable to exercise combined with manual therapy, the outcome of which was unclear clinical importance.

Table 2.4 Systematic reviews relating to the effectiveness of exercise combined with manual therapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Green et al. 2003)	9	Rotator cuff tendinitis	Exercise combined with manual therapy	Results from two RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000); n = 66): Evidence supportive of short-term effectiveness in terms of improved pain, function and ROM compared to exercise alone	Unclear
(Desmeules et al. 2003)	5	Impingement syndrome, rotator cuff tendinitis or bursitis		Results from two RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000); n = 66): Evidence supportive of short-term effectiveness compared to exercise alone	NC
(Michener et al. 2004)	7	Subacromial impingement syndrome		Results from two RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000); n = 66): Evidence supportive of effectiveness in the short-term compared to exercise alone	NC
(Trampas & Kitsios 2006)	6	Shoulder impingement syndrome		Results from one RCT ((Citaker et al. 2005); n = 40): Evidence suggestive of no significant difference in terms of pain or function compared to proprioceptive neuromuscular facilitation with exercise	NA

(Faber et al. 2006)	5	Shoulder impingement syndrome		Results from one RCT ((Bang & Deyle 2000); n = 52): Evidence supportive of effectiveness in the short-term with regard to functional limitations compared to exercise alone	NC
(Ho et al. 2009)	3	Shoulder impingement syndrome		Results from three RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000; Citaker et al. 2005); n = 106): Conflicting evidence regarding effectiveness in the short-term with regard to pain and function compared to other active interventions including exercise, proprioceptive neuromuscular facilitation and soft tissue massage Results from two RCTs ((Conroy & Hayes 1998; Citaker et al. 2005); n = 54): Evidence suggestive of no significant difference in the short-term with regards to ROM compared to other active interventions	NC NA
(Kuhn 2009)	4	Rotator cuff impingement		Results from three RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000; Senbursa et al. 2007); n = 96): Evidence supportive of effectiveness compared with exercise alone	Conflicting evidence
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from two RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000); n = 66): Evidence supportive of effectiveness in the short-term compared to exercise alone	NC
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from two RCTs ((Bang & Deyle 2000; Senbursa et al. 2007); n = 82): Evidence supportive of effectiveness compared to exercise alone	NC
(Braun & Hanchard 2010)	7	Impingement-related pain		Results from one RCT ((Senbursa et al. 2007); n = 30): Evidence supportive of effectiveness in the short-term compared to exercise alone Results from one RCT ((Cloke et al. 2008); n = 112): Evidence suggestive of no significant difference in the medium- or long-term compared to CCS injections or NSAIDs	NC NC
(Kelly et al. 2010)	6	Subacromial impingement syndrome		Results from three RCTs ((Conroy & Hayes 1998; Citaker et al. 2005; Senbursa et al. 2007); n = 84): Conflicting evidence regarding effectiveness compared to exercise alone	NA

(NC = No commentary available; NA = Not applicable)

2.2.3.3 Multimodal physiotherapy for rotator cuff tendinopathy

Seven systematic reviews relating to the effectiveness of multimodal physiotherapy for rotator cuff tendinopathy were retrieved from 2009 to 2012 (table 2.5). For the purpose of this review, multimodal physiotherapy refers to combined treatment including, but not restricted to,

exercise, manual therapy, electrotherapy and corticosteroid injections. Inclusion in this category was based upon the intervention offered in the primary study or due to the method of analysis offered by the systematic review; for example when studies evaluating exercise or manual therapy or electrotherapy were combined for the purpose of evidence synthesis. According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 7/11). Despite this variability, the reviews consistently supported the effectiveness of multimodal physiotherapy in the medium and longer-term, in terms of statistical significance, when compared to no treatment or placebo but in the short-term the evidence suggests no significant difference. Surgical intervention does not offer additional benefit over multimodal physiotherapy. The clinical importance of any treatment effects due to multimodal physiotherapy was not considered in any of the systematic reviews.

Table 2.5 Systematic reviews relating to the effectiveness of multimodal physiotherapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Kuhn 2009)	4	Rotator cuff impingement	Multimodal physiotherapy	Results from four RCTs ((Brox et al. 1993; Brox et al. 1999; Rahme et al. 1998; Haahr et al. 2005; Peters & Kohn 1997); n = 299): Evidence suggestive of no significant difference compared to surgery	NA
(Dorrestijn et al. 2009)	5	Subacromial impingement syndrome		Results from four RCTs ((Brox et al. 1993; Brox et al. 1999; Rahme et al. 1998; Haahr et al. 2005; Peters & Kohn 1997); n = 299): Evidence suggestive of no significant difference compared to surgery	NA
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from one RCT ((Dickens et al. 2005); n = 85): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from one RCT ((Dickens et al. 2005); n = 85): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
(Braun & Hanchard 2010)	7	Impingement-related pain		Results from one RCT ((Dickens et al. 2005); n = 85): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
(Brantingham et al. 2011)	4	Rotator cuff disorders		Results from ten RCTs ((Conroy & Hayes 1998; Bang & Deyle 2000; Citaker et al. 2005; Senbursa et al. 2007; Dickens et al. 2005; Bennell et al. 2010; Munday et al. 2007; Surenkok & Aytar 2009; Atkinson et al. 2008; Pribicevic et al. 2011); n = 504): Evidence supportive of effectiveness	NC

(Hanratty et al. 2012)	6	Subacromial impingement syndrome		Results from sixteen RCTs ((Brox et al. 1993; Brox et al. 1999; Ludewig & Borstad 2003; Walther et al. 2004; Haahr et al. 2005; Lombardi et al. 2008; Engebretsen et al. 2009; Conroy & Hayes 1998; Bang & Deyle 2000; Senbursa et al. 2007; Cloke et al. 2008; Bennell et al. 2010; Osteras et al. 2009; Szczurko et al. 2008; Polimeni et al. 2003; Ginn & Cohen 2005; Kachingwe et al. 2008); n = 1162): Evidence supportive of effectiveness in the short-term with regard to pain and function Evidence supportive of effectiveness in the long-term with regard to function Pooled results from four RCTs ((Lombardi et al. 2008; Engebretsen et al. 2009; Bennell et al. 2010; Szczurko et al. 2008); n = 369) Evidence suggestive of no significant difference in the short-term with regard to pain Pooled results from five RCTs ((Ludewig & Borstad 2003; Lombardi et al. 2008; Engebretsen et al. 2009; Bennell et al. 2010; Szczurko et al. 2008); n = 409) Evidence suggestive of no significant difference in the short-term with regard to function but supportive of effectiveness in the long-term	 NC NC NA NA

(NC = No commentary available; NA = Not applicable)

2.2.3.4 Corticosteroid injection for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of corticosteroid injection for rotator cuff tendinopathy were retrieved from 1998 to 2007 (table 2.6). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 5 to 9/11). Early reviews, meeting most quality criteria, supported the short-term effectiveness of corticosteroid injections, in terms of statistical significance, compared with placebo. One review (Green et al. 2003) reported effectiveness compared to physiotherapy but this review included primary studies comprising mixed diagnoses despite reporting to the contrary. The latest review (Koester et al. 2007), comprising the greatest number of primary studies, reported conflicting evidence regarding effectiveness of corticosteroid injections but this review was of lower quality than the others (5/11). The clinical importance of any treatment effects due to corticosteroid injections was considered by three reviews (Buchbinder et al. 2002; Arroll & Goodyear-Smith 2005; Koester et al. 2007). However, due to methodological concern relating to the method of estimation compounded by variability in estimates of effect size, clinical importance of any positive findings remains unclear.

Table2.6 Systematic reviews relating to the effectiveness of corticosteroid (CCS) injection for rotator cuff tendinopathy

Study	Score	Population	Interventions	Main outcomes	Clinical significance
(Green et al. 1998)	9	Rotator cuff tendinitis	CCS injection	Pooled results from two RCTs ((Adebajo et al. 1990; Petri et al. 1987); n = 90): Evidence supportive of short-term effectiveness in terms of improved abduction ROM compared to placebo Evidence not supportive of effectiveness in terms of reduced pain in short-term compared to placebo	NC NA
(Johansson et al. 2002)	5	Subacromial pain		Results from one RCT ((Blair et al. 1996); n = 40): Evidence supportive of short-term and long-term effectiveness in terms of reduced pain and improved abduction ROM compared to subacromial injection of local anaesthetic	NA
(Buchbinder et al. 2002)	9	Rotator cuff disease		Pooled results from two RCTs ((Adebajo et al. 1990; Petri et al. 1987); n = 90): Evidence supportive of short-term effectiveness in terms of reduced pain, function and abduction ROM compared to placebo Results from five RCTs ((Blair et al. 1996; Vecchio, Hazleman, et al. 1993; Strobel 1996; Kirkley et al. 1999; Plafki et al. 2000); n = 228): Conflicting evidence regarding effectiveness compared to placebo	SMD 0.83 (95% CI 0.39 to 1.26), 0.82 (0.39 to 1.25, 0.63 (0.20 to 1.06) respectively NA
(Green et al. 2003)	9	Rotator cuff tendinitis		Results from four RCTs ((Berry et al. 1980; Bulgen et al. 1984; Winters et al. 1997; van der Windt et al. 1998); n = 342): Evidence supportive of effectiveness compared to physiotherapy interventions	NA
(Arroll & Goodyear-Smith 2005)	8	Rotator cuff tendonitis		Results from five RCTs ((Adebajo et al. 1990; Petri et al. 1987; Blair et al. 1996; Vecchio, Hazleman, et al. 1993; Plafki et al. 2000); n = 222): Evidence supportive of effectiveness in terms of 'improvement' in the short- to mid-term compared to placebo	RR of improvement 3.1 (95% CI 1.94 to 4.87)
(Koester et al. 2007)	5	Rotator cuff disease		Results from seven RCTs ((Adebajo et al. 1990; Petri et al. 1987; Blair et al. 1996; Vecchio, Hazleman, et al. 1993; Berry et al. 1980; McInerney et al. 2003; Alvarez et al. 2005); n = 341): Conflicting evidence regarding effectiveness with regard to pain compared to placebo Results from eight RCTs ((Adebajo et al. 1990; Petri et al. 1987; Blair et al. 1996; Vecchio, Hazleman, et al. 1993; Berry et al. 1980; McInerney et al. 2003; Akgun et al. 2004; Withrington et al. 1985); n = 366): Conflicting evidence regarding effectiveness with regard to ROM compared to placebo	With regard to pain and ROM, only one study offered clinically significant results

				Results from four RCTs ((Adebajo et al. 1990; Petri et al. 1987; Alvarez et al. 2005; Akgun et al. 2004); n = 180): Conflicting evidence regarding with regard to function compared to placebo	

(NC = No commentary available; NA = Not applicable; SMD = standardised mean difference; RR = relative risk)

2.2.3.5 Laser for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of laser therapy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (table 2.7). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). Despite this variability, the reviews consistently concluded that the evidence did not support the effectiveness of laser therapy when compared to other interventions. The exception to this was evidence supportive of high-intensity laser compared to ultrasound based upon one RCT included in one systematic review (Nyberg et al. 2010). No comment was made about the clinical importance of this finding and due to the lack of positive findings relating to low-intensity laser, commentary about clinical importance was not applicable.

Table 2.7 Systematic reviews relating to the effectiveness of laser therapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Green et al. 2003)	9	Rotator cuff tendinitis	Laser	Results from two RCTs ((Vecchio, Cave, et al. 1993; Saunders 2012); n = 59) : Evidence not supportive of effectiveness compared to placebo	NA
(Grant et al. 2004)	5	Rotator cuff pathology		Results from one RCT ((Vecchio, Cave, et al. 1993); n = 35): Evidence not supportive of effectiveness compared to placebo	NA
(Faber et al. 2006)	5	Shoulder impingement syndrome		Results from one RCT ((Vecchio, Cave, et al. 1993); n = 35): Evidence not supportive of effectiveness in the short-term with regards to functional limitations compared to placebo	NA
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from two RCTs ((Vecchio, Cave, et al. 1993; Saunders 2012); n = 59) : Conflicting evidence regarding effectiveness in the short-term compared to placebo	NC
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from one RCT ((Santamato et al. 2009); n = 70): Evidence supportive of effectiveness of high intensity laser with regard to pain compared to ultrasound Results from two RCTs ((Bal et al. 2009; Yeldan et al. 2009); n = 104):	NC

				Evidence not supportive of effectiveness of low intensity laser	NA
(Tumilty et al. 2010)	5	Rotator cuff tendinopathy		Results from three RCTs ((Vecchio, Cave, et al. 1993; Saunders 2012; Saunders 2003); n = 95): Conflicting evidence regarding effectiveness of low intensity laser	NC

(NC = No commentary available; NA = Not applicable)

2.2.3.6 Ultrasound for rotator cuff tendinopathy

Five systematic reviews relating to the effectiveness of ultrasound for rotator cuff tendinopathy were retrieved from 2002 to 2009 (table 2.8). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 5 to 9/11). Despite this variability, the reviews consistently concluded that the evidence did not support the effectiveness of ultrasound.

Table 2.8 Systematic reviews relating to the effectiveness of ultrasound for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Johansson et al. 2002)	5	Subacromial pain	Ultrasound	Results from one RCT ((Nykanen 1995); n = 61): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
(Green et al. 2003)	9	Rotator cuff tendinitis		Results from one RCT ((Nykanen 1995); n = 61): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
(Michener et al. 2004)	7	Subacromial impingement syndrome		Results from two RCTs ((Berry et al. 1980; Nykanen 1995); n = 85): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
(Faber et al. 2006)	5	Shoulder impingement syndrome		Results from one RCT ((Downing & Weinstein 1986); n = 20): Evidence not supportive of effectiveness in the short-term with regard to functional limitations compared to placebo	NA
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from two RCTs ((Nykanen 1995; Johansson et al. 2005); n = 146): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo or acupuncture	NC

(NC = No commentary available; NA = Not applicable)

2.2.3.7 Extracorporeal shock wave therapy for rotator cuff tendinopathy

Four systematic reviews relating to the effectiveness of extracorporeal shock wave therapy for rotator cuff tendinopathy were retrieved from 2004 to 2011 (table 2.9). According to the quality appraisal based upon AMSTAR, the systematic reviews were of similar quality (all 5/11). The reviews consistently concluded that the evidence did not support the effectiveness of extracorporeal shockwave therapy when compared to placebo.

Table 2.9 Systematic reviews relating to the effectiveness of extracorporeal shockwave therapy for rotator cuff tendinopathy

Study	Score	Population	Interventions	Main outcomes	Clinical significance
(Grant et al. 2004)	5	Rotator cuff pathology	Extracorporeal shock wave therapy	Results from one RCT ((Speed et al. 2002); n = 74): Evidence not supportive of effectiveness compared to placebo	NA
(Harniman et al. 2004)	5	Rotator cuff tendonitis		Results from one RCT ((Schmitt et al. 2001); n = 40): Evidence not supportive of effectiveness in terms of pain, function or ROM compared to placebo	NA
(Faber et al. 2006)	5	Shoulder impingement syndrome		Results from two RCTs ((Speed et al. 2002; Schmitt et al. 2001; Schmitt et al. 2002); n = 108): Evidence not supportive of effectiveness in the short-, medium- or long-term with regard to functional limitations compared to placebo	NA
(Huisstede et al. 2011)	5	Rotator cuff tendinosis		Results from six RCTs ((Speed et al. 2002; Schmitt et al. 2001; Schmitt et al. 2002; Melegati et al. 2000; Gross et al. 2002; Schofer et al. 2009); n = 314): Evidence not supportive of effectiveness compared to placebo or other interventions	NA

(NC = No commentary available; NA = Not applicable)

2.2.3.8 Acupuncture for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of acupuncture for rotator cuff tendinopathy were retrieved from 2002 to 2010 (table 2.10). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews (Johansson et al. 2002; Grant et al. 2004) that included the same RCT (Kleinhenz et al. 1999) supported short-term effectiveness, in terms of statistical significance, compared to placebo. These conclusions were confounded by failure to report one study (Berry et al. 1980) included in later reviews that did not support effectiveness.

Medium-term effectiveness of acupuncture is not supported by the reviews and neither is effectiveness compared to active interventions including ultrasound or corticosteroid injections, albeit based upon the findings of one primary study. One anomaly is the conclusion of (Trampas & Kitsios 2006) who concluded in favour of acupuncture compared to ultrasound. This conclusion, based upon Johansson et al. (2005), relates to acupuncture combined with exercise which makes it difficult to ascribe any treatment effect to acupuncture particularly when considered in the context of the above findings relating to exercise. Only one review comments upon clinical importance of the findings (Johansson et al. 2002). These authors report a standardised mean difference of 0.77 which is regarded as a moderate effect size (Cohen 1988) but no estimate of variance is offered which limits interpretation.

Table 2.10 Systematic reviews relating to the effectiveness of acupuncture for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Johansson et al. 2002)	5	Subacromial pain	Acupuncture	Results from one RCT ((Kleinhenz et al. 1999); n = 52): Evidence supportive of short-term effectiveness in terms of reduced pain and improved function compared to placebo	SMD 0.77
(Grant et al. 2004)	5	Rotator cuff pathology		Results from one RCT ((Kleinhenz et al. 1999); n = 52): Evidence supportive of short-term effectiveness in terms of reduced pain and improved function compared to placebo	NC
(Michener et al. 2004)	7	Subacromial impingement syndrome		Results from two RCTs ((Berry et al. 1980; Kleinhenz et al. 1999); n = 76): Evidence is conflicting in the short-term and not supportive of effectiveness in the mid-term with regard to pain, function or ROM compared to placebo	NA
(Green et al. 2005)	9	Rotator cuff disease		Results from two RCTs ((Berry et al. 1980; Kleinhenz et al. 1999); n = 76): Evidence is conflicting in the short-term and not supportive of effectiveness in the mid-term with regard to pain, function or ROM compared to placebo Results from one RCT ((Berry et al. 1980); n = 24): Evidence suggestive of no significant difference in terms of pain or ROM compared to CCS injection Results from one RCT ((Berry et al. 1980); n = 24): Evidence suggestive of no significant difference in terms of pain or ROM compared to ultrasound	NA NA NA

(Trampas & Kitsios 2006)	6	Shoulder impingement syndrome		Results from one RCT ((Johansson et al. 2005); n = 85): Evidence supportive of effectiveness with regard to pain compared to ultrasound	NC
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from three RCTs ((Johansson et al. 2005; Kleinhenz et al. 1999; Vas et al. 2008); n = 562): Conflicting evidence with regards to pain and function compared to placebo (including ultrasound)	NC

(NC = No commentary available; NA = Not applicable; SMD = standardised mean difference)

2.2.3.9 Pulsed electromagnetic energy rotator cuff tendinopathy

Four systematic reviews relating to the effectiveness of pulsed electromagnetic energy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (table 2.11). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews supported short-term effectiveness, in terms of statistical significance, compared to placebo but later reviews, including more primary studies, concluded that the evidence was conflicting and subsequently not supportive of effectiveness.

Table 2.11 Systematic reviews relating to the effectiveness of pulsed electromagnetic energy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
(Green et al. 2003)	9	Rotator cuff tendinitis	Pulsed electromagnetic energy	Results from one RCT ((Binder et al. 1984); n = 29): Evidence supportive of short-term effectiveness compared to placebo	NC
(Grant et al. 2004)	5	Rotator cuff pathology		Results from one RCT ((Binder et al. 1984); n = 29): Evidence supportive of short-term effectiveness compared to placebo	NC
(Kromer et al. 2009)	5	Shoulder impingement syndrome		Results from three RCTs ((Binder et al. 1984; Atkas et al. 2007; Chard et al. 1988b); n = 124): Conflicting evidence regarding effectiveness in the short-term compared to placebo	NC
(Nyberg et al. 2010)	4	Subacromial impingement syndrome		Results from one RCT ((Atkas et al. 2007); n = 46): Evidence not supportive of effectiveness	NC

(NC = No commentary available; NA = Not applicable)

2.3 Discussion

Current evidence suggests that exercise programmes confer superior outcomes over no treatment or placebo. Other active interventions, including multi-modal physiotherapy or surgery, confer no additional benefit over exercise alone. Similarly, multimodal physiotherapy appears to confer superior outcomes over no treatment or placebo whereas surgical intervention does not offer additional benefit over multimodal physiotherapy. However, the clinical importance, or change that would be regarded as important by the patient and clinician, of any positive effects remains unclear. Manual therapy, corticosteroid injections and acupuncture are not supported by current evidence. Other commonly prescribed interventions lack evidence of effectiveness including ultrasound, low-level laser and extracorporeal shock wave therapy.

This review was designed and conducted with reference to objective one of this thesis: To systematically review the current evidence base to evaluate the validity of evaluating the effectiveness of an exercise programme in contrast to other commonly prescribed conservative interventions. The results of this review suggest that further evaluation of exercise programmes for rotator cuff tendinopathy is appropriate and indicated in keeping with the suggestions by Littlewood et al. (2012b). Additionally, multimodal physiotherapy, which is reflective of current practice for rotator cuff tendinopathy (Littlewood et al. 2012a), is also regarded as an effective intervention but based upon current data does not appear to confer additional benefit over exercise alone. Hence, from the research perspective at least, there is equipoise and stimulus for further investigation. The results of this review also appear to add further credibility to the use of usual or multimodal physiotherapy treatment as a comparator which is important in the context of applied research where positive findings in favour of the intervention might serve as a stimulus to re-consider current approaches to treatment.

One issue that this review has not addressed thus far is that the term exercise does not describe one singular approach. Issues such as clinical context, for example setting; characteristics of the treating therapist, patient, for example baseline pain and disability; type of exercise intervention and prescription parameters, for example repetitions, sets, frequency and duration, are likely to influence the clinical outcomes (Osteras et al. 2009).

Hence exercise should not be regarded as a homogenous intervention but instead, it is suggested, a heterogeneous intervention with optimal parameters and dosage. Previously Kuhn (2009) attempted to synthesise an evidence-based rehabilitation protocol. Based upon the available literature, a specific and extensive exercise programme was presented which includes fifteen different exercises along with dose and frequency. The exercise component amounts to a compendium of all exercises used in studies included in the systematic review. Manual therapy is advocated but, according to the results of this review, inclusion of manual therapy in a 'gold standard' rehabilitation protocol appears to be premature. Heat or cold or both are recommended due to the inclusion of this approach within some of the multimodal approaches evaluated. Other modalities are not recommended which is in keeping with the recommendations from this review. However, it is suggested that it might be more appropriate to regard the rehabilitation protocol as a 'best fit' rather than a 'gold standard' at this stage as evidence for the effectiveness of such a surmised programme is not available. Additionally, other factors need to be taken into account when evaluating such an extensive programme particularly levels of exercise adherence that can realistically be expected from patients/ participants (McLean et al. 2010).

Although exercise is regarded as an effective intervention on average, it is apparent that the optimal range of parameters around which an exercise programme for rotator cuff tendinopathy should be developed has not been established (Hanratty et al. 2012). It is with this knowledge and with reference to objective two of this thesis: To systematically review the current evidence base to evaluate the validity of the exercise programme proposed for evaluation within the SELF study, that the process and findings from a further systematic review will be presented in the second part of this chapter.

2.3.1 Strengths and limitations

In the presence of an expansive primary and secondary evidence base it is now considered logical and appropriate to conduct a review of systematic reviews (Smith et al. 2011). Hence, a clear strength of such an approach is the capacity to synthesise a large body of evidence in a single place (Gough et al. 2012; Smith et al. 2011). However, a potential consequence of this approach includes double counting of studies (Gough et al. 2012). Where double counting occurs greater power might be erroneously assumed because a

primary study appears repeatedly in similar reviews. This is a particular concern when conducting a meta-analysis within a review of systematic reviews where greater statistical power and precision might be erroneously inferred (Smith et al. 2011). In this current review it was apparent that the same primary studies appeared repeatedly in the secondary systematic reviews and in some situations, for example acupuncture for rotator cuff tendinopathy, there was a greater number of systematic reviews than primary studies. This should be borne in mind when considering the strength of any conclusions drawn. A further potential limitation of the review of systematic reviews approach is the dilution of detail, for example in relation to the prescribed exercise programmes, which hinders the opportunity to translate such evidence in to practice. As discussed above, this was apparent in this current review which necessitates further exploration to be undertaken to determine the useful detail.

For pragmatic and educational reasons, one reviewer searched, retrieved, extracted and appraised studies. It should be recognised that use of a single reviewer might increase the potential for bias and error during these stages. However, due to the repetitive nature of the process errors, for example erroneous data input, were minimised as the review was conducted. Additionally, judgements that were made that might be regarded as being susceptible to reviewer bias, for example in relation to quality appraisal, were based upon explicit criteria in relation to published work and hence any decision can be judged by the reader. Nevertheless, these limitations should be borne in mind when considering the results of this review.

Part Two: Exercise for rotator cuff tendinopathy – A systematic review of contextual factors and prescription parameters

2.4 Introduction

Exercise is regarded as an effective intervention to address the pain and disability associated with symptomatic rotator cuff tendinopathy (Littlewood et al. 2013c). However, exercise is not a panacea and prescription is diverse (Littlewood et al. 2012a). In terms of exercise programmes, it is currently unknown what works for whom and in what circumstances (Hanratty et al. 2012). With this in mind, in line with the methods of realist synthesis proposed by Pawson (2006), the purpose of this systematic review is to identify and synthesise the published evaluative data relating to exercise interventions for rotator cuff tendinopathy. Through comparison of the different contextual factors and prescription parameters of the exercise programmes with reference to patient-reported outcome, the aim is to generate recommendations, based upon current evidence, against which the validity of the exercise programme proposed for evaluation within the SELF study, and also future exercise programmes, can be judged.

2.5 Methods

2.5.1 Data sources & search strategy

An electronic search of AMED, CiNAHL, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PEDro and SPORTDiscus was undertaken from their inception to July 2013. The Cochrane highly sensitive search to identify randomised trials was adopted (Lefebvre et al. 2008). The search terms used for the MEDLINE search are displayed in table 2.12.

Table 2.12 MEDLINE Search Strategy

	Search Term	Limited to:
1	shoulder pain or shoulder impingement$ or shoulder tend$ or shoulder burs$ or rotator cuff$ or subacromial impingement$ or subacromial burs$ or supraspinatus$ or impingement$ or contractile dysfunction or painful arc$	Title & Abstract
2	Exercis$ or eccentric$ or concentric$ or loaded$ or resistance$ or muscle$ or physiotherap$ or physical therap$ or rehabil$ or conservative management	Title & Abstract
3	Randomized controlled$ or randomised controlled$ or controlled clinical trial or randomized or placebo or randomly or trial or groups	Title & Abstract
4	1 and 2 and 3	

The electronic search was complemented by hand searching the reference lists of the articles found and a recent review of systematic reviews (Littlewood et al. 2013c). This process was undertaken by one reviewer (CL).

2.5.2 Study selection

Studies had to meet the following criteria to be included:

2.5.2.1 Participants

Studies of adult patients presenting with signs and symptoms suggestive of rotator cuff tendinopathy were included. A pragmatic approach was taken in relation to identification of the participants partly due to the previously recognised diagnostic limitations and overlapping nomenclature. Essentially, studies were included which investigated a condition described as or synonymous with rotator cuff tendinopathy, for example subacromial impingement syndrome, where other diagnoses, for example frozen shoulder, had been ruled out. Typically this included patients complaining of shoulder pain provoked with impingement tests, for example Hawkins-Kennedy, and resisted tests while the range of shoulder movement was maintained.

2.5.2.2 Interventions

Studies that evaluated the effectiveness of any active exercise intervention in one of the treatment arms were included. Combined interventions, for example exercise and electrotherapy or exercise and manual therapy, which might confound judgements, were excluded.

2.5.2.3 Outcomes

Studies that described patient-reported outcomes (PROMs) of pain and disability where a minimally clinically important change (MCIC) had been established, as of July 2013, were included. The MCIC is defined as the smallest change in health status which patients perceive as beneficial from, for example, baseline measurement to another follow up point, i.e. the within, intra-group or intra-patient change (Pool et al. 2007). In contrast, the minimal clinically important difference (MCID) refers to the between, inter-group or inter-patient difference (Pool et al. 2007). The MCIC and the MCID might actually be the same value for a PROM. In the context of this review where the aim was to investigate contextual factors and prescription parameters of exercise programmes with reference to clinical outcome, the MCIC criterion and hence need for a PROM (Roy & Esculier 2011) was important to enable this aim to be met.

2.5.2.4 Study design

Only RCTs were included but only data relating to the exercise intervention were extracted, typically from one intervention arm, because this review is based upon the assumption that exercise is an effective intervention (Littlewood et al. 2012b; Littlewood et al. 2013c) and hence comparative data is largely redundant for the purpose of this review. However, inclusion of RCTs only is still important to minimise the potential for selection bias. Quasi-experimental and case studies/ -series were excluded due to the risk of bias associated with these designs (Centre for Reviews and Dissemination 2009).

2.5.2.5 Language

For pragmatic reasons, only studies published in full in English prior to July 2013 were included.

Following the search, screening of titles and abstracts was undertaken by CL who identified articles that should be retrieved for full-text review.

2.5.3 Data extraction

CL extracted data in relation to the study context, for example setting, characteristics of the treating therapist, characteristics of the patient, for example baseline pain and disability, type of exercise intervention and prescription parameters, for example repetitions, sets, frequency and duration (table 2.13).

2.5.4 Risk of bias assessment

The risk of bias of the included studies was undertaken by CL using the Cochrane Back Review Group (CBRG) risk of bias tool (Furlan et al. 2009). It has been recognised that this tool is also useful for the assessment of trials in other conditions (van Tulder et al. 2009) and has been employed in other systematic reviews evaluating the effectiveness of exercise for shoulder related disorders (Hanratty et al. 2012; Littlewood et al. 2012b). The completed risk of bias tool is displayed in table 2.14. Each item was rated as yes (= 1), no (= 0), unclear (= 0). A study with a low risk of bias was defined as one fulfilling six or more of the criteria items and with no fatal flaw which is defined as:

1. Drop-out > 50%.
2. Statistically and clinically important differences between groups at baseline indicating unsuccessful randomisation.

This approach has previously been validated (van Tulder et al. 2009).

2.5.5 Data synthesis

Due to the heterogeneity with regard to the exercise interventions evaluated a narrative synthesis was conducted in relation to contextual factors and exercise prescription parameters.

2.6 Results

Figure 2.2 depicts the study selection process; 13 studies (n = 384) were included in this review.

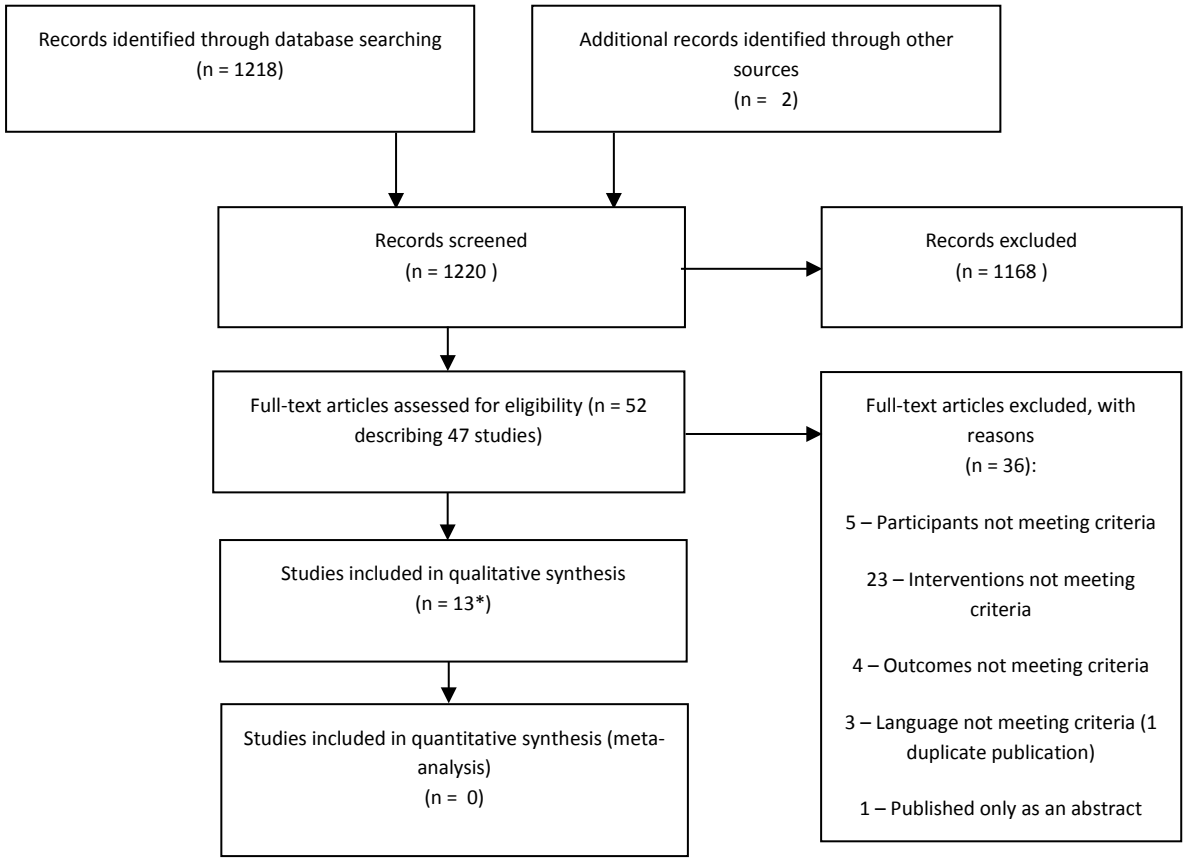


Figure 2.2 Study selection process (* 13 studies described by 16 full-text papers)

Table 2.14 Risk of bias appraisal of the included studies

Study	Cochrane RoB appraisal												Cochrane RoB score
	1	2	3	4	5	6	7	8	9	10	11	12	
(Bal et al. 2009)	-	-	x	x	x	✓	-	✓	x	-	-	✓	3/12
(Baskurt et al. 2011)	-	-	-	-	-	✓	✓	✓	✓	-	-	✓	5/12
(Calis et al. 2011)	-	-	x	x	x	x	x	✓	x	✓	x	✓	3/12
(Engebretsen et al. 2009; Engebretsen et al. 2011)	✓	✓	x	x	x	✓	✓	✓	✓	-	-	✓	7/12
(Giombini et al. 2006)	-	-	x	x	x	✓	✓	✓	✓	✓	✓	✓	7/12
(Kachingwe et al. 2008)	x	x	✓	x	✓	✓	-	-	x	-	-	-	3/12
(Kromer et al. 2013)	✓	✓	x	x	x	✓	✓	✓	✓	✓	✓	✓	9/12
(Lombardi et al. 2008)	✓	✓	x	x	x	✓	✓	✓	✓	✓	✓	✓	9/12
(Ludewig & Borstad 2003)	✓	✓	x	x	x	✓	✓	✓	✓	✓	-	✓	8/12
(Martins & Marziale 2012)	-	-	x	x	x	✓	✓	-	-	-	✓	-	3/12
(Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010)	✓	✓	-	x	x	✓	✓	✓	✓	-	-	✓	7/12
(Walther et al. 2004)	✓	✓	✓	x	✓	✓	✓	✓	✓	✓	✓	✓	11/12
(Yiasemides et al. 2011)	✓	✓	x	x	x	✓	✓	✓	✓	-	-	✓	7/12

(*1. Adequate randomisation? 2. Concealed allocation? 3. Patient blinded? 4. Therapist blinded? 5. Outcome assessor blinded? 6. Drop-out rate described and acceptable? 7. Intention-to-treat analysis? 8. Free of selective reporting? 9. Similarity of baseline characteristics? 10. Co-interventions avoided or similar? 11. Compliance acceptable? 12. Timing of outcome assessments similar?)*

The list of excluded full-text articles along with the reasons for exclusion is presented in table 2.15.

Table 2.15 Excluded full-text articles

Number	Study	Reason for exclusion
5	(Ginn & Cohen 2005; Ginn et al. 1997; Senbursa et al. 2007; Surenkok et al. 2009; Wang & Trudelle-Jackson 2006)	Participants not meeting criteria
23	(Abrisham et al. 2011; Bae et al. 2011; Beaudreuil et al. 2011; Bennell et al. 2010; Celik et al. 2009; Cheng & Hung 2007; Citaker et al. 2005; Cloke et al. 2008; Conroy & Hayes 1998; Cook et al. 2013; Crawshaw et al. 2010; Dickens et al. 2005; Eslamian et al. 2012; Haahr & Andersen 2006; Haahr et al. 2005; Holmgren et al. 2012; Ketola et al. 2009; Maenhout et al. 2013; Miller & Osmotherly 2009; Paoloni et al. 2005; Polimeni et al. 2003; Struyf et al. 2013; Szczurko et al. 2008)	Intervention not meeting criteria
4	(Bang & Deyle 2000; Brox et al. 1993; Brox et al. 1999; Djordjevic et al. 2012)	Outcomes not meeting criteria
3	(Just & Stelzer 2009; Weiner & Mayer 2005; Werner et al. 2002) Werner et al (2002) appears to be duplicate of Walther et al (2004)	Language not meeting criteria
1	(Wies et al. 2008)	Publication status not meeting criteria

2.6.1 Risk of bias assessment

The results of the risk of bias assessment are shown in table 2.14. In terms of the number of criteria met, scores ranged from 3 to 11/12 (mean = 6). The majority of studies (8/13) were regarded as presenting a low risk of bias (Engebretsen et al. 2009; Engebretsen et al. 2011; Giombini et al. 2006; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004; Yiasemides et al. 2011). As table 2.14 demonstrates, the most common design flaw across studies related to a lack of blinding of the patients, therapists and outcome assessors. An association between risk of bias and patient-reported outcome is not clearly supported by the data from this appraisal.

2.6.2 Study characteristics

A summary of the characteristics of the exercise intervention arm(s) of the included studies along with the main results is shown in table 2.13. Due to the nature and aims of this review, the outcome measures used and patient-reported outcomes will be described first as a basis upon which to subsequently report and consider the contextual and prescription parameters of the exercise interventions of the included studies.

2.6.2.1 Outcome measures and outcomes

Five studies reported the Shoulder Pain & Disability Index (SPADI) (Bal et al. 2009; Engebretsen et al. 2009; Engebretsen et al. 2011; Kachingwe et al. 2008; Kromer et al. 2013; Yiasemides et al. 2011), three studies (Calis et al. 2011; Giombini et al. 2006; Walther et al. 2004) reported the Constant score, two studies (Baskurt et al. 2011; Martins & Marziale 2012) reported the Western Ontario Rotator Cuff (WORC) index, two studies (Ludewig &

Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) reported the Shoulder Rating Questionnaire (SRQ) and one study (Lombardi et al. 2008) reported the Disabilities of the Arm, Shoulder & Hand (DASH) questionnaire (table 2.16).

Table 2.13 Characteristics of the included studies

Study	Context	Participants	Intervention	Dosage parameters	Outcomes
(Bal et al. 2009)	Based in Turkey No detail relating to experience or training of therapists	n = 20 i) Positive Neer & Hawkins-Kennedy tests **Mean age of participants;** 53years **Mean duration of symptoms;** not reported **Median baseline Shoulder pain and disability index (SPADI);** 69.1	Home exercise programme: Commenced with pendular circumduction and passive self-shoulder stretching followed by isometrics in all planes, Theraband exercises with progressive resistance, scapular stabilisation exercises and 'advanced' muscle strengthening with dumbbells	Repetitions; not reported Sets; not reported Frequency; not reported Duration; 12 weeks No further detail provided	SPADI (0 to 12 weeks); 69.1 to 19.6 = 49.5 median improvement (p<0.001)
(Baskurt et al. 2011)	Based in Turkey No detail relating to experience or training of therapists	n = 20 i) Positive Neer, Hawkins or Jobe test ii) Confirmatory x-ray and diagnostic ultrasound **Mean age of participants;** 51 years **Mean duration of symptoms;** 11 months **Mean baseline Western Ontario rotator cuff (WORC) index;** 40	Clinic-based exercise programme under direct supervision: Comprised stretches for anterior, posterior and inferior capsule and flexion, abduction and internal rotation with a towel. Strengthening component consisted of subscapularis, infraspinatus, supraspinatus and anterior/ posterior deltoid exercise using Theraband.	Repetitions; 10 Sets; 3 Frequency; X 3/ week clinic visits Duration; 6 weeks Resistance was progressed when the exercise prescription was completed without substantial pain or fatigue	WORC (0 to 6 weeks) 37.1 to 70.9= 33.8 mean improvement (p<0.05)
(Calis et al. 2011)	Based in Turkey Treated by one physiotherapist No further detail reported	n = 16 i) 18 to 65 years ii) Stage II subacromial impingement syndrome according to MRI **Mean age of participants;** 50 years **Mean duration of symptoms;** 3 months **Mean baseline Constant score;** 48.4	Clinic-based exercise programme with direct supervision: Comprised stretching, and gradually progressed to strengthening exercise for the rotator cuff, biceps and deltoid No further detail reported	Repetitions; 5 (5 second hold) Sets; 1 Frequency; x 2/ week clinic visits Duration; 3weeks No further detail reported	Constant (0 to 3 weeks) 48.4 to 56.3 = 7.9 mean improvement (p=0.001)
(Engebretsen et al. 2009; Engebretsen et al. 2011)	Based in Norway Treated by two experienced	N = 51 i) Age 18 to 70 years	Home-based exercise programme with direct supervision x 2/ week:	Repetitions; 50 Sets; 3 Frequency; X 2/ week	SPADI (0 to 6 weeks) 48.8 to 25.8 = 23.0 mean improvement (significance

	physiotherapists No further detail reported	ii) Shoulder pain > 3 months iii) Pain with shoulder abduction iv) Maintained ROM, v) Pain with isometric tests vi) Positive Hawkins-Kennedy impingement test **Mean age of participants;** 49 years **Mean duration of symptoms;** Unclear **Mean baseline SPADI score;** 48.8	Commenced with sling suspension to negate gravity; repeated movement through all ranges in sequence Resistance gradually added as pain free range of movement increases, using Theraband, to strengthen the rotator cuff and scapular stabilizers	clinic visits and home exercise daily Duration; 12 weeks Low-load exercise emphasised	not reported) SPADI (0 to 12 weeks) 48.8 to 27.0 = 21.8 mean improvement (significance not reported) SPADI (0 to 18 weeks) 48.8 to 24.5 = 24.3 mean improvement (significance not reported) SPADI (0 to 52 weeks) 48.8 to 24.0 = 24.8 mean improvement (significance not reported)
(Giombini et al. 2006)	Based in Italy Treated by a 'fully trained' rehabilitation specialist No further detail reported	n = 11 i) Positive Hawkins impingement test ii) Positive empty-can test iii) Tissue changes evident through ultrasonography without tear iv) Athletes attending a rehabilitation unit **Mean age of participants;** 26 years **Mean duration of symptoms;** 4.8 months **Mean baseline Constant score;** 59.5	Home exercise programme with direct supervision x 1/ week: Comprised pendular swinging and stretching No further detail reported	Repetitions; 5 minutes Sets; Unclear Frequency; x 2/ day Duration; 4 weeks Unloaded exercise emphasised	Constant score (0 to 4 weeks) 59.5 to 61.2 = 1.7 mean improvement (p=0.07) Constant score (0 to 6 weeks) 59.5 to 63.3 = 3.8 mean improvement (p=0.07)
(Kachingwe et al. 2008)	Based in USA Treated by one experienced research physiotherapist (14 years of clinical experience)	n = 8 i) Superolateral shoulder pain ii) 2 out of 4 positive tests – Neer, Hawkins-Kennedy, painful limitation of active shoulder elevation, pain or limitation of hand-behind-back or hand-behind-head **Mean age of participants;** 47 years **Mean duration of symptoms;** 33	Home exercise programme with direct supervision x 1/ week: Comprised stretching, postural correction and resistance exercises for the rotator cuff and scapular stabilisers No further detail reported	Repetitions; Unclear Sets; Unclear Frequency; X 1/ week clinic visits and home exercise daily Duration; 6 weeks No further detail reported	SPADI (0 to 6 weeks) 48.0 to 18.4 = 29.6 (transformed from original data) mean improvement (significance not reported)

		months **Mean baseline SPADI score;** 48.0			
(Kromer et al. 2013)	Based in Germany Treated by 12 experienced physiotherapists (mean clinical experience > 23 years) across 6 centres	n = 44 i) Age 18 to 75 years ii) Symptoms > 4 weeks iii) Local shoulder and/ or upper arm pain iv) Positive Neer, Hawkins-Kennedy or painful arc v) Pain with at least one resisted test **Mean age of participants;** 54 years **Mean duration of symptoms;** 10 months **Mean baseline SPADI score;** 41.3	Home exercise programme with direct supervision x 2/ week for 5 weeks: Progressive strengthening exercises for the rotator cuff and scapula stabilisers using Theraband and combined with stretches and exercises for pain relief, e.g. pendular exercises, longitudinal self-traction	Repetitions; 10 to 20 Sets; 2 to 3 Frequency; x2/ day during week 1, then once daily for next 4 weeks and x 3/ week for further 7 weeks Duration; 12 weeks Gradual increase of resistance, e.g. yellow to red to green theraband Pain < 3/10 permitted	SPADI (0 to 5 weeks) 41.3 to 26.8 = 14.4 mean improvement (95% CI 9.2 to 19.6) SPADI (0 to 12 weeks) 41.3 to 19.8 = 21.5 mean improvement (significance not reported)
(Lombardi et al. 2008)	Based in Brazil No further detail reported	n = 30 i) Positive Hawkins and Neer test ii) Pain between 3 and 8 on a numeric rating scale **Mean age of participants;** 56 years **Mean duration of symptoms;** 14 months **Mean baseline Disabilities of the arm, shoulder & hand (DASH) score;** 44.0	Clinic-based exercise programme with direct supervision: Exercises included flexion, extension, medial and lateral rotation	Repetitions; 8 Sets; 2 Frequency; x2/ week Duration; 8 weeks Exercise prescription based upon 6 repetition maximum Comprised 2 sets of 8 repetitions; 50% of 6RM for the first set and 70% of 6RM for the second set Pain production was not permitted	DASH (0 to 8 weeks) 44.0 to 33.2 = 11.8 mean improvement (p=0.046)
(Ludewig & Borstad 2003)	Based in USA No further detail reported	n= 34 i) Occupational exposure to overhead work > 1 year ii) Minimum of 130° abduction iii) Painful arc on abduction iv)Local tenderness to palpation v) Positive Neer, Hawkins-Kennedy, Yocum, Jobe and/ or Speeds test	Home exercise programme: Exercise programme comprised of relaxation, stretching and then progressive resistance exercises for serratus anterior and shoulder external rotators using hand-weights and Theraband Initial instruction provided by a physiotherapist re-enforced through written/ pictorial instructions. Return was	Repetitions; 10 (week 1) to 15 (week 2) to 20 (week 3 onwards) Sets; 3 Frequency; x 3/ week Duration; 8 weeks Gradual increase of resistance, e.g. yellow to red to green Theraband	SRQ (0 to 12 weeks) 65.9 to 75.8 = 9.9 mean improvement (significance not reported)

		vi) Pain with at least one resisted test **Mean age of participants;** 48 years **Mean duration of symptoms;** 29 months **Mean baseline Shoulder rating questionnaire (SRQ) score;** 44.6	arranged one week later with a follow-up telephone call at 4 weeks with optional visit to the physiotherapist at this stage	Shoulder fatigue permitted but no increase in shoulder pain	
(Martins & Marziale 2012)	Based in Brazil No further detail reported	i) Registered nurse, nurse technician or nurse aid at the host institution ii)Medical diagnosis of rotator cuff disorder **Mean age of participants;** unclear **Mean duration of symptoms;** unclear **Mean baseline WORC score;** unclear	Clinic-based exercise programme with direct supervision: N = 9; Cryotherapy, stretching and strengthening N = 9; Cryotherapy, stretching, strengthening and proprioceptive drills Proprioceptive regime included exercises aimed at improving joint position and rhythmic stabilisation Programme comprised pendular exercises, stretching of the neck and shoulder muscles, active-assisted shoulder range of movement exercise and exercise to strengthen the rotator cuff and scapula stabilisers	Repetitions; Unclear Sets; Unclear Frequency; x 2/ week clinic visits Duration; 6 weeks Progressive increase in resistance after 3 sessions No further detail reported	i) Cryotherapy, stretching and strengthening and proprioceptive drills; WORC (0 to 6 weeks) reported as statistically significant change (p=0.01) ii) Cryotherapy, stretching and strengthening alone; WORC (0 to 6 weeks) reported as statistically significant change (p=0.06) No significant difference between groups (p=0.11)
(Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010)	Based in Norway Treated by 3 experienced physiotherapists (many years of experience) across 3 centres	i) Age 18 to 60 years ii) Unilateral shoulder pain iii) Positive Hawkins impingement test iv) Symptoms > 3 months **Mean age of participants;** 44 years **Mean duration of symptoms;** 36 months **Mean baseline SRQ score;** 43.8	Clinic-based exercise programme with direct supervision: N = 31; High dosage medical exercise therapy 3 sets of 30 repetitions N = 30; Low dosage medical exercise therapy 2 sets of 10 repetitions Medical exercise therapy (MET) consists of one hours active group therapy (max. 5 participants) under the supervision of a physiotherapist MET applies progressive resistance exercise combined with aerobic activity, e.g. cycling 9 to 11 exercises are performed with aim of achieving over 1000 repetitions	Frequency; x 3/ week clinic visits Duration; 12 weeks Exercise is undertaken close to the pain-free threshold; shoulder pain should not increase significantly	i) High dose MET; SRQ (0 to 12 weeks) 43.7 to 69.1 = 25.4 mean improvement (95% CI 19.1 to 32.1) SRQ (0 to 36 weeks) 43.7 to 76.8 = 33 mean improvement (p<0.01) SRQ (0 to 60 weeks) 43.7 to 79.1 = 35.4 mean improvement (p<0.01) ii) Low dose MET; SRQ (0 to 12 weeks) 43.8 to 51.5 = 7.7 mean improvement (95% CI 4.5 to 10.9) SRQ (0 to 36 weeks) 43.8 to 56.3 = 12.5 mean improvement (significance not reported)

					SRQ (0 to 60 weeks) 43.8to 54.7 = 10.9 mean improvement (significance not reported) Statistically significant differences between groups at all 3 and 6-month follow-up in favour of high-dose MET
(Walther et al. 2004)	Based in Germany No further detail reported	n = 20 i) Positive Neer impingement test ii) Confirmatory x-ray and ultrasonography **Mean age of participants;** 52 years **Mean duration of symptoms;** 23 months **Mean baseline Constant score;** 59.0	Home exercise programme with option to return to physiotherapist for advice and guidance up to a maximum of 4 sessions Comprised 7 strengthening exercises and one cervical stretch, primarily using theraband, with the aim of centering the humeral head and training the scapula stabilisers	Repetitions; 10 Sets; Unclear – encouraged to exercise for 10 to 15 minutes Frequency; at least x 5/ week Duration; 12 weeks No further detail reported	Constant score (0 to 6 weeks) 59.0 to 8.0 = 9.0 mean improvement (significance not reported) Constant score (0 to 12 weeks) 59.0 to 75.0 = 16.0 mean improvement ($p < 0.05$)
(Yiasemides et al. 2011)	Based in Australia Treated by 17 physiotherapists with a range of experience (2 to 28 years of clinical experience) across 1 large centre	n = 51 i) Age > 18 years ii) Symptoms > 1 month iii) Painful active shoulder flexion or abduction iv) Minimum of 140° abduction v) Positive Neer, Hawkins-Kennedy or Jobes test vi) Pain with at least two resisted tests **Mean age of participants;** 58 years **Mean duration of symptoms;** 22 months **Mean baseline SPADI score;** 50.0	Home exercise programme with 1 or 2 sessions with a physiotherapist per week for the first month followed by additional treatment over the next 4 weeks to a maximum of 12 sessions Individualised exercise programme comprised of stretching and strengthening to regain normal dynamic stability	Repetitions; Unclear/ individualised Sets; Unclear/ individualised Frequency; daily Duration; 12 weeks Pain was not permitted during exercise	SPADI (0 to 4 weeks) 50 to 34 = 16 mean improvement (significance not reported) SPADI (0 to 12 weeks) 50 to 21 = 29 mean improvement (significance not reported) SPADI (0 to 24 weeks) 50 to 14 = 36 mean improvement (significance not reported)

Table 2.16 Outcome measures employed by the included studies and a summary of the main outcomes

Primary outcome measure	Psychometric properties	Study	Within-group change (mean unless otherwise indicated)	
Shoulder Pain & Disability Index	Valid, reliable MCIC of 8 to 13 points (Roy et al. 2009)	(Bal et al. 2009)	49.5 at 12/52 (median)	
		(Engebretsen et al. 2009; Engebretsen et al. 2011)	23.0 at 6/52 21.8 at 12/52 24.3 at 18/52 24.8 at 52/52	
		(Kachingwe et al. 2008)	29.6 at 6/52	
		(Kromer et al. 2013)	14.4 at 5/52 21.5 at 12/52	
		(Yiasemides et al. 2011)	16 at 4/52 29 at 12/52 36 at 24/52	
Constant Score	Valid, reliable (Roy et al. 2010) MCIC of 10 points (Kukkonen et al. 2013)	(Calis et al. 2011)	7.9 at 3/52	
		(Giombini et al. 2006)	1.7 at 4/52 3.8 at 6/52	
		(Walther et al. 2004)	9.0 at 6/52 16.0 at 12/52	
Western Ontario Rotator Cuff Index	Valid, reliable (de Witte et al. 2012) MCIC of 12 points (Kirkley et al. 2003)	(Baskurt et al. 2011)	33.8 at 8/52	
		(Martins & Marziale 2012)	Unclear	
Shoulder Rating Questionnaire	Valid, reliable MCIC of 12 points (L'Insalata et al. 1997)	(Ludewig & Borstad 2003)	9.9 at 12/52	
		(Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010)	High dose MET; 25.4 at 12/52 33 at 36/52 35.4 at 60/52	Low dose MET; 7.7 at 12/52 12.5 at 36/52 10.9 at 60/52
Disabilities of the Arm, Shoulder & Hand	Valid, Reliable (Roy et al. 2009) MCIC of 10 points (Roy & Esculier 2011)	(Lombardi et al. 2008)	11.8 at 8/52	

(MCIC; minimal clinically important change)

Post-randomisation follow-up periods ranged from three to 60 weeks (median = 12 weeks). Below 12 weeks of follow-up, six of nine studies (Baskurt et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kachingwe et al. 2008; Kromer et al. 2013; Lombardi et al. 2008; Yiasemides et al. 2011) reported clinically important changes. Of the three that did not, one study (Walther et al. 2004) subsequently demonstrated clinically important changes by 12 weeks but the other two (Calis et al. 2011; Giombini et al. 2006) did not follow up to this time point. At and beyond the 12 week follow-up point, six of seven studies (Bal et al. 2009; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004; Yiasemides et al. 2011) reported clinically important changes with a general trend towards greater change over time.

Below 12 weeks of follow-up; the mean change in SPADI score was 21 (range 14.4 to 29.6); the mean change in Constant score was 5 (range 1.7 to 9.0); only one study provided an

interpretable WORC index score which indicated a 33.8 point change; and only one study provided a DASH score which indicated an 11.8 point change.

At and beyond the 12 week follow-up point; the mean change in SPADI score was 26 (range 21.5 to 36)*; only one study provided a Constant score which indicated a 16.0 point change; the mean change in SRQ score was 19 (range 7.7 to 35.4). At the 12 week follow-up point; the mean change in SPADI score was 24 (range 21.5 to 29). * Bal et al (2009) excluded from this analysis due to reporting of SPADI as median

2.6.2.2 Contextual factors

Eight studies were conducted in Europe (Bal et al. 2009; Baskurt et al. 2011; Calis et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Giombini et al. 2006; Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004); two studies were conducted in North America (Kachingwe et al. 2008; Ludewig & Borstad 2003); two in South America (Lombardi et al. 2008; Martins & Marziale 2012); and one study was conducted in Australia (Yiasemides et al. 2011). In the context of limited data, an association between geographical location and clinical outcome is not clearly supported.

Seven (7/13) studies (Calis et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Giombini et al. 2006; Kachingwe et al. 2008; Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Yiasemides et al. 2011) referred to the therapists involved in the delivery of the exercise interventions. One study (Giombini et al. 2006) referred to a rehabilitation specialist whereas the other six studies referred to physiotherapists. Three studies involved one therapist (Calis et al. 2011; Giombini et al. 2006; Kachingwe et al. 2008), one study utilised two physiotherapists (Engebretsen et al. 2009; Engebretsen et al. 2011), one study utilised three physiotherapists (Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010), one study utilised 12 physiotherapists (Kromer et al. 2013) and one study utilised 17 physiotherapists (Yiasemides et al. 2011). Five studies (Engebretsen et al. 2009; Engebretsen et al. 2011; Kachingwe et al. 2008; Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Yiasemides et al. 2011) referred to the experience of the therapists, typically in relation to the number of years post-qualification. All but one of these studies (Yiasemides et al. 2011) utilised 'experienced' physiotherapists. In the context of limited data, an exercise programme prescribed by physiotherapists seems preferable but an association

between the experience, number of physiotherapists involved in delivery and patient outcome was not clearly supported, i.e. studies including physiotherapists with a range of experience reported results that were at least comparable with those studies that included experienced physiotherapists only.

2.6.2.3 Patient factors

The mean age of the participants was 49 years (range 26 to 58). Ten of 13 studies (Baskurt et al. 2011; Calis et al. 2011; Giombini et al. 2006; Kachingwe et al. 2008; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004; Yiasemides et al. 2011) provided sufficient data to calculate an overall mean duration of symptoms of 19 months (range 3 to 36). An association between age, duration of symptoms, in the context of limited data, and patient-reported outcome was not clearly supported.

All but one of the included studies (Martins & Marziale 2012) described patient-reported pain and disability at baseline. One study (Bal et al. 2009) reported a median value which hampers comparisons with other studies reporting mean values and was hence omitted from this aspect of the synthesis. The mean SPADI score at baseline for the four studies using this measure (Engebretsen et al. 2009; Engebretsen et al. 2011; Kachingwe et al. 2008; Kromer et al. 2013; Yiasemides et al. 2011) was 47 (range 41.3 to 50.0). In the context of limited data and heterogeneity within the presented data, an association between baseline pain and disability and clinical outcome is not clearly supported (figure 2.0). The variability across the other included studies in terms of the PROMs employed and the heterogeneous follow-up points hamper further attempts to usefully synthesise the data.

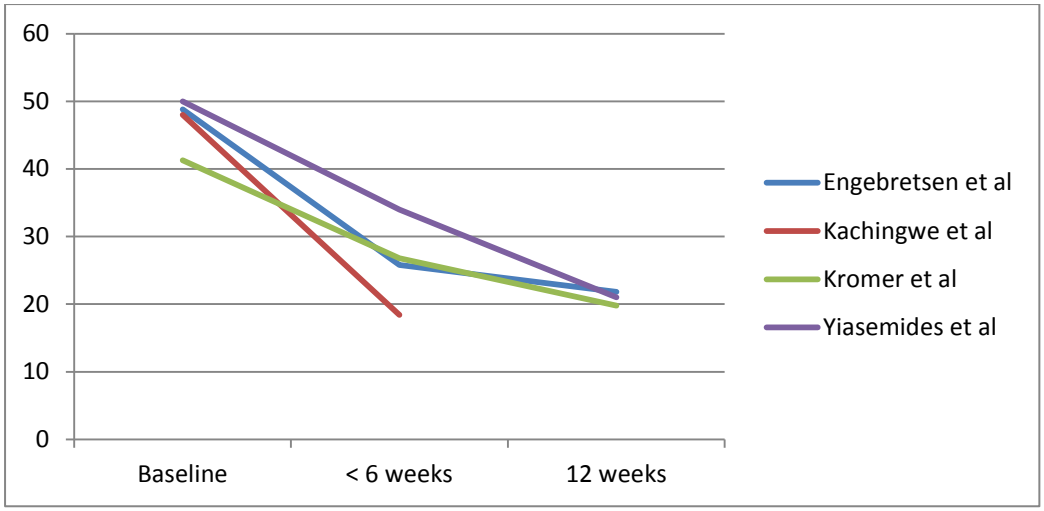


Figure 2.0 Baseline SPADI and follow-up scores

2.6.2.4 Type of exercise

2.6.2.4.1 Home versus clinic based exercise

The included studies evaluated exercise programmes that could be broadly categorised as; home-based (Bal et al. 2009; Giombini et al. 2006; Kachingwe et al. 2008; Ludewig & Borstad 2003; Walther et al. 2004; Yiasemides et al. 2011), home-based with therapist supervision and clinic attendance > 1/ week (Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013), and clinic-based with therapist supervision (Baskurt et al. 2011; Calis et al. 2011; Lombardi et al. 2008; Martins & Marziale 2012; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010). An association between the location of the exercise programme, degree of supervision by the therapist and patient-reported outcome was not clearly supported by this data.

2.6.2.4.2 Content of the exercise programmes

The content of the individual programmes is described in table 2.13. Three of 13 studies (Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Yiasemides et al. 2011) evaluated individually adapted exercise programmes but, in contrast, the majority of studies reported largely formulaic and standardised programmes. However, some level of tailoring of the exercise prescription was evident in the exercise commencement and progression criteria. Seven of 13 studies (Baskurt et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Yiasemides et al. 2011) described their exercise progression criteria; for five of the seven this related to provocation

of pain/ fatigue, i.e. pain/ fatigue not provoked beyond a pre-defined threshold (Baskurt et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010). One study (Lombardi et al. 2008) used the six repetition maximum and one study (Yiasemides et al. 2011) used therapist judgement regarding motor control.

Five of seven adequately reported studies (Baskurt et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Lombardi et al. 2008; Ludewig & Borstad 2003; Yiasemides et al. 2011) did not permit pain production during exercise whereas two studies (Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010). Kromer et al. (2013) utilised a patient-reported numeric rating scale where less than 3/10 pain production was permitted. Osteras et al. (2009; 2010) and Osteras & Torstensen (2010) stated that exercise was undertaken close to the pain–free threshold and should be no worse upon cessation of the exercise. Whether pain production or pain avoidance during exercise is associated with improved clinical outcomes is not clear from this data.

A wide variety of exercises were used across the different studies which, again, hampers attempts at useful synthesis. Most programmes included a number of different exercises but resistance exercises thought to activate the rotator cuff and scapula stabilisers were a central component to most. Typically resistance was achieved using resistive elastic band, for example Theraband. One study (Giombini et al. 2006) omitted resistance exercises from their programme and in doing so reported negligible patient-reported change according to the Constant score at four and six weeks. Osteras et al. (2009; 2010) and Osteras & Torstensen (2010) is the only study to compare exercise intervention versus exercise intervention where high dose exercise conferred superior patient-reported outcomes over low dose exercise.

2.6.2.5 Dosage parameters

2.6.2.5.1 Repetitions

Eight of 13 studies (Baskurt et al. 2011; Calis et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004) adequately reported the number of exercise repetitions prescribed. Five of these studies

(Baskurt et al. 2011; Kromer et al. 2013; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004) prescribed 10 repetitions with two studies (Kromer et al. 2013; Ludewig & Borstad 2003) progressing the number of repetitions according to ability and/ or time rather than maintaining a fixed number. One study (Calis et al. 2011) prescribed five repetitions with five second holds. One study (Lombardi et al. 2008) prescribed 8 repetitions, another (Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) prescribed 30 repetitions and Engebretsen et al. 2009; 2011) prescribed 50 repetitions. Clinically important changes were reported across all repetition prescriptions but Osteras et al. (2009; 2010) and Osteras & Torstensen (2010) reported a dose response effect with higher repetitions and sets conferring superior patient-reported outcomes over lower repetitions and sets.

2.6.2.5.2 Sets

Seven of 13 studies (Baskurt et al. 2011; Calis et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) adequately reported the number of exercise sets prescribed. Five of these studies (Baskurt et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Ludewig & Borstad 2003; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) prescribed three sets. Two studies (Lombardi et al. 2008; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) prescribed two sets and one study (Calis et al. 2011) prescribed one set. In the context of limited data and with knowledge of a potential interaction between repetitions, sets, frequency and duration, an association between number of sets and patient-reported outcome is apparent. Lower numbers of sets, i.e. one and two, are associated with change in patient-reported outcomes that are not regarded as clinically important at three weeks (Calis et al. 2011) and 12 weeks (Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) and of marginal clinical importance at eight weeks (Lombardi et al. 2008).

2.6.2.5.3 Frequency

Twelve of 13 studies (Baskurt et al. 2011; Calis et al. 2011; Engebretsen et al. 2009; Engebretsen et al. 2011; Giombini et al. 2006; Kachingwe et al. 2008; Kromer et al. 2013; Lombardi et al. 2008; Ludewig & Borstad 2003; Martins & Marziale 2012; Osteras et al.

2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004; Yiasemides et al. 2011) adequately reported the frequency of undertaking the prescribed exercise. Of the seven studies that evaluated largely home-based exercise programmes (Engebretsen et al. 2009; Engebretsen et al. 2011; Giombini et al. 2006; Kachingwe et al. 2008; Kromer et al. 2013; Ludewig & Borstad 2003; Walther et al. 2004; Yiasemides et al. 2011), three (Engebretsen et al. 2009; Engebretsen et al. 2011; Kachingwe et al. 2008; Yiasemides et al. 2011) prescribed daily exercise; one (Giombini et al. 2006) prescribed twice-daily exercise; one (Kromer et al. 2013) commenced with twice daily exercise and gradually reduced frequency over time; one (Walther et al. 2004) prescribed a minimum of five exercise sessions per week; one (Ludewig & Borstad 2003) prescribed three exercise sessions per week. Of the five studies that evaluated largely clinic-based exercise programmes (Baskurt et al. 2011; Calis et al. 2011; Lombardi et al. 2008; Martins & Marziale 2012; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010), two (Baskurt et al. 2011; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010) prescribed three exercise sessions per week, three (Calis et al. 2011; Lombardi et al. 2008; Martins & Marziale 2012) prescribed two exercise sessions per week. In the context of limited data and with knowledge of a potential interaction between repetitions, sets, frequency and duration, an association between frequency of undertaking a home exercise programme and patient-reported outcome is not apparent. With regard to frequency of undertaking a clinic-based exercise programme, lower frequency i.e. twice per week, is associated with change in patient-reported outcomes that are not regarded as clinically important at three weeks (Calis et al. 2011) and of marginal clinical importance at eight weeks (Lombardi et al. 2008).

2.6.2.5.4 Duration

All of the included studies adequately reported the duration of the exercise programme. Six studies (Bal et al. 2009; Engebretsen et al. 2009; Engebretsen et al. 2011; Kromer et al. 2013; Osteras et al. 2009; Osteras et al. 2010; Osteras & Torstensen 2010; Walther et al. 2004; Yiasemides et al. 2011) reported a duration of 12 weeks; two (Lombardi et al. 2008; Ludewig & Borstad 2003) reported a duration of eight weeks; three (Baskurt et al. 2011; Kachingwe et al. 2008; Martins & Marziale 2012) reported a duration of six weeks; one (Giombini et al. 2006) reported a duration of four weeks; one (Calis et al. 2011) reported a duration of three weeks. All studies prescribing a twelve week exercise programme reported

clinically important change in patient-reported outcomes except for the low dose exercise intervention evaluated by Osteras et al. (2009; 2010) and Osteras & Torstensen (2010). In contrast, the programmes lasting eight weeks reported change in outcomes that are not regarded as clinically important (Ludewig & Borstad 2003) and of marginal clinical importance (Lombardi et al. 2008). Two of three studies (Baskurt et al. 2011; Kachingwe et al. 2008) reported clinically important change in outcomes at six weeks with the remaining study (Martins & Marziale 2012) providing inadequate data. Exercise programmes lasting four weeks or less were not associated with clinically important change in outcomes.

2.7 Discussion

The limited or heterogeneous data evaluated within this systematic review offers some preliminary guidance in relation to the development and application of an exercise programme for rotator cuff tendinopathy. Geographical location does not appear to be a barrier to achieving clinically important change in patient-reported outcomes and hence such exercise programmes might be regarded as widely applicable. Significant outcomes can be achieved when programmes are prescribed by physiotherapists with varying degrees of experience and so there is pragmatic value associated with such programmes. Similarly, patients of varying age, duration of symptoms and severity of pain and disability can achieve a significant outcome which adds further utility. From the perspective of patient-reported outcome, whether the exercise is completed at home or within a supervised clinic setting does not appear to matter and neither does pain production or pain avoidance during exercise, based upon this data. Inclusion of some level of resisted exercise does seem to matter although the optimal level is unclear and this notion might be challenged in future research. Also unclear is the optimal number of exercise repetitions, although higher repetitions might confer superior outcomes in some circumstances. Three sets of exercise are preferable to two or one set but the optimal frequency, for example daily, three times weekly, is unknown. It can be expected that most exercise programmes should demonstrate clinically important change in patient-reported outcomes by twelve weeks but the potential for achieving significant outcomes is less clear prior to this time point.

In keeping with the findings of Kuhn (2009), described previously, specific guidance regarding the superiority of one or a group of related exercises is not forthcoming from the

available literature. Hanratty et al. (2012) were unable to draw conclusion or offer specific recommendation regarding the content of an exercise programme citing heterogeneity of exercise interventions and poor reporting as barriers. Although limited in similar ways to these previous systematic reviews, this current review has been able to shed some light upon what might and what might not be important when developing and applying an exercise programme. Notably such programmes can be successfully prescribed by a wide range of physiotherapists and undertaken by a wide range of patients in a home-based or clinic setting. Resistance exercise might be an important core component of such programmes but the optimal level of resistance remains unclear. Pain and/ or fatigue can successfully be used to guide treatment prescription but whether pain should be produced or avoided during exercise is not clear; it is possible that such judgements might be most appropriately made in conjunction with knowledge of both patient and therapist preference (Littlewood et al. 2013d). Indeed, it might also be sensible to suggest that, from a pragmatic perspective, decisions regarding exercise dosage, i.e. repetitions, sets and frequency, might also be prescribed in the context of knowledge of relevant patient factors, for example motivation, on the understanding that higher dosage, at least in terms of repetitions and sets, might confer superior outcomes. Finally, based upon what is currently known, an exercise programme should be maintained for at least 12 weeks before a decision regarding the potential of such an approach to confer a clinically important change in outcome is taken.

2.7.1 Implications for this thesis

This review has highlighted the heterogeneity of exercise programmes which limits attempts to synthesise data. Similarly the patient-reported outcome measures are heterogeneous which also limits attempts to synthesise data. Within this current review, the SPADI is the most commonly used outcome measurement tool and an MCIC has been established. Hence the use of the SPADI, considered in more detail later, in future studies appears justified from this perspective.

Resistance appears to be a core component of most exercise programmes that confer clinically significant patient-reported outcomes; this warrants further evaluation within adequately powered and reported RCTs. Although blinding of key study personnel including the patient, therapist and outcome assessor is a consistent weakness of this body of

evidence, it is unlikely that recognition of this will change the way that future studies are conducted. Informed consent requires that the participants understand the content of each treatment arm and, in the absence of credible placebo interventions, in this context patient blinding cannot be maintained. This also has an implication for blinding of the outcome assessor. Where patient reported-outcome are preferred but patients cannot be blinded the outcome assessor cannot be blinded either. Finally, therapist blinding is not practically attainable in this context where a physiotherapist is required to deliver one or the other intervention. Blinding would be a barrier to delivering the intervention.

2.7.2 Limitations of this review

For pragmatic and educational reasons, one reviewer searched, retrieved, extracted and appraised studies. It should be recognised that use of a single reviewer might increase the potential for bias and error during these stages, as recognised previously and hence these limitations should be borne in mind when considering the results of this review.

The search was restricted to studies published in English. It has been suggested that identifying non-English language and unpublished studies for inclusion is important to minimise language and publication bias respectively (Lefebvre et al. 2008). However, this has been questioned and suggested that many unpublished studies eventually become published and truly unpublished studies might have poor or unclear methodology which in turn might serve to introduce bias to any systematic review (van Driel et al. 2009). During the literature searching phase some non-English language articles were identified and partially translated using Google translate where this option was feasible. Similar to the issues raised in relation to unpublished studies, it was apparent that these studies tended to suffer from poor reporting and unclear methodology and hence their potential value to this current systematic review is questionable. With this in mind, it is difficult to determine whether a lack of non-English language or unpublished studies is a weakness of this review and whether inclusion, if available, would alter the conclusions drawn.

2.8 Conclusion

Although the data is limited and there is significant heterogeneity across the different exercise programmes evaluated to date, this systematic review has been able to offer some preliminary guidance in relation to contextual factors and prescription parameters to aid

development and application of exercise programmes for rotator cuff tendinopathy. Specific factors relating to the patient and the physiotherapist, at least as currently reported in RCTs, might not be a barrier to successful outcome and neither is geographical location or setting, for example home- or clinic-based exercise. Resistance exercise might be an important core component of such programmes but the optimal level of resistance remains unclear. Pain and/ or fatigue can successfully be used to guide treatment prescription but whether pain should be produced or avoided during exercise is not clear. Higher doses of exercises might confer superior outcomes and an exercise programme should be maintained for at least 12 weeks before a decision regarding the potential of such an approach to confer a clinically significant change in outcome is taken.

Based upon this, the next chapter will now describe the self-managed exercise intervention that was developed for evaluation within the SELF study (ISRCTN 84709751) (Littlewood et al. 2012c) and consider the selected parameters with reference to the findings from this current review.

Chapter 3: Development of the self-managed exercise programme

*Based upon Littlewood et al (2013d). Development of a self-managed loaded exercise programme for rotator cuff tendinopathy . Physiotherapy 99(4), 358-3 (**Appendix 2**)*

Summary

This chapter describes the self-managed exercise intervention that was developed for evaluation within the SELF study and considers the selected parameters with reference to the findings from the systematic review in chapter two as well as considering potential mechanisms of action.

3.0 Introduction

In 2010, the UK government published its white paper Equity & Excellence: Liberating the National Health Service (NHS)(Department of Health 2010). The emphasis of this paper was towards improving the outcomes of healthcare with the patient at the centre of every decision that is taken. However, this proposition is in the face of significant financial challenges and the need for the NHS to deliver unprecedented efficiency gains.

Self-management has been proffered by some as one solution to this increasingly untenable situation (Barlow et al. 2002). In a situation of rising demand and falling supply, strategies to facilitate self-managed behaviour offer an opportunity to redress the balance by reducing the requirement and hence demand for regular contact with health care professionals. As well as offering a pragmatic solution to an organisational issue, self-management offers opportunities to individualise care and there is evidence to suggest that an approach where patients are encouraged to take responsibility for their own care is at least comparable to treatment requiring regular clinic attendance, as described in the previous chapter.

Additionally, it has been suggested that rotator cuff tendinopathy is a common problem with increasing prevalence as age increases (Littlewood et al. 2013a). Hence it is expected that the demand for health care in this area will increase as the population ages. It has also been identified that this condition is resistant to treatment and possibly recurrent in nature in certain populations (Chard, et al. 1988a; Croft et al. 1996; Luime et al. 2005) and so it is hypothesised that outcomes will be superior where the patients are equipped to deal with

this condition on an on-going basis. It is upon this background and the literature reviews from the previous chapter that this chapter describes the self-managed exercise programme developed for evaluation within the SELF study; the methods of which are described in detail in subsequent chapters.

3.1 An introduction to the self-managed exercise intervention

The intervention is self-managed exercise. The exercise, prescribed by the physiotherapist but completed by the patient, involves exercising the affected shoulder against gravity, a resistive therapeutic band or hand weight over three sets of ten to 15 repetitions twice per day. This exercise can be uncomfortable but is prescribed to ensure that this is manageable. Exercise prescription is guided by symptomatic response requiring that pain is produced during exercise but symptoms are no worse upon cessation, i.e. within one to two minutes following the test (Littlewood & May 2007; McKenzie & May 2000). Participants with more severe symptoms tend to commence a lighter regime initially and a typical outline programme is presented in figure 3.1 which is adapted to meet individual needs.

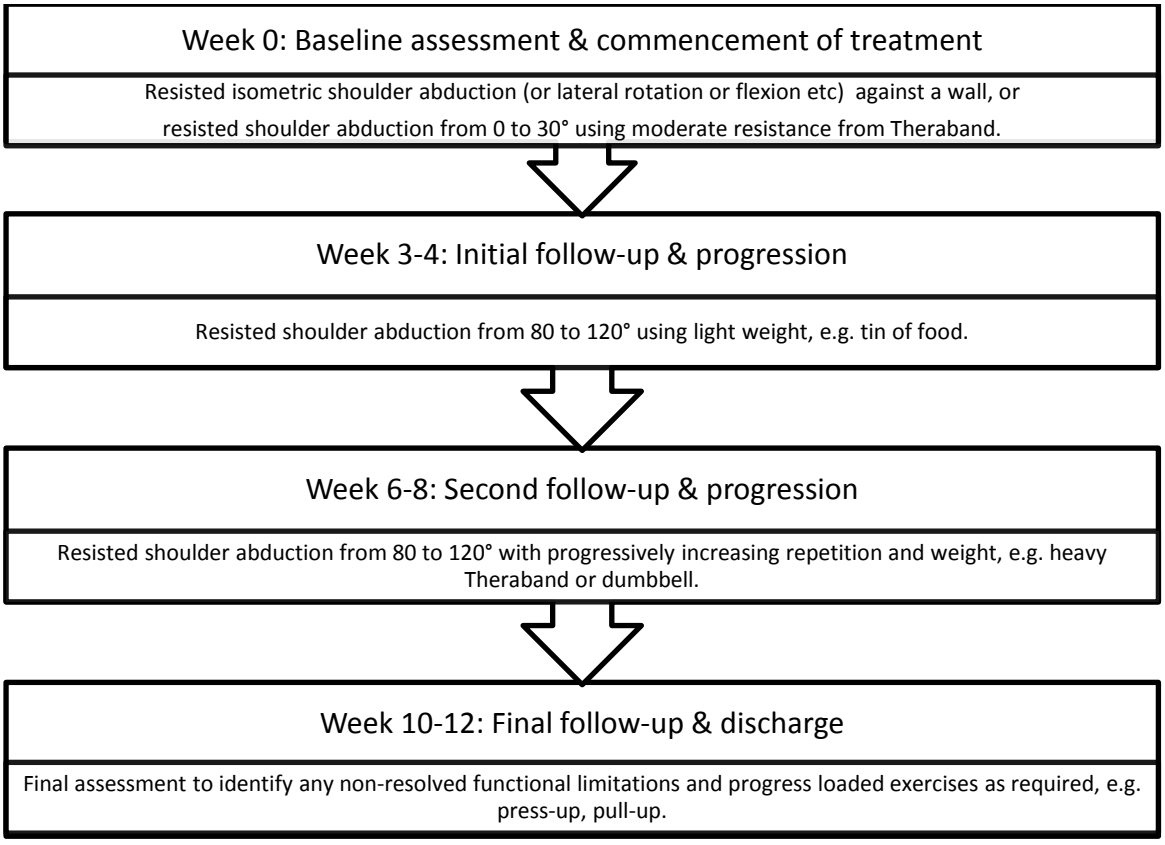


Figure 3.1 Typical loaded exercise programme and progression

The self-managed intervention comprises only one exercise at any one time and is targeted at the most symptomatic direction of movement initially, usually abduction or lateral rotation, providing that the symptoms are no worse after loading. If symptoms are provoked during initial testing and subsequently made worse, then a different direction would be selected, for example lateral rotation rather than abduction. Although the patients are asked to undertake only one type of exercise they are taught how to regress or progress the exercise as indicated; for example, if pain is no longer produced during exercise then that might be a stimulus to progress the exercise or if pain remained worse after the exercise then that might be a stimulus to regress the exercise.

3.1.1 Pathoaetiology; what is causing the pain of rotator cuff tendinopathy?

*Based upon Littlewood et al (2013b). The central nervous system – An additional consideration in 'rotator cuff tendinopathy' and a potential basis for understanding response to loaded therapeutic exercise. Manual Therapy 18(6), 468-472 (**Appendix 3**)*

Despite being a common and well-recognised clinical presentation, a definitive understanding of the pathoaetiology of rotator cuff tendinopathy or these 'subacromial' pain syndromes remains elusive (Lewis 2009; Rees et al. 2013; Rio et al. 2014). Using magnetic resonance imaging, Frost et al. (1999) could not distinguish individuals diagnosed with subacromial impingement from asymptomatic age-matched controls according to structural pathology. In keeping with this, up to 40% of the general population have asymptomatic rotator cuff tears (Templehof et al. 1999; Worland et al. 2003; Yamamoto et al. 2010). Studies investigating prognosis have suggested that the biomedical diagnosis, relating to specific tissues at fault, was not associated with clinical outcomes (Littlewood et al. 2013a). Furthermore, it has been reported that structural change does not explain response to therapeutic exercise because, as clinical outcomes improve, a corresponding change in observable structural pathology is not seen (Drew et al. 2012). Hence, in the context of this literature, the limitations of suggesting that tissue injury/ structural pathology result in nocioceptive input and a pain response in proportion to the extent of injury seem inadequate, if considered in isolation.

Others have suggested a local biochemical basis for the pain associated with tendinopathy where biochemical mediators in the tissue stimulate nocioceptive afferent fibres (Khan et al. 2000). Degenerative pathology is associated with neurovascular ingrowth and potential pain mediators such as substance P and acetylcholine. However, it remains unclear whether

biochemical substances are a cause of tissue degradation and/ or pain or whether they are an associated by-product of tendinopathy (Danielson 2009). But, because biochemical models make no assumption about the underlying pathology, such biochemically driven nocioceptive pathways might offer further understanding of symptomatic versus asymptomatic pathology and further research in this area is ongoing (Rees et al. 2013).

However, one perspective that is not widely considered is the role of the CNS. It is also not recognised that, critically, nocioception is neither sufficient nor necessary for a pain experience (Moseley 2007; Rio et al. 2014). A contemporary understanding of pain suggests that there might be other mechanisms involved in pain associated with tendinopathy that might act with the local mechanisms outlined above or in isolation.

Hence for the purpose of this thesis, the pathoaetiology of rotator cuff tendinopathy is recognised as being poorly understood but likely to be multi-factorial in nature. However, it is suggested that the pain associated with rotator cuff tendinopathy should be evaluated within a framework that recognises the potential for altered processing and modulated output of the CNS rather than solely a product of peripherally-driven nocioception secondary to persistent tissue abnormality, for example tendon degeneration or tear.

3.1.1.1 Rationale for response to loaded therapeutic exercise

From a biological perspective initially, tendons are regarded as being mechanosensitive, which means they are capable of responding to mechanical stimuli (Maffulli & Longo 2008). The term 'mechanotherapy' has been coined to describe how a programme of structured exercise might stimulate human tissue and reverse tendon de-conditioning (Reeves 2006; Abate et al. 2009; Khan & Scott 2011). It is proposed that a progressive exercise regime will stimulate a process of re-conditioning and improve the capacity of the rotator cuff to withstand greater load and stress (McKenzie & May 2000; Reeves 2006; Kjaer et al. 2009). This idea has been substantiated in the literature where tendon tissue has been shown to become stronger through increases in tensile strength and elastic stiffness in response to programmes of structured exercise (Abate et al. 2009).

In addition to local biological changes, it is feasible that appropriate prescription of therapeutic exercise has an impact upon CNS scrutiny or processing with a resultant modified output (Gifford 1998). From a psychological perspective, the prescription of

exercise within a framework that suggests hurt does not equal harm; hurt, in some circumstances, equals a tissue that is de-conditioned and needs using/exercising, has the potential to reframe the meaning of pain (Butler & Moseley 2003). In addition to this, a progressive exercise programme has the capacity to address the hypothesised de-conditioning as the frequency and load of exercise increases over time (Reeves 2006). Basically, if the way a person conceives their shoulder pain is adapted then there is potential for beneficial change in CNS output to be realised, particularly if the prescribed exercise programme resembles their usual functional activities (Gifford 1998). Clearly, in this context, intelligent but individualised prescription of therapeutic exercise and return to normal function is required that does not provoke a threat response from the CNS in terms of a lasting and exaggerated pain output (Gifford 1998). In practice this requires that our patients have an understanding of why the exercise has been prescribed, that hurt does not equal harm, in their circumstance, and it requires an understanding of the patient's acceptable pain response. Although an inexact science for which the boundaries have not yet been adequately defined, acceptable pain responses can be elicited through simple questioning, for example; *'Is that amount of pain acceptable to you while you are exercising or after you have exercised? Should we add more/ less load?'*

Finally, from a social perspective, in terms of the influence of surroundings and significant others, the prescription of loaded exercise within this framework challenges diagnostic and therapeutic approaches that promote fear avoidance, for example *'the pain is a sign of further tissue damage so don't move it if it is painful.'* Such prescription also has the potential to challenge public perception that hurt equals harm in all circumstances. As opposed to some previous approaches, a constructive, non-threatening means around which restoration of function can be achieved is offered.

It is apparent that the pain associated with rotator cuff tendinopathy is likely to be multi-dimensional. The key to future success will be to discover indicators of each dimension along with reasoned and relevant multi-dimensional management strategies. However, at this stage figure 3.2 summarises the rationale underpinning the prescription of exercise within this thesis. It can be conceptualised as a process beginning with perceived tissue de-conditioning, secondary to a known or unknown cause, for example chronic underuse. An episode of relative overuse or overload results in short term tissue responses that are

scrutinised by the CNS in the context of other inputs and the surrounding environment and, if the input is regarded as a threat, a painful output as a means of protection will ensue. In this situation this might promote avoidance of shoulder movement if the pain is believed to be indicative of harm, and will also result in a unique pain experience, for example absence from work and low mood due to activity withdrawal. Such fear avoidance might result in further tissue de-conditioning and a continuation of the cycle. However, appropriate contextualisation and intervention might result in a different outcome. If pain is regarded as a sign of de-conditioning rather than actual or impending tissue damage then an alternative process of CNS scrutiny might result in an active output, for example engagement with a structured exercise regime, with the potential to re-condition peripheral (tendon) and central tissue. Additionally, active engagement and 'permission' to resume normal activity without fear of causing harm to self might facilitate an improved outcome in contrast to existing approaches.

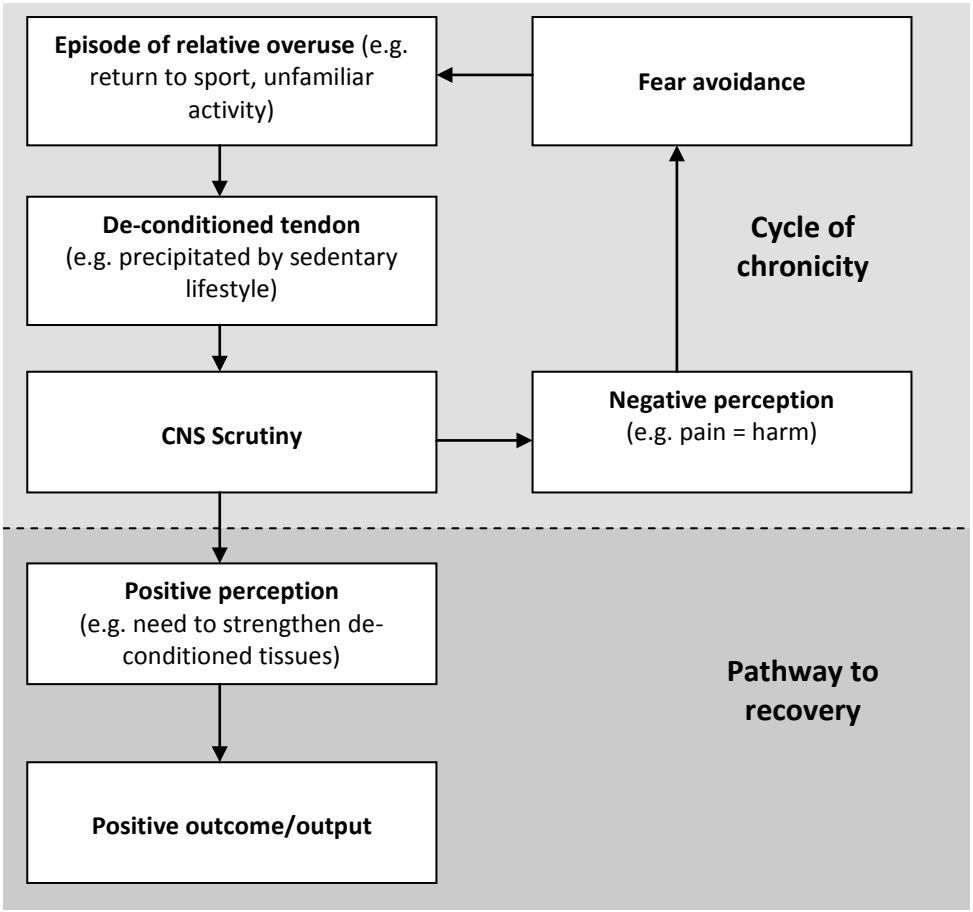


Figure 3.2 Summary of the rationale underpinning the prescription of therapeutic exercise

Although it is suggested that a majority of patients managed routinely in the UK NHS might benefit from conceptualisation of their presenting problem within this framework, there are exceptions and additional considerations need to be made. In the context of this thesis, de-conditioned refers to the capacity of the tendon, or person, to deal with the task(s) in hand. However, it is suggested, that there are two components to this; a. the amount of load, b. the 'condition' of the tendon. For the vast majority of people encountered in routine UK NHS practice it is proposed that the predominant problem relates to the 'condition' of the tendon because it is assumed that the amount of daily load is not excessive and the deficit relates to the capacity of the tendon rather than excess or deleterious load. However, on the few occasions that, for example, an athlete with high functional demand is encountered then load management needs to be considered, i.e. reducing the deleterious load, to enable recovery while tendon condition is maintained or even improved through a structured programme of exercise.

3.1.2 Is the self-managed exercise intervention evidence-based?

As a pre-cursor to considering whether the self-managed exercise intervention developed for evaluation within the SELF study is evidence-based, table 3.1 summarises the recommendations from the review in the previous chapter and indicates whether this current intervention meets those recommendations.

Table 3.1 Summary of review recommendations and indication of whether the recommendation is met by the current self-managed exercise intervention

Factor	Descriptor	Met?
Location	Global applicability	✓
	Home or clinic-based	✓
Therapist	Physiotherapists of varying experience	✓
Patient	Patients with varying age, duration and severity of symptoms	✓
Type of exercise	Resistance based programme	✓
Repetitions	High repetitions	?
Sets	Three sets preferred to one or two	✓
Frequency	Unknown	?
Duration	Minimum of 12 weeks	✓
Exercise prescription and progression guidance	Pain, strength or therapist judgement for initial prescription guidance	✓
	Pain provoked or not during exercise	?

In the context of the limited data presented in the systematic review in chapter two, the basic appraisal summarised in table 3.1 suggests that the self-managed exercise intervention should largely be regarded as being grounded upon the recommendations from the evidence base at our current disposal. But, of course, some aspects warrant further consideration. In contrast to most studies, the self-managed exercise programme described here employs a single exercise approach. This is preferred for two main reasons: (1) As a pragmatic time-saving solution that might facilitate successful engagement with the exercise programme where low levels of engagement with exercise programmes are a widely recognised problem which potentially limits the opportunity for a favourable outcome. It is suggested that single exercise prescription minimises some of the barriers that patients might face in terms of time to complete and recall which hence might increase the exercise dosage applied, in keeping with the recommendations. (2) The incremental benefit of adding more exercises that are theoretically stressing the same tissue is unknown and it is possible that such additions are unnecessary.

A further issue that might be perceived as a consequence of a single exercise approach is that exercises regarded as specific scapula stabilisation exercises to address perceived scapula dyskinesis would generally be omitted. In this context, this might be regarded as a concern because recognition of scapula dyskinesis and prescription of specific exercises to correct these positional or movement aberrations form a key component of much of current physiotherapy practice in the UK (Littlewood et al. 2012a). Although scapula dyskinesis is

widely believed to be relevant in the onset and development of rotator cuff tendinopathy (Kibler 2003), this has been increasingly questioned (Ratcliffe et al. 2013).

It seems logical to suggest that if scapula dyskinesis contributes to painful shoulder syndromes then such movement aberrations would present more in those complaining of shoulder pain and less so in those who do not complain of shoulder pain. Previous studies have investigated whether there is such an association between dyskinesia, measured in various ways, and shoulder pain and have concluded that the evidence does not support such a theory (Catlin et al. 1995; Lucasiewicz et al. 1999). This evidence highlights that scapula dyskinesis is present in those with and without painful shoulder syndromes. Further to this, a recent study evaluated movement of the scapula in healthy subjects (Morais & Pascoal 2013). In comparison to the scapula of the non-dominant shoulder, this study found that the scapula of the dominant shoulder showed greater retraction and upward rotation at all points during elevation of the arm. This is an interesting finding because the presence, absence or relevance of scapula dyskinesis in a painful shoulder syndrome is often identified in comparison to the asymptomatic shoulder. This study questions the validity of such an assessment process and also further highlights the presence of relative movement differences in the scapulae of asymptomatic or healthy individuals. Furthermore, Struyf et al. (2013) evaluated the effect of a scapula focused rehabilitation programme incorporating specific scapula stabilisation exercises and manual therapy. They found that despite significant improvements in shoulder pain and disability at the end of treatment and after three months, the measurements of scapula dyskinesis did not change. Although there are methodological limitations recognised across this body of literature (Ratcliffe et al. 2013) it does seem justifiable to question the role and relevance of scapula stabilisation exercises for scapula dyskinesis in the rehabilitation of rotator cuff tendinopathy. This perspective might change as new data becomes available but it is interesting to note a similar theme in relation to low back pain. A recent systematic review by Laird et al. (2012) found that movement-based interventions for low back pain, for example stabilisation exercises, were rarely found to be effective for changing observable movement patterns, for example dyskinesia. Thus it is suggested, at this stage, that there is sufficient uncertainty regarding the relevance of scapula dyskinesis to defend the omission of specific scapula stabilisation exercises from an evidence-based exercise programme.

Returning to the recommendations from the systematic review, it is suggested that higher repetitions are preferable to lower repetitions but an absolute recommendation is lacking. The self-managed programme described here prescribes 10 to 15 repetitions twice per day within a pragmatic framework that allows adjustment for specific factors relating to the patient, for example degree of pain provocation. Such an approach is in keeping with the majority of studies included in the review but at this stage it is unclear whether such an approach is facilitating an optimal dosage.

Following on from this point, the exercise is prescribed for twice daily completion which is in keeping with some studies but not others and no definitive guidance can be generated from the review. Hence, again, it is unclear whether such an approach is facilitating an optimal dosage.

Possibly the most contentious aspect of the self-managed exercise programme is that pain provocation is desired during the activity. This is in contrast to the beliefs of the majority of physiotherapists in the UK who regard themselves as having a special interest in shoulder disorders (Littlewood et al. 2012a). The source of this disparity in belief that exercises should or shouldn't be painful is unclear. In relation to the rotator cuff some of these perceptions might be historical in nature and relate to Neer's model of impingement that suggested subacromial pain was secondary to abrasion and inflammation and hence should be avoided (Neer 1972). In contrast, the systematic review presented in chapter two highlights favourable patient-reported outcomes in exercises programmes that both permitted and prevented pain or discomfort during exercise. Furthermore, other studies, excluded from the systematic review due to issues related to design and intervention have also reported favourable outcomes when painful loaded exercise has been prescribed (Bernhardsson et al. 2010; Holmgren et al. 2012; Jonsson et al. 2005; Maenhout et al. 2013). The findings from the work of these authors are in keeping with the pioneering work undertaken by Alfredson in Sweden in relation to the Achilles tendon which has revolutionised rehabilitation of Achilles tendinopathy (Alfredson et al. 1998). Despite this, based upon the findings of the systematic review, it seems fair to suggest that the presence or absence of pain provocation might not be the key factor in achieving optimal patient-reported outcomes in relation to the rotator cuff. This suggestion is put forward at this time based upon current data because studies evaluating both painful and non-painful exercise

programmes have reported clinically significant outcomes. However, for the purpose of this thesis, a painful exercise programme is favoured and a theoretical rationale underpinning that choice has been presented above from a biopsychosocial perspective.

The final aspect of the exercise programme that warrants further consideration at this stage is the duration. In keeping with the recommendations from the review, this exercise programme is prescribed over a 12 week period but the framework suggests that the duration should be adapted to meet the needs of the individual. In this situation, the treating physiotherapist and patient will determine the point of treatment cessation. It is recognised that a favourable response might require a minimum of 12 weeks but the choice to omit a pre-specified time frame reflects the nature and response times of individual patients and thus is felt to be more pragmatic in nature.

3.1.3 The self-managed framework

The exercise is operationalized within a self-managed framework. Here self-management refers to situations where people are encouraged to actively manage their symptoms, treatment, consequences and life-style changes associated with their condition (Barlow et al. 2002; Lorig & Holman 2003). This process is facilitated through an equal therapeutic alliance, or partnership, between patient and therapist. The self-managed framework consists of several inter-connecting components currently regarded as effective mechanisms by which to enhance self-efficacy and facilitate self-management (de Silva2011; Jones 2006) and are depicted in figure 3.3.

Figure 3.3 Components of the self-managed framework

3.1.3.1 Knowledge transfer

In line with the Common Sense Model of self-regulation of health and illness (Hale et al. 2007; McAndrew et al. 2008; Newman et al. 2009; Phillips et al. 2011), how the patient perceives the problem is pivotal. Success of the intervention is dependent upon the patient interpreting their pain response in a way that facilitates the use of exercise as a management strategy. If beliefs persist that the pain is a sign of tissue damage and that rest is required to enable the tissue to recover then it is doubtful that the programme could be implemented successfully. Such an appraisal would result in avoidance behaviour and would preclude any level of engagement. To address this concern, the patient is encouraged to communicate their understanding of the problem and the therapist is encouraged to frame the discussion from the perspective that the muscles and tendons are de-conditioned (or weakened or lacking fitness) and need a progressive programme of exercise to restore condition and function. Description of tissue-based pathology, for example rotator cuff tear, is avoided, or challenged. In this situation, reliance is placed upon the development of a therapeutic alliance where doubts and concerns can be expressed by the patient and reassurance offered by the physiotherapist along with an acceptable explanation of the cause of the problem. The purpose of this knowledge translation is to facilitate understanding upon which a successful partnership can be developed. Understanding is re-

visited using simple questions such as: What do you understand is the cause of your problem? Why could exercise help?

3.1.3.2 Skill attainment

Enhancement of self-efficacy expectation, defined as the confidence or conviction that one can successfully perform a specific task or behaviour (Newman et al. 2009), which is one of the major constructs of Bandura's Social Cognitive Theory of behaviour change (Newman et al. 2009), is a key goal of this self-management programme. Bandura (1977) suggested that behaviour is directly influenced by self-efficacy expectations and indirectly by outcome expectations which he defined as a person's estimate that certain behaviour, for example regular exercise, will lead to certain outcomes, for example reduced shoulder pain. Bandura (1977) qualified this by suggesting that a person might believe that, for example, exercise has the potential to remedy their shoulder complaint but if they doubt whether they can successfully undertake the programme due to, for example, time limitations or technical difficulties, then their behaviour will not change. Four potential strategies to enhance self-efficacy expectations have been suggested; mastery, modelling, interpreting physiological signs and feedback/ persuasion (Jones 2006; Bandura 1977); depicted in figure 3.4.

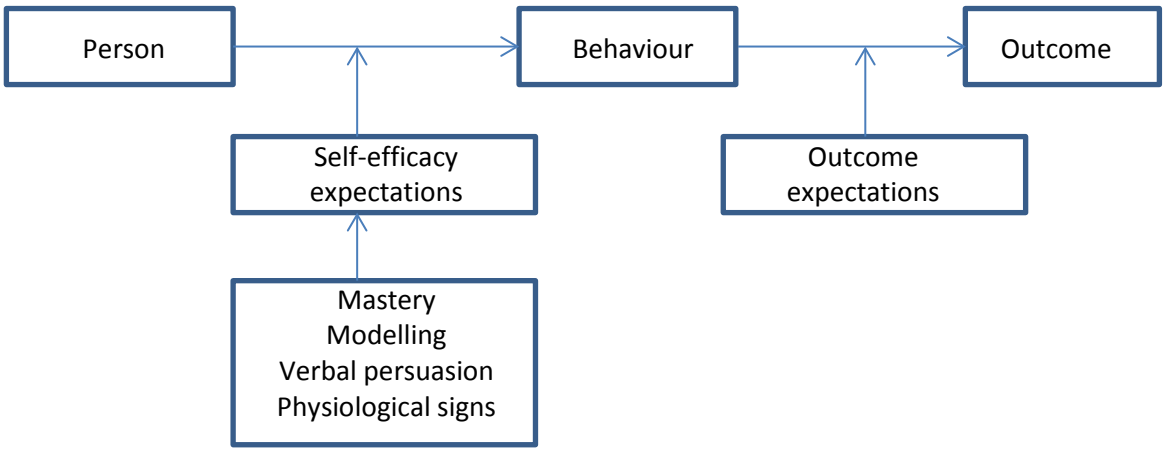


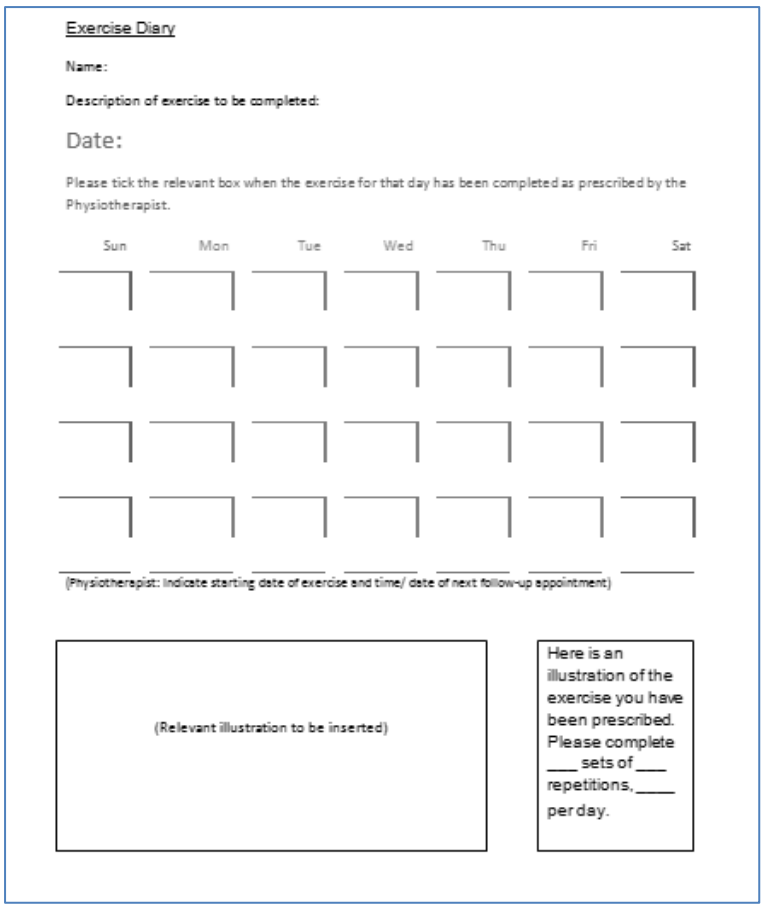
Figure 3.4 Role of self-efficacy and outcome expectation in Social Cognitive Theory (adapted from Bandura 1977)

Enhancement of self-efficacy is seen as a key component to facilitate regular engagement with the programme and a large body of evidence supports this notion (Newman et al. 2009). A single exercise is prescribed and although progressions and regressions of the exercise are discussed, only one exercise is completed at any one time. The reason for this

restricted prescription is pragmatic in nature, as discussed previously, but it is expected that a simple prescription will also facilitate mastery of the task (Newman et al. 2009). The patients have the opportunity to observe the therapist undertaking the exercise and subsequently model their behaviour on that of the therapist whilst repeating the exercise themselves. This is reinforced by a diagram, drawn by the patient, on an exercise diary (figure 3.5) which serves as a visual memory stimulus.

3.1.3.3 Self-monitoring

Self-monitoring and appropriate interpretation of physiological signs is regarded as a cornerstone of successful self-management (Newman et al. 2009). Within this programme the patients are encouraged to monitor their pain response whilst exercising, which is recorded in the self-report diary, in the knowledge that pain should be produced whilst exercising but should be no worse upon cessation. When the pain response abates this is the stimulus to progress the exercise. In contrast to others who have used a numeric pain rating scale, for example pain no greater than 5/10 (Holmgren et al. 2012), to guide exercise progression, the intervention described here enables the patient to judge what is manageable in terms of symptom response. This decision reflects individual perceptions of what constitutes acceptability in terms of pain. Some patients might be more tolerant and more willing than others to provoke pain whilst exercising and it is felt unwise to limit the potential of some because of unsubstantiated fears relating to potential tissue damage.



Exercise Diary

Name:

Description of exercise to be completed:

Date:

Please tick the relevant box when the exercise for that day has been completed as prescribed by the Physiotherapist.

Sun	Mon	Tue	Wed	Thu	Fri	Sat

(Physiotherapist: indicate starting date of exercise and time/ date of next follow-up appointment)

(Relevant illustration to be inserted)

Here is an illustration of the exercise you have been prescribed. Please complete ___ sets of ___ repetitions, ____ per day.

Figure 3.5 Sample exercise diary

3.1.3.4 Goal setting

At the initial meeting between physiotherapist and patient, goals are set using the patient specific functional scale (PSFS) (Stratford et al. 1995) as a guide. The PSFS is a patient-specific measure which investigates functional status. The PSFS has been shown to be valid and responsive in various musculoskeletal populations (Sterling 2007). The PSFS is completed at baseline and then completed, until the end of the treatment episode, in the presence of the attending physiotherapist. A goal is negotiated, for example being able to reach into a cupboard, and the current level of difficulty is established. This is monitored, discussed at follow-up appointments and new goals set as appropriate. Such a component has the capacity to be a useful form of mid- to long-term self-monitoring by offering reassurance regarding progress. The primary aim of the self-managed exercise programme is to facilitate movement and functional restoration and goal setting is encouraged along these lines.

3.1.3.5 Problem solving

Following this the patients are encouraged to consider any barriers to implementation. Some pragmatic solutions to common problems, particularly time limitations, are factored in to the intervention but the idea is raised pro-actively by the physiotherapist at the initial meeting by asking the patient how confident they are that they will be able to complete the task in hand. Any uncertainty is discussed and the patient is encouraged to consider potential solutions. Barriers to implementation are also raised and discussed with reference to the exercise diary at subsequent follow-up appointments.

3.1.3.6 Pro-active follow-up

The patients are offered the opportunity to return to the clinic at a convenient and appropriate time with the intention that this meeting will offer the opportunity for useful feedback and possibly the opportunity for persuasive intervention by the therapist if difficulties have been encountered (Jones 2006). Typically follow-up appointments are scheduled on a monthly basis to begin with but the needs of the patients inform this decision. For example, some patients feel confident and able following the initial meeting and do not require a scheduled follow-up appointment, only the opportunity to contact the physiotherapist should things not go to plan. Conversely some patients will return to the physiotherapist within a few days to seek re-assurance and guidance where necessary. The flow of a typical follow-up session is displayed in figure 3.6.

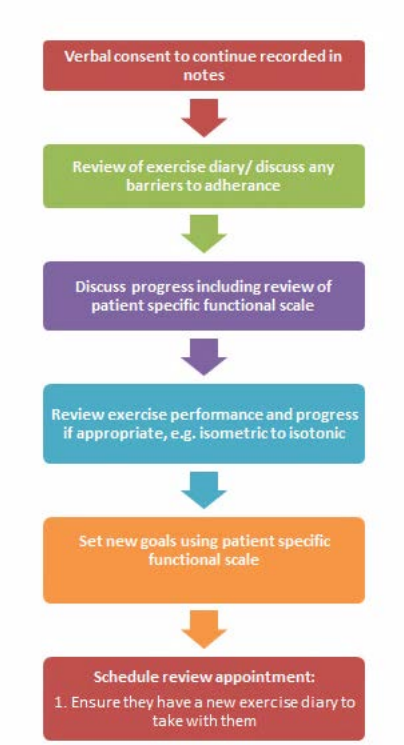


Figure 3.6 The flow of a typical follow-up appointment

This intervention has been designed with practice context in mind where typical physiotherapy appointments consist of an initial session lasting 40 minutes and subsequent sessions lasting 20 minutes. The intervention requires minimal training and can be adopted in the current practice context from a logistical perspective.

3.2 Conclusion

This chapter has described and appraised the self-managed exercise programme which has been designed to address the pain and disability associated with rotator cuff tendinopathy for evaluation within the SELF study. Although there is some uncertainty it is suggested that the exercise programme largely reflects the recommendations arising from the current evidence base and hence is a valid intervention that warrants further evaluation. The subsequent chapter will now describe the methodology underpinning this evaluation with further subsequent chapters detailing the specific research methods and results.

Chapter 4: Research methodology

Summary

This chapter introduces the methodological approach taken in this thesis. The choice of approach is initially framed within a relevant paradigm before a justification of the research methodology and methods is presented.

4.0 Introduction and overview

The SELF study is a mixed-methods study designed to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders (tendinopathy). Additionally, the study aimed to evaluate treatment adherence and experience, particularly in relation to any barriers to implementation of the self-managed exercise programme, from the perspective of both the patient and physiotherapist. In this multiphase design, four main phases were conducted over time. These phases were a preliminary patient and public involvement event informing study design and delivery of the intervention, a mixed-methods pilot study, a quantitative study evaluating clinical and cost-effectiveness and a further qualitative study exploring participant experience. The study design is sequential in nature with interaction between the qualitative and quantitative methodologies.

4.1 Research paradigm

This thesis is presented from a critical realist ontological perspective. Ontology refers to the nature of the world and what we can know about it (Ritchie & Spencer 1994) and critical realism has been defined by Creswell & Clark (2011) as a perspective where the real world exists independently of our perceptions and constructions but the understanding of this world is constructed from our own perspectives and viewpoints.

As a basis for a mixed-methods study, the realisation of this ontological perspective is important. Within the context of the current clinical community, a realist perspective is evident where a RCT would be regarded by many as the most appropriate research design to enable an evaluation of effectiveness (Littlewood 2011; O'Cathain et al. 2010). Realism relates to the idea of an external reality independent of individual perceptions and

constructions (Ritchie & Spencer 1994). In the realist paradigm the idea of an external reality applicable to a population holds true where a summary measure is derived at a group level and used to inform clinical decision making at an individual patient level (Mengshoel 2012). This realist ontological perspective aligns with a positivist epistemological stance which in turn aligns with quantitative methodology which tends to be reductionist in nature (Ritchie & Spencer 1994). Within this thesis this author does not currently wish to contest the role of quantitative research methodology but instead would prefer to offer enhancements, in light of what is known, to further understanding and add new knowledge.

Here the critical realist perspective is offered as an advancement that will be readily recognised by most clinicians. In relation to rotator cuff tendinopathy this theoretical or philosophical position is taken to mean that the clinical presentation exists independently of individual construction but the perceptions and beliefs of a person generate an individual experience. This stance is highlighted in chapters one and three where the role of the CNS in rotator cuff tendinopathy is highlighted and individual presentations in terms of pain and disability are considered based upon this model. For example, whereas some will choose to continue working, others will not and whereas some will choose to access health care, others will not. There is clearly an individual aspect that needs to be considered, which is recognised in the world view of a critical realist where a constructivist epistemological stance, which offers understanding of phenomena through the interpretations of individuals (Creswell & Clark 2011), is valued. Such a constructivist approach tends to align with qualitative methodology. This perspective resonates with that of the World Health Organisation (WHO) who in 2001 proposed the International Classification of Functioning, Disability and Health (ICF) as a framework for classifying the aspects of health and the consequence of disease (Bossmann et al. 2011; Ustun et al. 2010). The ICF suggests that the problems associated with a disease might concern body functions and structures as well as the activities and participation in life situations. Furthermore, such problems might be modified by contextual factors including environmental and personal factors. Hence, the critical realist perspective aligns well with that of the WHO where commonalities across presentations are recognised in tandem with the individualised experience.

It is the belief here that the theoretical or philosophical position of critical realism lends itself to both positivist and constructivist approaches to research. Hence in terms of research methodology within this thesis, a pure quantitative or qualitative methodology appears inadequate. A case for a mixed-methods approach is evident and necessitated by the nature of the research question. Mixed-methods research has been defined as the integration of qualitative and quantitative research approaches (Creswell & Clark 2011) and it is suggested that a pluralistic approach to combining research methods is needed to enhance the breadth and depth of understanding in this area, particularly where the output of research will be used to inform decision-making at the level of the individual patient. It is in this context that a rationale for a mixed-methods approach is presented.

4.1.1 Mixed-methods research

Over recent decades the use of mixed-methods research has developed as 'paradigm wars' relating to the incompatibility of qualitative and quantitative research have subsided and the value of such a methodology has been recognised in a complex social world (Creswell & Clark 2011; O'Cathain et al. 2010; O'Cathain et al. 2007; Bergman 2011). In contrast to some, proponents of mixed methods research suggest that quantitative and qualitative paradigms can be mixed to develop a better understanding of research problems than what would be achieved by using either approach alone (Creswell & Clark 2011). Enhanced understanding is a central premise underlying the use of mixed-methods research (Creswell & Clark 2011; O'Cathain et al. 2010).

In the context of current literature, this notion of enhanced understanding appears important but under-recognised where it is not uncommon for RCTs to conclude in favour of the null hypothesis, suggesting no difference or clinically insignificant differences between interventions. A lack of statistical power is a common reason for statistically insignificant results (Pike & Leith 2009) and it is also possible that a true difference does not exist between interventions and that both should be regarded as equally effective or ineffective. Both of these reasons appear entirely feasible. However, with regard to the latter option, within a pure quantitative paradigm, the reasons for a lack of superiority remain unknown. It seems surprising that such a pure paradigm persists in the context of frequent null findings, particularly when a favourable theoretical argument, at least, will have been proposed prior to initiating a RCT. In the UK, research protocols are developed to persuade

ethical review committees and funding bodies of proof of concept before such studies are initiated so it is interesting that null findings are so common.

In the context of this study, which evaluated a complex intervention, the need for mixed-methods research is clearly evident. It is widely recognised now that evaluation means more than investigating effectiveness in a tightly controlled research environment (O'Cathain 2009). Implementation in the real-world is also a key aspect of an evaluative process. Previously Littlewood et al (2012a) recognised that the self-managed exercise programme did not fully align with current practice. The intervention is painful and delivered within a self-managed framework which was expected to raise challenges to both the physiotherapists and patient participants involved. Despite a theoretical rationale supporting efficacy along with other preliminary research in different environments, these factors might impact upon implementation and hence outcome. If the intervention is not delivered as intended or if adherence to exercise is compromised it is expected that the treatment outcomes will be compromised. When interpreting the data from such a study it is vital to recognise which factors might enhance or detract from the outcomes. Such an assessment enables interventions regarded as equivalent to be developed, where appropriate, rather than further time and resource being used to develop new interventions which are destined to also be regarded as equivalent. Indeed it almost seems arrogant to ignore the potential for iterative development of interventions whilst exposing them to evaluation in RCTs. In keeping with this stance, (Oakley et al. 2006) advocate what might be regarded as process evaluation alongside clinical trials.

So, although a quantitative study is currently widely accepted as being required to determine if one group performs better than another, qualitative enquiry is needed to offer an optimal platform upon which to conduct a study and to also explore the multiple perspectives of the participants involved to understand individual experience. Clearly a pluralistic rather than purist approach is needed to develop understanding here (O'Cathain et al. 2007).

4.1.2 Mixed-methods design of the SELF study

Although qualitative and quantitative methods were used sequentially in this study it is described as a multiphase study by Creswell & Plano Clark (2011) because of the multiple,

sequentially aligned, phases with each phase building upon the previous one. To highlight this, a patient and public involvement event was conducted to inform design of a quantitative pilot and subsequent substantive RCT. Then, the outcome from the RCT informed the sampling frame of the second qualitative stage which aimed to better understand outcome in terms of barriers to implementation from the perspective of the patients and physiotherapists.

The following chapter will now report upon the patient and public event which was conducted prior to submission of the SELF study protocol for ethical approval.

Chapter 5: The patient and public involvement event

*Based upon Littlewood et al (2013e). Developing the SELF study: A focus group with patients and the public. International Journal of Therapy & Rehabilitation, 20(4), 200-206 (**Appendix 4**)*

Summary

Patient and public involvement (PPI) in the research process is a key feature of NHS Research & Development policy. This chapter reports the PPI event that was undertaken to develop the proposed methods of the RCT aspect of the SELF study. The outcome of the focus group discussion is described and the suggestions made by the panel members, which were incorporated into the proposed study prior to submitting for ethical approval, are reported.

5.0 Introduction

Patient and public involvement (PPI) in research has been defined as research undertaken with members of the public, as partners in the process, rather than research being conducted on them (INVOLVE 2012; Thornton 2008). With the aim of creating world-class research which is focused upon the needs of patients and the public, PPI has become a key feature of UK NHS Research and Development policy (Telford et al. 2004) and as a result its importance has become more recognised over recent years (Boote et al. 2006; Brett et al. 2010). Many funding bodies now expect to see PPI embedded within the research that they support (Staniszewska et al. 2008). It has been suggested that PPI contributes to better quality research due to the unique perspective that patients and the public can offer (Boote et al. 2002). In the wider literature, the benefits of PPI have been reported to include identification of more patient-centred research topics, improved feasibility of the study design, more effective recruitment, more patient-centred data analysis, improved dissemination and closer links to the community (Brett et al. 2010).

Hence this chapter describes a PPI event that was conducted to facilitate the development of the SELF study (Littlewood et al. 2012c). Prior to conducting this work, general messages previously reported from the PPI literature were available but in relation to the SELF study the aim was to more specifically consult regarding the acceptability of the proposed

methods of blinding and the acceptability of the intervention which could not be gleaned from previous reports.

5.0.1 Aims and objectives

The aim of the PPI event was to facilitate development of the SELF study by seeking lay consultation in relation to;

- the acceptability of the proposed methods of recruitment
- the acceptability of the proposed methods of blinding
- the acceptability of the intervention
- measures to minimise loss to follow-up

These objectives were set to reflect issues that are widely regarded as being problematic when conducting RCTs (Torgerson & Torgerson 2008) generally but in relation to blinding and acceptability of the intervention these objectives were set to reflect specific issues relating to the SELF study. To maintain ongoing PPI an additional objective was to;

- recruit lay people to the SELF study trial steering committee with the remit of monitoring the progress of the study

This final objective reflects a move from consultative PPI where the control remains with the academic researchers to a more equal partnership where decision-making is shared (Brett et al. 2010).

5.1 Methods

This event was supported by a grant awarded by the Research Design Service – Yorkshire and the Humber (RDS-YH) and hence the proposed structure of the event was externally reviewed prior to commencement. In accordance with the National Research Ethics Service (NRES) guidance, ethical approval was not required for this involvement event. This is qualified by NRES through clarification of the role of the patient and public members who are not acting as research participants but rather as specialist advisers providing their knowledge and experience, even if recruited via the NHS.

Whilst the protocol for the SELF study was under development, the focus group discussion was undertaken. The focus group was advertised to potential lay members via posters placed in the physiotherapy department of the host NHS institution where the SELF study was to be conducted and simply asked for volunteers who would be willing to contribute to a discussion about the proposed research. Adults (>18 years old) who were under the care of physiotherapy services were invited to get in touch via telephone or e-mail to indicate their interest and to discuss their potential role and extent of involvement. A convenience sampling approach was undertaken for pragmatic reasons relating to recruitment and time available prior to submission of the RCT protocol for ethical approval. Although most of the objectives of this study, with the possible exception of the acceptability of the intervention, might be regarded as generic and therefore appropriate to be considered by any willing service user, it is unclear whether purposive sampling of those who might be eligible for the RCT would have offered any further or contradictory information over and above that offered by patients currently attending physiotherapy for non-shoulder-related disorders.

When members consented to be involved they were invited to attend the focus group discussion led by CL and JA (local principal investigator) within the physiotherapy department of the host institution. To express gratitude for their involvement the participants received a £25 voucher and re-imbursement of travel expenses. This sum was approved by the RDS-YH, the funder, and was in keeping with the amount offered through other similar events at the time. It was felt that this was a fair amount to offer and reflected the input required without concern about undue inducement.

The focus group commenced with introductions and all members were aware that CL and JA were researchers and physiotherapists by background. A structured topic guide was developed, with reference to the objectives of the study; to facilitate discussion which was recorded and transcribed verbatim by CL. Member responses were anonymised and subsequently summarised in relation to the themes. This summary was undertaken by CL before being reviewed and subsequently verified by JA.

Subsequently a lay summary was produced detailing key messages from the discussion and how the proposed research was to be developed as a result. The participants were sent a copy of this summary and were invited to respond. Three out of the four members

responded and approved the proposed changes. One member did not respond for unknown reasons, despite prompting.

5.2 Results

Four patient members contributed to the focus group. Six initially volunteered but two did not attend on the day without explanation. All patients were female (age range 19 to 80 years) and were currently attending physiotherapy with a range of musculoskeletal disorders, including past and present shoulder disorders.

The discussion began with the members briefly describing their previous involvement with research. Two of the four had previously participated in research; one as a patient and one as the partner of a patient. They were asked to consider if they would volunteer for future research and the factors that might motivate them to do so. All of the members described personal benefit as a factor but also considered the benefits to the NHS and the wider population. This point was recognised by member A:

'...anything that's gonna help me and other people is important...'

5.2.1 Acceptability of the proposed methods of recruitment

We proposed to make initial contact with potential participants of the SELF study by telephone. Upon receipt of the referral to the physiotherapy department the information would be screened by a physiotherapist and then the call would be made to those who were potentially eligible. Although the members felt that this was appropriate, they suggested that it might not be the most effective way. The idea of a letter informing the potential participants of the study and the intention to contact them prior to a telephone call was suggested. Member A reflected:

'If you just get a random call then it's not very good for you. You might be out doing something and if you're busy or whatever and you're not expecting the call then you might just brush it off and not want anything to do with it so I think the letters a good idea.'

Following initial contact the participants would need to undergo a physical examination screening prior to recruitment. This means that some of the invited participants will be subsequently excluded and we were concerned that this might negatively impact upon willingness to volunteer. However, member B, in agreement with the others, stated:

'No, it wouldn't because (the research physiotherapist) would have decided who were going to be the best people to do this. You would be allocated a physiotherapist anyway wouldn't you, so no.'

5.2.2 Acceptability of the proposed methods of blinding

The SELF study is designed to evaluate the clinical and cost effectiveness of a self-managed exercise programme versus usual physiotherapy. A survey of current UK physiotherapy practice (Littlewood et al. 2012a) relating to rotator cuff tendinopathy has identified that usual physiotherapy might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection at the discretion of the treating physiotherapist. However, a proportion of physiotherapists would engage with the philosophy of self-management and prescribe exercise within this framework. Hence in some instances a programme of self-managed exercise might actually be termed usual physiotherapy. To reflect usual care arrangements, where patients would not typically be aware of the exact content of their physiotherapy programme prior to attending and also to introduce participant and outcome-assessor blinding, to maximise the rigor of the proposed study, we initially proposed to describe the intervention and control treatments within the SELF study participant information sheet simply as 'physiotherapy'.

Unanimously the group found this to be acceptable:

'It wouldn't bother me.' (Member B)

'Well you don't know in the first place when you come for physio what it entails so personally it wouldn't bother me.' (Member C)

'No, I don't think it's important to know exactly what you're going to be doing because you do trust them and you're going to physiotherapy to get your shoulder better. You don't go thinking what am I gonna be doing because you trust them to know what to do.' (Member A)

However, some of the participants recognised that the perceptions that some people hold regarding physiotherapy might contribute to resentful demoralisation:

'...he thought that physiotherapy was massage. He was gonna lay there, you were gonna lay your hands on him and he were gonna walk away and he'd be fine and because he found out it was exercise he didn't want to come.' (Member D)

With this stimulus member A then reflected:

' Personally I like both, the massage and the exercise because the exercise... I don't think that I should just have one...'

So although the members initially responded favourably to this design feature they recognised that for some, including themselves, if participants were recruited without prior knowledge of the intervention then retention might be more problematic than usual.

5.2.3 Acceptability of the intervention

As previously described, the intervention is self-managed exercise. We were concerned about resentful demoralisation affecting the intervention group if they were allocated to a self-managed programme. However, member B recognised the role that participant blinding would play:

'I was just thinking about what (member D) said about people going to think that someone's going to have massage and they're going to have to do exercises but how would they know that other people are going to have massage because that's not what you're going to say are you?'

However we recognised the contentious nature of our blinding proposal and were keen to seek lay opinion relating to the study if blinding was not deemed ethically acceptable. The group raised concerns about the issue of participants maintaining motivation and hence adherence to the exercise programme if they weren't attending frequent clinic appointments. For different reasons member C recognised that this was a problem that she was currently encountering:

'... personally this last time I've been coming with my knee each week she's sort of changed it and I've gone home and though ooh I can't remember which exercise I'm supposed to be doing...I am an exercise person anyway, but it went.'

Member D suggested:

'...I would suggest people that are doing it [exercise] at home need encouragement so they would have to be seen more regularly for me than three weeks because I think they will go home perhaps do the exercise for a week and then think um not bothered with this, they're having that done. You know they do, people do that.'

The group were reassured that participants would be followed up at a time convenient to them and which best met their needs but the responsibility to carry out the exercise would remain with the patient and it is not expected that they would be returning to the clinic to receive therapist-led interventions, for example mobilisation, electrotherapy, acupuncture. We were proposing to provide patients with exercise diaries to monitor adherence, an idea which the group felt was useful and additionally member C also suggested a modification to enhance the diary by including a picture of the prescribed exercise. Member A commented:

' I like the idea for the calendar because I think if I had that in my room and every day I looked at it and thought that's the exercise I need to do. I'd probably do it when I got up and do it before I went to bed if I kept it in my bedroom...I think it's important to have a regular time when you do it and then when you get into a routine you're not going to forget it.'

So, as is recognised in the literature, the group identified a potential problem with exercise adherence but felt that the idea of an annotated exercise diary supplemented with intermittent clinic attendance, which would include a review of progress, exercise prescription and setting of further goals, might go some way to addressing this. All the participants were interested to hear that the intervention tends to include only one exercise at any one time which also has clear pragmatic advantages relating to adherence in contrast to member C's experience.

Member B had a different perspective upon self-management suggesting that for some it might be preferred:

' Yes, well the other thing is that some people are busier than others. You know I've been up there when some people are making an appointment and saying ooh no I can't come then. So that's something else that you've got to take into account isn't it?'

A further issue that we have identified relating to acceptability of the intervention is that the exercise intervention tends to be uncomfortable. It has been suggested that pain associated with exercise might be a barrier to adherence. However, member C stated:

'I would assume personally that it's gonna hurt...it's so easy not to do that because it hurts but if you do that then you're causing more problems so I would expect it to hurt to make it move.'

This was a view shared by the group but this came with the caveats that it was acceptable to undertake painful exercise providing that it was reasonably expected that there would be a positive outcome and providing that progress could be measured by setting specific goals:

'And then thinking well at least I might be able to get that cup in that cupboard up there then that's something to aim for.' (Member B)

Member D offered another useful view point concerning an experience with her husband which highlights that even when an intervention is not regarded as acceptable initially, these barriers can be overcome with support:

'My husband badly damaged his shoulder cuff and he's not an exerciser and course he came here and came home; 'you'll never believe what they've given me.' I said 'a rubber band' he said 'yeah, how on earth is that going to sort anything?' (laughter). And I said (husband), it will and I made him do it every day and he's like 'I don't wanna do it, it's hurting' and I'll say 'well right keep pushing, keep pushing. No pain, no gain and eventually his shoulder's fine now.'

5.2.4 Measures to minimise loss to follow-up

As with all studies, particularly with longer term follow-up, loss to follow-up is a significant problem. The group was aware of this issue and member B again recognised:

'I don't know I think you're bound to get people not filling them in no matter what you do...'

The others recognised that a telephone prompt and stamped addressed envelopes to return the forms would provide a stimulus to them but an incentive, particularly a monetary incentive, would significantly increase their chances of completing and returning follow-up data forms:

'There's got to be some carrot...It doesn't have to be a big incentive, just an incentive.' (Member D)

5.2.5 Participant reflection

To conclude the focus group discussion, the members were asked to reflect upon their experience. They were pleased that research was being undertaken and were keen to be involved in such a process. They felt that they had contributed positively to the development of the study and all wished to remain involved in some capacity and to understand how their input has influenced the research. Member A concluded:

'...if it helps other people what we've done today it's a good thing...and I've enjoyed being able to do that.'

5.3 Discussion

The value of involving patients and the public in the design and conduct of research is now widely recognised. This study sought the opinion of people currently attending physiotherapy in relation to the design and conduct of the SELF study.

Throughout the focus group discussion the members found the proposals to be generally acceptable but, in keeping with the wider body of literature (Brett et al. 2010) offered strategies with the potential to enhance the design of the study. With regard to recruitment the group suggested that an initial approach by letter to potential research participants of the SELF study could counter the draw backs associated with our initial proposal of 'cold calling' which in turn might enhance our recruitment strategy and hence the proposed research was modified to reflect this.

We were aware of the contentious nature of our proposal to blind participants to the exact content of the intervention and control arms of the SELF study. Interestingly the participants did not express concern regarding this in relation to themselves. The participants recognised that this was in line with usual clinical practice but also they trusted the physiotherapists responsible for their care. However, other reasons for re-considering this feature were offered. The idea that potential participants might have specific expectations of what physiotherapy might entail was raised including that physiotherapy should incorporate 'hands-on' treatment. Hence if participants with this perception were enrolled without full

knowledge of the intervention they could receive then they might withdraw from the study post randomisation. So, even though there are clear benefits associated with participant blinding there is an important consequence, i.e. attrition bias, which might compromise the validity of the SELF study. This was an issue that we had not previously considered and when initial ethical concerns were raised regarding this feature we opted to remove participant blinding from the study design, and include a full description, rather than defend this aspect.

The group discussed two aspects relating to acceptability of the intervention. Firstly, the self-managed nature and secondly, the uncomfortable nature of the prescribed exercise. Self-management was an approach that the group valued partly because they recognised the recurrent or chronic nature of musculoskeletal disorders and hence effective self-management was a valuable tool. However, they did recognise the issue of exercise adherence as a potential problem. The group was re-assured to know that the self-managed intervention would be supported through intermittent clinic attendance and would be facilitated through the use of an exercise diary. However, they felt this could be enhanced by including a visual illustration of the exercise as well as encouraging the patient and physiotherapist to set specific goals; both of these ideas were incorporated into the proposed research. The uncomfortable nature of the exercise was not a concern, indeed there was almost an expectation that the exercise should be painful to be of value. The only caveat offered in relation to this was that there should be a reasonable expectation that the intervention will be of benefit which clearly would always be the case.

Loss to follow-up is a problem across RCTs. The group recognised this and acknowledged the potential value of the methods we were proposing to address this. However, the idea of including an incentive for participants to return all questionnaires seemed to be the most appealing and would apparently stimulate this group to return the questionnaires. Due to lack of funds, this idea was not incorporated into the SELF study.

Finally we were keen to maintain and enhance PPI with the SELF study. We were hoping to recruit one or two lay members to the trial steering committee from this focus group but surprisingly when invited all four participants were very keen to maintain involvement and actively contribute to the conduct of the study and two became fully engaged members of the SELF trial steering committee.

5.3.1 Implications

The PPI event has proven to be a useful component whilst designing the SELF study. The unique lay perspectives offered have resulted in changes to the proposed study including:

1. Initial approach by letter
2. A full description of the content of the treatment arms
3. An enhanced exercise diary incorporating a visual illustration of any prescribed exercise
4. Enhanced recognition of the potential training needs of the physiotherapists involved

These features were incorporated into SELF study protocol and a platform upon which to maintain lay involvement throughout the conduct of a study was developed.

5.3.2 Limitations

One focus group was conducted on one occasion with four members. This small number of participants was not a random sample of the population and might not be representative of the opinions that would be reported by the wider population. This small number partly reflects difficulties in recruiting lay members using the recruitment strategies described and also reflects the limited time frame in which to conduct and usefully apply the findings. It is expected that a more expansive recruitment strategy along with an extended time frame could have enhanced the value of this work. If this event were to be repeated with other groups of participants, for example men, at other times then clearly the opinions expressed might be different. The focus group was an appropriate and convenient method of data collection but the potential influence of the group dynamic, including the role of the facilitators, on the discussion should be recognised. Data generated through individual interviews, where the influence of others is not as apparent, may result in different findings. Despite knowledge of the role and background of the facilitators, it is reassuring that the lay members were able to offer a critique of the proposals and offer alternative ideas. In the face of these limitations, the objectives of the PPI event were still met ultimately resulting in useful amendments to the SELF study.

5.4 Conclusion

The lay members of the PPI event found our proposals generally acceptable but were able to recognise the limitations of some aspects and offer useful suggestions to enhance the design and conduct of the SELF study. The unique perspective offered has resulted in what we regard as positive changes to the proposed study.

The following chapter will now describe the pilot RCT, the design of which reflected the outcomes of the PPI event where possible.

Chapter 6: The pilot RCT

Based upon Littlewood et al (2013f). Self-managed loaded exercise versus usual physiotherapy treatment for rotator cuff tendinopathy: a pilot randomised controlled trial. Physiotherapy, http://dx.doi.org/10.1016/j.physio.2013.06.001 (***Appendix 5***)

Summary

This chapter reports the single-centre pragmatic unblinded parallel group external pilot RCT that was undertaken prior to conducting the substantive RCT as a component of the mixed methods SELF study. Twenty four participants with rotator cuff tendinopathy were recruited and randomised to a programme of self-managed exercise or usual physiotherapy treatment. Baseline assessment included the SPADI and the Short-Form 36 (SF-36) which were repeated three months post randomisation.

6.0 Introduction

Based upon the rationale described in chapter two the purpose of this study was to pilot the methods proposed to conduct the substantive RCT component of the SELF study and thus meet objective iii of this thesis.

6.1 Methods

The protocol was approved by the School of Health and Related Research, University of Sheffield Research Ethics Committee on the 2nd December 2011 (Ref 0517/CAO) (**Appendix 6**) and the research was conducted according to the Declaration of Helsinki.

6.1.1 Aims and objectives

The aim of this study was to pilot the methods proposed to conduct a substantive study to evaluate the effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. The objectives were to evaluate;

a. the process of recruitment and retention rates

b. willingness of participants to be randomised

c. the extent of contamination between treatment groups

d. participant adherence with treatment.

A secondary aim was to undertake a preliminary comparison of patient reported-outcomes and to estimate the variability of these outcomes in this patient population.

6.1.2 Design and setting

A single-centre pragmatic unblinded parallel group RCT conducted in one private physiotherapy clinic in West Yorkshire, northern England.

6.1.3 Participants

Between January and June 2012 participants were recruited according to the following criteria: (i) Age > 18 years, (ii) Willing and able to participate, (iii) Primary complaint of shoulder pain with or without referral into the upper limb for > 3 months, (iv) No/ minimal resting shoulder pain, (v) Range of shoulder movement largely preserved, and (vi) Shoulder pain provoked consistently with resisted muscle tests, usually abduction or lateral rotation. Participants were excluded according to the following criteria: (i) Shoulder surgery within last 6 months, (ii) Reasons to suspect systemic pathology including inflammatory disorders, (iii) Cervical repeated movement testing affects shoulder pain and/ or range of movement. Participants were recruited via posters, word of mouth and advertisements in the local press.

Potential participants were asked to contact CL via e-mail or telephone to express interest and undergo initial telephone screening, where appropriate, for inclusion criteria i to iv and exclusion criteria i to ii. If these criteria were met then the potential participant was sent a full participant information sheet and consent form. Upon receipt of the signed consent form the details of the participant were passed onto the physiotherapy clinic who subsequently arranged a mutually convenient appointment time to undertake a physical examination screening by one of the study physiotherapists for inclusion criteria v to vi and exclusion criteria iii.

6.1.4 Baseline/ outcome assessment

Participants were initially assessed for eligibility and then consent was gained. Subsequently the patient-reported outcome measures were completed to establish baseline pain, function, quality of life and level of self-efficacy. After completion of the baseline measures, the participants were randomly allocated to the self-managed exercise or usual physiotherapy treatment groups. The measures of pain, function and quality of life were

repeated three months post randomisation by the participants, in keeping with most other similar studies, and returned by post. It is important that participants in both the intervention and control groups are followed up at the same time points, post randomisation; therefore the common reference time point, for all patients, is the date of randomisation.

The primary outcome measure was the SPADI (Williams et al. 1995). The SPADI is a self-report measure specifically developed to evaluate pain and function in patients with shoulder pathology (MacDermid et al. 2006). The SPADI has been validated for use in this patient population and a minimally clinically important change of 10 points has been identified (MacDermid et al. 2006; Roy et al. 2009). Additionally, excellent levels of reliability (ICC 0.66 to 0.95), high internal consistency (Cronbach α typically > 0.9) and responsiveness over time have been reported in tandem with no floor and ceiling effects (Roy et al. 2009). Although other shoulder specific measures have been shown to demonstrate similar psychometric properties, for example the Disabilities of the Shoulder Arm and Hand (DASH), it was felt that the SPADI, as the most commonly used measure, was an appropriate choice in this context. To minimise response burden for the participant's further shoulder specific questionnaires were not included. The SPADI includes 13 items divided into two sub-scales; pain (5 items), disability (8 items). The responses are indicated on a visual analogue scale where 0 = no pain/no difficulty and 10 = worst imaginable pain/so difficult it requires help. The items are summed and converted to a total score out of 100 where a high score indicates more pain.

The secondary outcome measure, the SF-36 is a generic measure of health related quality of life (Ware & Sherbourne 1992) and is the most widely used measure of this nature. The SF-36 is acceptable to patients, is internally consistent and is a valid measure of health status across a wide range of patients (Bennell et al. 2007; Garratt et al. 1993; Walters et al. 2001). Additionally, the SF-6D, a single summary preference-based measure of health, can be derived from the SF-36 which enables calculation of Quality Adjusted Life Years (QALYs) for use in economic analysis (Walters & Brazier 2003).

It was expected that success of the self-managed exercise intervention was likely to be related to the level of exercise adherence and hence we were interested in evaluating this

as well as exploring possible factors that might predict non-adherence in this context. A range of such factors have been identified including level of pain at baseline, levels of physical functioning, levels of well-being (Jack et al. 2010), all of which can be captured with the aforementioned measures. However, levels of self-efficacy appear to be an important determinant of adherence (Jack et al. 2010) and so the General Self-efficacy scale (GSES) (Schwarzer & Jerusalem 1995) was completed at baseline. The GSES is a 10-item measure that has been developed to measure this construct and has been validated across different populations in different countries (Scholz et al. 2002). In the absence of objective measures of adherence, levels of treatment adherence were measured through the use of an exercise diary indicating the number and percentage of exercises completed as reported by the patient.

6.1.5 Randomisation

A computer-generated randomisation sequence was produced by an independent statistician (SJW) in blocks of two and four to ensure an equal number of participants were randomised to each group. This was regarded as essential due to the small total sample size. The treating physiotherapists allocated participants to the self-managed exercise or usual physiotherapy treatment group by selecting the next consecutively numbered sealed opaque envelope, which concealed the group allocation. The participants name and study identification number were written on the envelope before it was opened.

6.1.6 The intervention and comparator

6.1.6.1 The intervention; self-managed exercise

The intervention, self-managed exercise has been described in chapter three.

6.1.6.2 The comparator; usual physiotherapy treatment

Usual physiotherapy treatment might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection at the discretion of the treating physiotherapist (Littlewood et al 2012a).

Due to the private-practice setting in which the study was conducted, an agreement had to be reached prior to initiation of the study regarding how many sessions would be funded through the research for each of the trial arms respectively. Based upon the author's prior

clinical experience it was agreed that participants in the self-managed exercise arm could receive a maximum of four sessions funded by the research and based upon information from the clinic it was agreed that participants in the usual physiotherapy treatment arm could receive a maximum of eight funded sessions.

6.1.7 Sample size justification

The primary aim of this study was to pilot the methods proposed to conduct a substantive study not to detect a true difference between treatment groups. In this context it was felt that a total of 24 participants would be sufficient for this purpose (Julious 2005).

6.1.8 Data analysis

Recruitment, retention, adherence rates, proportion of participants randomised and GSES scores are presented descriptively as is description of the interventions offered in both treatment arms to enable an evaluation of contamination. The mean change in SPADI score from baseline to three months is calculated for each group along with its associated 95% confidence interval. For the primary outcome, the SPADI score after three months, the mean scores are presented for each group along with the mean difference in SPADI scores between the groups and its associated 95% confidence interval. Analysis of the SF-36 scores was undertaken in a similar way.

6.2 Results

Figure 6.1 shows the study profile; 45 people were assessed for eligibility and 29 (64%) of these were potentially eligible for the study. Only one out of 45 (2%) declined to participate due to an unwillingness to be randomised. Twenty four participants were randomly assigned to the self-managed exercise or usual physiotherapy treatment groups. The mean age at baseline of the participants was 63.2 years (range 44-79) and 50% (12/24) were male. The mean duration of symptoms was 38.6 months (range 3 to 168) and mean SPADI score was 42.2 (range 15.4 to 73.1); higher scores indicate higher pain and disability. The baseline characteristics of the participants by treatment group are presented in table 6.1. The groups appeared well balanced at baseline except that the self-managed exercise group reported higher baseline shoulder pain and disability via the SPADI and the usual physiotherapy treatment group reported a longer mean duration of symptoms (49 versus 29 months). This estimate is influenced by one participant who reported duration of 168 months. When the

influence of this outlier was removed the revised estimate of mean duration of symptoms was 37 months for the usual physiotherapy group.

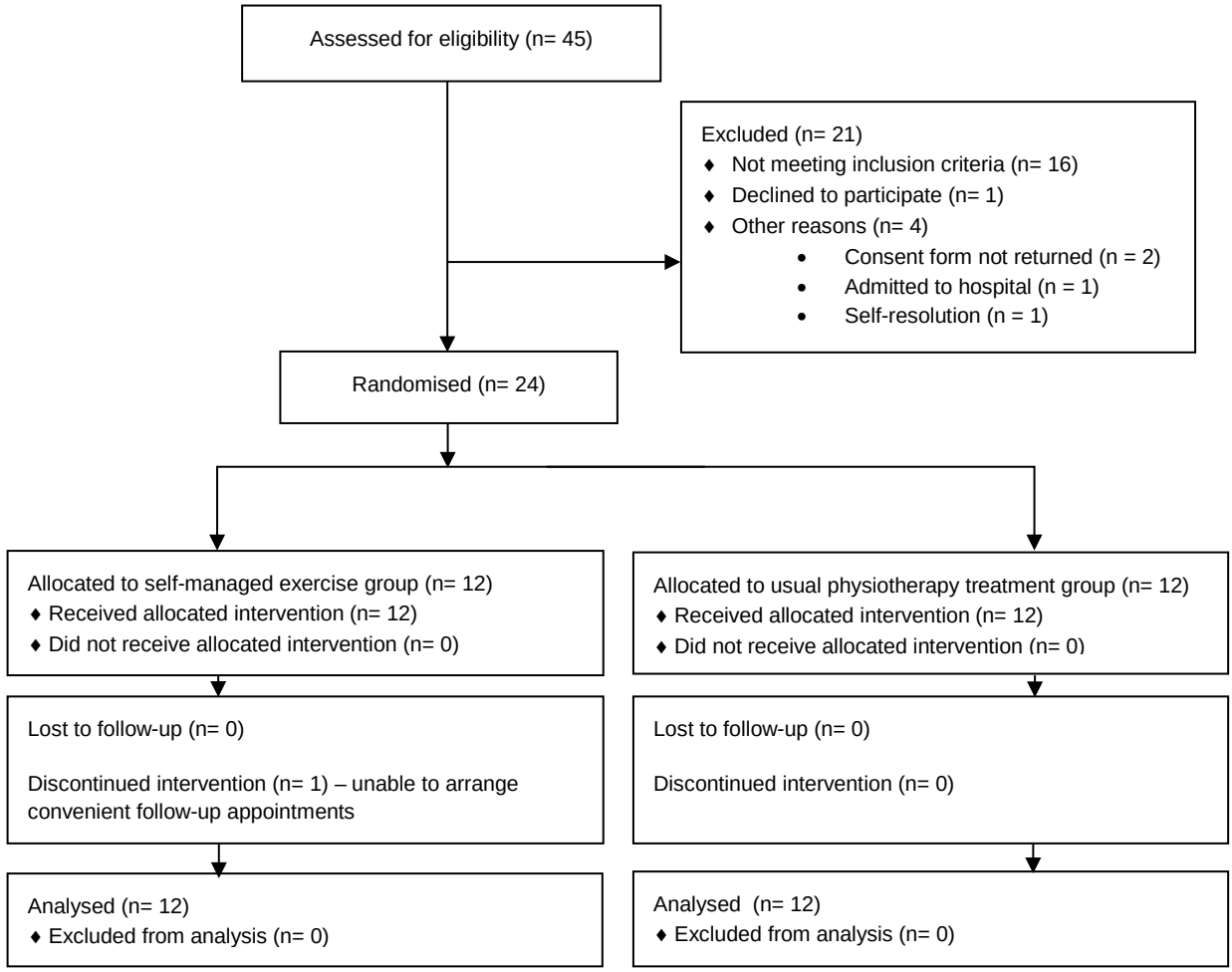


Figure 6.1 Participant flow through the study

Table 6.1 Baseline characteristics of the participants by treatment group

Characteristic	Treatment group			
	Self-managed exercise		Usual physiotherapy treatment	
	n	Mean or %	n	Mean or %
Age (years) (range)	12	62.6 (46 to 76)	12	63.9 (44 to 79)
Gender - male	12	5/12 (42%)	12	7/12 (58%)
Duration of shoulder symptoms (months) (range)	12	29 (3 to 120)	11	49 (3 to 168)
SPADI (SD)	12	44.6 (15.2)	12	39.7 (18.3)
SF-36 Bodily pain (SD)	12	51.4 (12.9)	12	49.4 (18.3)
SF-36 Physical functioning (SD)	12	71.9 (19.3)	12	72.9 (25.2)
GSES (SD)	12	33.5 (3.9)	11	35.3 (3.4)

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation)*

6.2.1 Number and content of treatment sessions

The mean number of treatment sessions in the self-managed exercise group was less than the usual physiotherapy treatment group (3.9 versus 7.6 respectively). All participants in the self-managed exercise group received the intervention but two participants also

received mobilisation and massage within their treatment packages. Participants in the usual physiotherapy treatment group received a range of treatments; described in figure 6.2.

6.2.2 Adherence

In the self-managed exercise intervention group, eleven out of 12 (92%) participants returned self-report exercise adherence data in the form of annotated exercise diaries. Of the eleven, seven participants returned complete data and four returned partial data. Complete data refers to the return of consecutive annotated diaries dated from initial assessment to final follow-up. According to the exercise protocol, the participants were required to exercise twice daily and so where this occurred 100% adherence was recorded for that day. Of the seven participants who returned completed data, the mean percentage adherence was 89% (range 77 to 99%). Of the four participants who returned partial data, the mean percentage adherence was 93% (range 83 to 100%). Overall self-report adherence was 90% (range 77 to 100%).

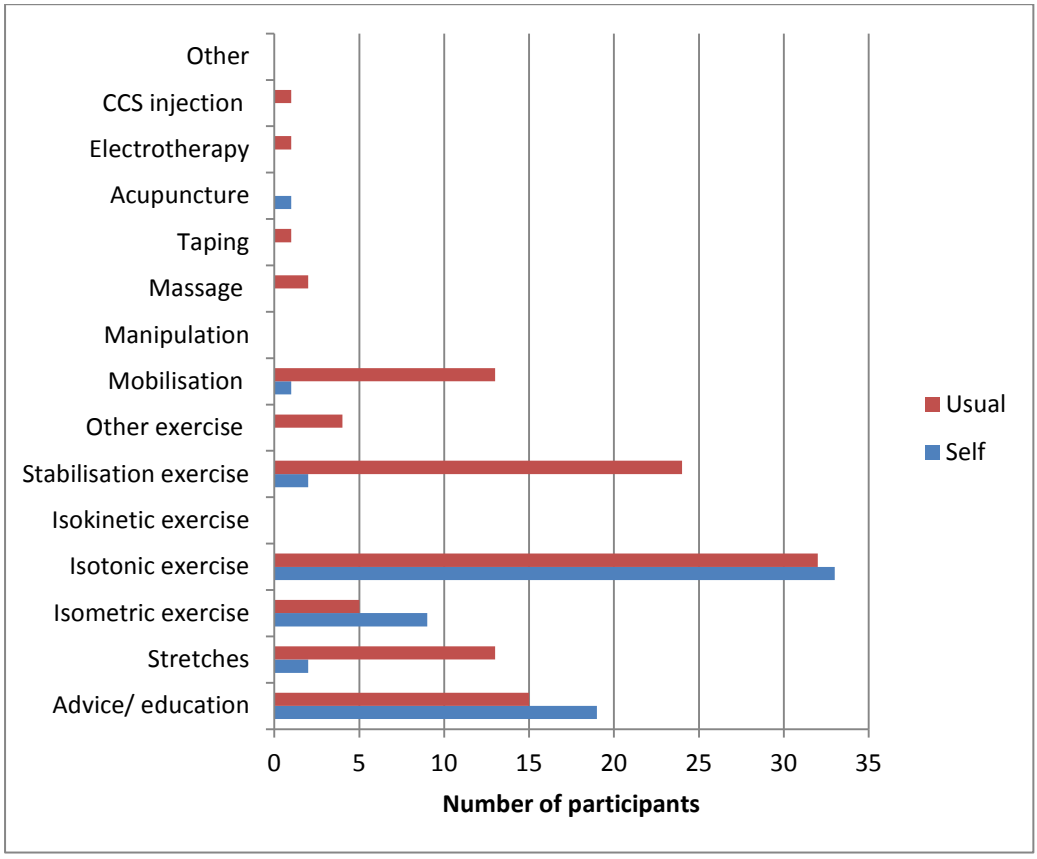


Figure 6.2 Description of the interventions offered (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)

6.2.3 Self-efficacy

The mean GSES score at baseline for the self-managed exercise group was 33.5 (SD 3.9) and 35.3 SD 3.4) for the usual physiotherapy treatment group.

6.2.4 Clinical outcomes

All SPADI and SF-36 outcome measures were returned for the three month follow-up. The mean change in SPADI score from baseline to three months was -23.7 (95% CI -14.4 to -33.3) points for the self-managed exercise group and -19.0 (95% CI -6.0 to -31.9) points for the usual physiotherapy treatment group. These within-group changes were regarded as clinically important.

Table 6.2 shows the outcome scores of the self-managed exercise and usual physiotherapy treatment groups at three months. The mean SPADI score at 3 months was 20.9 (SD 19.2) points for the self-managed exercise group and 20.7 (SD 20.3) points for the usual physiotherapy treatment group. The difference in three month SPADI scores was 0.1 (95% CI -16. 6 to 16.9) points in favour of the usual physiotherapy treatment group. The 95% confidence interval includes a 10-point difference in SPADI scores between the groups which is a clinically relevant range confirming the value of progressing with the substantive study.

Table 6.2 Outcome scores at three months

Outcome	Self-managed exercise			Usual physiotherapy treatment			Difference (95% CI)
	n	Mean	SD	n	Mean	SD	
SPADI[1]	12	20.9	19.2	12	20.7	20.3	+0.14 (-16.6 to +16.9)[3]
SF-36 Physical functioning[2]	12	78.2	17.7	12	73.3	29.3	+4.9 (-15.6 to +25.4)[4]
SF-36 Role-physical[2]	12	88.5	18.0	12	79.2	20.0	+9.4 (-6.7 to +25.5)[4]
SF-36 Bodily pain[2]	12	61.4	13.4	12	71.8	18.2	-10.3 (-23.9 to +3.2)[3]
SF-36 General health[2]	12	74.2	20.3	12	72.9	11.6	+1.2 (-12.7 to +15.2)[4]
SF-36 Vitality[2]	12	69.3	12.1	12	70.8	21.5	-1.6 (-16.3 to +13.2)[3]
SF-36 Social functioning[2]	12	45.8	11.1	12	50.0	10.7	-4.2 (-13.4 to +5.0)[3]
SF-36 Role emotional[2]	12	95.8	10.4	12	97.2	7.4	-1.4 (-9.0 to +6.2)[3]
SF-36 Mental health[2]	12	84.6	12.9	12	82.5	13.1	+2.1 (-8.9 to +13.1)[4]

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation /* [1] *Higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100) /* [2] *Higher scores indicate better quality of life (scored on a scale of 0 to 100) /* [3] *Usual physiotherapy treatment group reports better outcomes /* [4] *Self-managed exercise group reports better outcomes)*

6.3 Discussion

The primary aim of this study was to pilot the research methods and self-managed exercise intervention proposed for a substantive study. With reference to the specific objectives of the pilot study; a) recruitment was to target and retention rates were excellent; b) the vast majority of participants were willing to be randomised; c) contamination was minimal, and; d) exercise adherence rates were excellent. Finally, the outcome measures used were acceptable, in terms of 100% completion at three months, and preliminary statistical analysis indicated an improvement in outcomes in both groups.

The process of recruitment and randomisation ran smoothly. The self-managed exercise intervention appears to have been delivered with minimal contamination and with recognition of the significant differences between what constitutes a self-managed exercise programme and usual physiotherapy treatment which is important in the context of planning further study so that an appropriate evaluation of different approaches can be undertaken. The concern here was that the physiotherapists might gradually adopt the self-

managed exercise into their usual treatment regimen as they became accustomed to working within this framework which would subsequently limit the value of any comparisons made.

Despite prior concerns relating to pain produced whilst exercising serving as a barrier to engagement, retention and reported levels of adherence were excellent which is in contrast to other exercise programmes (McLean et al. 2010). Reasons for such high levels of adherence might relate to the minimal time requirement of undertaking a single exercise, or might relate to aspects of the self-managed framework within which the exercise was prescribed. This framework included a focus upon knowledge translation meaning that participants had an understanding of why they were undertaking the specific exercise and also included goal setting, self-monitoring and proactive follow-up, all of which might enhance engagement (de Silva 2011; Jones 2006). Contrary to this, it is also possible that the self-report exercise diaries which were used as a measure of adherence were an inadequate measure of this construct and hence present an inaccurate picture of true levels of adherence. However, in the absence of alternative methods, such a self-report approach appears to be the most suitable means of gathering this data at this time.

In this underpowered pilot study, the patient-reported outcomes in terms of the SPADI and SF-36 were comparable after three months but the patients in the self-managed group attended fewer follow-up sessions. However, this data does not provide adequate evidence of equivalence of the interventions but instead should be regarded as a stimulus to conduct a substantive RCT based upon the methods employed here.

6.3.1 Considerations and limitations

Although it is beyond the scope of any pilot study to claim findings that are generalisable, it should be recognised that this study was conducted in a private practice setting where the intervention was delivered by two highly experienced physiotherapists which might limit translation into more generalised settings. Additionally, the participants recruited to this study were not currently seeking healthcare for their shoulder problem which again is in contrast to other settings and hence the underlying characteristics of these participants might be different to those who were already actively seeking healthcare. The mean SPADI score at baseline in this group was 42.2 compared to 47.3 in a study recently conducted in

the UK NHS where people with moderate to severe shoulder pain were sought (Crawshaw et al. 2010). Although the mean baseline SPADI score was less in this study, the difference would not be regarded as clinically significant and might actually be more reflective of the range of people who seek healthcare for this problem. To support this, a study recently conducted in Belgium that recruited a similar group of patient-reported mean SPADI scores at baseline of 43.1 (Maenhout et al. 2013).

Similar to other RCTs of physiotherapy interventions, this trial was unblinded which introduces a potential source of bias. Although we initially proposed a double-blind study, i.e. patient and hence outcome assessor, this was regarded as unacceptable by the ethics committee.

6.4 Conclusion

Rotator cuff tendinopathy is a burdensome problem and, as previously highlighted, there is a clear evidence deficit in relation to conservative management and specifically self-managed exercise. The research methods employed within this pilot RCT appear to offer a suitable foundation upon which to conduct a substantive study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for chronic rotator cuff disorders/ tendinopathy. Chapter seven will now report upon the qualitative aspect of the pilot phase of the study which was conducted alongside the pilot RCT.

Chapter 7: The pilot qualitative study

Based upon Littlewood et al (2013g). Patients with rotator cuff tendinopathy can self-manage, but with certain caveats: a qualitative study. Physiotherapy, http://dx.doi.org/10.1016/j.physio.2013.08.003 (***Appendix 7***)

Summary

This chapter reports the qualitative study undertaken during the pilot phase. The purpose of this study was to explore some of the anticipated barriers in relation to the intervention that might prevent engagement in the substantive RCT. Six patients and two physiotherapists were purposively sampled from those allocated to the self-managed exercise group within the pilot RCT. The factors highlighted are discussed and used to inform the development of the substantive RCT.

7.0 Introduction

While there is emerging evidence supporting the value of loaded exercises for the treatment of rotator cuff tendinopathy, as described in chapter two, there are real and significant barriers that might serve to prevent implementation in the real world (McLean et al. 2010). Such exercises are frequently painful to perform, require the patient to take responsibility for their management, and such exercise prescription does not align with the clinical reasoning processes of many physiotherapists (Littlewood et al. 2012a). This chapter presents a qualitative investigation of these potential barriers that was undertaken alongside the pilot RCT designed to compare a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy.

7.1 Methods

The protocol was approved by the School of Health and Related Research, University of Sheffield Research Ethics Committee on the 2nd December 2011 (Ref 0517/CAO) (**Appendix 6**) and the research was conducted according to the Declaration of Helsinki.

7.1.1 Design

A qualitative study was undertaken within the framework of a mixed-methods research design where clinical quantitative outcome data from the pilot RCT was used to inform the recruitment to this study.

7.1.2 Setting

One private physiotherapy clinic in West Yorkshire, northern England.

7.1.3 Participants

A purposive sample of patients complaining of shoulder pain attributable to rotator cuff tendinopathy was recruited from the twelve patients who undertook a programme of self-managed exercise within the pilot RCT. Patients were selected by CL to gain maximum variation in terms of age, gender and clinical outcome, as determined by change in SPADI from baseline to three month follow-up. As there were only two physiotherapists involved in the delivery of the intervention both were eligible for inclusion.

Initial recruitment to the pilot RCT included the procedure for gaining informed consent for taking part in a future related qualitative investigation. CL contacted patients by phone or e-mail to ask whether they would be willing to participate. If their response was favourable then a convenient time to undertake an interview was scheduled at the patient's home or physiotherapy clinic.

7.1.4 Data collection

Interviews were directed by semi-structured topic guides which were developed to focus discussion upon the self-managed nature of the intervention and also the painful nature of the intervention (**Appendices 8 and 9**). The interviews were recorded using a digital voice recorder and transcribed verbatim. All interviews were conducted by CL. The participants were aware that CL was a researcher undertaking the study and also a physiotherapist by background.

7.1.5 Data analysis

The qualitative data were analysed independently by CL using the framework method of analysis (Lacey & Luff 2001; Pope et al. 2000). The framework method, described in chapter five, has been developed specifically for applied research in which the objectives of the investigation are set *a* priori (Pope et al. 2000). Analysis began with data familiarisation which underpinned the development of a thematic framework. The framework formed the basis upon which key issues and themes were developed and by which the data were examined. Subsequently the data were indexed according to the framework before a charting process took place; where the data were organised according to the defined

thematic framework. Finally the charts were used to define concepts and find associations to provide explanations for the findings (Lacey & Luff 2001; Pope et al. 2000).

7.2 Results

Eight participants were recruited; six patients and two physiotherapists. Three of the patients were male (50%), age range was 51 to 74 years (mean 64.7 years) and the change in SPADI score ranged from +3.1, indicating worse status, to -42.3, indicating improved status, (mean change -19.7). Both of the physiotherapists were female, each with greater than 20 years of experience working as physiotherapists in a variety of settings.

Six themes were generated and are displayed in figure 7. 1. The themes are substantiated with reference to the data where both positive and negative perspectives are offered to verify the relevance of the theme. A positive perspective, in this context, is synonymous with a successful treatment outcome which is determined by change in SPADI of greater than ten points, the MCIC. A negative perspective is synonymous with an unsuccessful treatment outcome which is determined by change in SPADI of less than ten points.

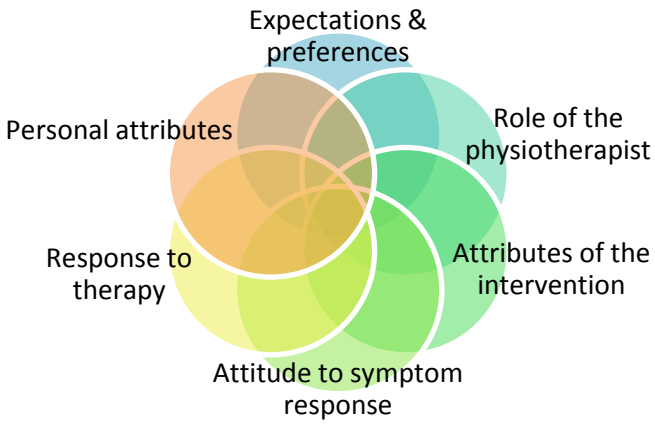


Figure 7.1 Qualitative themes

7.2.1 Expectations and preferences

The self-managed exercise programme required patients to take responsibility for the management of their condition and although they returned to the physiotherapist for follow-up, the focus of this return was to facilitate self-managed behaviour not to offer

hands-on care (Littlewood et al. 2013e). However, at the outset it was evident that most of the patients expected physiotherapy to be therapist-led and include 'hands-on' intervention:

'I expected a bit of a pummel actually and a bit of a tug about and somebody to go and make it all feel better.' (ID 18)

'I think I probably expected more physiotherapy than exercises…I think that I might have benefitted more from hands-on…' (ID17)

This expectation was aligned to how the physiotherapists viewed their role:

'I am very, very hands-on normally.' (T2)

The patients' expectations appeared to be largely informed by previous experiences of physiotherapy. Prior to recruitment to the pilot RCT, patients were informed that they had an equal chance of being randomised to the self-managed exercise or usual physiotherapy treatment arm. However, when patients were allocated to undertake self-managed exercise these prior expectations appeared to contribute to resentful demoralisation:

'I was quite sceptical I have to say when I went and we drew the envelope and it was, you've got, you know, self I thought ohh…that's not gonna do anything…I literally walked down the stairs of (the physiotherapy clinic thinking what av I signed up for!?' (ID 29)

This perspective was in keeping with the experience of the physiotherapists;

'…there were a few crestfallen faces when they got the self-managed side of it.' (T2)

One of the patients, who had previously received physiotherapy with an exercise component did not express strong preference;

'...I don't mind what you did, it was alright with me.' (ID13)

In contrast, one patient who had previously received extensive physiotherapy, incorporating a range of therapist-led interventions, without benefit entered the trial hoping to be randomised to the self-managed exercise intervention:

'I'd experienced a year and a half of physiotherapy and it brought about a relatively limited improvement…exercises erm I think that worked much better than periodic injections and err weekly physiotherapy.' (ID 15)

However, for the majority of patients, irrespective of final outcome, and the physiotherapists it was clear that their expectations and preferences did not initially align with the philosophy of self-management.

7.2.2 Role of the physiotherapist

It would be reasonable to expect that where expectations are not met treatment outcome would be compromised. In this situation, this was not always the case and a more complex relationship between expectations and outcome arose. In addition to reporting alternative expectations of physiotherapy, patients regarded as having an unsuccessful outcome also expressed concerns about the nature of their problem and whether self-managed exercise was an adequate intervention. In some situations these negative prior beliefs appeared to be compounded by the physiotherapist;

'…she thought I needed an x-ray to see before she started working on me …it was like it was catching something going up and coming down err and (physiotherapist) wondered if it was because of the operation as well…' (ID17)

'… well I think (physiotherapist) felt more or less straight away that it was unfortunate that I'd drawn the short straw in terms of that…' (ID 37)

This narrative from the patient perspective was in concordance with opinion expressed by one of the physiotherapists, where it can be seen that an existing belief set might impact upon their role in this context:

'I think there are some clients who from interviewing them, doing the examination, that you get an idea of whether they would be compliant and appropriate, and others you just think it's totally inappropriate and a waste of time.' (T1)

In contrast, others patients framed the therapeutic encounter in a more positive way;

'… she explained it very well and said what the aim was and that if it did hurt what to do……I could ring her if I had problems, and she was very responsive, she rang me back the same day and said what to do…I felt very comfortable, very confident.' (ID 18)

Additionally, with regard to follow-up, the monitoring and motivational role of the physiotherapist was recognised;

'…for a week or whatever I'd done a bit of a wrong exercise and I said it hurt and it did. Anyway she put me straight and it got back to being alright...' (ID 13)

'…having to show the diary to the (physiotherapist) each month as well, that was motivating…' (ID15)

7.2.3 Attributes of the intervention

The self-managed exercise programme was also designed to facilitate engagement in terms of minimal time needed to undertake and master the exercise. Despite this, some patients still expressed concern about these attributes of the intervention;

'… it's more of a problem doing it on your own than if you say go to a physio and you've someone with you to do it…' (ID37)

'…at first it seemed like a big task to do, because it was an additional thing to do through the day.' (ID 18)

Unexpectedly, disquiet was expressed about the simplicity of the intervention and hence its lack of potential effectiveness;

'…to cap it all it's such a simple exercise...I just came out thinking waste of time.' (ID 29)

But this perception appeared to change over time and the simplicity of the exercise programme was appreciated;

'…with it being such an easy exercise it…became part of a routine …I would do, it was short, short and sweet. So it wasn't a case of having to find time to do it, it just naturally fell into a little sort of routine that I have.' (ID 29)

With reference to the exercise diary which is used as a key component of the programme as a means of self-monitoring, one patient reflected:

'I have the piece of paper with it marked out in days, twice a day and I ticked it off each time and that helped me to the routine.' (ID 15)

7.2.4 Attitude to symptom response

Despite our initial concerns that pain provoked whilst undertaking the exercise programme might serve as a barrier, this wasn't expressed by the patients during the individual interviews. Also, patients did not express any anxiety about what the pain response meant in terms of tissue damage;

'… I suppose you expect to have a little bit of pain but erm I certainly wasn't worrying about any long-term erm, erm problems.' (ID 37)

This perspective wasn't shared by one of the physiotherapists;

'…but they weren't sold by that idea. They didn't like the idea of that.' (T1)

Also, patients expressed an interesting opinion regarding pain and exercise:

'…if it's not hurting it's not helping……you have to go through pain really haven't you to get, to make sure you've got the right muscles or whatever. It didn't stop me doing them' (ID 13)

But, this was further clarified by one of the patients who reflected that there was what appeared to be an acceptable limit to the pain response:

'I would perhaps say the level of pain wasn't sufficient to put me off.' (ID15)

7.2.5 Response to therapy

All patients reported that they initially engaged with the self-managed exercise programme. However, a key barrier to ongoing engagement appeared to be a lack of an early and appreciable response to the therapy:

'I would have gone on but I knew I wasn't getting any better.' (ID17)

'…I think that when you find that they're not making a great deal of improvement, you're less inclined to erm continue it.' (ID 37)

Conversely, when the symptoms improved to a certain point, although not resolved, the impetus to continue was also challenged;

'…I would continue if it was still badly hurting…' (ID 13)

Importantly, despite initial feelings of demoralisation, patients experienced a favourable therapeutic response that persuaded them of the potential value of the programme to them;

'…when I started seeing the results…I was so pleased with it that that motivated me on more and more to keep going.' (ID 18)

'…it just carried on improving erm and it made me realise how weak the arm was …I was quite pleased that it came on so quickly.' (ID 29)

7.2.6 Personal attributes

The self-managed exercise programme was designed to be progressive. This requires that the patients understand how to progress the exercise when indicated or regress if necessary. Following some early reported benefit from the exercise programme, one patient indicated subsequent difficulty as the symptoms failed to respond as the programme progressed. Despite this, they did not consider regressing the programme or seeking advice, indicating an external locus of control as a potential barrier:

'I just followed whatever the next one was……I just kept thinking I'll be glad when I go back and I might have something to do a bit easier or something. (ID 17)

Conversely some patients described personal traits that indicated their self-efficacious nature and they took greater control of the programme;

'…while I was waiting for the kettle to boil, I would do it…' (ID 29)

Other personal attributes were also described;

'…I was driven to get rid of this pain really, so I thought I'm going to give this a really good go and do it properly.' (ID 18)

'I'm used to exercise and I know that repeated exercise improves strength and mobility.' (ID 15)

In some circumstances the physiotherapists felt able to identify patients who they expected would successfully engage with the self-managed exercise programme;

'…I think it's a certain type of person where you're going to be able to have success with a regime of exercises and no hands-on, I would say… People who were very positive about life… they were usually quite outgoing, quite confident in themselves and quite determined.' (T1)

However, despite these inherent individual traits, one patient, regarded as having a successful outcome, reflected upon a previous episode of physiotherapy when engagement with a prescribed exercise programme was limited:

'I didn't do them...I don't know - because I thought they were doing it for me. So I came back with the booklet but I didn't do them. I thought oh well, I'm going back next week.' (ID 18)

In summary, a range of factors can be identified which might affect engagement with the self-managed exercise programme and hence serve as a facilitator or barrier to implementation in the real world. In this study, prior expectations of what constitutes useful physiotherapy did not serve as a barrier to successful treatment outcome with a self-managed exercise programme. This held true when the programme was offered within a positive and supporting environment where patients understood the reasons for undertaking the exercise and had means to self-monitor and return for pro-active follow-up. Response to therapy appeared to be a key factor influencing engagement. Individual traits, including self-efficacy, also appeared to play an important role in facilitating successful self-managed behaviour. These factors do not seem to act in isolation. Instead there appears to be a complex interplay between them which ultimately might impact upon the therapeutic response and experience.

7.3 Discussion

The primary aim of this study was to explore participant experience and barriers that might serve to prevent implementation of the self-managed exercise intervention. Despite most patients expressing expectations of physiotherapy contrary to the philosophy of self-management, this did not serve as a barrier to successful treatment outcome when the intervention was offered within a positive and supporting environment where patients understood the reasons for undertaking the exercise, effectively self-monitored and engaged with pro-active follow-up. Additionally, an early and appreciable response to

therapy appears to have been a key factor influencing continuing engagement with the exercise programme.

Within the context of this study, most patients expressed discontent when randomised to the self-managed exercise arm of the pilot RCT; a phenomenon recognised in other areas of research as resentful demoralisation (Torgerson & Sibbald 1998). The importance of recognising patient preferences and meeting patient expectations as a means of improving treatment outcome is not a new phenomenon. The influence of expectations in clinical practice has long been recognised and patient preference trials have been developed for evaluation in research settings (Torgersen & Sibbald 1998). In this context, if a self-managed intervention is to be successfully implemented, the relevance of expectations needs to be recognised and pro-actively addressed through open discussion.

Interestingly, despite negative initial feelings, the patients reported that they still engaged with the intervention, in terms of adhering to the exercise programme. However, a key feature of continuing engagement appeared to be an early and appreciable therapeutic response. Where this did not happen, the motivation of some patients waned. This is a concern because worthwhile response to therapeutic exercise is generally expected to take time (Bennell et al. 2010). In the context of planning further study, this highlights the need for educational strategies to foster more realistic expectations of prognosis but also indicates that pro-active follow-ups by the physiotherapists, in the form of a telephone call or clinic appointment, should be offered.

Prior concerns relating to pain, produced whilst exercising, as a barrier to engagement were not apparent here in relation to the patients at least which adds confirmation to the perspective offered by the lay members involved in the PPI event, described in chapter five. However, it was evident that patients had a level of acceptable pain response which, if exceeded, had the potential to impact negatively. When delivering the self-managed exercise intervention, physiotherapists would need to be aware of this when progressing the programme and also when working with patients to help them adapt the programme to their individual capacity which includes an understanding of how to regress the exercise but maintain engagement if the pain response becomes unacceptable.

The influence of patient preference was evident but so too were the preferences or beliefs of the physiotherapists, which might impact upon delivery of the intervention. In a profession where therapist-led 'hands-on' intervention is regarded as a vital and central intervention (Hanchard et al. 2004; Littlewood, et al. 2012a), a move towards a self-managed approach represents a seismic shift which would need to be managed appropriately through, among other things, education and training relating to the theory and application of self-management.

In addition to the role of the physiotherapist, personal attributes of the patients were important, particularly self-efficacy, defined as the confidence to perform a specific task or behaviour (Newman et al. 2009). Self-efficacious individuals were able to organise themselves and their lifestyle to incorporate the exercise programme. However, it does appear that the programme has the capacity to enhance individual self-efficacy through processes including knowledge translation, exercise/ skill acquisition, self-monitoring, goal setting, problem solving and proactive follow-up and hence a self-managed approach in this context does not necessarily require wholly self-efficacious individuals at the outset.

7.3.1 Limitations

This study was conducted with eight participants recruited via their involvement in a pilot RCT and the data were collected and analysed by one individual. Although most readers would now not judge qualitative research from the perspective of its capacity to generate data regarded as being generalisable, such a context might hamper the transferability, credibility and confirmability of the findings. However, it is reassuring to note that the patient recounted similar ideas and themes, both in the positive and negative whilst reflecting upon their experience which might actually enhance both the transferability and credibility. Furthermore, the participants were fully aware of the chief investigator's background and role in the research and in spite of this were not put off from relaying both positive and negative experiences.

7.4 Conclusion

With certain caveats including the need to recognise individual traits, implement effective knowledge translation strategies for both patients and physiotherapists and the need to engage with appropriately timed proactive follow-up the potential to implement

programmes of self-managed exercise for patients with rotator cuff tendinopathy in further research studies appears feasible but challenging.

Chapter 8: The SELF study – RCT

*Partly based upon Littlewood et al (2012c). A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: protocol for the SELF study. BMC Musculoskeletal Disorders, 13(1), 62 (**Appendix 10**)*

Summary

This chapter reports the multi-centre pragmatic unblinded parallel group RCT that was conducted as a component of the mixed methods SELF study. Eighty-six participants with rotator cuff tendinopathy were recruited and randomised to a programme of self-managed exercise or usual physiotherapy treatment. Baseline assessment included the SPADI and the SF-36 which were repeated three and six months post randomisation.

8.0 Introduction

Based upon the rationale described in chapter two and the methodological development work described in chapters five, six and seven in relation to the patient and public involvement event and the pilot study, this chapter describes the substantive RCT aligned with objective v of this thesis.

8.1 Methods

The protocol was approved by the National Research Ethics Service (NRES) Committee Yorkshire & the Humber – Leeds West on the 6th January 2012 (Ref 11/YH/0443) (**Appendix 11**) and the research was conducted according to the Declaration of Helsinki.

Prior to commencing recruitment, the approved protocol was made publicly available via Current Controlled Trials (ISRCTN84709751) and the full original version of the protocol was subsequently published online (Littlewood et al. 2012c).

8.1.1 Aims and objectives

The aim of this study was to evaluate the clinical effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy in terms of patient-reported outcomes of pain, disability and quality of life.

A secondary aim was to evaluate patient adherence with the prescribed exercise programme.

8.1.2 Design and setting

A multi-centre pragmatic unblinded parallel group RCT conducted in three NHS physiotherapy departments; one in northern England, one in the midlands and one in the south. Local research governance approval was gained from each site prior to commencing recruitment.

The initial protocol described a single-centre RCT alongside an optimistic recruitment rate. Recruitment for the first centre opened in April 2012 and it quickly became apparent that the required recruitment rate would not be attainable within the allotted time frame. Hence a second centre was opened in October 2012 and a third centre in March 2013.

8.1.3 Participants

Between April 2012 and July 2013 participants were recruited according to the following criteria: (i) Age > 18 years, (ii) Willing and able to participate, (iii) Primary complaint of shoulder pain with or without referral into the upper limb for greater than 3 months, (iv) No/ minimal resting shoulder pain, (v) Range of shoulder movement largely preserved, and (vi) Shoulder pain provoked consistently with resisted muscle tests, usually abduction or lateral rotation. Participants were excluded according to the following criteria: (i) Shoulder surgery within last 6 months, (ii) Reasons to suspect systemic pathology including inflammatory disorders, (iii) Cervical repeated movement testing affects shoulder pain and/ or range of movement. The process of excluding the cervical spine as a relevant contributory factor was undertaken by initially asking the participant to perform a painful movement as baseline, for example elevating the arm. Following this, the physiotherapist asked the participant to repeat cervical retraction ten times before re-testing the baseline movement. In the event of no change in the shoulder presentation, the physiotherapist then asked the patient to repeat cervical retraction/ extension and then re-tested the baseline movement before examining repeated cervical side flexion, rotation and flexion, if necessary. In the event of any ambiguity, for example an apparent increase in pain-free shoulder elevation, the physiotherapist could ask the participant to undertake more repetitions or apply an overpressure to the cervical movement (Littlewood & May 2007; McKenzie & May 2000). At the end of this process if there was no obvious change in the

shoulder presentation then the cervical spine was excluded as a potential contributory factor.

Potential trial participants were identified from the local NHS physiotherapy waiting list by a physiotherapist who usually had access to this information as part of their clinical role. Initial contact was made through an introductory letter and along with this letter the potential participants also received a participant information sheet (PIS) (**Appendix 12**) and consent form (**Appendix 13**). The letter was followed up with a telephone call made by the physiotherapist approximately one week later where further study information was relayed as required and an enquiry about further participant involvement was made. If the call recipient expressed interest in participating in the study the physiotherapist then undertook initial telephone screening for inclusion criteria i to iv and exclusion criteria i to ii. If these criteria were met the potential participant was invited to attend a physical examination screening for inclusion criteria v to vi and exclusion criteria iii. If the participant did not wish to pursue the discussion or did not meet the criteria they were thanked for their time and told that their referral would continue to be treated as per usual arrangements.

Physical examination screening was carried out by clinical physiotherapist's and included assessment of neck and shoulder movements and any associated symptomatic responses as per a typical musculoskeletal examination. Participants were eligible for inclusion if they met inclusion criteria v and vi and exclusion criteria iii, i.e. shoulder range of movement was largely preserved and shoulder pain was provoked with resisted testing but cervical repeated movement testing did not alter shoulder pain and/ or range of movement. The process of recruitment did not interfere with the timing of receiving physiotherapy and took place whilst the referral remained on the waiting list. If this was not feasible then the participant was excluded.

8.1.3.1 Informed consent

Prior to attending the physical examination screening the PIS and consent form were sent by post. The physiotherapist offered an overview of the PIS and answered questions at the time of the initial telephone call. Signed consent forms were required prior to the physical examination.

8.1.4 Baseline/ outcome assessment

As per the pilot RCT reported in chapter six, baseline assessment was conducted prior to randomisation and included collection of basic demographic details including date of birth, gender and duration of symptoms, as well as the SPADI, SF-36 and GSES. The rationale underpinning the use of these measures has been described in chapter six and will not be repeated here.

The primary outcome remained the SPADI at three months but, unlike the pilot RCT where intervention was commenced immediately post randomisation, for some participants there was a significant waiting time delay. In one centre this peaked at 14 weeks on one occasion which meant that a minority of patients had not received any intervention by the three month follow-up point and a majority had not received what might be regarded as a therapeutic dose of the self-managed exercise intervention; regarded as 12 weeks based upon the findings from the systematic review presented in chapter two. Hence, although the SPADI at three months remains the primary outcome measure, the six month SPADI data will also be presented to compensate for this delay and to enable a comparison once a therapeutic dose of the self-managed exercise intervention has been received.

Again mirroring the pilot study, the PSFS and exercise adherence data in the form of an exercise diary were completed during the intervention period.

8.1.5 Randomisation

A computer generated randomisation sequence was produced by an independent statistician (SJW) in blocks of two and four. Group allocation was concealed in consecutively numbered sealed opaque envelopes. Following receipt of written informed consent, confirmation of eligibility and baseline assessment, the name of the patient and study identification number was written on the next consecutive envelope before being opened to reveal group allocation.

8.1.6 The intervention and comparator

8.1.6.1 The intervention; self-managed exercise

The intervention, self-managed exercise, has been described in full above in chapter three.

8.1.6.2 The comparator; usual physiotherapy treatment

The nature of the comparator, usual physiotherapy treatment, has been described in full above in chapter six.

8.1.7 Sample size calculation

The original sample size calculation was based upon the primary outcome measure, the SPADI where a 10-point change was regarded as a minimally clinically important change in shoulder function (Williams et al. 1995). We assumed a standard deviation of 24 points (Crawshaw et al. 2010), a power of 80% and a (two-sided) significance level of 5% which meant that 91 participants per group were required. We allowed for a 15% loss to follow-up and aimed to recruit 105 participants per group over a 12-month period or 17 to 18 participants per month.

As described above, recruitment to the RCT began in April 2012. By September 2012, five months in to the twelve month recruitment period, five participants had been randomised. Due to the lower than anticipated recruitment rate, a second centre was opened in October 2012 and during this month, a further eight participants were randomised.

Based upon a revised estimate of our recruitment rate and in light of new information to inform our sample size calculation we requested an extension to our recruitment window to September 2013 and submitted a revised sample size calculation to the ethics committee. This was approved on the 19th December 2012 (**Appendix 14**).

The new information related to a narrower estimate of population variance from our external pilot RCT (n = 24) of 16.8 points on the SPADI, derived from a pooled estimate of the standard deviation of the baseline SPADI (table 6.1), compared to the estimate of 24 points used in the initial calculation. Furthermore, data from a recently published trial (Maenhout et al. 2013), which investigated a similar patient population, recruited 61 participants with mean baseline SPADI of 43.1 and a standard deviation of 11.3 points. Hence, the true variance appeared to be narrower than 24 points and our revised estimate appeared more realistic but still cautious in light of current research. Additionally data from our pilot RCT identified a correlation between baseline and three-month SPADI scores of 0.5. Julious (2010) suggests that, due to a reduction in variance, it is appropriate to adjust

sample size estimates when baseline covariates are accounted for by a factor of 0.75 when one covariate with a correlation of 0.5 to the outcome variable is included.

These changes had the effect of reducing the total number of participants required from 210 to 78. The parameters of the revised calculation are as follows; based upon the primary outcome measure, the SPADI, where a 10-point change is regarded as a minimally clinically important change in shoulder function (Williams et al. 1995), assuming a standard deviation of 16.8 points, a power of 80% and a (two-sided) significance level of 5% and taking into account adjustment for baseline SPADI scores (correlation with follow-up SPADI = 0.5), 34 participants per group are required. To account for 15% loss to follow-up, we aimed to recruit a total of 78 participants.

8.1.8 Data analysis

As the trial is a pragmatic parallel group RCT, the data is reported and presented according to the revised CONSORT statement and statistical analyses were performed on an intention-to-treat basis. All statistical exploratory tests are two-tailed with $\alpha = 0.05$. Baseline demographic, pain, disability and health-related quality of life data are assessed for comparability between the treatment groups.

Participants were classified as responders if they had valid primary outcome data, i.e. three month SPADI score. Graphical methods were used to compare the baseline characteristics of the responders and non-responders at three month follow-up between the self-managed exercise group and usual physiotherapy treatment group.

The primary aim was to compare the effect of a self-managed exercise programme versus usual physiotherapy treatment. The mean SPADI total score at three months follow-up is the primary efficacy response variable. Analysis of covariance (ANCOVA) is used to compare mean SPADI total scores between the groups at 12 weeks post-randomisation adjusted for baseline SPADI score. The 95% confidence interval for the treatment effect, adjusted for baseline SPADI score, is also reported.

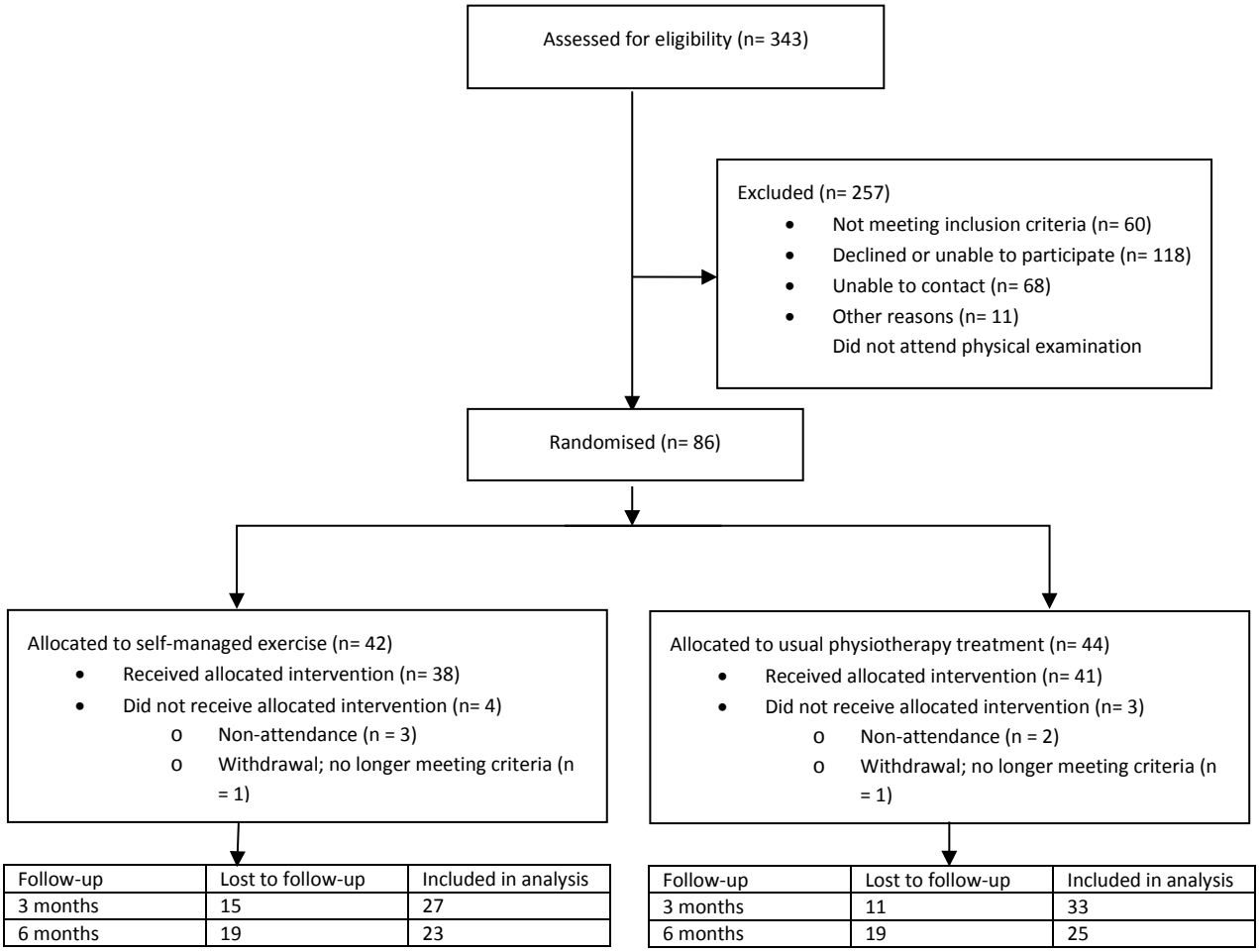
Within group changes in mean SPADI score between baseline and 12 weeks post randomisation were compared using a paired t-test. A 95% confidence interval for the mean change in each group is also reported. Secondary outcomes, including the SPADI score 6 months post-randomisation, are analysed in a similar way. As part of a sensitivity analysis

for the primary outcome, missing 12 week SPADI scores were imputed using Last Observation Carried Forward (LOCF) and regression imputation using the baseline score as a covariate.

8.2 Results

Figure 8.1 shows the study profile; 343 patients were contacted based upon the detail provided on clinical referral letters. Of this number, 68 patients could not be contacted and 118 declined or were unable to participate. The most common reasons for being unable to participate were already having a scheduled physiotherapy appointment, symptom resolution or going on holiday. Sixty people did not meet the inclusion criteria; most commonly this was because the symptoms were felt to be cervical in origin or a diagnosis of frozen shoulder was made. Eleven patients met the first stage of inclusion criteria but subsequently did not attend the physical examination to confirm the diagnosis of rotator cuff tendinopathy, as defined in this thesis. Eighty six patients were randomly assigned to the intervention and control groups. Our target of 78 was exceeded due to the recruitment process employed. At the time that the target was met other patients had been invited and were in the recruitment system but had not completed stage one, (the telephone interview) and/ or stage two (the physical examination).

The baseline characteristics of the participants by treatment group are presented in table 8.1. The groups appear well balanced at baseline except that the usual physiotherapy treatment group reported a longer mean duration of symptoms. From an epidemiological perspective this might be regarded as important because longer duration of symptoms might be a prognostic factor associated with unfavourable outcome (Littlewood et al. 2013a). However, graphical inspection of this data highlights positive skewness and median duration of symptoms for the self-managed exercise group is seven months compared to six months for the usual physiotherapy treatment group. Hence this discrepancy might be more readily explained as a product of the summary measure used rather than a true difference between groups.



Follow-up	Lost to follow-up	Included in analysis
3 months	15	27
6 months	19	23

Follow-up	Lost to follow-up	Included in analysis
3 months	11	33
6 months	19	25

Figure 8.1 Study profile

Table 8.1 Baseline characteristics of the participants by treatment group

Characteristic	Treatment group			
	Self-managed exercise		Usual physiotherapy	
	n	Mean or %	n	Mean or %
Age (years) (range)	42	53.8 (23 to 83)	44	55.6 (23 to 80)
Gender - male	42	17/42 (40.5%)	44	26/44 (59%)
Duration of shoulder symptoms (months) (range)	42	11.7 (3 to 78)	43	17.5 (3 to 120)
SPADI (SD)	42	49.1 (18.3)	43	49.0 (18.0)
SF-36 Bodily pain (SD)	42	41.6 (16.3)	43	44.2 (18.8)
SF-36 Physical functioning (SD)	42	65.7 (22.5)	43	67.1 (23.4)
GSES (SD)	42	32.5 (3.9)	43	32.4 (3.5)

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation)*

Forty two patients were allocated to the self-managed exercise group and 44 were allocated to the usual physiotherapy treatment group. At the three month post-randomisation follow-up 27/42 (64.3%) and 33/44 (75%) participants in the self-managed exercise group and usual physiotherapy treatment group respectively provided primary outcome data. At the six month post-randomisation follow-up 23/42 (54.8%) and 25/44 (56.8%) participants in the self-managed exercise group and usual physiotherapy treatment group respectively provided SPADI outcome data.

Table 8.2 shows the baseline characteristics of those patients who provided follow-up data at three months, i.e. responders, compared to those who did not, i.e. non-responders. This information is useful to enable a judgement about whether the known characteristics of those patients lost to follow-up are significantly different from those who provided follow-up data and are included in the statistical analysis. A difference might suggest a possible treatment-related effect, for example a lack of acceptability to a particular sub-group, which might limits attempts at inference (Walters 2009). Critically a difference between responders and non-responders across the intervention and control groups might also suggest that the outcome of the initial randomisation process has been compromised meaning that the sample of participants with valid outcome data who are included in the analysis are no longer the same as those randomised.

Table 8.2 Baseline characteristics of responders and non-responders at three months

Characteristic	Treatment group			
	Self-managed exercise (n =42)		Usual physiotherapy (n = 44)	
	Responder (n = 27)	Non-responder (n = 15)	Responder (n = 33)	Non-responder (n = 11)
	Mean or count	Mean or count	Mean or count	Mean or count
Age (years)	58.3 (34 to 83)	45.7 (23 to 71)	58.5 (23 to 80)	46.9 (32 to 72)
Gender - male	12/27 (44%)	5/15 (33%)	18/33 (55%)	8/11 (73%)
Gender – female	15/27 (56%)	10/15 (67%)	15/33 (45%)	3/11 (27%)
Duration of shoulder symptoms (months)	11.8 (3 to 78)	11.5 (3 to 36)	18.1 (3 to 120)	15.6 (3 to 60)
SPADI (SD)	44.8 (16.4)	56.9 (19.5)	47.4 (18.4)	53.6 (17.0)
GSES (SD)	32.9 (4.1)	31.9 (3.5)	32.4 (3.5)	32.6 (3.6)

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation)*

From table 8.2, it can be seen that the mean age of responders compared to non-responders across the treatment groups is different where it seems that responders are more likely to be older than non-responders. However, the mean age of non-responders is similar in both the self-managed exercise group and the usual physiotherapy treatment group suggesting that the effects of randomisation have been maintained. Figure 8.2 is a graphical comparison of the mean age by treatment group and response status. Although there is a clear difference between the age of responders and non-responders, indicated by the distant between the lines, the lines are broadly horizontal and do not cross suggesting that the mean age at baseline is similar and does not vary by response status at three month follow-up.

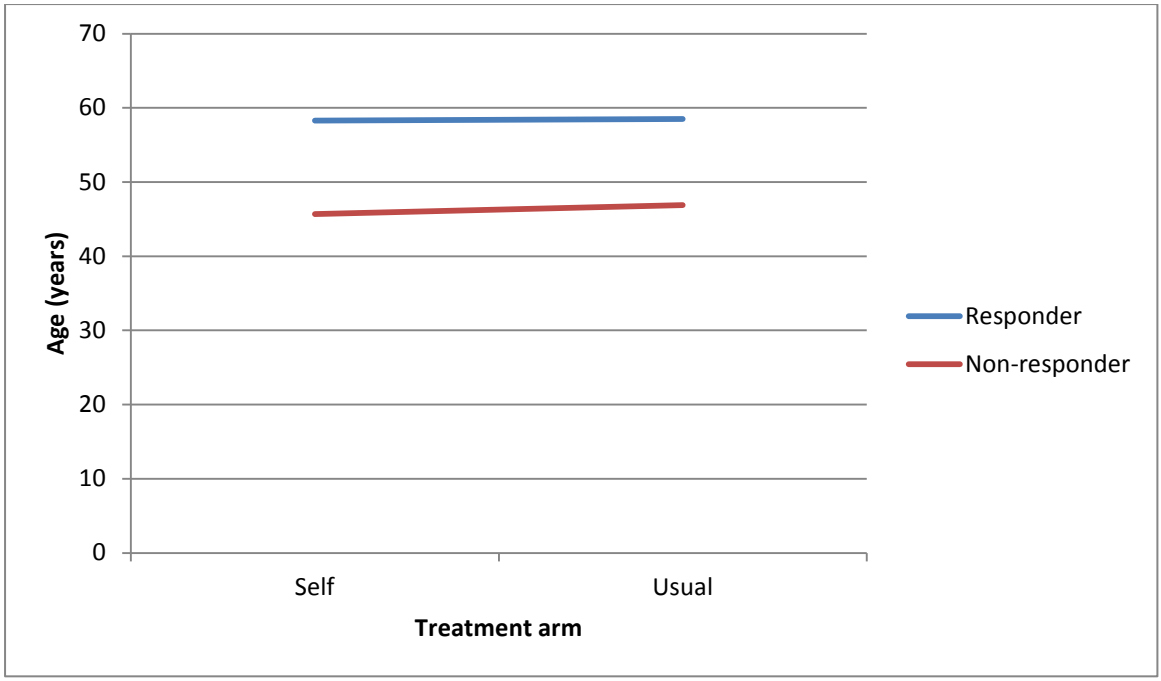


Figure 8.2 Comparison of the mean age by treatment group and response status (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)

Similarly, from table 8.2, it can be seen that the mean SPADI score of responders compared to non-responders at baseline across the treatment groups is different where it seems that responders are more likely to report lower levels of pain and disability. However, the mean SPADI score of non-responders is similar or at least not different by a clinically significant margin, in both the self-managed exercise group and the usual physiotherapy treatment group suggesting that the effects of randomisation have again been maintained. Figure8.3 is a graphical comparison of the mean SPADI score at baseline by treatment group and response status. Although there is a clear difference between the mean SPADI score of responders and non-responders the lines are broadly horizontal and do not cross suggesting that the mean SPADI score at baseline is similar and does not vary by response status at three month follow-up.

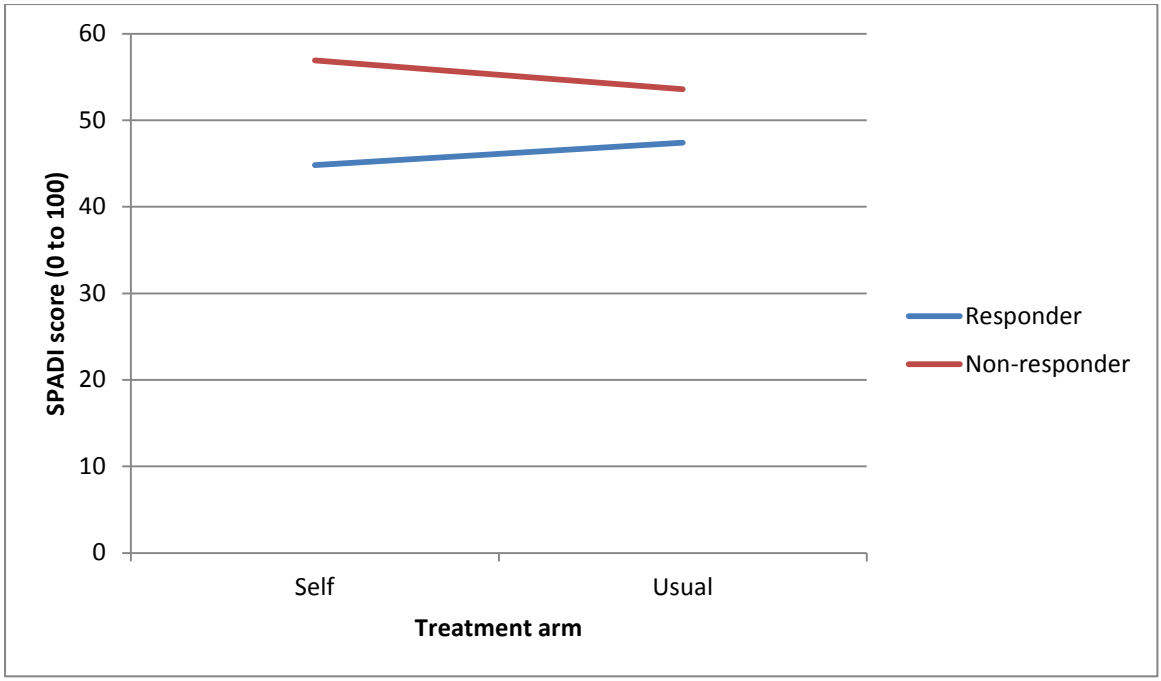


Figure 8.3 Comparison of the mean SPADI score at baseline by treatment group and response status (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)

Further to the exploration above, linear regression was used to formally evaluate whether the baseline characteristics collected had any predictive value in relation to whether the primary outcome data was returned at three months. The only statistically significant characteristic was the SPADI at baseline ($p < 0.01$) which, as seen in figure 8.3, did not differ in terms of response status between groups. So, although the baseline SPADI score appears important in terms of predicting response it does not seem to be important in terms of predicting differential response between the treatment groups. Age ($p=0.24$), duration of symptoms ($p = 0.44$) and GSES ($p = 0.78$) did not demonstrate statistically significant predictive value. The proportion of males and females between treatment groups and across responders and non-responders was examined using Pearson's chi squared test for independence. Despite the observed frequency of non-responding females in the self-managed exercise group, this difference was not statistically significant ($\chi^2 = 4.55$; $p = 0.21$).

8.2.1 Number and content of treatment sessions

The mean number of treatment sessions in the self-managed exercise group was marginally less than the usual physiotherapy treatment group 3.1 versus 3.4 respectively; this difference of 0.4 (95% CI -1.2 to +0.5) was not statistically significant ($p = 0.40$). Most of the attendance occurred during the first three months post-randomisation; 2.2 sessions in the

self-managed exercise group versus 2.5 sessions in the usual physiotherapy treatment group. Within six months this had reduced to 1.1 versus 1.0 session respectively.

Thirty eight out of 42 participants randomised to the self-managed exercise arm received the intervention but two participants also received stretches, two received stabilisation exercises, one received mobilisation and one received acupuncture in addition to the self-managed exercise programme. Three of the four participants who did not receive the self-managed exercise intervention did not attend the initial treatment session post-randomisation hence the reason for not receiving the intervention and one patient withdrew in consultation with the treating physiotherapist when it was felt that the presenting problem was primarily related to the cervical spine rather than the shoulder as defined by the inclusion criteria.

Forty one out of 44 participants randomised to the usual physiotherapy treatment arm received the intervention. Two of the three participants who did not receive usual physiotherapy treatment did not attend the initial treatment session post-randomisation and one patient withdrew because they received surgical intervention in the form of a subacromial decompression prior to beginning physiotherapy treatment.

Those participants in the self-managed exercise arm primarily received exercise treatment in the form of isometric and/ or isotonic exercise supplemented with advice. Those participants in the usual physiotherapy treatment arm primarily received a range of exercises supplemented with advice and manual therapy; described in figure 8.4.

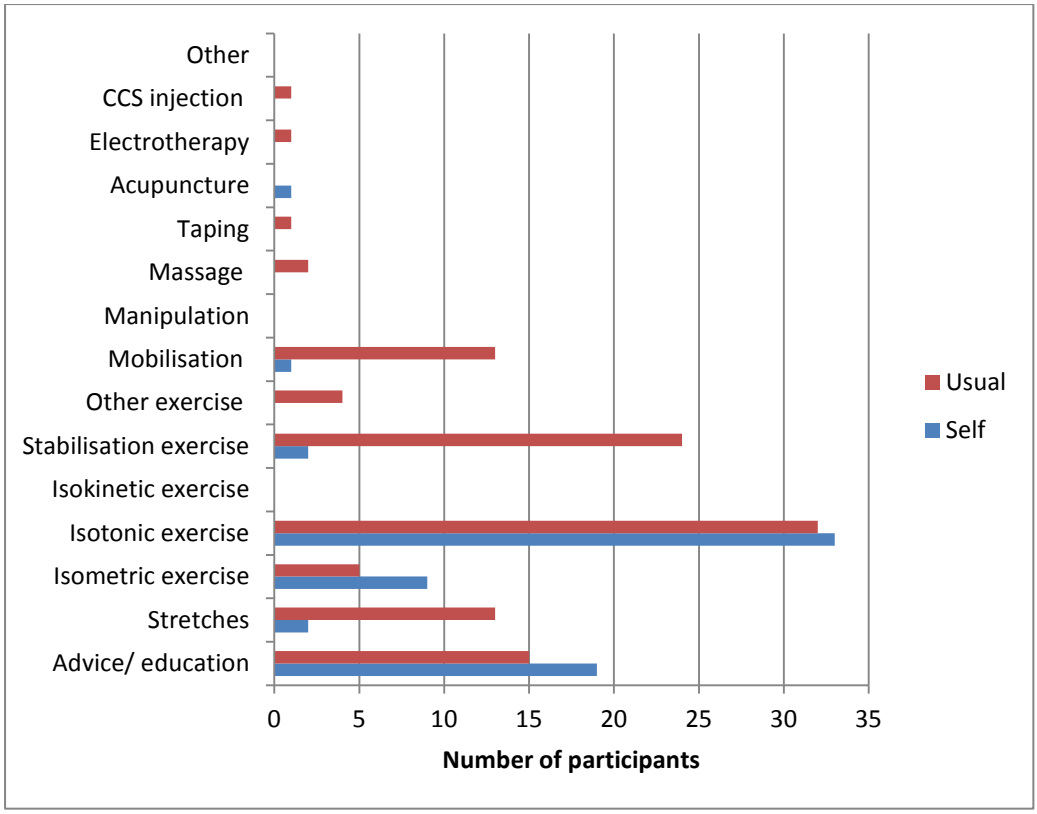


Figure 8.4 Description of the interventions offered (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)

During the six-month follow-up period six of the participants in the self-managed exercise group reported that they received a corticosteroid injection compared to four in the usual physiotherapy treatment group; typically this was administered by a general practitioner although one injection was administered within the course of usual physiotherapy treatment which is reflected in figure 8.4. Additionally, five of the participants in the self-managed exercise group reported that they took medication, including analgesics and non-steroidal anti-inflammatory drugs, for their shoulder problem compared to eight in the usual physiotherapy treatment group. Four of the participants in the self-managed exercise group reported that they accessed private treatment compared to three in the usual physiotherapy treatment group. This private treatment comprised physiotherapy (n = 2), osteopathy (n = 1), chiropractic (n = 1), massage therapy (n = 2) and acupuncture (n = 1). None of the participants in the self-managed exercise group reported that they underwent surgery for their shoulder problem but one participant in the usual physiotherapy treatment did in the form of an arthroscopic subacromial decompression.

8.2.2 Adherence

In the intervention arm, 29% (12/42) participants returned self-report exercise adherence data in the form of annotated exercise diaries. Of the twelve, five participants returned complete data and seven returned partial data. Complete data refers to the return of consecutive annotated diaries dated from initial assessment to final follow-up. According to the exercise protocol, the participants were required to exercise twice daily and so where this was indicated 100% adherence was recorded for that day. Of the five participants who returned complete data, the mean percentage adherence was 74% (range 20 to 98%). Of the seven participants who returned partial data, the mean percentage adherence was 82% (range 40 to 100%). Overall self-report adherence was 78% (range 20 to 100%).

8.2.3 Self-efficacy

The mean GSES score at baseline for the self-managed exercise group was 32.5 (SD 3.9) and 32.4 SD 3.5) for the usual physiotherapy treatment group. The difference of 0.1 (95% CI -1.5 to +1.7) was not statistically significant ($p = 0.90$).

8.2.4 Clinical outcomes

The SPADI and SF-36 outcomes at three and six month follow-up are presented in table 8.3.

Paired t-test analysis demonstrated statistically significant within group changes on the SPADI from baseline to three months; 12.4 point change (95% CI -5.4 to -19.5; $p < 0.01$) for the self-managed exercise group ($n = 27$) and 16.7 (95% CI -9.6 to -23.7; $p < 0.01$) for the usual physiotherapy treatment group ($n = 32$). These changes are regarded as clinically important.

Paired t-test analysis also demonstrated statistically significant within group changes on the SPADI from baseline to six months; 29.1 point change (95% CI -21.0 to -37.1; $p < 0.01$) for the self-managed exercise group ($n = 23$) and a 12.5 point change (95% CI -6.1 to -18.8; $p < 0.01$) on the SPADI from three to six months. These changes are regarded as clinically important.

Further paired t-test analysis demonstrated statistically significant within group changes on the SPADI from baseline to six months; 23.5 point change (95% CI +5.4 to +19.5; $p < 0.01$) for the usual physiotherapy treatment group ($n = 24$) which is regarded as clinically important

but within group change on the SPADI of 5.7 points (95% CI -12.7 to +1.3; p = 0.10) from three to six months was not statistically or clinically significant.

Table 8.3 shows the unadjusted and adjusted differences in outcome scores between the self-managed exercise and usual physiotherapy groups at three and six months. There were no statistically significant differences between the groups across all the outcomes at three months but there was a general trend favouring the usual physiotherapy treatment group across most outcomes. By six months there remained no statistically significant difference between the groups across most outcomes but the trend favouring the usual physiotherapy treatment group had reversed somewhat with most outcomes favouring the self-managed exercise group, particularly in relation to the SPADI score with the SPADI pain subscale demonstrating statistically significant difference between the groups in favour of the self-managed exercise group ($p < 0.05$).

In terms of the primary outcome, the mean difference in three month SPADI score was +1.7 (95% CI -8.7 to +12.0; p = 0.75) points in favour of the usual physiotherapy treatment group. After adjustment for baseline SPADI score the mean difference was +3.2 (-6.0 to +12.4; p = 0.49) points in favour of the usual physiotherapy treatment group. Although both the unadjusted and adjusted analyses suggest no statistically significant difference in SPADI scores between the groups, the 95% confidence intervals for the treatment effect are wide and exceed a 10-point difference, regarded as clinically important, between the groups in favour of the usual physiotherapy treatment group. Hence definitive conclusions about superiority or non-inferiority at three months, based upon an MCID of 10 points on the SPADI, of one approach or another cannot be made with confidence based upon this data.

By six months the mean difference in SPADI score was 7.3 (95% CI -18.3 to +3.6; p = 0.19) points in favour of the self-managed exercise group. After adjustment for baseline SPADI score the mean difference was -6.2 (-16.1 to +3.8; p = 0.22) points in favour of the self-managed exercise group.

Table 8.3 Unadjusted and adjusted differences in outcome scores between the self-managed exercise and usual physiotherapy groups at three and six months

Outcome	Treatment group						Unadjusted difference (95% CI)	P-value[3]	Adjusted difference[4] (95% CI)	P-value[5]
	Self-managed exercise			Usual physiotherapy						
	n	Mean	SD	n	Mean	SD				
SPADI[1] (3 months)	27	32.4	(20.2)	33	30.7	(19.7)	+1.7 (-8.7 to +12.0)[6]	0.75	+3.2 (-6.0 to +12.4)[6]	0.49
SPADI[1] (6 months)	23	16.6	(17.9)	25	24.0	(19.7)	-7.3 (-18.3 to +3.6)[7]	0.19	-6.2 (-16.1 to +3.8)[7]	0.22
SPADI – Pain (3 months)	27	40.5	(23.7)	33	36.6	(19.5)	+3.9 (-7.2 to +15.1)[6]	0.48	+2.8 (-7.9 to +13.4)[6]	0.60
SPADI – Pain (6 months)	23	19.4	(19.3)	25	32.4	(22.5)	-13.0 (-25.2 to -0.8)[7]	0.04	-11.6 (-23.1 to -0.06)[7]	0.05
SPADI – Disability (3 months)	27	27.3	(20.0)	33	27.0	(21.7)	+0.4 (-10.5 to +11.2)[6]	0.95	+3.3 (-6.1 to +12.7)[6]	0.48
SPADI – Disability (6 months)	23	14.9	(18.3)	25	18.7	(20.2)	-3.8 (-15.1 to +7.4)[7]	0.50	-2.8 (-13.0 to +7.4)[7]	0.58
SF-36 Physical functioning[2] (3 months)	28	62.3	(27.7)	33	70.4	(25.5)	-8.1 (-21.7 to +5.5)[6]	0.24	-5.3 (-12.7 to +2.2)[6]	0.16
SF-36 Physical functioning[2] (6 months)	22	66.3	(28.6)	25	67.8	(26.5)	-1.6 (-17.7 to +14.6)[6]	0.85	-1.1 (-17.9 to +15.7)[6]	0.89
SF-36 Role-physical[2] (3 months)	27	68.3	(23.6)	32	72.3	(26.9)	-4.0 (-17.4 to +9.3)[6]	0.55	-1.0 (-11.7 to +9.7)[6]	0.85
SF-36 Role-physical[2] (6 months)	22	69.3	(25.4)	25	78.0	(22.0)	-8.7 (-22.6 to +5.3)[6]	0.22	-8.1 (-22.9 to +6.7)[6]	0.27
SF-36 Bodily pain[2] (3 months)	26	52.9	(19.1)	33	58.4	(15.0)	-5.5 (-14.4 to +3.4)[6]	0.22	-3.2 (-11.5 to +5.1)[6]	0.44
SF-36 Bodily pain[2] (6 months)	23	63.1	(26.0)	25	58.1	(17.6)	+5.1 (-7.7 to +17.9)[7]	0.43	+5.7 (-8.1 to +19.4)[7]	0.41
SF-36 General health[2] (3 months)	28	62.5	(20.6)	32	62.0	(21.1)	+0.48 (-10.3 to +11.3)[7]	0.93	-2.7 (-10.7 to +5.3)[6]	0.50
SF-36 General health[2] (6 months)	23	57.0	(19.4)	25	61.1	(22.7)	-4.1 (-16.4 to +8.2)[6]	0.51	-6.2 (-18.2 to +5.9)[6]	0.31
SF-36	27	59.8	(18.0)	33	52.1	(19.6)	+7.7 (-2.1	0.12	+4.9 (-2.8	0.21

Vitality[2] (3 months)							to +17.5)[7]		to +12.7)[7]	
SF-36 Vitality[2] (6 months)	22	56.2	(21.0)	25	51.0	(19.3)	+5.2 (-6.7 to +17.0)[7]	0.39	+4.5 (-7.4 to +16.3)[7]	0.45
SF-36 Social functioning[2] (3 months)	28	46.0	(16.3)	33	47.3	(13.9)	-1.4 (-9.1 to +6.4)[6]	0.73	-1.6 (-9.5 to +6.3)[6]	0.69
SF-36 Social functioning[2] (6 months)	23	46.2	(9.6)	25	44.5	(13.5)	+1.7 (-5.2 to +8.6)[7]	0.62	+3.1 (-3.8 to +10.1)[7]	0.37
SF-36 Role emotional[2] (3 months)	27	80.9	(24.7)	32	83.9	(26.9)	-3.0 (-16.6 to +10.6)[6]	0.66	-3.5 (-16.2 to +9.3)[6]	0.59
SF-36 Role emotional[2] (6 months)	21	80.6	(24.8)	25	88.0	(24.1)	-7.4 (-22.0 to +7.1)[6]	0.31	-6.9 (-21.9 to +8.2)[6]	0.36
SF-36 Mental health[2] (3 months)	27	77.2	(15.6)	33	75.2	(12.8)	+2.1 (-5.3 to +9.4)[7]	0.58	+2.0 (-4.0 to +8.1)[7]	0.50
SF-36 Mental health[2] (6 months)	22	70.8	(14.1)	25	71.0	(16.4)	-0.2 (-9.3 to +8.8)[6]	0.96	+0.3 (-8.8 to +9.3)[7]	0.95

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation /* [1] *Higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100) /* [2] *Higher scores indicate better quality of life (scored on a scale of 0 to 100) /* [3] *P-value derived from independent samples t-test /* [4] *Adjusted for corresponding baseline score, e.g. follow-up SPADI adjusted for baseline SPADI /* [5] *P-value derived from analysis of covariance (ANCOVA) /* [6] *Usual physiotherapy group reports better outcomes /* [7] *Self-managed exercise group reports better outcomes)*

Figure 8.5 shows the trend in change in total SPADI score from the patients who had complete data sets by the six month follow-up.

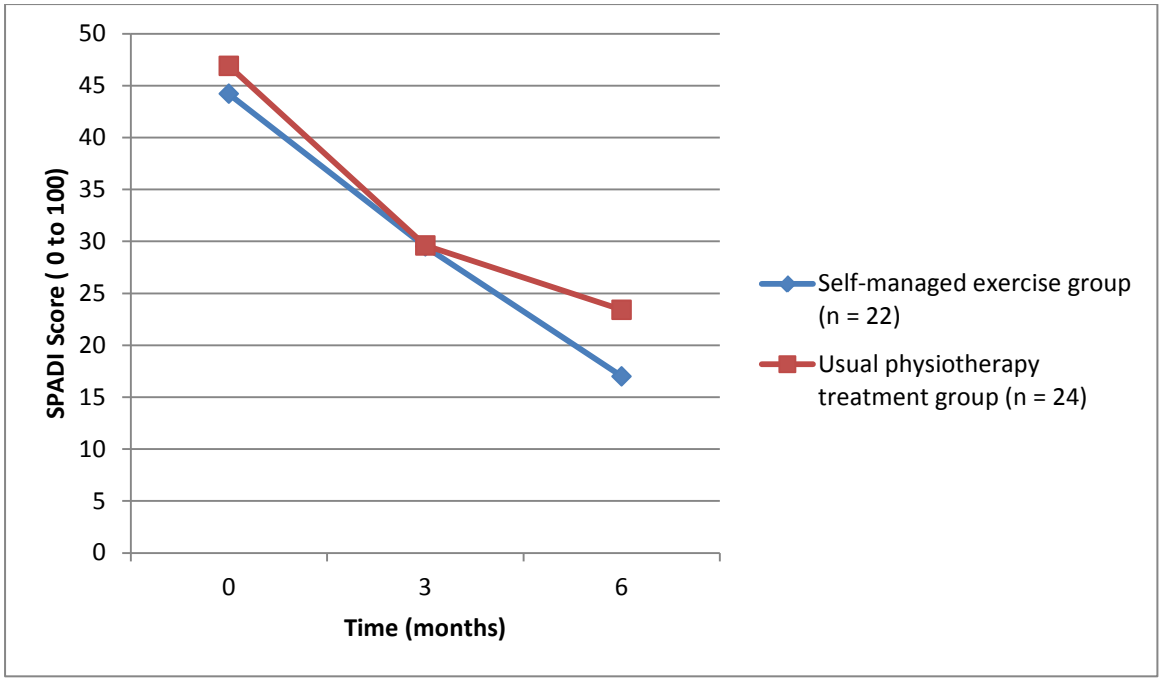


Figure 8.5 Mean total SPADI score over time by treatment group

Figure 8.6 shows the trend in change in the SPADI subscale pain score from the patients who had complete data sets by the six month follow-up.

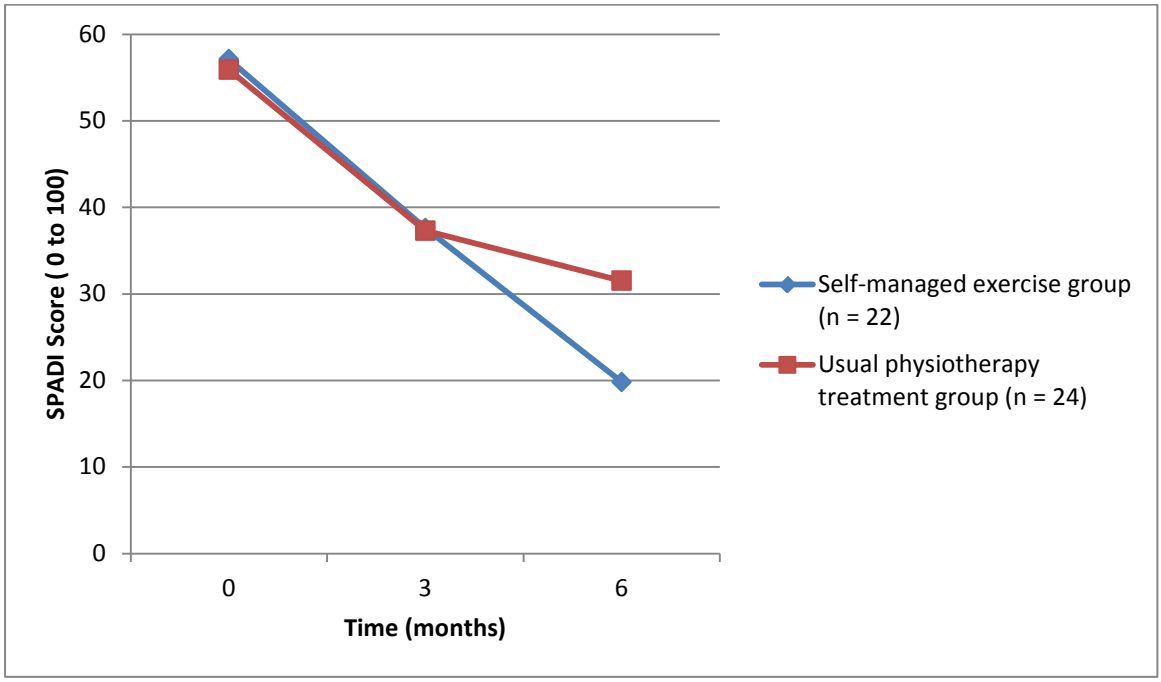


Figure 8.6 Mean SPADI subscale pain score over time by treatment group

We also initially proposed to analyse the PSFS scores collected during the intervention periods (Littlewood et al. 2012c). However, due to the varied functional activities recorded and the heterogeneity in terms of when follow-up data was collected it was felt that such analysis would not add value over the analysis of the SPADI data and hence formal analysis has not been undertaken.

The patients reported a range of functional limitations secondary to their shoulder disorder including activity above shoulder height, for example brushing hair and reaching up high, activity below shoulder height, for example lifting the kettle, self-care limitations, for example back washing, bra fastening and putting a coat on, recreational limitations, for example swimming and badminton, and work-related limitations, for example driving and lifting, as well as some participants describing sleep as their primary functional limitation. Figure 8.7 depicts the primary functional limitations reported by the participants

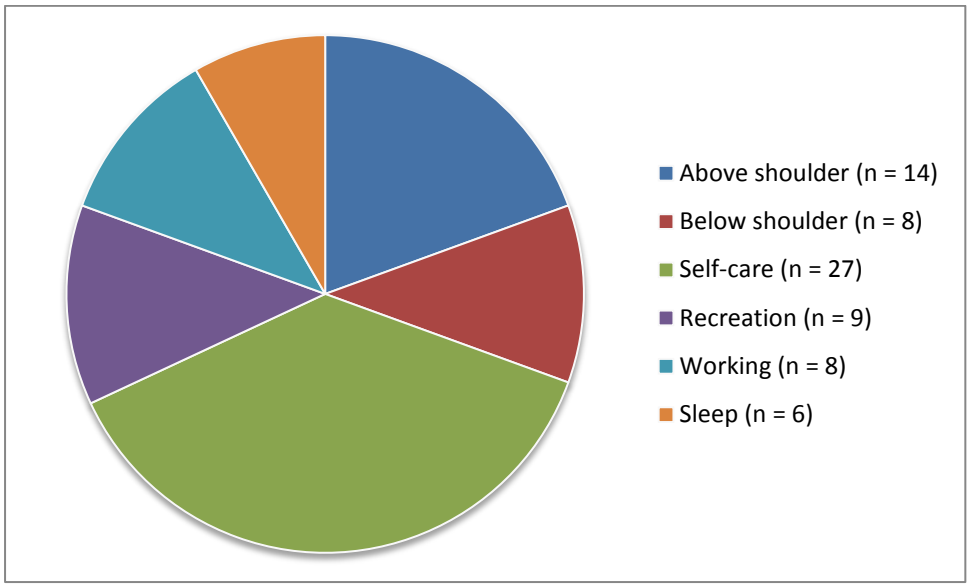


Figure 8.7 Description of the primary functional limitations reported by the participants on the patient specific functional scale (data available for 72/86 participants)

8.2.4.1 Clinical outcomes with imputation of missing data

Table 8.4 shows the mean difference in SPADI scores at three months according to the method of data analysis; with and without imputation of missing data.

8.2.4.1.1 Last Observation Carried Forward

The mean difference in three month SPADI scores with imputation of the last observation carried forward was 4.7 (95% CI -4.8 to 14.2; p = 0.895) points in favour of the usual physiotherapy treatment group. After adjustment for baseline SPADI score the mean

difference was 4.4 (-2.8 to 11.7; p = 0.225) points in favour of the usual physiotherapy treatment group.

8.2.4.1.2 Regression imputation

The mean difference in three month SPADI scores with regression imputation, using baseline SPADI scores, was 2.3 (95% CI -5.3 to 9.9; p = 0.861) points in favour of the usual physiotherapy treatment group. After adjustment for baseline SPADI score the mean difference was 2.2 (-4.1 to 8.4; p = 0.490) points in favour of the usual physiotherapy treatment group.

This additional analysis using two different methods of imputation does little to alter the inferences drawn previously. The analysis using regression imputation narrows the upper limit of the 95% confidence interval to below the range that might be regarded as a clinically significant change in favour of usual physiotherapy treatment but this remains borderline and with the limitations of analysis using various methods of imputation in mind should be treated with caution.

Table 8.4 Unadjusted and adjusted differences in outcome scores between the self-managed exercise and usual physiotherapy groups at three months with imputation of missing values

	Mean difference in SPADI score at 3 months*	Lower 95% CI	Upper 95% CI
Observed data (n=60)	1.7 [1]	-8.7	12.0
	3.2 [2]	-6.0	12.4
Last Observation Carried Forward (n=86)	4.7 [1]	-4.8	14.2
	4.4 [2]	-2.8	11.7
Regression imputation (n=86)	2.3 [1]	-5.3	9.9
	2.2 [2]	-4.1	8.4

(**All in favour of usual physiotherapy treatment group / [1] unadjusted analysis/ [2] adjusted analysis)*

8.3 Discussion

The primary aim of this study was to evaluate the clinical effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. The results from this study provide insufficient evidence to reject the null hypothesis that there is no difference between the two treatment approaches in terms of the primary outcome, the SPADI score, three months post-randomisation. With reference to both the SPADI and SF-36 at three months, there is a reasonably consistent but non-significant trend favouring the usual physiotherapy treatment group. By six months there is evidence of a reversal of this trend, particularly in relation to the SPADI score, with most outcomes

remaining non-significant but favouring the self-managed exercise group. The exception to this non-significant trend is the pain subscale of the SPADI which demonstrated a statistical significant between-group difference by six months in favour of the self-managed exercise group. However, no inference should be drawn from this data in terms of potential superiority of one approach or another.

The findings of this current study are in keeping with other similar studies; significant within group effects are apparent but superiority of one approach over an active comparator is not apparent. In contrast to other studies, the patient-reported outcomes in terms of change in SPADI score at three months post-randomisation in this current study might be regarded as relatively meagre; 12.4 points for the self-managed exercise group and 16.7 points for the usual physiotherapy group. Although these changes would be regarded as clinically important with reference to the MCIC of 10 points suggested by Williams et al. (1995), the changes reported by other studies, for example Engebretsen et al. (2009), Kromer et al. (2013) and Yiasemides et al. (2011), in excess of 20 points on the SPADI, are greater and in the case of Yiasemides et al. (2011), greater by an amount than would be regarded as clinically important (change score of 29 on the SPADI by three months). Such a difference might be explained by contextual factors as discussed in chapter two, for example factors relating to the patient population, the treating physiotherapist and the content of the treatment package. However, based upon the available data from this and other studies it is difficult to substantiate such hypotheses with confidence. One relevant factor though is the time required to receive or undertake what might be regarded as a therapeutic dose of the intervention. In this current study it was apparent that the majority of patients did not commence treatment immediately post-randomisation and for a minority treatment had not commenced by the three month follow-up point. This is an important consideration with reference to chapter two, where it was suggested that a minimum intervention period of twelve weeks should be implemented, particularly with reference to an exercise programme. The validity of this claim is substantiated with reference to the six month follow-up data where, on average, patients in both groups reported further improvement and the majority had been discharged from physiotherapy and hence, from a pragmatic perspective, would be regarded as having received a therapeutic dose of the intervention. By six months the patients in the self-managed exercise group reported a 29.1 point change

in SPADI score from baseline and the patients in the usual physiotherapy treatment group reported a 23.5 point change. In addition to the minimum therapeutic dose time period, the implication of this is that the signs and symptoms associated with rotator cuff tendinopathy continue to improve, on average, over time whether that be due to natural history or the effects of the intervention. This point should be recognised when advising patients regarding length of rehabilitation, prognosis and when considering referral for other intervention, for example surgery.

Interestingly only the self-managed exercise group reported what would be regarded as a clinically important change between three and six months; 12.5 points on the SPADI for the self-managed exercise group compared with 5.7 points for the usual physiotherapy treatment group. Although this difference needs to be considered in the context of the high drop out from this current study, which will be discussed later, this offers potential new insight into the management of rotator cuff tendinopathy. The intervention was developed with reference to self-management theory with the aim of enhancing self-efficacy and hence engagement with the programme. It seems feasible to suggest, in the context of the theory presented, that this between-group difference in the longer-term might actually reflect the constructs of the self-managed exercise programme with certain patients afforded the opportunity to effectively self-manage what is regarded as a persistent and/ or recurrent disorder. In contrast, although multimodal packages including, for example manual therapy, might confer superior outcomes in the short-term, a treatment package comprising therapist-led interventions might actually compromise motivation to self-manage. This point was reflected in chapter seven where the qualitative aspect of the pilot study was reported and is difficult to substantiate on a wider scale but seems plausible if the locus of control is shifted from the patient during the therapeutic encounter.

In contrast to the pilot study and the report of current practice in the UK by Littlewood et al. (2012a), the range of interventions offered within the usual physiotherapy treatment group in this current study was more restricted and largely centred upon exercise. Despite this there did appear to be a different focus in terms of exercise prescription between the two groups. Whereas the self-managed exercise group largely received a single loaded exercise, the participants in the usual physiotherapy treatment group were exposed to a wider range of exercise including stretching and stabilisation exercise. However, loaded exercise,

including isometric and/ or isotonic exercise, was a feature of most patients' prescription in the usual physiotherapy treament group also but, as will be discussed in chapter ten, this was frequently not as aggressive in terms of load and pain provocation as that prescribed for those in the self-managed exercise group. It is unclear whether this more aggressive approach to loading might be one potential explanatory factor for the superior, albeit statistically non-significant, clinical outcomes for those patients who returned SPADI scores at six months. Certainly, others, for example Konsgaard et al. (2009), have reported superior outcomes secondary to more aggressive loading when treating tendinopathy. However, this notion is directly challenged by the findings of the study by Yiasemides et al. (2011). These authors reported the effects of an exercise programme designed to address neuromuscular control of the shoulder with all exercise being undertaken in a pain-free manner where, hence, aggressive loading was not a feature but excellent clinical outcomes in terms of the SPADI were still reported at six months. That clinically important results can be attained via potentially quite different exercise regimes, and other interventions including surgery, appears to confirm the lack of understanding of the true mechanism of action of current interventions for rotator cuff tendinopathy (Drew et al. 2012; Littlewood et al. 2013b).

Furthermore, this study, to the authors knowledge, is the first to evaluate the effectiveness of a single exercise for rotator cuff tendinopathy. This is in contrast to much of current physiotherapy practice in the UK and is also in contrast to other studies evaluating effectiveness where a range of exercises, often offered alongside other modalities, tend to be prescribed (Littlewood et al. 2012a; Littlewood et al. 2013c). Notwithstanding the limitations of this current study, it is suggested that the data presented here in tandem with that of the pilot RCT presented in chapter six might serve to challenge the idea that a range of exercises are needed to effect a worthwhile clinical change in all patients. This is a particularly relevant issue when considered in context of the issue of exercise adherence and the notion that higher dose of exercise might confer superior clinical outcome in terms of pain and disability. The pragmatic benefits of a single exercise approach were considered in detail in chapter three and the comparability of the single exercise approach and mulit-modal or multi-exercise approach reported in this current study might suggest that a single exercise approach is a valid and worthwhile prescription for certain patients, at least as a

first line rehabilitation intervention. Currently interventions in clinical practice and research studies appear to be offered concurrently as part of a multimodal package. Although there is a wide range of interventions currently offered to people with signs and symptoms associated with rotator cuff tendinopathy none of them are a panacea. In light of the results of this current study it seems sensible to suggest that a move towards sequential care where response to therapy, recognising prognostic factors and required minimum time frames, is used as a form of stratification might be indicated. Forms of stratified care have been evaluated favourably in relation to low back pain and seem to offer the potential for a more efficient allocation of health care resource (Hill et al. 2011). In practice this would mean that patients, particularly those with a preference for self-management, could be prescribed a single loaded exercise within the self-managed framework and additional interventions might only be considered if favourable clinical response was not forthcoming. The added benefit of a sequential rather than concurrent approach is currently unknown but appears to warrant further consideration and evaluation.

In terms of other interventions offered as part of a multimodal package within the usual physiotherapy treatment arm, approximately one-third of patients received some form of manual therapy; other techniques or modalities, for example electrotherapy and taping, were only sparsely used. This contrast in treatment prescription between this current NHS based study and the private practice based pilot study might reflect the priorities and/ or focus in the different settings but also, with reference to the survey of current practice by Littlewood et al. (2012a), might reflect a change in practice to reflect the evidence base as reported by Littlewood et al. (2013c) where exercise is proffered as an effective intervention for rotator cuff tendinopathy. Unexpectedly and again in contrast to the pilot study, the mean number of treatment sessions was similar between the two groups; 3.1 for the self-managed exercise group and 3.4 for the usual physiotherapy treatment group. The similar number of sessions offered might be reflective of the exercise based nature of the usual physiotherapy treatment and might also suggest that many current UK NHS based physiotherapists encourage patients to actively self-manage.

With regard to exercise adherence, a disappointingly low rate of return of exercise diaries was observed. Only 29% of exercise diaries were available for inspection which makes meaningful inference, beyond speculation, difficult.

8.3.1 Strengths and limitations

The strengths of this RCT include valid methods of concealed random allocation, its multi-centre nature, pragmatic evaluation, use of a valid primary outcome measure and longer-term follow-up. Inadequate methods of allocation and concealment are regarded as significant sources of bias within RCTs (Furlan et al. 2009). In the SELF RCT, low tech but acceptable methods of random allocation and concealment were employed successfully from the perspective that the treatment groups appeared to be comparable at baseline. Participants were recruited to this trial via three centres across the UK. Such a recruitment spread enhances the generalisability of any relevant findings. Secondly, a pragmatic evaluation was undertaken; the inclusion criteria could be readily applied by clinical physiotherapists and hence patients similar to those recruited in to this trial could be identified in routine clinical practice. Furthermore, the self-managed exercise intervention was designed to align with usual NHS physiotherapy practice. Hence, where applicable, the intervention could be adopted without the need for extra resource, for example time or equipment. A valid and reliable primary outcome measure, the SPADI, was adopted. In contrast to other studies, as identified by Littlewood et al. (2012b), this affords the reassurance that relevant dimensions of shoulder pain and disability are being measured. Furthermore, because the SPADI is now a commonly used measure of shoulder pain and disability in studies evaluating the effectiveness of conservative interventions, the data collected in this current study offers further relevant data for future evidence synthesis. Finally, as recognised in chapter two, many published studies reporting an evaluation of the effectiveness of an intervention for rotator cuff tendinopathy only report short-term outcome, up to three months. This current study has reported outcomes to six months which, upon a backdrop of a persistent and/ or recurrent disorder, is important to inform clinical decision making.

It has been suggested that clinical outcomes might be improved if the intervention is staged according to the continuum model of tendon pathology (Cook & Purdam 2009; McCreesh & Lewis 2013). The limitations of the pathology based models in terms of explaining symptoms have been recognised (Littlewood et al. 2013b; McCreesh & Lewis 2013) but criticism of this current study in terms of applying an intervention to a heterogeneous sample is potentially credible. Just as heterogeneity in relation to psychological or social profile of both patients

and physiotherapists might influence outcome (Horsley 2011), the role or stage of pathology in relation to treatment prescription and outcome might be relevant and become more apparent over time. In the absence of evidence indicating the relevance of pathology as currently understood though this limitation remains hypothetical. Also, in a pragmatic trial of this nature, treatment prescription was individualised to reflect examination findings and more specifically response to load. Hence, via these mechanisms, the heterogeneity of the sample in terms of clinical presentation might actually have been addressed.

In addition to the limitations discussed with regard to blinding in chapter six with reference to the pilot RCT, one clear limitation to this RCT is the loss-to-follow-up. By three months 70% (60/86) of patients had returned primary outcome data and this diminished further to 56% (48/86) by six months. The original sample size calculation only accounted for 15% loss to follow-up which, in the planning phase, appeared appropriate when considering other similar trials. In a recent pragmatic trial undertaken in the UK NHS, Crawshaw et al. (2010) reported that 88% of patients provided valid three month primary outcome data which reduced marginally to 83% by six months. Although the three month data was collected during a follow-up visit, the six-month data was collected via return of postal questionnaire which reflects the SELF RCT.

Although such a high loss to follow-up would not be regarded as a fatal flaw (Furlan et al. 2009; van Tulder et al. 2009), clearly the precision of the estimate of clinical effect is compromised as is any attempt to infer beyond those patients who returned follow-up data. Despite this, it is reassuring to note that comparable between-group treatment effects were also found in the pilot study which was conducted in a different context.

The issue of loss to follow-up is a consideration for all those conducting research studies. Beyond speculation, it is unclear why the loss was so marked and in the wider literature there is no clear and consistent guidance about how to minimise loss to follow-up (Torgerson & Torgerson 2008; Walters 2009). Completion time of the questionnaires did not appear too burdensome and stamped addressed envelopes were provided to return the completed forms. One postal reminder was sent if the questionnaires had not been returned within two weeks but interestingly this only prompted a minority to respond if they hadn't done so after the first time of asking. Previously the lay members of the PPI

panel had suggested that an incentive might be useful to encourage return of the questionnaires. This was the only recommendation from the panel that was not taken forward due to funding limitations at the time but in hindsight was an error. When considering the actual cost of loss to follow-up and impact in terms of an underpowered study, the financial implication of an incentive, for example an iPad mini as a prize in a draw at £249, appears almost inconsequential.

Other studies, for example Yiasemides et al. (2011), have utilised telephone follow-up to minimise data loss. The SPADI has been found to be suitable for administration over the telephone (Williams et al. 1995) and although the impact of following some patients up via postal questionnaire and some via the telephone is unknown, it seems preferable to a situation where no data is available. This method of follow-up should be considered in future research studies where, potentially, patient preference for method of follow-up could be sought at baseline and/ or telephone follow-up could be utilised instead of sending a postal reminder.

A final consideration, rather than limitation, is the use of parametric methods of data analysis on ordinal level data in this chapter and throughout this thesis. Some authors argue that non-parametric methods should be used in these situations whereas others suggest that the utility of parametric methods, for example estimating confidence intervals, and their robustness to deviations from the suggested assumptions warrants their use (Walters 2009). It is for these latter reasons that parametric methods have been employed in this thesis along with recognition that most other authors in this field have adopted a similar approach and hence there is pragmatic value from a data synthesis perspective also.

8.4 Conclusion

This RCT does not provide sufficient evidence of superiority of either a programme of self-managed exercise or usual physiotherapy treatment for patients with shoulder pain and disability attributable to rotator cuff tendinopathy in the short-term. Also, in the mid-term, this RCT does not provide sufficient evidence of superiority of the self-managed exercise programme except in relation to shoulder pain as measured by the pain subscale of the SPADI. By six months post-randomisation, a statistically significant between-group difference in favour of the self-managed exercise group was demonstrated. However, these

findings need to be considered in the context of a relatively high loss to follow-up which might confound validity of these conclusions.

Chapter 9: The SELF study - economic analysis

Summary

This chapter reports the economic analysis that was conducted as a component of the mixed methods SELF study. The analysis was undertaken from an NHS and personal social service perspective. Patient-level costs and outcomes were assessed over six months. The SF-6D, derived from the SF-36, was combined with standard valuation sources to measure QALYs in each treatment arm.

9.1 Introduction

In an arena where resources are limited, for example the UK NHS, it makes sense to consider both the effectiveness of an intervention in tandem with the associated cost or resource use in an attempt to gain maximal health benefit for the limited resources available (Brazier et al. 2007; Walters 2009). Economic analysis is the comparative analysis of alternative courses of action, or interventions, in terms of their costs and consequences, or health outcomes (Drummond et al. 2005). Despite the apparent relevance of economic analysis in health-care decision making, relatively few such analyses have been taken in relation to physiotherapy-related interventions and particularly in relation to shoulder disorders (Jowett et al. 2013).

Jowett et al. (2013) undertook an economic analysis alongside a pragmatic trial conducted in the UK NHS by Crawshaw et al. (2010). The trial aimed to evaluate the effectiveness of exercise therapy after corticosteroid injection compared with exercise alone for moderate to severe pain due to subacromial impingement syndrome. Crawshaw et al. (2010) concluded that the two interventions were similarly effective at 12 weeks. However, due to the lower resource use reported by the participants in the injection plus exercise group, Jowett et al. (2013) concluded that this intervention might be a cost-effective use of resources compared with exercise alone. Hence the conclusions reported by Jowett et al. (2013) offer a useful insight in to how economic analysis might usefully inform clinical decision making beyond isolated clinical effectiveness results. In this case it is suggested

that an intervention of similar clinical effectiveness is preferentially prescribed due to the lower associated health care costs representing a more efficient allocation of resources and hence less opportunity cost (NICE 2012).

The aim of this chapter is to present the economic analysis undertaken alongside the SELF RCT reported in chapter eight. This analysis will be undertaken from a NHS and Personal Social Services (PSS) perspective as recommended by the National Institute for Health and Care Excellence (NICE 2012).

9.2 Methods

9.2.1 Health outcomes

The economic analysis reports the consequences or health outcomes in terms of quality-adjusted life years (QALYs). The QALY combines length and quality of life into a single index number between 0 and 1 where 0 corresponds to a health state judged to be equivalent to death and 1 corresponds to optimal health (Drummond et al. 2005). In this context, due to the nature of rotator cuff tendinopathy, the focus was upon quality of life gain secondary to a reduction in pain and disability rather than an extension to life.

In addition to completion of the primary outcome measure, the SPADI, participants in the SELF RCT completed the SF-36, a generic measure of health-related quality of life, at baseline, three and six months. Subsequently the Short-Form 6D (SF-6D) score was derived from a selection of SF-36 items to generate individual utility values.

The SF-6D was developed by Brazier et al. (2002) in response to the popularity and growing use of the SF-36 in clinical trials. Any patient who completes the SF-36 can be uniquely classified according to the SF-6D (Brazier et al. 2007). The SF-6D is composed of six multi-level dimensions; physical functioning, role limitation, social functioning, pain, mental health, and vitality (Brazier et al. 2007). The SF-36 derived SF-6D describes 18,000 health states in all (Brazier et al. 2007).

The QALY score for each patient over the six-month follow-up was estimated by calculating the area under each patient's health utility curve using straight line interpolation between data points. So, for example, if a patient reported a SF-6D derived utility value equal to one at three and six months during the trial this would equate to a QALY of 0.5 because six

months equates to half of one year. If they reported SF-6D derived utility value equal to 0.3 at three and six months during the trial this would similarly equate to a QALY of 0.15.

9.2.2 Costs

Data regarding resource utilisation was collected via patient-reported resource use questionnaires (**Appendix 15**) returned at three and six months along with the other measures of clinical outcome. Additionally patient notes were reviewed to confirm resource use in relation to the number of physiotherapy sessions attended and other interventions received, where reported.

A range of health care costs were considered including the number of physiotherapy sessions, number of GP attendances, number of attendances with other healthcare professionals, for example extended scope physiotherapists or surgeons, other interventions received, for example medication, corticosteroid injections, and referrals to surgery. These costs were derived from the Personal Social Services Research Unit (PSSRU) publication 'unit costs of health and social care' (PSSRU 2012), the NHS Reference Costs (Department of Health 2012) and the British National Formulary (BNF 2012). Table 9.1 highlights the most common unit costs used to inform the economic analysis.

Table 9.1 Unit costs used to inform economic analysis

Resource	Cost per activity (£)
Visit to Physiotherapist	34.00
Visit to General Practitioner	43.00
Visit to Orthopaedic Surgeon	147.00
Corticosteroid injection (1ml vial 40mg/ml triamcinolone (Kenalog) and 10ml 0.5% bupivacaine)*	2.43

(*always combined with practitioner cost)

Medication and surgical costs were estimated on a case-by-case basis to reflect the medication prescribed and dosage and the surgical intervention offered. Collection of cost data in this way enabled an estimation of the total cost for each participant as well as the average total cost for each treatment group.

Since the follow-up period was less than one year, discounting of costs was not indicated (Jowett et al. 2013)

9.2.3 Data analysis

As with the clinical outcomes, economic analysis was conducted on an intention-to-treat basis and the between groups differences were compared using 2-independent samples t-tests. As part of an additional post-hoc analysis, missing SF-6D scores were imputed using simple LOCF to generate complete data sets for those patients who returned complete resource use data at six months but where missing SF-36 data prohibited calculation of SF-6D scores.

9.3 Results

Table 9.2 shows the baseline demographic data from the patients who returned complete resource use data at six months.

Table 9.2 Baseline characteristics of the participants who returned complete resource use data at six months by treatment group

Characteristic	Treatment group			
	Self-managed exercise		Usual physiotherapy	
	n	Mean or %	n	Mean or %
Age (years) (SD)	20	57.7 (13.7)	25	59.1 (13.3)
Gender - male	20	7/20 (35%)	25	14/25 (56%)
Duration of shoulder symptoms (months) (SD)	20	12.7 (17.4)	24	19.8 (26.8)
SPADI (SD)	20	43.1 (17.8)	24	46.9 (18.6)
SF-6D (SD)	20	0.60 (0.08)	25	0.60 (0.07)
GSES (SD)	20	32.6 (4.1)	24	32.3 (3.7)

(*For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/ The Short Form (SF)-6D is scored on a scale of 0 to 1.0 and higher scores indicate higher utility / The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy / SD = standard deviation)*

By six months, the costs associated with the self-managed exercise group (n = 20) were £172.86 (SD 91.94) and £235.45 (SD 301.31) for the usual physiotherapy treatment group (n = 25). This difference of £62.58 (95% CI -203.70 to 78.54) in favour of the self-managed exercise group was not regarded as statistically significant (p = 0.38). However, it was apparent that the data for the usual physiotherapy treatment group were skewed secondary to one patient undergoing surgery in that group; costed at £1346.00 (Minimal Shoulder and Upper Arm Procedures for Non-Trauma; NHS Reference Costs 2012 to 2013) (Department of Health 2012). When the outlying resource use data from this patient were removed the cost associated with the usual physiotherapy treatment group (n = 24) fell to £178.80 (SD 104.98). The difference between this revised estimate and the estimate of cost

associated with the self-managed exercise group was £5.94 (95% CI -66.61 to +54.73) in favour of the self-managed exercise group; this was not statistically significant (p = 0.84).

The mean QALY in the self-managed exercise group was 0.31 (SD 0.04) and 0.31 (SD 0.03) for the usual physiotherapy treatment group. The mean difference in QALY was negligible (+0.0001; 95% CI -0.03 to +0.02), in favour of the self-managed exercise group, and was not regarded as statistically significant (p = 0.99). The number of participants returning resource-use data, the mean costs, mean QALY and between-group differences is presented in table 9.3 where it can be seen that the additional post-hoc analysis using LOCF does little to alter the negligible mean QALY difference between groups.

Table 9.3 Results of the economic analysis at six months

Outcome	Self-managed exercise group			Usual physiotherapy treatment group			Mean difference	95% confidence interval		P-value *
	n	Mean	SD	n	Mean	SD		Lower	Upper	
NHS cost (£)	20	171.11	89.97	25	235.45	301.31	-64.34	-201.94	+73.26	0.35
				24[#]	178.80	104.98	-7.70	-66.92	+51.54	0.79
QALY (SF-6D)	17	0.31	0.04	20	0.31	0.03	+0.0001	-0.02	+0.03	0.99
QALY (SF-6D)~	20	0.31	0.03	25	0.31	0.03	-0.004	-0.2	+0.2	0.68

(QALY = Quality Adjusted Life Year / *The Short Form (SF)- 6D is scored on a scale of 0 to 1.0 and higher scores indicate higher utility / SD = standard deviation /* * p-value from two independent samples t-test; [#] data with outlier omitted; ~ analysis with LOCF for those patients who provided resource use data but missing data SF-36 data prohibited calculation of SF-6D value)

The self-managed exercise arm was associated with marginally lower costs than the usual physiotherapy treatment group but comparable clinical outcomes in terms of the QALY.

During the six-month follow-up period six of the participants in the self-managed exercise group reported that they received a corticosteroid injection compared to four in the usual physiotherapy treatment group; typically this was administered by a general practitioner although one injection was administered within the course of usual physiotherapy treatment which is reflected in figure 8.4. The mean number of GP visits was less than one across both treatment arms; 0.9 (SD 1.2) in the self-managed exercise group; 0.9 (SD 1.2) in the usual physiotherapy treatment group. Additionally, five of the participants in the self-managed exercise group reported that they took medication, including analgesics and non-steroidal anti-inflammatory drugs, for their shoulder problem compared to eight in the usual physiotherapy treatment group. Four of the participants in the self-managed exercise

group reported that they accessed private treatment compared to three in the usual physiotherapy treatment group. This private treatment comprised physiotherapy (n = 2), osteopathy (n = 1), chiropractic (n = 1), massage therapy (n = 2) and acupuncture (n = 1). None of the participants in the self-managed exercise group reported that they underwent surgery for their shoulder problem but one participant in the usual physiotherapy treatment did in the form of an arthroscopic subacromial decompression.

9.4 Discussion

The results of this economic analysis indicate that a programme of self-managed exercise for rotator cuff tendinopathy is broadly comparable to usual physiotherapy treatment in terms of both cost and effect. Clinical outcomes in terms of the SF-6D, derived from the SF-36, were comparable between the groups and costs were similar, although marginally lower, in the self-managed exercise group. However, these results do need to be interpreted with caution and the uncertainty recognised due to the relatively limited amount of data secondary to the high loss to follow-up.

In comparison to other economic evaluations relating to the conservative management of shoulder pain, the results of this current study are broadly similar in terms of QALY. Jowett et al. (2013) in their NHS based study reported a mean QALY of 0.35 across the two treatment arms; exercise therapy alone and injection plus exercise therapy for subacromial impingement syndrome. Despite generating QALYs from a different preference based utility measure, the EuroQol-5D, (Jowett et al. 2013), the QALY of 0.35 is similar to the 0.31 reported here. However, Jowett et al. (2013) reported NHS costs at £255 for the injection plus exercise therapy group and £297 for the exercise therapy alone group in the first six months which are greater than the estimates generated in this current study. The overall lower costs reported in this current study appear to reflect less primary care visits and medication usage; approximately one primary care visit per patient in this current study compared to approximately three in the Jowett et al. (2013) study. Approximately one-third of patients in the Jowett et al. (2013) study reported medication usage compared to approximately one-sixth of patients in this current study. Again, the reasons for this difference are unclear; one potential reason could be that a shift in practice has occurred from the period when the data to inform the Jowett et al. (2013) was collected (2006 to

2008). The benefits of active, non-medical, management, particularly exercise, have become increasingly recognised over recent years (Littlewood et al. 2013). Alternatively the discrepancy between the studies might simply reflect uncertainty around the estimates and/ or might reflect true differences in resource use across the UK NHS.

Similar to the Jowett et al. (2013) study, this current study has reported comparable outcomes in terms of clinical effectiveness but, based upon the limited data presented in this economic analysis, also comparable usage of health care resource.

9.4.1 Strengths and limitations

This economic analysis was contemporaneously conducted alongside a RCT. A validated measure of quality of life was used and data regarding resource use was collected using a questionnaire based upon previous similar tools used in economic analyses alongside clinical trials from an NHS and PSS perspective.

However, as recognised in chapter eight, the high loss to follow-up clearly compromises the precision of the estimate of cost-effectiveness and any attempt to infer beyond those patients who returned follow-up data is limited. Despite this, it is reassuring to note that comparable QALYs were reported in a similar large pragmatic trial based in the UK NHS (Crawshaw et al. 2010; Jowett et al. 2013).

Although the economic analysis was conducted alongside the trial in a contemporaneous manner which might be regarded as being preferable to a retrospective analysis, it did become apparent that recall bias was still a feature. During the case-note review during the data-collection period it was clear that the participants did struggle to accurately recall, for example, the number of physiotherapy appointments attended. In this case, the numbers could be amended to reflect the case notes but it is expected that these difficulties with recall would extend to other aspects of resource use, for example visits to GP, medication usage, which might also compromise the validity of any estimate of resource use. One possible solution to this could be to increase the frequency of completion of the resource use questionnaires but it is unclear whether this extra burden to the participants would contribute to an even greater loss to follow-up than has already been observed.

The issue of the insensitivity of generic measures of quality of life has long been recognised (Walters 2009). Although such measures enable comparison across illnesses/ conditions

which might inform useful health care planning, they might fail to identify specific issues of concern in specific patient populations (Walters 2009). Also, an apparent change in quality of life, as measured by a generic tool, might reflect other changes, for example pain secondary to an osteoarthritic knee rather than change in pain status secondary to rotator cuff tendinopathy. This insensitivity is a concern in the context of this study particularly where such modest QALYs are reported. So, as well as reflecting the loss to follow-up described in this study, the lack of identified difference between the two treatment arms might actually reflect the insensitive nature of the generic tool employed. However, in the absence of a valid condition specific measure with associated utility values capable of informing an economic analysis, this limitation cannot be addressed at this stage.

9.5 Conclusion

The results of this economic analysis suggest that a programme of self-managed exercise for rotator cuff tendinopathy is comparable to usual physiotherapy treatment in terms of both costs and effect. However, these results do need to be interpreted with caution and the uncertainty recognised due to the relatively limited amount of data secondary to the high rate of loss to follow-up.

Chapter 10: The SELF study – qualitative

Summary

This chapter reports the qualitative study undertaken as a component of the mixed methods SELF study. The purpose of this study was to explore possible implementation barriers and facilitators with regard to the self-managed exercise programme in the context of the UK NHS from both the patient's and the physiotherapist's perspective. Eight patients and 13 physiotherapists were purposively sampled and the findings considered in the context of the data derived from the substantive RCT.

10.1 Introduction

In keeping with the aims of the qualitative pilot study we were interested to explore possible implementation barriers and facilitators with regard to the self-managed exercise programme in the context of the UK NHS from both the patient's and the physiotherapist's perspective. The rationale for this exploration is in keeping with the background that has already been presented in previous chapters in relation to the self-managed and painful nature of the exercise which does not align with the clinical reasoning processes of many physiotherapists (Littlewood et al. 2012a). Hence this chapter presents a qualitative investigation of these potential barriers that was undertaken alongside the RCT aspect of the SELF study. Due to the different setting of this qualitative study, a secondary aim was also to compare the findings with those conducted in the pilot study, reported in chapter seven, where the setting was private practice.

Part One: The patient's perspective

10.2 Methods

The protocol was approved by the National Research Ethics Service (NRES) Committee Yorkshire & the Humber – Leeds West on the 6th January 2012 (Ref 11/YH/0443) (**Appendix 11**) and the research was conducted according to the Declaration of Helsinki.

10.2.1 Design

A qualitative study was undertaken within the framework of a mixed-methods research design where, again, clinical quantitative outcome data from the RCT was used to inform the recruitment to this study with the intention of developing depth of understanding.

10.2.2 Setting

Three NHS physiotherapy departments; one in northern England, one in the midlands and one in the south.

10.2.3 Participants

A purposive sample of patients, randomised to the self-managed exercise intervention, was recruited. CL selected patients according to their gender and response to the primary outcome measure, as determined by change in SPADI from baseline to three-month follow-up, with a view to gaining maximal variation in terms of response to the self-managed exercise intervention. The initial protocol (Littlewood et al. 2012c) stated that patients would also be recruited according to the level of self-report exercise adherence. However, due to the patchy nature of this data, this criterion could not usefully be applied.

Initial recruitment to the RCT aspect of the SELF study included the procedure for gaining informed consent for taking part in a future related qualitative investigation. CL initially telephoned patients to discuss participation and if the initial conversation was positive the purpose of the qualitative study was re-affirmed and, where appropriate, a convenient time and location was agreed to conduct an interview. An additional consent form (**Appendix 16**) was signed prior to commencing the interview.

10.2.4 Data collection

Interviews were directed by a semi-structured topic guide that was developed during the pilot phase to focus discussion upon the self-managed nature of the intervention and also the painful nature of the intervention (**Appendix 8**). The interviews were recorded using a digital voice recorder and transcribed verbatim by CL. All interviews were conducted by CL. Participants were aware that CL was a researcher and principal investigator and physiotherapist by background.

10.2.5 Data analysis

The qualitative data were analysed by CL using the framework method of analysis (Lacey & Luff 2001; Pope et al. 2000). The approach taken was similar to the approach described in chapter seven and the data was examined with reference to the thematic chart developed during the pilot phase (figure 10.2). To avoid unnecessary duplication, the framework method of data analysis will not be described again here.

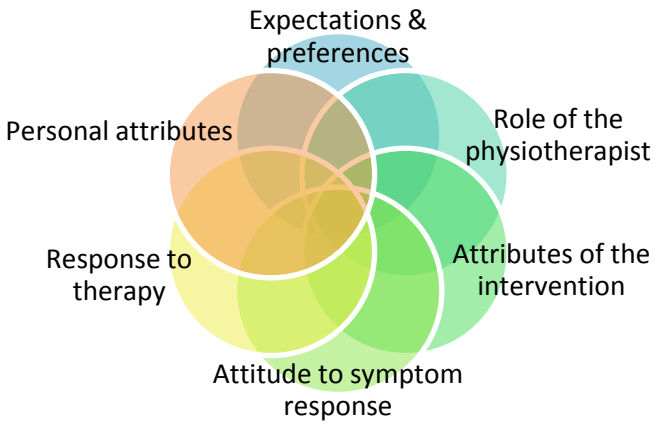


Figure 10.1 Inter-linking qualitative themes

10.3 Results

Ten patients were approached and eight were recruited and interviewed; four of the patients (50%) were male; age range was 46-77 years (mean 64 years). The self-report duration of symptoms ranged from three to 24 months (mean 9 months). The change in SPADI score from baseline to three months ranged from +11.8, indicating worse status, to -52.7, indicating improved status (mean change -12)(table 10.2). Recruitment continued until saturation point where it was felt that no new themes were emerging.

Of the two remaining patients, one patient who had reported worsening status according to the SPADI (+13.8 points) did not wish to participate stating ongoing health problems. The second patient, who reported worsening status according to the SPADI (+7 points) agreed to participate but then did not attend the scheduled meeting and did not contact to explain why.

All of the completed patient interviews were conducted at the patient's home between three and nine months post-randomisation in the RCT. All of the patients had been discharged from physiotherapy by this time. This variation was secondary to pragmatic reasons relating to researcher time, patient contact and convenience.

Table 10.2 Patient demographics for qualitative study

ID	Age	Gender	Duration of symptoms	Change in SPADI score
8	65	Male	18	-1.5
105	73	Female	3	+8.1
117	47	Female	12	-52.7
123	61	Female	4	-6.9
128	77	Male	24	-24.6
133	46	Male	3	-6.9
135	68	Male	6	-22.4
137	76	Female	4	+11.8

It was apparent that the framework developed in the pilot study around which the qualitative data collected in a private practice setting was analysed was also relevant to this current qualitative study conducted in the NHS.

10.3.1 Expectations and preferences

In contrast to most of the patient narratives in the pilot study the patients here did not seem to express strong expectations or preferences regarding physiotherapy. Although a couple of the participants indicated that they expected that more or more regular contact might be a feature of physiotherapy this was not expressed in a forthright manner:

'I didn't really think about it I don't think.' (ID137)

'I thought I'd end up going there p'haps once or twice a week and having to whatever, you know.' (ID 105)

The patients did not express strong preferences for therapist-led or hands-on treatment but most participants did suggest that they expected exercise to form at least part of the treatment:

'I just presumed I would get given exercises; come back every week; erm so I was just hoping they could do something…' (ID117)

'…I wasn't really quite sure exactly what it was going to be but I knew exercises would be involved in it to strengthen the muscle.' (ID123)

Hence this background was in contrast to that of the pilot study with less well defined expectations but acknowledgement that exercise could/ should form a component of the intervention.

'It was kind of what I was expecting to be honest.' (ID133)

10.3.2 The role of the physiotherapist

For all of the patients the physiotherapist played a key role but in different ways and to different degrees. The role of the physiotherapist included initial exercise prescription, knowledge transfer, ongoing support, reassurance and monitoring as well as a source of information or expert guidance when progress was not as expected. For some of the patients they were happy to continue independently of the physiotherapist following the initial meeting where developing an understanding of the condition was important;

'…I prefer that way round…plus knowing the physics of it, you know the actual description of what muscles it was, what's happening to it; I prefer to have that.' (ID133)

The physiotherapist was an important source of reassurance when questions or difficulties emerged during the rehabilitation process:

'The only problem I did have to start off with was me wrist and me thumb. Cos I've arthritis in me hand, trying to hold it so then she told me to tie knots in each end of it and slip them over me wrist so I wasn't actually physically pulling it with that hand anymore and getting a pain there. So she just said do that, that worked.' (ID123)

'…I wanted to consult an expert before doing anything different.' (ID133)

In the context of a long-term rehabilitation programme the physiotherapist appeared to be an important point of contact for the purpose of monitoring and support;

'…she said there was an improvement in the power of my arm but the pain was still there and then as I say she gave me this other one to try and within a few weeks after that it had just about gone altogether.' (ID123)

'I mean obviously it was going to get there because (the physiotherapist) told me how good it would work out eventually and I've got great faith in him.' (ID137)

Hence, along with other attributes of the intervention, it was apparent in this context that the physiotherapist, as a dependable source combined with the use of verbal persuasion contributed to enhanced self-efficacy.

10.3.3 Attributes of the intervention

Similar to the patients in the pilot study, the patients here initially expressed disquiet about the simple nature of the intervention and also, for some, whether the self-managed exercise intervention was sufficient for their problem:

'Well from the first, my first err appointment with the physiotherapy with that, that band I came away thinking, an elastic band?! Is this gonna work?' (ID8)

'Cos at first it just didn't seem to be getting any better and I just thought this exercise is too simple basically, it wasn't complex it was very simple.' (ID117)

However, the self-managed nature of the intervention appealed to the patients, particularly from the perspective that regular trips to the hospital and the physiotherapist were not required;

'…would you prefer to do this at home? Oh, yeah obviously rather than keep coming backwards and forwards to the hospital…' (ID105)

'I thought it was great because doing it at home you could fit it in to your life rather being tied to going to the physio at a certain time on a certain day or two or three times a week.' (ID123)

Again, as was reported in the pilot study, the initial concern about the simplicity of the exercise programme changed and was subsequently regarded in a positive light by the patients;

'…it's the best thing I've had…something so simple can help …' (ID135)

The future benefits of this simplicity were also recognised in contrast to previous exercise prescriptions;

'…it was fairly simple what I was explained to do this time round. Erm, more so than the previous one. Erm, so yeah it would be easy to remember and just go back and do it again.' (ID133)

Some of the patients had continued with the programme as a means of prophylaxis. Other patients suggested they would, or already had in some circumstances; re-commence the programme if the disorder were to recur:

'Definitely, definitely. I wouldn't bother hospital or doctor. I'd give it three or four week of the band.' (ID8)

The notion that patients felt they had the capacity to undertake the exercise independently in the face of a future episode might be regarded as an important finding in the context of a disorder with a high likelihood of recurrence.

10.3.4 Attitude to symptom response

Again, similar to the pilot study, patients did not report concerns about the pain produced during exercise. There was somewhat of an expectation that the exercise should be painful to be of any value:

'Yes, yes. It hurt a bit at first which he told me it would. Things do don't they? Get a little bit worse but then after that it was fine.' (ID105)

'…no pain, no gain I suppose.' (ID133)

It was apparent that there was an upper level in terms of what constitutes an acceptable pain response and provocation beyond this might have served as a barrier to engagement. But, the on-off nature of pain attributable to tendinopathy appeared to facilitate engagement with the self-managed programme;

'…it was manageable…Yes, because the pain was only when I lifted my arm, it hurt me when I lifted my arm so yeah.' (ID117)

Additionally the participants experienced a change in the nature of pain with time which appeared to reassure:

'No, no after the first few weeks you sort of got used to it. The time when you sort of noticed it more was when you changed from one coloured band to the next coloured band.' (ID123)

10.3.5 Response to therapy

Whereas an early and appreciable response to therapy appeared to be a key factor underpinning continued engagement with the exercise programme, this was not so much of a feature of the patient narratives here. Although some patients did describe an early response for those that didn't there appeared to be more realistic expectations and a greater awareness of the longer-term nature of rehabilitation for rotator cuff tendinopathy. Secondary to the findings from the pilot study, the training of the physiotherapists involved in the SELF study focused upon this aspect and the need to foster realistic expectations.

'I got given these simple exercises and at first I thought these aren't doing much good, I must say. But, I persevered with them, I got my own weights luckily so I just used one of them every day and my shoulder is a lot better now…I would say probably a couple of months… It was quite a long time, yeah.' (ID117)

'You can't expect something that you've had for four months to disappear overnight and that was explained that it was going to take time.' (ID123)

10.3.6 Personal attributes

In keeping with the patient narratives in the pilot study where successful outcome was reported, the patients here recognised the central role they had in achieving optimal outcomes and were generally able to incorporate the exercise programme into their daily routines.

'You know, you've got to put your own effort in. Erm, I didn't just expect to turn up every month or so, do something and then everything was fixed.' (ID133)

'I just made it fit in.' (ID135)

Some of the patients described a history of undertaking exercise and had a belief in its capacity as an intervention and seemed to reflect in a positive way within the context of a self-managed exercise intervention:

'I've done isometric exercises all my life.' (ID8)

10.4 Discussion

This qualitative study has added weight to the relevance of the themes, previously identified in the pilot study, which might facilitate engagement with a self-managed exercise programme and hence might subsequently contribute to successful outcome. Factors relating to expectations, the physiotherapist, the intervention, attitude to symptom response, response to therapy and personal attributes appear relevant in the UK NHS and private sector. However, discrepancies between the patients across the two sectors were apparent in relation to their expectations of physiotherapy, attributes of the intervention and also response to therapy. In this study the patients did not express strong expectations or preferences, they appeared to value the self-managed nature of the intervention which meant that they did not need to attend a clinic appointment and they were prepared and accepting of the sometimes lengthy therapeutic response time.

During chapter three, where the development of the self-managed exercise programme was considered, some different models of behaviour change were presented. One of these models is the highly influential Social Cognitive Theory (Bandura 1977) and it is from this perspective that the relevance of these findings can be usefully considered. Bandura (1977) proposed that self-efficacy expectation directly influences whether behaviour change will be initiated, how much effort will be expended, and how long it will be sustained in the face of adverse experience. In the context of this study this can be interpreted in terms of the whether the patients initiated the exercise programme, adhered to the prescription and continued in the face of, for example, increasing pain or lack of short term response to therapy.

In this study the participants recognised the benefits of exercise and some had previously engaged with exercise programmes and gained benefit. Hence, in the absence of alternative entrenched expectations and/ or negative prior beliefs, it seems that the patients in this study were able to engage with the physiotherapists in a fruitful way to understand their shoulder pain and, where necessary, frame this understanding in a way that helped them to appreciate the potential value of exercise. Bandura (1977) originally proposed that verbal persuasion from a credible source is a key factor in developing self-efficacy expectation and subsequent behaviour change. It is evident that such persuasion took place in this context and that consistently the patients regarded the physiotherapists as credible and at times the

'expert'. Within this model the importance of the ongoing role of the physiotherapist becomes apparent where self-efficacy and/ or outcome expectations might wane in the face of adverse experience or lack of response to therapy. In these situations the physiotherapists were able to intervene and support the patients to continue their journey in a constructive way.

Within this model, the role and attributes of the behaviour change intervention become apparent. Here the patients referred to the exercise programme as simple and, for the most, suggested that they were able to fit the requirements in to their daily routine. So although the simplicity appeared to generate negative thoughts initially, particularly in relation to outcome expectations, the simplicity and brevity was subsequently appreciated from a pragmatic perspective. This is in contrast to, for example, prescribed exercise programmes that require the patient to complete exercises every hour or prescribed exercise programmes that include a wide range of different exercises that take up a lot of time. This highlights the interplay between the factors identified in this study; for example it is conceivable that self-efficacy expectations will be compromised in an individual perceived to be self-efficacious who is working with a credible or expert physiotherapist who subsequently prescribes an extensive exercise programme that simply does not fit with the lifestyle of the patient.

Aligned with the attributes of the intervention is the attitude to symptom response. Simply put, if the patients were concerned that the exercise provoked pain and they construed this as harmful, then it is unlikely that they would engage with the programme. However, with consistency across the pilot and this study, the exercise-related discomfort was not a concern and some patients actually viewed this as a necessary component of a worthwhile intervention. Also, returning to Social Cognitive Theory where self-monitoring is seen as a key feature of sustained behaviour change (Bandura 1977; Jones 2006), and in the absence of strong evidence suggesting that exercise should or should not be painful, this attitude to symptom response might be regarded as a necessary conduit to sustained behaviour change and hence successful outcome. The expectation was that the exercise should be progressed in relation to symptom response. This afforded the opportunity for patients to consistently monitor their response and adapt their exercise and/ or feedback to the physiotherapist. This feedback loop might be regarded as an important feature of this self-managed exercise

intervention but overlooked in other exercise regimes where the opportunity to self-monitor in terms of pain response, or other credible means, is not inherent.

Finally, it was interesting to see that the patients reported that they continued to exercise despite, for some, a lack of an early and appreciable response to therapy. As one of the outputs of the pilot study this notion was fed in to the training package of the physiotherapists involved in the RCT aspect of the SELF study and it appears that, with respect to the patients here, this message was conveyed successfully. The patient-reported expectations of response to therapy were more realistic and in line with what tends to be considered typical for rehabilitation of tendinopathy. However, as is reasonable, this response time was not open ended but did provide a platform upon which continued engagement with the exercise programme could be facilitated. This finding adds further weight to the Social Cognitive Theory which describes self-efficacy expectation as a principal agent of behaviour change rather than outcome expectations.

Thus far, data from a sample of patients who generally reflected positively upon the self-managed approach has been considered. But, as evidenced in the pilot study this is not and will not always be the case. So, at this stage, it seems appropriate to consider what the ramifications might be when these factors are not aligned with this philosophy; for example, when a patient believes that hurt is harmful or where a physiotherapist has a strong preference for therapist-led care. Clearly, as discussed, there is interaction between the factors; some of which might be modifiable, for example the beliefs of the patient, some of which might not, for example the beliefs of the physiotherapist. More of the latter issue, related to the role of the physiotherapist, will be considered in the second part of this chapter. But, to differing degrees, it is likely in such circumstances that the behaviour change, engagement with the programme and hence outcome will be likely compromised. Within the limitations of current knowledge, it is suggested that the first critical factor is recognition that these non-tissue, non-pathology issues might impact upon outcome; as advocated in chapter three, a shift away from reliance on the medical model in relation to ‘tendinopathy’ is needed and is increasingly being recognised (Littlewood et al. 2013b; Rio et al. 2014). Secondly, where these factors can be modified, for example through evidence-based education and ongoing support, this should be capitalised upon. One example of this could relate to response to therapy; a patient might return after six weeks and report no

discernible change. Based upon evidence presented in chapter two, it seems fair to suggest that a minimum period of twelve weeks of rehabilitation is required before the exercise intervention should be considered as unlikely to confer a clinically significant outcome. Alongside this it is suggested that higher dose of exercise confers superior outcomes, so issues such as monitoring of exercise adherence also come into play. Hence the discussion could be reframed around expected response times and the importance of adherence to achieve successful outcome; clearly other factors such as appropriate goal setting could also be considered. And finally, where these factors are recognised and attempts to address in a constructive way are regarded as unsuccessful then the wisdom of the prescription of a self-managed exercise programme should be re-considered.

10.4.1 Limitations

The limitations of this qualitative study are similar to those of the pilot study; it was conducted with eight patients recruited via their involvement in a RCT and the data were collected and analysed by one individual. Despite the small numbers involved, the patients in this study, in the context of the UK NHS, broadly reflected upon similar factors to those patients interviewed in the private sector which might actually enhance both the transferability and credibility of the findings.

However, in terms of reflexivity, it is a concern that all of the patients tended to generally reflect positively upon their experience. The patients were fully aware of the principal investigator's background and role in the research and it is unclear whether this influenced and put them off relaying negative experiences. However, it cannot be discounted that these accounts might reflect the patient's 'truths' and it is unlikely that negative accounts would alter the importance of the identified factors, only strengthen their relevance from a different perspective as was seen in the pilot study.

Attempts were made to recruit patients who might have been able to communicate negative experiences based upon the self-report of outcome at three months. However at the time of the interviews the patients all reported that they had improved further and regarded the intervention as a success.

10.5 Conclusion

Within the context of the prescription of a self-managed exercise programme for rotator cuff tendinopathy this qualitative study has identified factors in addition to exercise prescription parameters that need to be considered from the patient's perspective if successful engagement and outcome are to be achieved. These factors include recognition of the role of patient expectations, the role of the physiotherapist, attributes of the intervention, attitude to symptom response and response to therapy; all of which can impact positively or negatively from the behaviour change perspective.

Part Two: The physiotherapist's perspective

10.6 Methods

10.6.1 Design

A qualitative study was undertaken within the framework of a mixed-methods research design.

10.6.2 Setting

Three NHS physiotherapy departments; one in northern England, one in the midlands and one in the south.

10.6.3 Participants

A convenience sample of physiotherapists, who had prescribed the self-managed exercise intervention within the SELF study, was recruited. The physiotherapists were initially briefed about this qualitative study during the regular training sessions and were subsequently approached via group e-mail inviting them to participate. Interviews were scheduled to coincide with site visits by CL and mutually convenient appointments were arranged. Participants had the opportunity to review the PIS (**Appendix 17**) and to discuss any concerns before the consent form (**Appendix 18**) was signed. Participants who were not available at the time of the site visits or had not prescribed the self-managed exercise intervention within the SELF study were excluded.

10.6.4 Data collection

The process of data collection resembled the process employed during patient interviews. The semi-structured topic guide, designed to focus the discussion upon how the self-managed exercise intervention differed from their usual care and whether they encountered any difficulties during the treatment episode, is presented in Appendix 9.

10.6.5 Data analysis

The process of data analysis resembled the process employed during the patient interviews. The data were examined with reference to the thematic chart developed during the pilot phase but this was further developed iteratively; the expectation theme evolved to reflect the narratives around how the physiotherapists might usually treat patients with rotator cuff tendinopathy and was renamed preferred therapeutic option. Secondly, personal attributes was merged with the role of the physiotherapist to reflect the overlap in the

messages that emanated from the data. Additionally it became clear that the physiotherapists reflected upon their involvement in the trial from the perspective of professional development, hence this theme was added to the thematic chart. The final themes are depicted in figure 10.2:

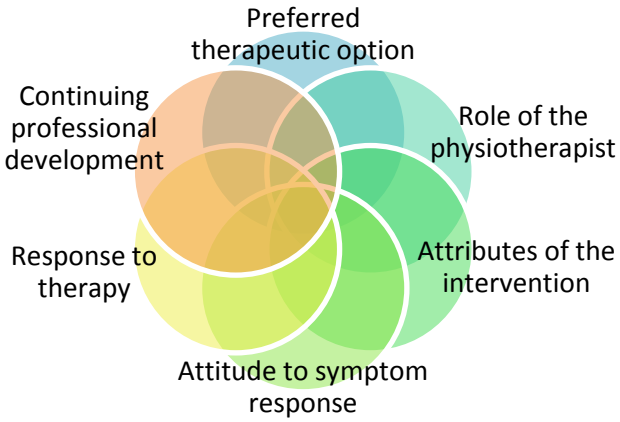


Figure 10.2 Inter-linking qualitative themes

10.7 Results

A total of 31 physiotherapists were involved in the SELF study and thirteen across the three centres, who delivered the self-managed exercise intervention, were recruited to this qualitative study according to convenience sampling. Seven of the physiotherapists (54%) were male. The number of years qualified ranged from one to 32 years (mean 9.4 years). Five out of the 13 reported post-graduate qualifications at the level of diploma or beyond (table 10.2).

Table10.3 Demographic data for the physiotherapists included in the study

ID	Gender	Years qualified	Post-graduate qualifications
P1	Male	5	No
P2	Female	15	No
P3	Male	4	No
P4	Male	4	No
P5	Female	32	No
P6	Female	1	No
P7	Female	13	MSc
P8	Male	6	No
P9	Male	8	MSc
P10	Female	9	MSc
P11	Female	10	MSc
P12	Male	9	PG Diploma
P13	Male	6	No

10.7.1 Preferred therapeutic option

The physiotherapists were asked to reflect upon how the self-managed exercise approach differed from their usual or preferred approach for these patients. For all of the physiotherapists exercise was a central tenet of the treatment they prescribed. However, in contrast to the single exercise approach of the self-managed intervention, the vast majority of physiotherapists would prescribe a greater number and range of exercises for their patients. Typically this related to a greater number and range of strengthening exercises and/or exercises thought to address scapula dyskinesis in tandem with a less aggressive approach to initial loading:

'I might give them three or four things to do…rather than one isolated thing...' (P10)

'…scapular stability maybe a little bit more rather than just working to a certain exercise without focusing so much…' (P4)

'…maybe less load initially erm. I would maybe have gone in more of a pain free range to start with knowing that I had sort of control of the symptoms.' (P9)

It was apparent that electrotherapy was not a preferred therapeutic option in this context;

'…I generally don't use electrotherapy for anything I feel is rotator cuff related or impingement related.' (P4)

But, manual therapy was a preferred option for some of the physiotherapists. The use of manual therapy was rationalised with reference to dealing with movement restriction at the shoulder, neck or thoracic spine and/ or as a means of improving motor control:

'I typically always have a look at hands-on stuff first erm as well to try and improve the movement.' (P6)

'I'd certainly be altering, trying to do hands-on stuff in terms of the neck or maybe scapular position; trying to recruit more scapular stabilisation muscles, more sort of functional muscle patterning…' (P8)

For some of the physiotherapists prescription of the self-managed exercise programme was a challenge in terms of what might be regarded as the simplistic and restricted nature of the intervention;

'…if it was self-management I always wanted to do extra things that I could identify there and then and that was quite hard for me to take a step back…' (P8)

The physiotherapist's prior education, experience and beliefs regarding the most appropriate management for rotator cuff tendinopathy shaped their opinion. This reflection offered a basis upon which the physiotherapists considered how their current clinical reasoning processes aligned with that proposed within the self-managed exercise programme. For some of those with less experience, these beliefs were less developed:

'I didn't have as much experience, probably, as other people in the study I wasn't one of these practitioners who had a definitive plan…' (P3)

For others with greater experience it was apparent that their existing belief system served to facilitate for some, but challenge for most the rationale underpinning the self-managed exercise programme;

' …in terms of the training it was always saying, taught that you don't want to push in to pain…' (P7)

'…to give one exercise…it was more I had a bit of an issue with that more than the patient did to start with.' (P11)

'…you're fearing doing someone damage because it's going against clinical reasoning.' (P12)

10.7.2 Role of the physiotherapist

The physiotherapists recognised their role in terms of helping the patient understand the nature of their disorder and the role of the intervention in assisting them to achieve a positive outcome. They also recognised their role as a means of ongoing support. So, the physiotherapists recognised the importance of knowledge translation and the need to 'sell' the self-managed exercise intervention; both of which were underpinned by the need to develop a therapeutic relationship:

'It's that trust thing…if you give it confidently enough they believe you.' (P1)

'With a good explanation I think people seem to fully accept it...' (P4)

'I think I sold it quite well to her…' (P13)

However, as identified in section 10.7.1, the self-managed exercise programme did not align with usual practice for most and challenged existing clinical beliefs around what constitutes the most appropriate treatment for rotator cuff tendinopathy. For some of the physiotherapists, although they still recognised the need to 'sell' the intervention, they found it difficult:

'I worried they wouldn't get on board and stuff so I find it very hard to really embrace it.' (P2)

'…initially my concern was selling it…' (P5)

As discussed in previously, the need for ongoing monitoring and support appears to be a key determining factor in attaining a successful outcome for most people. The physiotherapist recognised this, particularly when the patients were faced with limited progress and or apparent worsening status:

'I can definitely remember one guy coming back after the first lot saying he was no better and but I just had to kind of erm, you know, re-iterate to him that I wouldn't expect him to be better at this stage, it normally takes a time period of at least four to six weeks before they even start to be able to see any change in their symptom and it can be longer and the

whole period of this is usually 12 week minimum; again can be longer, can be four months.' (P11)

'I always gave the patients a window; I always said if you're struggling just phone up...' (P1)

10.7.3 Attributes of the intervention

The simplicity of the self-managed exercise programme, in terms of a single exercise approach, was reflected in both a positive and negative light. Most of the physiotherapists appreciated the simplicity, particularly from the perspective of the patient, in terms of improving communication and exercise adherence:

'I think people seemed quite clear, people seemed quite happy that they didn't have to do a great deal.' (P4)

'…it's been a lot simpler treating the self-management group; keeping the exercise regime simpler, the patients have understood it more, erm the conversation between therapist and patient has been clearer' (P11)

'I think, the more simple you keep things for people, the better the response and the easier it is as a clinician and as a patient.' (P13)

But, as reflected in the patient narratives, this simplicity was not appreciated by all and the physiotherapists considered this from their own perspective and that of the patient:

'For my patients, they certainly found it slightly different, especially those that had experienced private physio before, erm they said oh, is that it? They were, well are you not doing anything else? Is it just one exercise? Is that it?' (P8)

Additionally, where the physiotherapists identified factors that they felt relevant to the presenting condition but did not feel that it would necessarily be addressed by the single self-managed exercise programme, they expressed disquiet:

'I had a feeling one of them was a lady who I needed to do serratus stuff and scapular control with and so rather than just flogging the pushing into the tendon loading side...' (P2)

Other aspects of the intervention, for example, infrequent follow-up, goal setting using the patient specific functional scale and monitoring of exercise adherence using the exercise

diary were only sparingly mentioned. As highlighted here, the main focus of the narratives related to the single exercise approach and its simplicity.

10.7.4 Attitude to symptom response

One guiding principle of the self-managed exercise programme was that exercise should be prescribed that produces pain. It is feasible that if the physiotherapists have doubt about the value of prescribing painful exercise then the likelihood of them facilitating behaviour change towards undertaking a regular programme is likely to be compromised. Discussion around this factor generated a broad range of responses from those who were very comfortable with the notion, those who were very uncomfortable and those who might be regarded as taking more of a middle ground:

'I kinda got to the stage where I was getting people to do exercises through pain anyway.' (P1)

'It was only a concern for me if she was going away and it was making her pain worse later in that evening or later that day. If it was painful at the time and it stopped I wasn't concerned at all.' (P13)

'…for me I'm so used to doing the type of exercise I do in the sense of not pushing through pain…' (P2)

'I wouldn't avoid pain previously, I would avoid certain levels of pain but I wouldn't avoid working into it particularly providing it would stop after exercise.' (P4)

'Those who are above and beyond the moderate pain I would probably choose a different exercise to load them with.' (P11)

For some, discussion around this generated reflection;

'…in terms of the training it was always saying, taught that you don't want to push in to pain that you don't, you might get associated inhibition and sort of, of the muscles alongside it so, so different from that point of view. But then, like you said, if you have a look at it from the eccentric loading perspective then we do ask people to, to go in to pain when they're exercising so erm I could see how it might fit…' (P7)

10.7.5 Response to therapy

The physiotherapists were asked to consider how the patients had responded to therapy and whether they had encountered any problems during the follow-up period. For reasons relating to the narrative above, there appeared to be a general pre-trial sense that the physiotherapists doubted the potential value of the self-managed exercise programme. The doubt seemed to originate in relation to the self-managed nature of the intervention and the painful loading aspect using just one exercise. However, it seems that these prior beliefs were challenged through exposure and experience:

'I was pleasantly surprised that actually I've had a few patients who did really and actually some of the older patients did very well very quickly, potentially those who don't normally load their tendons much at all.' (P11)

'I was just surprised actually how effective it's been…' (P3)

'I don't think they reported any problems.' (P2)

The only concern that was consistently expressed with reference to response to therapy was time. The physiotherapists felt that most of the patients took longer to achieve a worthwhile clinical outcome than might be expected using other means of treatment:

'The only slight barrier was more of the slightly slow progress' (P13)

However, this was a concern that the physiotherapists appeared to deal with effectively as described above in relation to the role of the physiotherapist.

10.7.6 Professional development

Many of the physiotherapists reflected upon their involvement in the SELF study from the perspective of professional development. Although this was not specifically questioned during the interviews it is something that the physiotherapists offered when they were invited to make any further comments. It was apparent that reflection had taken place in terms of challenging their current practice and the reasons underpinning their current approaches but also, for some, practice had changed during the course of the trial.

'One patient, when I initially started on self-managed exercise, I did feel that perhaps if I'd assessed them not for that I would have done some cervical mobilisations because they were

stiff in rotation. Err, but actually through the course of the treatment, the shoulder improved and the patient was very pleased with the outcome at the end. So, in some respects that challenges what I think about how I should treat patients.' (P5)

'We do the same thing with eccentric loading for the Achilles and for the patellar tendon so why not for the shoulder?' (P11)

'I didn't realise I guess how much manual therapy I did, I think it's probably made me a bit more aware of that…' (P7)

'…in fact I've started to trial it in some of my other patients that I'm seeing; just trying to push them a little bit harder with their exercises…' (P7)

Rather than been seen as a threat, this reflection and challenge was reflected upon positively:

'…it's probably challenged my way of thinking which has been nice.' (P12)

10.8 Discussion

This qualitative study has identified some of the physiotherapist-related barriers and facilitators concerning implementation of the self-managed exercise intervention in the SELF study. For most of the physiotherapists there were clear differences between their preferred therapeutic approach and the self-managed exercise intervention. This mainly related to the type and number of exercises, the use of manual therapy and the extent of loading introduced through exercises. The physiotherapists recognised their role as one of knowledge translator in relation to understanding the nature of the disorder and 'sales person' in relation to persuading the patient about the potential value of the intervention. The simplistic nature of the single-exercise intervention was viewed in both a positive and a negative light; positive in terms of communication of what is required and exercise adherence but negative in terms of restricting the physiotherapist in relation to the range of interventions that they prefer to offer in this context. The importance of ongoing monitoring and the physiotherapist as a source of self-management support were recognised. Attitudes towards pain provocation during exercise varied within the sample but it was apparent that where the physiotherapists felt that pain provocation was not the most effective

management strategy this contributed to implementation difficulties. There appeared to be an underlying uncertainty regarding the potential value of the self-managed exercise programme prior to commencement of the trial; a view-point that, for most, was challenged while the study was ongoing and the physiotherapists experienced the intervention and response to the therapy. However, in relation to the latter, response to therapy, there was a feeling from many of the physiotherapists that response time was slower for the patients undertaking the self-managed exercise intervention in comparison to what might be expected with other approaches to treatment. Finally, the physiotherapists reflected upon their experience in the trial in a mostly positive way in terms of how involvement had challenged their current thinking and in some instances stimulated a change in practice.

From an implementation science, or getting research knowledge in to practice (Eccles et al. 2009), perspective these findings highlight an interesting point for discussion and further consideration. It was suggested in chapter two that there is emerging evidence to support the value of loaded exercise for rotator cuff tendinopathy although there is much uncertainty around the prescription parameters. This uncertainty is present across the spectrum of interventions currently offered for rotator cuff tendinopathy but the clinical effectiveness of manual therapy, in this context, has been challenged (Littlewood et al. 2013c), based upon systematic review evidence, and questions were raised about the value of specific exercise to address scapula dyskinesia. Hence, uncertainty is a key summary descriptor in relation to the effectiveness of interventions for rotator cuff tendinopathy. Despite this, the absence of manual therapy and scapula stabilisation exercise from the self-managed exercise intervention appeared to be a challenge for many of the physiotherapists who perceived their omission as a weakness of the intervention. Among other things, this might suggest that research evidence is not a central or strong driver of physiotherapy practice in this context but instead other factors, for example beliefs influenced by prior teaching and experience as reflected in the narratives, are more dominant (Bishop et al. 2007). This has been reflected in other areas where early training, experience and interactions with colleagues and opinion leaders informed practice rather than appraised research evidence (Gabbay & le May 2004).

It has been estimated that on average it takes 17 years for research evidence to impact upon clinical practice (Morris et al. 2011). Although this figure might initially seem excessive,

its validity can be appreciated when it is realised that appraised research evidence is not the prime driver of change in clinical practice. Although the data presented in this thesis does not provide a strong argument for all physiotherapists to change their current practice in relation to rotator cuff tendinopathy, these qualitative narratives do raise an important point, also recognised in other areas, in relation to the challenges of implementing future research evidence.

Further to this, what is apparent from this study is that physiotherapists do seem to engage more with research if they are directly involved with it. Many of the physiotherapists involved in this study did reflect and question their current practice and some even began implementing change aligned with the philosophy of the self-managed exercise programme while participating in the study. Interestingly though, this implementation took place prior to knowledge of the final results which in many ways compounds the idea that clinical practice is largely driven by beliefs based upon experience and interaction with colleagues and opinion leaders; in this situation the research team might be viewed as the opinion leader(s).

There are also further considerations with regard to implementation and evaluation of effectiveness that these qualitative findings raise in relation to the SELF study. Implementation fidelity refers to whether an intervention was delivered as intended (Carroll et al. 2007). Measurement of implementation fidelity essentially amounts to the measurement of how far those responsible for delivering the intervention actually adhered to the intervention as described (Carroll et al. 2007). Implementation fidelity in relation to the pilot and SELF RCT was described quantitatively in chapters six and eight respectively. But, further to this quantitative description, it has been suggested that the beliefs of healthcare professionals influence the advice they offer to patients which might in turn influence the beliefs of their patients (Bishop et al. 2007; Darlow et al. 2012). Where beliefs about what constitute an effective intervention differ from the actual intervention offered, this might negatively influence the delivery of the self-managed exercise intervention, possibly as reflected in the patient narratives where initial disquiet about the intervention was expressed. In turn it is feasible that this might influence adherence, engagement and/ or clinical outcome although it is not possible to substantiate this claim within the design parameters of the SELF study. The potential influence of these therapist effects has been

previously recognised (Walters 2010) and these qualitative narratives from the physiotherapists affirm their relevance in clinical trials of this nature.

10.9 Conclusion

This qualitative study has identified some of the physiotherapist-related barriers and facilitators concerning implementation of the self-managed exercise intervention in the SELF study. For most of the physiotherapists there were clear differences between their preferred therapeutic approach and the self-managed exercise intervention particularly in relation to the type and number of exercises, the use of manual therapy and the extent of loading introduced through exercises. From an implementation perspective in relation to clinical practice and future research, these findings should be regarded as relevant and important.

Chapter 11: Discussion, conclusions and recommendations for future research

Summary

This chapter returns to the aims and objectives stated in chapter one and considers the extent to which each has been met as well as considering the implications of the work that has been conducted in relation to each aim or objective. The degree to which new knowledge has been generated is considered alongside some suggestions for further research in this field.

11.1 Aim of this thesis

In the context of a common, burdensome and poorly understood disorder, the aim of this work was to evaluate a self-managed exercise programme for rotator cuff tendinopathy in terms of both clinical and cost-effectiveness in an attempt to generate new knowledge and expand the evidence base. It is suggested that this aim has been met and new knowledge generated in relation to the optimal conservative management strategies for rotator cuff tendinopathy from both a clinical and cost-effectiveness perspective. Underpinning this aim were several objectives; the extent to which each of these has been met and the implications of the work that has been conducted will now be considered in turn.

11.1.1 Objective one

The first objective of this work was to consider the validity of evaluating the effectiveness of an exercise programme in contrast to other commonly prescribed conservative interventions. This objective was met in chapter two. Using established methods, a review of systematic reviews was conducted which suggested that further evaluation of exercise programmes for rotator cuff tendinopathy is appropriate and indicated. In contrast to other commonly prescribed interventions including corticosteroid injections, manual therapy and electrotherapeutic modalities, exercise programmes, with a reasonable degree of consistency, demonstrated the potential to achieve clinically significant outcomes despite significant heterogeneity in the way they were prescribed. Additionally multimodal physiotherapy, which is reflective of current practice for rotator cuff tendinopathy, was

regarded as a valid comparator and hence the basis for a useful and valid RCT was established.

11.1.2 Objective two

The second objective of this thesis, to evaluate the validity of the exercise programme proposed for evaluation within the SELF study, was met in chapter two and three; using systematic review methodology and narrative commentary. In the context of limited data and the significant heterogeneity across the different exercise programmes evaluated to date, it was suggested that the propose self-managed exercise programme reflected, for the most, current recommendations from the evidence base. It is suggested that the systematic review methods employed and reported in chapter two contribute new knowledge to the evidence base, particularly in relation to the contextual factors that appear important when developing exercise programmes for rotator cuff tendinopathy. Furthermore the limitations of the current evidence base were recognised, for example in relation to exercise dosage, which offers a foundation and stimulus upon which to conduct further useful research.

11.1.3 Objective three/ four

The third objective of this thesis was to establish the feasibility of conducting a substantive RCT to evaluate the clinical and cost-effectiveness of a self-managed exercise programme. In tandem with objective four; to understand the barriers which might prevent implementation of the self-managed exercise programme in to clinical practice or future research studies, these objectives were met using mixed-methods research. Underpinning this research was a PPI event which offered useful insight into the proposed design and suggested means of improving the methods from a patient perspective. Reports of PPI events conducted in relation to physiotherapy related trials do not appear to be widely accessible and hence this report, which was published during the course of the thesis preparation, added new knowledge in relation to trial development from the perspective of the patient and/ or public. Subsequent to this a pilot RCT was conducted which offered useful data to inform our sample size calculation and suggested that a substantive RCT was feasible. To complement the quantitative RCT, a qualitative study was also undertaken; the outcome of which provided direction and stimulus for the training of the physiotherapists involved in the substantive SELF RCT. Critical learning points from this qualitative study indicated the need to recognise and manage patient expectations in tandem with

recognising the beliefs and expectations of the physiotherapists involved in prescribing the intervention. The impact of the actions derived from the pilot qualitative study were apparent when a further qualitative study was undertaken alongside the SELF RCT where the patients described more realistic expectations in line with what might be regarded as constructive when managing rotator cuff tendinopathy. Additionally these qualitative studies offer useful new insight into the perceptions of the patients who were not concerned about pain provoked when exercising; indeed, for some, there was almost an expectation that exercise should be painful to be of value. Also, it was apparent that the patients who were interviewed valued the opportunity to self-manage which seemed to contrast with what some of the physiotherapists believed. Hence, through the use of mixed-methods research, it is felt that objective three and four of this thesis have been met and new knowledge generated.

11.1.4 Objective five

The fifth objective was to conduct and complete a substantive RCT and report clinical and cost-effectiveness results. This objective was met in chapters eight and nine; from a clinical effectiveness perspective, superiority of the self-managed exercise programme or usual physiotherapy treatment was not established in this study. In tandem with the results from the pilot RCT, this is an interesting finding. In the authors' knowledge, this is the first study to evaluate the effectiveness of a programme based upon a single exercise. The lack of superiority, for certain patients at least, of a multimodal approach, as defined in this thesis, suggests new opportunity for the management of rotator cuff tendinopathy; this will be discussed more later in this chapter. Although both the clinical and cost-effectiveness results need to be considered in the context of the uncertainty associated with the high loss to follow-up in this study, the economic analysis conducted here also suggested comparability of the two treatment arms in terms of cost and effect. This economic analysis is one of the few reported in relation to physiotherapy interventions and offers a basis upon which future studies can be developed with the aim of informing both clinical decision making and health care resource planning.

11.1.5 Objective six; recommendations for future research

The sixth and final objective of this thesis; to propose future research priorities relating to the management of rotator cuff tendinopathy, will now be considered. There are a number

of areas of further research that could be proposed including understanding pathoaetiology, development of valid and reliable assessment processes, understanding risk and prognosis as well as further evaluation of management strategies. Clearly the aforementioned directions for future research are linked, for example a valid assessment process could identify a relevant diagnosis, sub-group or classification of shoulder pain which in turn directs or informs which treatment strategy to select which in turn subsequently improves outcome. However, due to the focus of the preceding thesis and the potential infinite expanse of potential research ideas across the assessment, diagnosis and treatment outcome span, the subsequent section will consider ideas for management of rotator cuff tendinopathy as defined within this thesis.

Based upon the potential trend towards improved pain and disability in the mid-term, reported in this thesis, associated with the self-managed exercise programme it seems justified to initially recommend that replication of this trial is warranted. Such a further adequately powered trial which sufficiently anticipates and accounts for loss to follow-up, possibly incorporating telephone follow-up of the SPADI, will offer greater confidence and precision of the estimate of effect over time with the potential to usefully inform clinical decision making.

Furthermore, in contrast to usual or multimodal physiotherapy treatment, the self-managed exercise programme might be regarded as a relatively simple intervention. This simplicity was reflected in the patient narratives gained through the qualitative studies presented in this thesis. Hence, in the context of potentially comparable outcomes in the short-term and potential superiority in the mid-term, another logical step appears to be to consider whether such a simple management strategy could be implemented under the control of the person complaining of signs and symptoms associated with rotator cuff tendinopathy away from direct supervision of health care professionals. The obvious benefits of this include the potential for less health care resource use and importantly timely access to intervention which might improve clinical outcome; consider that some patients in the SELF RCT had not received physiotherapy intervention by the three month follow-up point. Also, with regard to maintaining the locus of control, such patient centred engagement might facilitate longer-term effective self-management strategies away from the potential for iatrogenic disability as considered in chapter three. In terms of evaluation, some factors to

consider include developing mechanisms by which patients can self-diagnose, initiate self-management and engage with effective monitoring procedures as well as offering opportunity to interact at the appropriate level if problems are encountered. Recent advancements in telemedicine or telerehabilitation might offer a platform through which an effective self-managed exercise programme could be implemented and monitored. Telerehabilitation refers to the remote delivery of rehabilitation and clinical information using telecommunications technology including telephone and internet (Odole & Ojo 2013). A recent RCT evaluated the effectiveness of a telephone-based physiotherapy intervention compared to clinic-based physiotherapy for patients with osteoarthritis of the knee (Odole & Ojo 2013). The focus of the telephone-based rehabilitation was to monitor the home-based exercise. By six weeks the measures of pain and disability were comparable between the telephone-based and clinic-based interventions. This physiotherapy related study is presented upon a backdrop of many studies reporting the positive benefits of telemedicine in a wide range of health conditions, for example Bacigalupo et al. (2013) in relation to weight management. Additionally, in the UK NHS, there is continued move towards recognising the benefit of remote assessment and management via PhysioDirect, a telephone-based service, and a recent large pragmatic trial has reported comparable effects between such a method of assessment and management and face-to-face contact (Salisbury et al. 2013). Thus, such studies and current context begins to indicate the potential worth and begins to establish the feasibility and potential of self-managed interventions for rotator cuff tendinopathy.

As well as replicating this current study and reconsidering the platform or mechanism of delivery of a self-managed exercise programme, it is apparent that the content of such programmes needs further comparative evaluation. As recognised in chapter two, exercise is an effective intervention for rotator cuff tendinopathy but there is a dearth of studies comparing exercise programmes, with different constituent parts, with one another. Furthermore, heterogeneity between different studies, including use of different outcome measures, coupled with inadequate reporting currently limits the potential for evidence synthesis. There is a clear indication for studies evaluating different types of exercise and importantly dosage, for example number of repetitions and sets, frequency and load. The

data presented in chapter two offers a platform upon which such studies could be developed and justified.

Finally, from a research design perspective, future studies need to be mindful of the difficulties associated with recruitment and retention and recognise that multi-centre studies are useful from both a numbers and generalisability perspective. The SPADI is one of the most commonly used outcome measures in studies evaluating conservative interventions for shoulder pain. With this in mind along with the current heterogeneous approach to outcome measurement in studies to date, it is recommended that the SPADI is incorporated as a means of facilitating both valid outcome measurement and useful evidence synthesis.

11.2 Conclusion

This PhD thesis has offered new insight into the understanding and management of rotator cuff tendinopathy. Using robust and inter-linked research methods, the work has established the value of exercise as a management strategy for rotator cuff tendinopathy and critically also identified some important components of effective programmes in relation to type and dosage. High quality pilot and substantive RCTs were conducted and reported which, despite high loss to follow-up, suggest potential comparability between a self-managed approach based upon a single exercise and multimodal physiotherapy, as defined in this thesis, in the short- and mid-term. Additionally, factors relating to future conduct of research studies have been identified and reported also the relevance of the perspectives of patients and physiotherapists with regard to implementation have also been revealed.

Despite the advancements presented in this thesis, it is clear that there are still many unanswered questions but a platform upon which further knowledge can be developed has been established.

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Appendix 1

REVIEW ARTICLE

A review of systematic reviews of the effectiveness of conservative interventions for rotator cuff tendinopathy

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ABSTRACT

Background Rotator cuff tendinopathy is common and a wide range of conservative interventions are currently used to treat this problem. The purpose of this review is to systematically review the systematic reviews that evaluate the effectiveness of conservative interventions for rotator cuff tendinopathy.

Methods An electronic search of PEDro, MEDLINE and the Cochrane Library was undertaken and supplemented by hand and citation searching. The AMSTAR checklist was adopted for quality appraisal and a narrative synthesis was undertaken.

Results Twenty-six systematic reviews were retrieved. Methodological quality was variable. Exercise and multimodal physiotherapy appear to confer superior outcomes over no treatment or placebo, although the clinical significance of these results remains unclear. Surgery does not confer an additional benefit over exercise alone or multimodal physiotherapy. Combining manual therapy with exercise is not currently supported, neither is the use of corticosteroid injections or acupuncture. Other commonly prescribed interventions lack evidence of effectiveness.

Conclusions Exercise and multimodal physiotherapy might be effective interventions for rotator cuff tendinopathy, although the clinical significance of this effect is unclear. This interpretation is drawn from systematic reviews comprising mainly small randomized controlled trials that frequently measure outcome in a heterogeneous manner, limiting the strength of any conclusions.

INTRODUCTION

Symptomatic rotator cuff tendinopathy is a common problem with prevalence rates as high as 14% in the working population [1]. Such disorders are not always short-lived or isolated episodes but, instead, might be somewhat of a resistant clinical presentation [2]. Although a proportion of people might recover within the first few months of onset, some do go on to develop persistent symptoms [2].

A range of conservative and surgical interventions are currently used to treat this condition. A recent survey of current practice highlighted that physiotherapists in the UK might offer a variety of conservative interventions and it is evident that clinical practice varies widely [3]. Over time, multiple systematic reviews relating to the effectiveness of interventions for rotator cuff tendinopathy have been published. As a result of this expansive secondary evidence-base, the purpose of this review is to systematically retrieve, appraise and synthesize findings from previous systematic reviews to help understand how knowledge has developed over time and what research currently tells us about the management of this common condition.

METHODS

Data sources and search strategy

Electronic searches of the Physiotherapy Evidence Database (PEDro), the Cochrane Library and MEDLINE from their inception to September 2012 were undertaken by one reviewer (CL). The search terms used for the MEDLINE search are displayed in Table 1.

The electronic search was complemented by citation searching of the identified systematic reviews followed by hand-searching the reference lists of these systematic reviews.

Study selection

Study selection was undertaken by one reviewer (CL). Systematic reviews including randomized controlled trials (RCTs) comprising participants presenting with signs and symptoms suggestive of rotator cuff tendinopathy were included. A range of terms exist that are synonymous with the term rotator cuff tendinopathy, including subacromial impingement syndrome, painful arc syndrome, shoulder impingement, subacromial bursitis, rotator cuff tendonitis, rotator cuff tendinosis, supraspinatus tendonitis, and contractile dysfunction. There appears to be significant overlap and replication

Table 1 MEDLINE search strategy

	Search term	Limited to
1	Soulder pain or shoulder impingement* or shoulder tend* or shoulder burs* or rotator cuff* or subacromial impingement* or subacromial burs* or supraspinatus* or impingement* or contractile dysfunction or painful arc*	Title and abstract
2	Review or systematic review or meta-analysis or synthesis	Title and abstract
3	1 and 2	—

in terms of what these diagnostic labels are actually referring to [4]. As a result of the diverse nature of classification in combination with poor reporting of diagnostic criteria, the diagnosis of rotator cuff tendinopathy was operationalized as pain presenting locally at the shoulder with a largely maintained range of movement, fracture, instability, calcific tendinitis or post-surgical status. Although not ideal, such a pragmatic approach is in keeping with the approach of other studies [5] and could include the range of diagnoses described above. For the purpose of this review, systematic reviews that included studies focusing solely upon participants with rotator cuff tears were excluded. Systematic reviews that comprised studies with a mix of diagnoses (e.g. frozen shoulder and rotator cuff tendinopathy) were included provided that subgroup analysis relating to rotator cuff tendinopathy was offered.

Systematic reviews that evaluated the effectiveness of conservative interventions typically offered by physiotherapists in the UK, including exercise, manual therapy, electrotherapy, acupuncture and corticosteroid injections [3], in comparison to no intervention, placebo, other conservative interventions or surgical interventions, were included. For pragmatic reasons, systematic reviews published in languages other than English were excluded.

Data extraction

One reviewer (CL) extracted data relating to the systematic review methods, type and number of studies included, diagnostic criteria, interventions evaluated and main outcomes.

Quality appraisal

Quality appraisal was undertaken by one reviewer (CL). The AMSTAR (assessment of multiple systematic reviews) checklist was utilized to evaluate the methodological quality of the included systematic reviews. AMSTAR consists of 11 items, which are not summed to give an overall quality score, each with a 'yes', 'no', 'can't answer' or 'not applicable' response [6]. Good face and content validity for measuring the quality of systematic reviews has been reported [6].

Data synthesis

Heterogeneity between primary studies evaluating the effectiveness of interventions in this field is well-recognized and has an obvious impact upon the ability to synthesize findings from subsequent systematic reviews. For this reason, a narrative approach was undertaken to synthesize the findings in relation to the various conservative interventions.

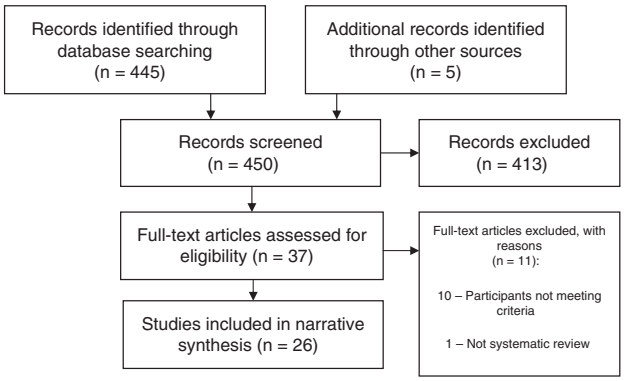

Fig. 1 Study selection process.

RESULTS

Study selection

Figure 1 depicts the study selection process. The electronic search yielded a total of 445 articles and a further five were identified though hand- and citation searching. The title and abstracts of 450 articles were screened, with 37 potentially relevant reviews identified for full-text review. Only one non-English language systematic review that was potentially relevant was identified but excluded at this stage. Of these 37 articles, 26 were selected. Ten articles [7–16] excluded at the stage of full-text review did not include participants with rotator cuff tendinopathy and/or the systematic review authors did not generate a relevant subgroup analysis pertaining to rotator cuff tendinopathy. One article was excluded because it was not a systematic review [17].

Quality appraisal

The results of the AMSTAR quality appraisal are shown in Table 2. The mean quality score was 6 (range 3 to 9). The most common reason for not meeting an AMSTAR criterion was a failure to assess the likelihood of publication bias (96%), a failure to search beyond published literature (88%), a failure to include a list of included and excluded studies (85%), a failure to undertake a comprehensive literature search (62%) and a failure to declare any potential conflicts of interest (62%).

Study characteristics

A summary of the characteristics of the included systematic reviews along with the main outcomes are shown in Tables 3 to 11.

Exercise for rotator cuff tendinopathy

Thirteen systematic reviews relating to the effectiveness of exercise for rotator cuff tendinopathy were retrieved from 2003 to 2012 (Table 3). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). Despite this variability, the reviews consistently supported

Table 2 Results of the AMSTAR quality appraisal

Study	1. Was an 'a priori' design developed?	2. Was there duplicate study selection and data extraction?	3. Was a comprehensive literature search performed?	4. Was the status of publication used as an inclusion criterion?	5. Was a list of studies (included and excluded) provided?	6. Were the characteristics of the included studies provided?	7. Was the scientific quality of the included studies assessed and documented?	8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	9. Were the methods used to combine the findings of the studies appropriate?	10. Was the likelihood of publication bias assessed?	11. Was the conflict of interest stated?
Green et al. [18]	√	√	√	x	√	√	√	√	√	x	√
Johansson et al. [19]	—	√	x	x	x	√	√	√	√	x	x
Buchbinder et al. [20]	√	√	√	x	√	√	√	√	√	x	√
Green et al. [21]	√	√	√	x	√	√	√	√	√	x	√
Desmeules et al. [22]	—	√	x	x	x	√	√	√	√	—	x
Grant et al. [23]	—	√	x	x	x	√	√	√	√	x	x
Michener et al. [24]	—	√	√	√	x	√	√	√	√	x	x
Harniman et al. [25]	—	√	—	x	x	√	√	√	√	x	x
Green et al. [26]	√	√	√	x	√	√	√	√	√	x	√
Arroll and Goodyear-Smith [27]	√	√	x	√	x	x	√	√	√	√	√
Trampas and Kitsios [28]	—	√	√	x	x	√	√	√	√	x	x
Faber et al. [29]	—	√	x	x	x	√	√	√	√	x	x
Woodley et al. [30]	—	—	x	x	x	√	√	√	NA	x	√
Koester et al. [31]	—	x	x	x	x	√	√	√	√	x	√
Ho et al. [32]	—	x	√	x	x	x	√	x	√	x	x
Kuhn [33]	√	x	x	x	x	√	√	x	√	x	x
Dorrestijn et al. [34]	—	√	√	x	x	√	√	x	√	x	x
Kromer et al. [35]	—	√	x	x	x	√	√	√	√	x	x
Nyberg et al. [36]	—	x	x	x	x	√	√	√	√	x	x
Braun and Hanchard [5]	√	x	x	x	√	√	√	√	√	x	√
Tumilty et al. [37]	—	√	x	x	x	√	√	√	√	x	x
Kelly et al. [38]	—	√	√	x	x	√	√	√	√	x	x
Huisstede et al. [39]	—	√	x	x	x	√	√	√	√	x	x
Brantingham et al. [40]	—	—	x	x	x	√	√	√	x	x	√
Littlewood et al. [4]	√	√	√	√	x	√	√	√	√	x	√
Hanratty et al. [41]	√	√	x	x	x	√	√	√	√	x	x

(√ = Yes, x = No, − = cannot answer, NA = not applicable).

Table 3 Systematic reviews relating to the effectiveness of exercise for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Green et al. [21]	9	Rotator cuff tendinitis	Exercise	Results from one RCT ([42,43]; $n = 80$): Evidence supportive of short- and long-term effectiveness in terms of improved function compared to placebo	RR of good/ excellent function 2.45 (95% CI 1.24 to 4.86)
Desmeules et al. [22]	5	Impingement syndrome, rotator cuff tendinitis or bursitis		Results from two RCTs ([42–44]; $n = 146$): Evidence supportive of effectiveness compared to placebo or no treatment	NC
Grant et al. [23]	5	Rotator cuff pathology		Results from one RCT ([42,43]; $n = 80$): Evidence supportive of short- and long-term effectiveness in terms of improved function compared to placebo	NC
Michener et al. [24]	7	Subacromial impingement syndrome		Results from two RCTs ([42,43,45]; $n = 147$): Evidence supportive of effectiveness in the short- and long-term in terms of improved function compared to placebo or no intervention	NC
				Results from two RCTs ([42,43,46]; $n = 137$): Evidence suggestive of no significant difference in short- and medium-term but conflicting in the long-term when compared to surgery	NA
Trampas and Kitsios [28]	6	Shoulder impingement syndrome		Results from one RCT ([45]; $n = 67$): Evidence supportive of effectiveness compared to no treatment	NC
				Results from one RCT ([47,48]; $n = 150$): Evidence suggestive of no significant difference in terms of pain or function compared to multimodal physiotherapy, functional brace or surgery	NA
Faber et al. [29]	5	Shoulder impingement syndrome		Results from two RCTs ([42,43,45]; $n = 147$): Evidence supportive of effectiveness in terms of functional limitations or work status compared to placebo or no intervention	NC
				Results from one RCT ([42,43]; $n = 95$): Evidence suggestive of no significant difference in terms of functional limitations compared to surgery	NA
Woodley et al. [30]	4	Rotator cuff tendinopathy		No relevant RCTs retrieved	NA
Kuhn [33]	4	Rotator cuff impingement		Results from two RCTs ([42,43,45]; $n = 147$): Evidence supportive of effectiveness compared to placebo or no treatment	Conflicting evidence
				Results from two RCTs ([47,49]; $n = 80$): Evidence suggestive of no significant difference between home exercise and supervised exercise	NA
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from two RCTs ([42,43,48,50]; $n = 179$): Evidence suggestive of no significant difference in the short-, medium- or long-term compared to surgery	NA
				Results from two RCTs ([47,49]; $n = 80$): Evidence suggestive of no significant difference between home exercise and supervised exercise	NA
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from two RCTs ([42,43,48,50]; $n = 179$): Evidence suggestive of no significant difference in the short-, medium- or long-term compared to surgery	NA

Table 3 Continued

Study	Score	Population	Intervention	Main outcomes	Clinical significance
				Results from two RCTs ([45,51]; $n = 127$): Evidence supportive of effectiveness compared to no treatment	NC
				Results from one RCT ([52]; $n = 104$): Evidence supportive of effectiveness in the short- and medium- term compared to extracorporeal shockwave therapy	NC
				Results from one RCT ([47] $n = 40$): Evidence suggestive of no significant difference between home exercise and supervised (physiotherapy) exercise	NA
				Results from one RCT ([53]; $n = 80$): Evidence supportive of effectiveness of high dose exercise compared to lower dose exercise	NC
Braun and Hanchard [5]	7	Impingement-related shoulder pain		Results from one RCT ([54]; $n = 37$): Evidence not supportive of effectiveness in the short-term compared to heat application	NC
				Results from one RCT ([51]; $n = 60$): Evidence supportive of effectiveness compared to no treatment	NC
				Results from one RCT ([50]; $n = 84$): Evidence suggestive of no significant difference in the long-term compared to surgery	NA
Kelly et al. [38]	6	Subacromial impingement syndrome		Results from two RCTs ([42,43,51]; $n = 140$): Evidence supportive of effectiveness compared to placebo or no treatment	NC
				Results from one RCT ([47]; $n = 60$): Evidence suggestive of no significant difference compared with functional brace or physiotherapy	NA
				Results from two RCTs ([42,43,46,48]; $n = 227$): Evidence suggestive of no significant difference compared to surgery	NA
Littlewood et al. [4]	10	Rotator cuff tendinopathy		Results from three RCTs ([42,43,45,51]; $n = 207$) Evidence supportive of effectiveness in the short-, medium- and long-term compared to placebo or no intervention	Unclear
				Results from one RCT ([42,43]; $n = 95$) Evidence suggestive of no significant difference in the short-, medium- and long-term compared to surgery	NA
				Results from one RCT ([47]; $n = 60$) Evidence suggestive of no significant difference in the short-term compared to multi-modal physiotherapy or functional brace	NA

NC, No commentary available; NA, not applicable; RCT, randomised controlled trial; RR, relative risk.

the superior effectiveness of exercise, in terms of statistical significance, compared to no treatment or placebo. Other active interventions, including multimodal physiotherapy or surgery, confer no additional benefit over exercise alone. The clinical significance of any treatment effects as a result of exercise are unclear and only a minority of systematic reviews considered this.

Exercise combined with manual therapy for rotator cuff tendinopathy

Eleven systematic reviews relating to the effectiveness of exercise combined with manual therapy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (Table 4). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 3 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews supported the short-term effectiveness of exercise combined with manual therapy, in terms of statistical significance, compared to exercise alone based upon the two studies by Conroy and Hayes [55] and Bang and Deyle [56]. Post 2006, the inclusion of Citaker et al. [57] and, subsequently Senbursa et al. [58], the evidence became conflicting. However, Citaker et al. [57] report a significant benefit in favour of exercise combined with manual therapy, although the between-group results presented in the paper do not support this. Braun and Hanchard [5] recognize this inconsistency but report in favour of manual therapy whereas Kelly et al. [38] do not. Kuhn [33] and Nyberg et al. [36] do not appear to recognize this inconsistency but this conflict in reporting might only be purely academic in nature because the change reported by Senbursa et al. [58] is not regarded as clinically significant [33]. Overall, only a minority of systematic reviews considered the clinical significance of any treatment effects attributable to exercise combined with manual therapy, the outcome of which was unclear clinical significance.

Multimodal physiotherapy for rotator cuff tendinopathy

Seven systematic reviews relating to the effectiveness of multimodal physiotherapy for rotator cuff tendinopathy were retrieved from 2009 to 2012 (Table 5). For the purpose of this review, multimodal physiotherapy refers to combined treatment including, but not restricted to, exercise, manual therapy, electrotherapy and corticosteroid injections. Inclusion in this category was based upon the intervention offered in the primary study or a result of the method of analysis offered by the systematic review (e.g. when studies evaluating exercise or manual therapy or electrotherapy were combined for the purpose of evidence synthesis). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 7/11). Despite this variability, the reviews consistently supported the effectiveness of multimodal physiotherapy in the medium and longer-term, in terms of statistical significance, compared to no treatment or placebo but, in the short-term, the evidence suggests no significant difference. Surgical intervention does not offer additional benefit over multimodal physiotherapy. The clinical significance of any treatment effects as a result of multimodal physiotherapy was not considered in any of the systematic reviews.

Corticosteroid injection for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of corticosteroid injection for rotator cuff tendinopathy were retrieved from 1998 to 2007 (Table 6). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 5 to 9/11). Early reviews, meeting most quality criteria, supported the short-term effectiveness of corticosteroid injections, in terms of statistical significance, compared to placebo. One review [21] reported effectiveness compared to physiotherapy, although this review included primary studies comprising mixed diagnoses despite reporting to the contrary. The latest review [31], comprising the greatest number of primary studies, reported conflicting evidence regarding the effectiveness of corticosteroid injections but this review was of lower quality than the others (5/11). The clinical significance of any treatment effects as a result of corticosteroid injections was considered by three reviews [20,27,31]. However, because of methodological concerns relating to the method of estimation compounded by variability in estimates of effect size, the clinical significance of any positive findings remains unclear.

Laser for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of laser therapy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (Table 7). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). Despite this variability, the reviews consistently concluded that the evidence did not support the effectiveness of laser therapy compared to other interventions. The exception to this was evidence supportive of high-intensity laser compared to ultrasound based upon one RCT included in one systematic review [36]. No comment was made about the clinical significance of this finding and as a result of the lack of positive findings relating to low-intensity laser, commentary about clinical significance was not applicable.

Ultrasound for rotator cuff tendinopathy

Five systematic reviews relating to the effectiveness of ultrasound for rotator cuff tendinopathy were retrieved from 2002 to 2009 (Table 8). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 5 to 9/11). Despite this variability, the reviews consistently concluded that the evidence did not support the effectiveness of ultrasound.

Extracorporeal shock wave therapy for rotator cuff tendinopathy

Four systematic reviews relating to the effectiveness of extracorporeal shock wave therapy for rotator cuff tendinopathy were retrieved from 2004 to 2011 (Table 9). According to the quality appraisal based upon AMSTAR, the systematic reviews were of similar quality (all 5/11). The reviews consistently concluded that the evidence did not support the effectiveness of extracorporeal shockwave therapy compared to placebo.

Table 4 Systematic reviews relating to the effectiveness of exercise combined with manual therapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Green et al. [21]	9	Rotator cuff tendinitis	Exercise combined with manual therapy	Results from two RCTs ([55,56]; $n = 66$): Evidence supportive of short-term effectiveness in terms of improved pain, function and ROM compared to exercise alone	Unclear
Desmeules et al. [22]	5	Impingement syndrome, rotator cuff tendinitis or bursitis		Results from two RCTs ([55,56]; $n = 66$): Evidence supportive of short-term effectiveness compared to exercise alone	NC
Michener et al. [24]	7	Subacromial impingement syndrome		Results from two RCTs ([55,56]; $n = 66$): Evidence supportive of effectiveness in the short-term compared to exercise alone	NC
Trampas and Kitsios [28]	6	Shoulder impingement syndrome		Results from one RCT ([57]; $n = 40$): Evidence suggestive of no significant difference in terms of pain or function compared to proprioceptive neuromuscular facilitation with exercise	NA
Faber et al. [29]	5	Shoulder impingement syndrome		Results from one RCT ([56]; $n = 52$): Evidence supportive of effectiveness in the short-term with regards to functional limitations compared to exercise alone	NC
Ho et al. [32]	3	Shoulder impingement syndrome		Results from three RCTs ([55–57]; $n = 106$): Conflicting evidence regarding effectiveness in the short-term with regards to pain and function compared to other active interventions including exercise, proprioceptive neuromuscular facilitation and soft tissue massage	NC
				Results from two RCTs ([55,57]; $n = 54$): Evidence suggestive of no significant difference in the short-term with regards to ROM compared to other active interventions	NA
Kuhn [33]	4	Rotator cuff impingement		Results from three RCTs ([55,56,58]; $n = 96$): Evidence supportive of effectiveness compared with exercise alone	Conflicting evidence
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from two RCTs ([55,56]; $n = 66$): Evidence supportive of effectiveness in the short-term compared to exercise alone	NC
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from two RCTs ([56,58]; $n = 82$): Evidence supportive of effectiveness compared to exercise alone	NC
Braun and Hanchard [5]	7	Impingement-related shoulder pain		Results from one RCT ([58]; $n = 30$): Evidence supportive of effectiveness in the short-term compared to exercise alone	NC
				Results from one RCT ([59]; $n = 112$): Evidence suggestive of no significant difference in the medium- or long-term compared to CCS injections or NSAIDs	NC
Kelly et al. [38]	6	Subacromial impingement syndrome		Results from three RCTs ([55,57,58]; $n = 84$): Conflicting evidence regarding effectiveness compared to exercise alone	NA

NC, No commentary available; NA, not applicable; ROM, range of motion; RCT, randomised controlled trial; CCS, corticosteroid.

Table 5 Systematic reviews relating to the effectiveness of multimodal physiotherapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Kuhn [33]	4	Rotator cuff impingement	Multimodal physiotherapy	Results from four RCTs ([42,43,46,48,60]; $n = 299$): Evidence suggestive of no significant difference compared to surgery	NA
Dorrestijn et al. [34]	5	Subacromial impingement syndrome		Results from four RCTs ([42,43,46,48,60]; $n = 299$): Evidence suggestive of no significant difference compared to surgery	NA
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from one RCT ([61]; $n = 85$): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from one RCT ([61]; $n = 85$): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
Braun and Hanchard [5]	7	Impingement-related shoulder pain		Results from one RCT ([61]; $n = 85$): Evidence supportive of effectiveness in the medium-term compared to no intervention	NC
Brantingham et al. [40]	4	Rotator cuff disorders		Results from ten RCTs ([55–58,61–66]; $n = 504$): Evidence supportive of effectiveness	NC
Hanratty et al. [41]	6	Subacromial impingement syndrome		Results from sixteen RCTs ([42,43,45,47,48,51,52,55,56,58,59,62,67–71]; $n = 1162$): Evidence supportive of effectiveness in the short-term with regards to pain and function	NC
				Evidence supportive of effectiveness in the long-term with regards to function	NC
				Pooled results from four RCTs ([51,52,62,68]; $n = 369$) Evidence suggestive of no significant difference in the short-term with regards to pain	NA
				Pooled results from five RCTs ([45,51,52,62,68]; $n = 409$) Evidence suggestive of no significant difference in the short-term with regards to function but supportive of effectiveness in the long-term	NA

NC, No commentary available; NA, not applicable; RCT, randomised controlled trial.

Table 6 Systematic reviews relating to the effectiveness of corticosteroid (CCS) injection for rotator cuff tendinopathy

Study	Score	Population	Interventions	Main outcomes	Clinical significance
Green et al. [18]	9	Rotator cuff tendinitis	CCS injection	Pooled results from two RCTs ([72,73]; $n = 90$): Evidence supportive of short-term effectiveness in terms of improved abduction ROM compared to placebo	NC
				Evidence not supportive of effectiveness in terms of reduced pain in short-term compared to placebo	NA
Johansson et al. [19]	5	Subacromial pain		Results from one RCT ([74]; $n = 40$): Evidence supportive of short-term and long-term effectiveness in terms of reduced pain and improved abduction ROM compared to subacromial injection of local anaesthetic	NA
Buchbinder et al. [20]	9	Rotator cuff disease		Pooled results from two RCTs ([72,73]; $n = 90$): Evidence supportive of short-term effectiveness in terms of reduced pain, function and abduction ROM compared to placebo	SMD 0.83 (95% CI 0.39 to 1.26), 0.82 (0.39 to 1.25, 0.63 (0.20 to 1.06) respectively
				Results from five RCTs ([74–78]; $n = 228$): Conflicting evidence regarding effectiveness compared to placebo	NA
Green et al. [21]	9	Rotator cuff tendinitis		Results from four RCTs ([79–83]; $n = 342$): Evidence supportive of effectiveness compared to physiotherapy interventions	NA
Arroll and Goodyear-Smith [27]	8	Rotator cuff tendonitis		Results from five RCTs ([72–75,78]; $n = 222$): Evidence supportive of effectiveness in terms of 'improvement' in the short- to mid-term compared to placebo	RR of improvement 3.1 (95% CI 1.94 to 4.87)
Koester et al. [31]	5	Rotator cuff disease		Results from eight RCTs ([72–75,79,84,85]; $n = 341$): Conflicting evidence regarding effectiveness with regards to pain compared to placebo	With regards to pain and ROM, only one study offered clinically significant results
				Results from seven RCTs ([72–75,79,84,86,87]; $n = 366$): Conflicting evidence regarding effectiveness with regards to ROM compared to placebo	
				Results from four RCTs ([72,73,85,86]; $n = 180$): Conflicting evidence regarding with regards to function compared to placebo	

NC, No commentary available; NA, not applicable; SMD, standardized mean difference; RR, relative risk; ROM, range of motion; RCT, randomized controlled trial.

Table 7 Systematic reviews relating to the effectiveness of laser therapy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Green et al. [21]	9	Rotator cuff tendinitis	Laser	Results from two RCTs ([88,89]; $n = 59$) : Evidence not supportive of effectiveness compared to placebo	NA
Grant et al [23]	5	Rotator cuff pathology		Results from one RCT ([88]; $n = 35$): Evidence not supportive of effectiveness compared to placebo	NA
Faber et al. [29]	5	Shoulder impingement syndrome		Results from one RCT ([88]; $n = 35$): Evidence not supportive of effectiveness in the short-term with regards to functional limitations compared to placebo	NA
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from two RCTs ([88,89]; $n = 59$): Conflicting evidence regarding effectiveness in the short-term compared to placebo	NC
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from one RCT ([90]; $n = 70$): Evidence supportive of effectiveness of high intensity laser with regards to pain compared to ultrasound	NC
				Results from two RCTs ([91,92]; $n = 104$): Evidence not supportive of effectiveness of low intensity laser	NA
Tumilty et al. [37]	5	Rotator cuff tendinopathy		Results from three RCTs ([88,89,93]; $n = 95$): Conflicting evidence regarding effectiveness of low intensity laser	NC

NC, No commentary available; NA, not applicable; RCT, randomised controlled trial.

Table 8 Systematic reviews relating to the effectiveness of ultrasound for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Johansson et al. [19]	5	Subacromial pain	Ultrasound	Results from one RCT ([94]; $n = 61$): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
Green et al. [21]	9	Rotator cuff tendinitis		Results from one RCT ([94]; $n = 61$): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
Michener et al. [24]	7	Subacromial impingement syndrome		Results from two RCTs ([79,94]; $n = 85$): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo	NA
Faber et al. [29]	5	Shoulder impingement syndrome		Results from one RCT ([95]; $n = 20$): Evidence not supportive of effectiveness in the short-term with regards to functional limitations compared to placebo	NA
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from two RCTs ([94,96]; $n = 146$): Evidence not supportive of effectiveness in terms of pain or ROM compared to placebo or acupuncture	NC

NC, No commentary available; NA, not applicable; ROM, range of motion; RCT, randomised controlled trial.

Table 9 Systematic reviews relating to the effectiveness of extracorporeal shockwave therapy for rotator cuff tendinopathy

Study	Score	Population	Interventions	Main outcomes	Clinical significance
Grant et al. [23]	5	Rotator cuff pathology	Extracorporeal shock wave therapy	Results from one RCT ([97]; $n = 74$): Evidence not supportive of effectiveness compared to placebo	NA
Harniman et al. [25]	5	Rotator cuff tendonitis		Results from one RCT ([98]; $n = 40$): Evidence not supportive of effectiveness in terms of pain, function or ROM compared to placebo	NA
Faber et al. [29]	5	Shoulder impingement syndrome		Results from two RCTs ([97 – 99]; $n = 108$): Evidence not supportive of effectiveness in the short-, medium- or long-term with regards to functional limitations compared to placebo	NA
Huisstede et al. [39]	5	Rotator cuff tendinosis		Results from six RCTs ([97 – 102]; $n = 314$): Evidence not supportive of effectiveness compared to placebo or other interventions	NA

NC, No commentary available; NA, not applicable; ROM, range of motion; RCT, randomised controlled trial.

Acupuncture for rotator cuff tendinopathy

Six systematic reviews relating to the effectiveness of acupuncture for rotator cuff tendinopathy were retrieved from 2002 to 2010 (Table 10). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews [19,23] that included the same RCT [103] supported short-term effectiveness, in terms of statistical significance, compared to placebo. These conclusions were confounded by failure to report one study [79] included in later reviews that did not support effectiveness. Medium-term effectiveness of acupuncture is not supported by the reviews and neither is effectiveness compared to active interventions including ultrasound or corticosteroid injections, albeit based upon the findings of one primary study. One anomaly is that noted by Trampas and Kitsios [28] who concluded in favour of acupuncture compared to ultrasound. This conclusion, based upon Johansson et al. [96], relates to acupuncture combined with exercise, which makes it difficult to ascribe any treatment effect to acupuncture particularly when considered in the context of the above findings relating to exercise. Only one review comments upon clinical significance of the findings [19]. Johansson et al. [19] report a standardized mean difference of 0.77 which is regarded as a moderate effect size [104], although no estimate of variance is offered, which limits interpretation.

Pulsed electromagnetic energy rotator cuff tendinopathy

Four systematic reviews relating to the effectiveness of pulsed electromagnetic energy for rotator cuff tendinopathy were retrieved from 2003 to 2010 (Table 11). According to the quality appraisal based upon AMSTAR, the systematic reviews were of variable quality (range 4 to 9/11). No clear trend relating to outcomes and systematic review quality emerged but early reviews supported short-term effectiveness, in terms of statistical significance, compared to placebo, whereas later reviews, including more primary studies, concluded that the evidence was conflicting and subsequently not supportive of effectiveness.

DISCUSSION

Current evidence suggests that exercise, whether completed at home or in a clinical setting, appears to confer superior outcomes over no treatment or placebo. Other active interventions, including multimodal physiotherapy or surgery, confer no additional benefit over exercise alone. Additional benefits might be gained with higher doses of exercise. Similarly, multimodal physiotherapy appears to confer superior outcomes over no treatment or placebo, whereas surgical intervention does not offer additional benefit over multimodal physiotherapy. However, the clinical significance (or change that would be regarded as important by the patient and clinician) of any positive effects remains unclear. Manual therapy, corticosteroid injections, acupuncture are not supported by current evidence. Other commonly prescribed interventions lack evidence of effectiveness, including ultrasound, low level laser and extracorporeal shock wave therapy.

Table 10 Systematic reviews relating to the effectiveness of acupuncture for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Johansson et al. [19]	5	Subacromial pain	Acupuncture	Results from one RCT ([103]; $n = 52$): Evidence supportive of short-term effectiveness in terms of reduced pain and improved function compared to placebo	SMD 0.77
Grant et al. [23]	5	Rotator cuff pathology		Results from one RCT ([103]; $n = 52$): Evidence supportive of short-term effectiveness in terms of reduced pain and improved function compared to placebo	NC
Michener et al. [24]	7	Subacromial impingement syndrome		Results from two RCTs ([79,103]; $n = 76$): Evidence is conflicting in the short-term and not supportive of effectiveness in the mid-term with regards to pain, function or ROM compared to placebo	NA
Green et al. [26]	9	Rotator cuff disease		Results from two RCTs ([79,103]; $n = 76$): Evidence is conflicting in the short-term and not supportive of effectiveness in the mid-term with regards to pain, function or ROM compared to placebo	NA
				Results from one RCT ([79]; $n = 24$): Evidence suggestive of no significant difference in terms of pain or ROM compared to CCS injection	NA
				Results from one RCT ([79]; $n = 24$): Evidence suggestive of no significant difference in terms of pain or ROM compared to ultrasound	NA
Trampas and Kitsios [28]	6	Shoulder impingement syndrome		Results from one RCT ([96]; $n = 85$): Evidence supportive of effectiveness with regards to pain compared to ultrasound	NC
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from three RCTs ([96,103,105]; $n = 562$): Conflicting evidence with regards to pain and function compared to placebo (including ultrasound)	NC

NC, No commentary available; NA, not applicable; SMD, standardized mean difference; ROM, range of motion; RCT, randomized controlled trial.

Table 11 Systematic reviews relating to the effectiveness of pulsed electromagnetic energy for rotator cuff tendinopathy

Study	Score	Population	Intervention	Main outcomes	Clinical significance
Green et al. [21]	9	Rotator cuff tendinitis	Pulsed electromagnetic energy	Results from one RCT ([106]; $n = 29$): Evidence supportive of short-term effectiveness compared to placebo	NC
Grant et al. [23]	5	Rotator cuff pathology		Results from one RCT ([106]; $n = 29$): Evidence supportive of short-term effectiveness compared to placebo	NC
Kromer et al. [35]	5	Shoulder impingement syndrome		Results from three RCTs ([106–108]; $n = 124$): Conflicting evidence regarding effectiveness in the short-term compared to placebo	NC
Nyberg et al. [36]	4	Subacromial impingement syndrome		Results from one RCT ([107]; $n = 46$): Evidence not supportive of effectiveness	NC

NC, No commentary available; NA, not applicable; RCT, randomized controlled trial.

These findings have important implications for research and clinical practice. Although exercise is regarded as potentially effective, the optimal type and dose remains unclear [109] and it is apparent that not all exercise has the same effect. Previously Jonsson et al. [110] in a non-RCT reported a favourable response to painful loaded exercise in five of nine patients awaiting surgery for impingement syndrome of the shoulder. This is a notable finding because they had previously not responded to conservative care prior to listing for surgery. Recently Holmgren et al. [109] conducted a RCT comparing specific (loaded) exercises versus nonspecific exercise in patients labelled with subacromial impingement syndrome. These authors also recruited patients who had not responded to previous conservative care, including exercise, and were on the surgical waiting list for a subacromial decompression. Additionally, all patients received a subacromial corticosteroid injection prior to commencing exercise therapy and patients in the specific exercise group also received manual therapy at the discretion of the treating physiotherapist. Patients in this group were advised to exercise according to the pain monitoring model, which was used to find the individual resistance level for the exercise for each patient. Participants were expected to experience discomfort during exercise (self-report $< 5/10$ on a visual analogue scale), which subsided before commencement of the next exercise session. Post-intervention, only 20% (10/51) of the specific exercise group opted for surgical intervention compared to 63% (29/46) of the nonspecific exercise group (odds ratio $= 7.7$; 95% confidence interval $= 3.1$ to 19.4, $p < 0.001$).

The results of the study by Jonsson et al. [110] and Holmgren et al. [109] are interesting and indicate the potential superiority of such an approach incorporating loaded exercise. However, the inclusion of manual therapy in the study by Holmgren et al. [109] confounds the conclusions that can be drawn about the potential sole effect of loaded exercise. It is also not possible to evaluate the effectiveness of manual therapy because a different exercise programme was offered in the control arm. Although such a multimodal approach might be reflective of much of current practice [3], this alone does not justify acceptance of such a combined approach. To date, the effect of conservative care, including exercise and multimodal physiotherapy, has been recognized but, in keeping with the findings of this review, doubts regarding the specific components (e.g. manual therapy; corticosteroid injection) persist. In a more recent RCT, not included in systematic reviews to date, Yiasemides et al. [111] has further questioned the added value of manual therapy. Yiasemides et al. [111] conducted the largest pragmatic RCT to date, with 98 participants, comparing exercise and manual therapy with exercise alone. Interestingly, these authors refrained from applying a biomedical diagnosis and, instead, referred to shoulder pain provoked with shoulder movement but with minimal movement restriction, which is in keeping with the approach taken in this review and recognizes the limited reliability of diagnostic tests and a lack of uniformity in relation to diagnostic labels. These authors followed-up participants for 1, 3 and 6 months up and between-group differences were reported as not statistically significant, which casts further doubt upon the added benefit of manual therapy in this patient group.

Kuhn [33] attempted to synthesize an evidence-based rehabilitation protocol. Based upon the available literature, a specific and extensive exercise programme is presented that includes fifteen different exercises along with dose and frequency. The exercise component amounts to a compendium of all exercises used in studies included in the systematic review. Manual therapy is advocated but, according to the results of this review, the inclusion of manual therapy in a 'gold-standard' rehabilitation protocol appears to be premature. Heat or cold or both are recommended as a result of the inclusion of this approach within some of the multimodal approaches evaluated in the systematic review by Kuhn [33]. Other modalities are not recommended, which is in keeping with the recommendations from this review. However, it is suggested that it might be more appropriate to regard the rehabilitation protocol as a 'best-fit' rather than a 'gold-standard' at this stage because evidence for the effectiveness of such a surmised programme is not available. Additionally, other factors need to be taken into account when evaluating such an extensive programme, particularly levels of exercise adherence that can realistically be expected from patients/participants.

Realistically, it remains unclear which components of a conservative rehabilitation programme are effective. The question of whether the sum outcome of a combination of interventions is superior to outcomes derived from the prescription of individual interventions remains unanswered. Clearly, there is scope for further research focusing upon this rather than further focus upon evaluation of interventions compared to no treatment or placebo. Based upon the findings of this review, exercise is one intervention that warrants further investigation, although more careful attention to the development of such programmes needs to be made with reference to the available literature. These developmental messages include the potential benefit of loaded exercise; similar outcomes between home and clinic based programmes and added benefit with higher doses of exercise.

The current recommendations from this review are in the context of significant potential for type II error in the literature as a result of the small sample sizes of most currently published RCTs pertaining to shoulder disorders. Pike and Leith [112] reviewed the literature to retrieve published randomized controlled trials that reported negative results. These authors found that only 41% of the studies retrieved were adequately powered to detect a true difference. Furthermore, a consistent concern has been raised by systematic reviewers over the years relating to the heterogeneity of outcome measurement, including the use of unvalidated measures that lack an established minimal clinical important difference. These deficiencies are important because such an approach prohibits the potential to usefully synthesize data from a range of studies and also limits the inference of any statistically significant findings into clinical practice.

Potential limitations of this review

When undertaking this review, a systematic search of the most relevant electronic databases was conducted. This search was complemented by citation searching of the identified systematic reviews followed by hand-searching the reference lists of these systematic reviews. We recognize that further relevant databases are available and that searching of these might have retrieved further relevant reviews. However, we feel that the potential for missed reviews is minimal due to the supplementary search strategies employed.

The search was not initially restricted by language but, for pragmatic reasons, only reviews published in English were included. Only one review was excluded on this basis and, hence, it is unlikely that this restricted criteria had a significant influence on the outcome of this review.

One reviewer searched, retrieved, extracted and appraised studies. Use of a single reviewer only increases the potential for error during these processes. However, this was minimized as a result of the checking processes put in place, as well as the overlapping nature of the systematic reviews included, which meant that errors could be identified because of the repetitive nature of the process.

Conclusions

Exercise and multimodal physiotherapy appear to be effective interventions for rotator cuff tendinopathy but the extent of this effect is unclear. Other commonly prescribed conservative interventions lack evidence of effectiveness. Surgery confers no additional benefit over exercise alone or multimodal physiotherapy. This interpretation is drawn from systematic reviews comprising mainly small RCTs that frequently measure outcome in a heterogeneous manner, which limits the strength of the conclusions.

There is a clear need for further high-quality research that takes into account the deficiencies of the current evidence base.

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Appendix 2

Physiotherapy

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Protocol

Development of a self-managed loaded exercise programme for rotator cuff tendinopathy

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Abstract

This paper describes a self-managed loaded exercise programme which has been designed to address the pain and disability associated with rotator cuff tendinopathy. The intervention has been developed with reference to current self-management theory and with reference to the emerging benefit of loaded exercise for tendinopathy. This self-managed loaded exercise programme is being evaluated within the mixed methods SELF study (ISRCTN 84709751) which includes a pragmatic randomised controlled trial conducted within the UK National Health Service.

Keywords: Rotator cuff; Tendinopathy; Exercise; Rehabilitation; Self-management

Introduction

In 2010, the UK government published its' white paper Equity & Excellence: Liberating the National Health Service (NHS) [1]. The emphasis of this paper was towards improving the outcomes of healthcare with the patient at the centre of every decision that is taken. However, this proposition is in the face of significant financial challenges and the need for the NHS to deliver unprecedented efficiency gains.

Self-management has been proffered by some as one solution to this increasingly untenable situation [2]. In a situation of rising demand and falling supply, strategies to facilitate self-managed behaviour offer an opportunity to redress the balance by reducing the requirement and hence demand for regular contact with health care professionals.

As well as offering a pragmatic solution to an organisational issue, self-management offers opportunities to individualise care and there is evidence to suggest that an approach where patients are encouraged to take responsibility for their own care is at least comparable to treatment requiring regular clinic attendance [3,4]. Upon this background, this paper describes a self-managed exercise programme for rotator cuff tendinopathy.

Rotator cuff tendinopathy is a common problem with increasing prevalence as age increases [5,6]. Hence it is expected that the demand for health care in this area will increase as the population ages. It has also been identified that this condition is resistant to treatment and possibly recurrent in nature in certain populations [7–9] and so it is hypothesised that outcomes will be superior where the patients are equipped to deal with this condition on an on-going basis. Additionally, there has been growing recognition of the benefit of loaded exercise for rotator cuff tendinopathy [3,10–12] and in 2012, the National Institute for Health Research funded a mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study (ISRCTN 84709751) [13].

According to the guidance offered by Craig *et al.* [14] self-managed loaded exercise should be regarded as a complex intervention because of the number of potential interactions between the components of the intervention. To facilitate the process of appraisal and implementation, an evaluation of a complex intervention should include a description of the intervention as an essential step of reporting [14,15]. Thus,

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the purpose of this paper is to offer a full description of the experimental self-managed exercise intervention for the SELF study.

Overview of the SELF study

The SELF study is a mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders. The study includes a randomised controlled trial (RCT) where participants will be allocated to self-managed loaded exercise (experimental) or usual physiotherapy (control) and followed-up after three, six and 12 months. The primary outcome measure for the RCT is the shoulder pain and disability index (SPADI). The full protocol has been published [13].

An introduction to the technology

The intervention is self-managed loaded exercise. The exercise, prescribed by the physiotherapist but completed by the patient, involves exercising the affected shoulder against gravity, a resistive therapeutic band or hand weight over three sets of 10 to 15 repetitions twice per day. This exercise can be uncomfortable but is prescribed to ensure that this is manageable. Exercise prescription is guided by symptomatic response requiring that pain is produced during exercise but symptoms are no worse upon cessation [16,17]. Participants with more severe symptoms tend to commence a lighter regime initially and a typical outline programme is presented in Fig. 1 which is adapted to meet individual needs.

Although there is emerging evidence supporting loaded exercise as the type of exercise to be prescribed [11] the optimal dose is unknown. In reporting favourable outcomes in people complaining of shoulder pain, Bernhardsson *et al.* [10], Holmgren *et al.* [11] and Jonsson *et al.* [12] prescribed three sets of 15 repetitions completed twice per day. Bernhardsson *et al.* [10] and Jonsson *et al.* [12] maintained this programme for 12 weeks whilst Holmgren *et al.* [11] maintained their programme for eight weeks before reducing to one set of exercise per day between weeks eight to 12. As well as consistency in terms of sets and repetitions all of these studies required the exercise to be uncomfortable. These parameters are consistent with those proposed here. However, in contrast to these studies a time-frame for the intervention has not been pre-specified. Instead the treating physiotherapist and patient will determine the point of treatment cessation. It is recognised that a favourable response might require a minimum of three months [16] but the choice to omit a pre-specified time frame reflects the nature and response times of individual patients [18] and thus is more pragmatic in nature.

In keeping with Jonsson *et al.* [12] the intervention comprises only one exercise. This is in contrast to Berharddson *et al.* [10] and Holmgren *et al.* [11] who prescribed multiple exercises. A single exercise approach is preferred here for two reasons: First, as a pragmatic time-saving solution [19]. Low levels of engagement with exercise programmes are a widely recognised problem and it is suggested that single exercise prescription minimises some of the barriers in terms of time to complete and recall. Secondly, the incremental benefit of adding more exercises that are theoretically stressing the same tissue is unknown and possibly unnecessary.

The self-managed framework

The exercise is operationalised within a self-managed framework. Here self-management refers to situations where

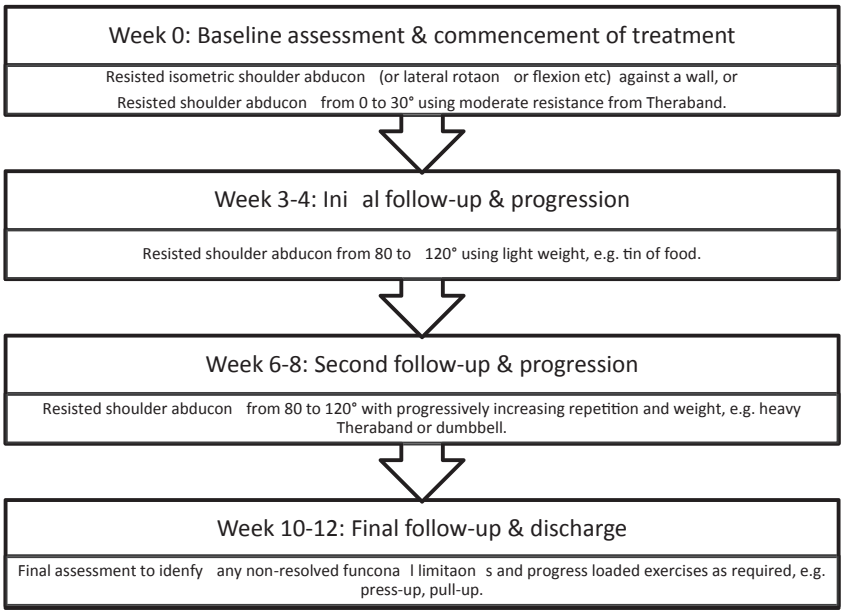

Fig. 1. Typical loaded exercise programme and progression.

people are encouraged to actively manage their symptoms, treatment, consequences and life-style changes associated with their condition [2,20]. This process is facilitated through an equal therapeutic alliance, or partnership, between patient and therapist. The self-managed framework consists of components currently regarded as effective mechanisms by which to enhance self-efficacy and facilitate self-management [21,22] including:

- Knowledge translation.
- Exercise/skill acquisition.
- Self-monitoring.
- Goal setting.
- Problem solving.
- Pro-active follow-up.

In line with the Common Sense Model of self-regulation of health and illness [23–26], how the patient perceives the problem is pivotal. Success of the intervention is dependent upon the patient interpreting their pain response in a way that facilitates the use of exercise as a management strategy. If beliefs persist that the pain is a sign of tissue damage and that rest is required to enable the tissue to recover then it is doubtful that the programme could be implemented successfully. Such an appraisal would result in avoidance behaviour and would preclude any level of engagement. To address this concern, the patient is encouraged to communicate their understanding of the problem and the therapist is encouraged to frame the discussion from the perspective that the muscles and tendons are de-conditioned (or weakened or lacking fitness) and need a progressive programme of exercise to restore condition and function. Description of tissue based pathology, *e.g.* rotator cuff tear, is avoided, or challenged. In this situation, reliance is placed upon the development of a therapeutic alliance where doubts and concerns can be expressed by the patient and reassurance offered by the physiotherapist along with an acceptable explanation of the cause of the problem. The purpose of this knowledge translation is to facilitate understanding upon which a successful partnership can be developed. Understanding is re-visited using simple questions such as: What do you understand is the cause of your problem? Why could exercise help?

Enhancement of self-efficacy, defined as the confidence to perform a specific task or behaviour [25], which is one of the major constructs of Bandura's Social Cognitive Theory of behaviour change [25], is a key goal of this self-management programme. Four potential strategies to enhance self-efficacy have been suggested; mastery, modelling, interpreting physiological signs and feedback/persuasion [22]. Enhancement of self-efficacy is seen as a key component to facilitate regular engagement with the programme. A single exercise is prescribed and although progressions and regressions of the exercise are discussed, only one exercise is completed at any one time. The reason for this restricted prescription is pragmatic in nature, as discussed previously, but it is expected that a simple prescription will also facilitate mastery of the task [25]. The patients have the opportunity to observe the therapist undertaking the exercise and will subsequently model their behaviour on that of the therapist whilst repeating the exercise themselves. This will be re-enforced by a diagram, drawn by the patient, on an exercise diary (Fig. S1) which will serve as a visual memory stimulus.

Self-monitoring and appropriate interpretation of physiological signs is regarded as a cornerstone of successful self-management [25]. Within this programme the patients are encouraged to monitor their pain response whilst exercising, which is recorded in the self-report diary, in the knowledge that pain should be produced whilst the exercising but should be no worse upon cessation [17]. When the pain response abates this is the stimulus to progress the exercise. Such a response is in line with others who advocate loaded exercise [10–12,16,17,27]. In contrast to others who have used a numeric pain rating scale, for example pain no greater than 5/10 [11], to guide exercise progression, the intervention described here enables the patient to judge what is manageable in terms of symptom response. This decision reflects individual perceptions of what constitutes acceptability in terms of pain. Some patients might be more tolerant and more willing than others to provoke pain whilst exercising and it is felt unwise to limit the potential of some because of unsubstantiated fears relating to potential tissue damage.

At the initial meeting between physiotherapist and patient, goals are set using the patient specific functional scale [28] as a guide. A goal is negotiated, for example being able to reach into a cupboard, and the current level of difficulty is established. This is monitored, discussed at follow-up appointments and new goals set as appropriate. Such a component has the capacity to be a useful form of mid- to long term self-monitoring by offering reassurance regarding progress. The primary aim of the self-managed exercise programme is to facilitate movement and functional restoration and goal setting is encouraged along these lines.

Following this the patients are encouraged to consider any barriers to implementation. Some pragmatic solutions to common problems, particularly time limitations, are factored in to the intervention but the idea is raised pro-actively by the physiotherapist at the initial meeting by asking the patient how confident they are that they will be able to complete the task in hand. Any uncertainty is discussed and the patient is encouraged to consider potential solutions. Barriers to implementations are also raised and discussed with reference to the exercise diary at subsequent follow-up appointments.

The patients are offered the opportunity to return to the clinic at a convenient and appropriate time with the intention that this meeting will offer the opportunity for useful feedback and possibly the opportunity for persuasive intervention by the therapist if difficulties have been encountered [22]. Typically follow-up appointments are scheduled on a monthly basis to begin with but the needs of the patients inform this decision. For example, some patients feel confident and able following the initial meeting and do not require a scheduled follow-up appointment, only the opportunity to contact the physiotherapist should things not go to plan.

Conversely some patients will return to the physiotherapist within a few days to seek re-assurance and guidance where necessary. The flow of a typical follow-up session is displayed in Fig. S2.

This intervention has been designed with practice context in mind where typical physiotherapy appointments consist of an initial session lasting 40 min and subsequent sessions lasting 20 min. The intervention requires minimal training and can be adopted in the current practice context from a logistical perspective.

Conclusion

This paper has described a self-managed loaded exercise programme which has been designed to address the pain and disability associated with rotator cuff tendinopathy. This intervention is being evaluated within the mixed methods SELF study which includes a pragmatic randomised controlled trial conducted within the UK NHS. The clinical and cost-effectiveness of the self-managed exercise programme compared to usual physiotherapy will be reported at the conclusion of the SELF study.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.physio.2012.12.002.

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Appendix 3

Contents lists available at ScienceDirect

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Review article

The central nervous system – An additional consideration in 'rotator cuff tendinopathy' and a potential basis for understanding response to loaded therapeutic exercise

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ABSTRACT

Tendinopathy is a term used to describe a painful tendon disorder but despite being a well-recognised clinical presentation, a definitive understanding of the pathoaetiology of rotator cuff tendinopathy remains elusive. Current explanatory models, which relate to peripherally driven nocioceptive mechanisms secondary to structural abnormality, or failed healing, appear inadequate on their own in the context of current literature. In light of these limitations this paper presents an extension to current models that incorporates the integral role of the central nervous system in the pain experience. The role of the central nervous system (CNS) is described and justified along with a potential rationale to explain the favourable response to loaded therapeutic exercises demonstrated by previous studies. This additional consideration has the potential to offer a useful way to explain pain to patients, for clinicians to prescribe appropriate therapeutic management strategies and for researchers to advance knowledge in relation to this clinically challenging problem.

1. Introduction

Tendinopathy is a term commonly used to describe tendon pathology and/or pain. Despite being a well-recognised clinical presentation, a definitive understanding of the pathoaetiology of rotator cuff tendinopathy remains elusive (Lewis, 2009). Over recent years there has been a focus upon understanding pain associated with tendinopathy from the perspective of local tissue based pathology. But, in light of the well-recognised dissociation between pathology and pain (Cook and Purdam, 2009; Drew et al., 2012), it is becoming clear that additional explanatory models are now needed (Drew et al., 2012).

In view of this, the aim of this paper is to present a theoretical extension to current models incorporating the integral role of the central nervous system (CNS) in the pain experience. For the purpose of clarity within this paper and to aid clinical translation, the terminology 'rotator cuff tendinopathy' refers to a presentation where a person complains of shoulder pain with movement that is provoked further with load, for example lifting or through resisted tests performed by a clinician during a physical examination (Littlewood et al., 2012a).

We recognise that the reader might object to or question the appropriateness of the term rotator cuff tendinopathy for two reasons. Firstly, the criteria we use to define rotator cuff tendinopathy is broad and might include a range of biomedical diagnoses, including subacromial impingement, subacromial bursitis, rotator cuff tear, acromioclavicular joint osteoarthritis etc. However, in the absence of evidence to support the validity or reliability of such diagnoses (May et al., 2010), particularly in relation to the lack of association between pathology and pain, it is difficult to substantiate such an objection. Secondly, in the context of attempts to highlight the role of the CNS, such specific pathology or impairment terminology might be regarded as a backwards step because of their reference to specific peripheral tissue or mechanical mechanisms. However, such a broad definition of tendinopathy in this

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translational paper is deliberate and purposeful to highlight how current practice models can be interpreted and usefully enhanced without wholesale, probably unrealistic, changes to practice and terminology; hence there is pragmatic value.

A secondary aim is to offer a potential rationale to explain the favourable response to loaded therapeutic exercises demonstrated by previous studies (Jonsson et al., 2005; Bernhardsson et al., 2010; Holmgren et al., 2012; Littlewood et al., 2012a). These further considerations have the potential to offer a useful basis upon which to explain pain to patients and for clinicians to prescribe appropriate therapeutic management strategies.

2. Local tissue pathology-pain models

This paper will begin by offering a critique of local pain models as a basis upon which to justify the need for greater consideration of the CNS. Tissue based pathology-pain models have been proposed (Cook and Purdam, 2009) and adapted to the rotator cuff (Lewis, 2010). However, as mentioned, these models are confounded by the lack of association between pathology and pain (Cook and Purdam, 2009; Drew et al., 2012). Using magnetic resonance imaging, Frost et al. (1999) could not distinguish individuals diagnosed with subacromial impingement from asymptomatic age-matched controls according to structural pathology. In keeping with this, up to 40% of the general population have asymptomatic rotator cuff tears (Templehof et al., 1999; Worland et al., 2003; Yamamoto et al., 2010). Studies investigating prognosis (van der Windt et al., 1996; Bonde et al., 2003; Ekeberg et al., 2010) have suggested that the biomedical diagnosis, relating to specific tissues at fault, was not associated with clinical outcomes. Furthermore, it has been reported that structural change does not explain response to therapeutic exercise because as clinical outcomes improve a corresponding change in observable structural pathology is not seen (Drew et al., 2012). Hence, in the context of this literature, traditional models that describe tissue injury/structural pathology resulting in nocioceptive input and a pain response in proportion to the extent of injury seem inadequate, if considered in isolation.

3. Local biochemical models

In light of the shortcomings of local tissue pathology-pain models, others have suggested a local biochemical basis for the pain associated with tendinopathy where biochemical mediators in the tissue stimulate nocioceptive afferent fibres (Khan et al., 2000). Degenerative pathology is associated with neurovascular ingrowth and potential pain mediators such as substance P and acetylcholine. However, it remains unclear whether biochemical substances are a cause of tissue degradation and/or pain or whether they are a by-product of tendinopathy (Danielson, 2009). But, because biochemical models make no assumption about the underlying pathology, such biochemically driven nocioceptive pathways might offer further understanding of symptomatic versus asymptomatic pathology. Further research in this area is on-going (Rees et al., 2013).

So, in light of what is currently known, local biochemical models appear to have the potential to enhance understanding and management of tendinopathy. But, neither these or local tissue pathology-pain models recognise the role of the CNS nor critically that nocioception is neither sufficient nor necessary for a pain experience (Moseley, 2007).

4. Background to the role of the CNS

A contemporary understanding of pain suggests that there might be other mechanisms involved in pain associated with tendinopathy that might act with the local mechanisms outlined above or in isolation. The notion that the state of the tissue does not provide an adequate measure of pain is recognised in relation to other pain syndromes (Moseley, 2007; Melzack and Wall, 2008) but in tendinopathy local tissue/biochemical based models are predominantly used to explain pain (Cook and Purdam, 2009; Lewis, 2010; Liu et al., 2011). Such models continue to be developed but fail to adequately recognise the integral role of the CNS in the pain experience. This omission neglects a whole body of pertinent literature, that might offer some further explanation as to why attempts to link symptoms to peripheral structural pathology continue to fall short (Moseley, 2007; Wand et al., 2011).

We suggest here that the pain associated with rotator cuff tendinopathy, that persists beyond expected recovery times, should be evaluated within a framework that recognises the potential for altered processing and modulated output of the CNS rather than solely a product of peripherally driven nocioception secondary to persistent tissue abnormality, for example tendon degeneration or tear. Note that we have used the term recovery time as opposed to healing time because many studies suggest that the rotator cuff does not always 'heal' from a structural perspective, even after attempts to surgically repair torn tissue (Galatz et al., 2004; Rees et al., 2006) although symptoms might still improve over time. In this context it is difficult to define a definitive time point by which we can assert that peripheral tissue recovery has been completed in terms of the inflammatory and proliferative stages. It is likely that this point will be highly individualised and compounded by factors specific to the rotator cuff including the relative hypovascularity of the tissue (Rees et al., 2006; Lewis, 2010). In practice, it might be more important to consider factors other than time-course of symptoms when considering whether local or CNS pain mechanisms predominate.

5. Explaining pain

The following section describes the potential mechanisms involved in pain associated with rotator cuff tendinopathy. The aim is to offer a reasoned explanation as to why pain state or output might persist and might not be proportionate to the state of the rotator cuff tissue. In addition to enhancing understanding of pain mechanisms, one further consequence of this might be a direct challenge to current practice where, for example, prescription of loaded exercise is limited due to fear of causing tissue damage (Littlewood et al., 2012b).

5.1. Central mechanisms

We begin by considering potential aberrations relating to processing of afferent inputs at the spinal cord level. Central sensitisation is a state that has been described in terms of altered processing where dorsal horn cells in the spinal cord become increasingly sensitised (Gifford, 1998a). In this altered state even non-noxious input, for example lifting the arm, can contribute to a painful output (Gifford, 1998a). Gwilym et al. (2011), recognising that anomalies existed between peripheral tissue structure and the degree of pain experienced, proposed the presence of central sensitisation in a significant proportion of their patients who underwent subacromial decompression. Furthermore, those patients who were regarded as having greater levels of central sensitisation pre-operatively reported worse outcomes three months following the operation. Clearly, pain mechanisms beyond peripherally driven nocioceptive mechanisms are in play here and the study by Gwilym et al. (2011) casts further doubt upon the validity of tissue state as the sole basis upon which to understand pain.

Although central sensitisation is often described as being a product of a barrage of afferent impulses, maybe secondary to acute tissue injury, it is now well recognised that this hyper-reactive state of the dorsal horn cells can persist in the absence of on-going afferent input, known as pain memory (Gifford, 1998a). This reflects the plasticity or adaptability of the CNS. So, even in the presence of a recovered peripheral tissue, for example a rotator cuff tendon, central sensitisation can continue to contribute to an on-going pain state where non-noxious input contributes to a painful output.

5.2. Pain as an output

Pain as an output, in response to a threat, is regarded as a protective mechanism which might be helpful in some acute situations, where the primary aim is to minimise further threat, but unhelpful in other situations where unhelpful interpretation of a pain response serves as a barrier to recovery (Moseley, 2007; Melzack and Wall, 2008). An example of this would be resting a shoulder that needs movement to facilitate functional restoration. The key feature proposed here is that pain is a product of CNS processing, at the level of the spinal cord and the brain, which is modulated by other factors including thoughts and feelings, and does not necessarily reflect the state of the peripheral tissues, at least from an observable structural perspective. CNS modulation might be influenced by a range of intrinsic inputs, for example beliefs about what the pain means, or extrinsic inputs, for example societal context. To highlight this, a person who has been advised to rest, believing that their shoulder pain is caused by tissues being compressed and catching is likely to present in a different way to someone who has been reassured and given guidelines about how best to get their arm moving. In this context it is perhaps possible to see how the subacromial impingement model might adversely contribute to the pain experience and rightfully is now regarded as an outdated and unhelpful way to understand shoulder pain (Lewis, 2011).

5.3. The mature organism model

To facilitate understanding and implementation, Gifford (1998b) proposed the mature organism model (MOM). This model describes a cyclical process beginning with an input to the CNS (sampling), for example nocioception. This is followed by CNS processing (scrutiny) before an output, for example an altered behaviour, is generated. The output subsequently serves as a further input to the sampling loop. The MOM suggests that the CNS is continually sampling tissue health, the surrounding environment and itself, consciously and unconsciously, before scrutinising this input in the context of past experience, knowledge, beliefs, culture, past successful behaviour, past successful behaviour observed in others (Gifford, 1998b; Jones et al., 2002).

This process of scrutiny before an output is generated is key and has the potential to create an environment for recovery or otherwise. For example, if this scrutiny takes place in the context of a subacromial impingement model, it is possible that an already de-conditioned tissue is allowed to de-condition further if any sign of pain is interpreted as impending tissue damage and is hence avoided. Considered in this context, Gifford (1998c) (p.58) suggests:

> *'It is perhaps far wiser to be involved in helping to establish the best possible conditions for natural recovery. This appears to involve a parallel and well balanced focus on functional restoration of best possible tissue health/ return of function in parallel with a recognition of and focus on relevant cognitive and affective factors'*

5.4. The de-conditioned rotator cuff

Perhaps one immediate question that arises is: Why would the CNS generate a painful output that is not directly related to the pathological status of the tissue? We believe that this can be understood in terms of a protective pain output from the CNS in response to a perceived threat to a de-conditioned tissue. We use the term de-conditioned to describe a situation where the CNS perceives the tissue to have a reduced capacity to perform required tasks (Butler and Moseley, 2003). It is the *perceived* nature of the de-conditioning and hence protective pain output from the CNS that might offer an alternative explanation as to why observed structural changes do not adequately explain pain, although subtle mechanical changes to the tissue that might not appear on imaging cannot be fully discounted at this stage (Malliaras and Cook, 2006). It should be recognised that de-conditioning does not mean degeneration, although degenerated tissue might be de-conditioned and tissues that have been injured previously might become de-conditioned, but not necessarily so.

The source of de-conditioning in relation to the rotator cuff is open to debate but some speculative claims can be offered within a biopsychosocial framework. In terms of biology, factors including relative hypovascularity and adverse mechanical loading might be relevant. Also underuse, whereby physical stress levels perhaps secondary to a sedentary lifestyle, are lower than the maintenance range, and result in decreased capacity of the tissues (Mueller and Maluf, 2002; Rees et al., 2006; Lewis, 2010). A biological theory appears plausible where studies have reported a reduction in tendon capacity with age (Reeves, 2006) in tandem with an epidemiological perspective where studies have reported increasing prevalence rates of rotator cuff tendinopathy with age (Chard et al., 1991). In terms of psychology, a broad range of attitudes, beliefs and experiences might contribute to this perceived de-conditioning. For example, a belief that; *'I've inherited weak shoulders so I'm limited in what I can do,'* or a past experience that resulted in a pain response might long be held in the memory and inform any future central scrutiny. From a social perspective, again many factors could contribute. The role of the health care professional and diagnostic labels was described above to demonstrate how a context can influence behaviour. Wandner et al. (2012) have also reported how the perception of pain varies across gender, race and age. It seems likely that a combination of these biopsychosocial factors might (mis)inform an individual's perception and hence pain response.

6. Rationale for response to loaded therapeutic exercise

From a biological perspective initially, tendons are regarded as being mechanosensitive, which means they are capable of responding to mechanical stimuli (Maffulli and Longo, 2008). The term 'mechanotherapy' has been coined to describe how a programme of structured exercise might stimulate human tissue and reverse tendon de-conditioning (Reeves, 2006; Abate et al., 2009; Khan and Scott, 2011). It is proposed that a progressive exercise regime will stimulate a process of re-conditioning and improve the capacity of the rotator cuff to withstand greater load and stress (McKenzie and May, 2000; Reeves, 2006; Kjaer et al., 2009). This idea has been substantiated in the literature where tendon tissue has been shown to become stronger through increases in tensile strength and elastic stiffness in response to programmes of structured exercise (Abate et al., 2009). Due to the paucity of evidence, the optimal load to stimulate re-conditioning remains unclear. However, when reporting favourable outcomes, recent studies have encouraged load prescription according to symptom response where pain was produced during exercise (Jonsson et al.,

2005; Bernhardsson et al., 2010; Holmgren et al., 2012). Such an approach might initially appear counter-intuitive within the context of the framework described here but we suggest that quite the opposite is true.

Drew et al. (2012) reported that observable structural change does not adequately explain response to therapeutic exercise and that other mechanisms are more likely to be responsible. In addition to local biological changes, it is feasible that appropriate prescription of loaded therapeutic exercise has an impact upon CNS scrutiny or processing with a resultant modified output. From a psychological perspective, the prescription of painful loaded exercise within a framework that suggests hurt does not equal harm; hurt, in some circumstances, equals a tissue that is de-conditioned and needs using/exercising, has the potential to reframe the meaning of pain. In addition to this, a progressive exercise programme has the capacity to address the hypothesised de-conditioning as the frequency and load of exercise increases over time. Basically, if the way a person conceives their shoulder pain is adapted then there is potential for beneficial change in CNS output to be realised, particularly if the prescribed exercise programme resembles their usual functional activities. Clearly in this context, intelligent but individualised prescription of painful loaded therapeutic exercise and return to normal function is required that does not provoke a threat response from the CNS in terms of a lasting and exaggerated pain output. In practice this requires that our patients have an understanding of why the exercise has been prescribed, that hurt does not equal harm, in their circumstance, and it requires an understanding of the patient's acceptable pain response. Although an inexact science for which the boundaries have not yet been adequately defined, acceptable pain responses can be elicited through simple questioning, for example; 'Is that amount of pain acceptable to you while you are exercising or after you have exercised? Should we add more/less load?' For such exercise prescription to be effectively implemented, the therapist must be mindful of the perspectives held by the patient. We suggest simple exploratory questions such as: What do you understand is the cause of your problem? (Littlewood et al., 2013 – see for further information relating to assessment and management). Such questioning can help to elicit understanding and begin to identify potential barriers to implementation.

Finally, from a social perspective, in terms of the influence of surroundings and significant others, the prescription of loaded exercise within this framework challenges diagnostic and therapeutic approaches that promote fear avoidance, for example *'the pain is a sign of further tissue damage so don't move it if it is painful.'* Such prescription also has the potential to challenge public perception that hurt equals harm in all circumstances. As opposed to some previous approaches, a constructive, non-threatening means around which restoration of function can be achieved is offered.

Clearly the pain associated with 'rotator cuff tendinopathy' has a multi-dimensional basis. The key to future success will be to discover indicators of each dimension along with reasoned and relevant multi-dimensional management strategies.

6.1. Summary

This primary message of this paper is summarised in Fig. 1. It can be conceptualised as a process beginning with perceived tissue de-conditioning, secondary to a known or unknown cause, for example chronic underuse. An episode of relative overuse or overload results in short term tissue responses that are scrutinised by the CNS in the context of other inputs and the surrounding environment and if the input is regarded as a threat, a painful output as a means of protection will ensue. In this situation this might promote avoidance of shoulder movement if the pain is believed to be indicative of harm, and will also result in a unique pain experience, for example absence from work and low mood due to activity withdrawal. Such fear avoidance might result in further tissue de-conditioning and a continuation of the cycle. However, appropriate contextualisation and intervention might result in a different outcome. If pain is regarded as a sign of de-conditioning rather than actual or impending tissue damage then an alternative process of CNS scrutiny might result in an active output, for example engagement with a structured exercise regime, with the potential to re-condition peripheral (tendon) and central tissue. Additionally, active engagement and 'permission' to resume normal activity without fear of causing harm to self might facilitate an improved outcome in contrast to existing approaches.

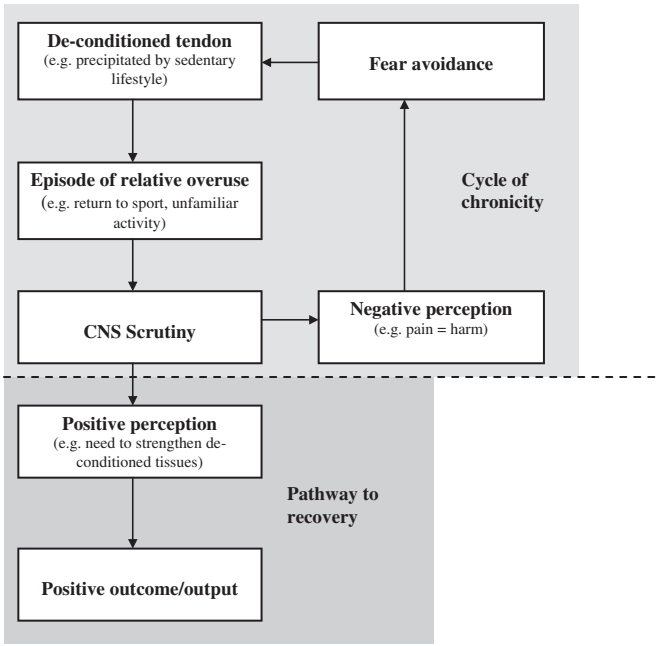

Fig. 1. Summary of the primary message.

7. Conclusion

The cause of pain associated with rotator cuff tendinopathy remains uncertain and there are clear limitations associated with current explanatory models that rely on a peripheral tissue based understanding. A theoretical addition to these pre-existing models has been presented with reference to current literature incorporating the integral role of the CNS in any pain experience. This additional consideration offers an accessible way to understand the pain associated with rotator cuff tendinopathy and to understand potential mechanisms underpinning therapeutic response to loaded exercise.

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Appendix 4

Developing the SELF study: A focus group with patients and the public

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Background: *Patient and public involvement (PPI) in the research process is a key feature of NHS Research and Development policy but reporting of the extent and value of PPI in relation to physiotherapy research is lacking.*

Aims: *To determine whether the proposed methodology within the randomized controlled trial aspect of the SELF study was acceptable to patients and to ascertain whether enhancements could be made in relation to elements that matter most to patients.*

Methods: *A focus group discussion was undertaken with four lay people who were currently attending physiotherapy. The data was transcribed verbatim and analysed using the framework method.*

Findings: *The lay members found the proposals to be generally acceptable but were able to suggest enhancements to the SELF study's design relating to recruitment, retention, blinding, and acceptability of the intervention. Additionally, we were able to recruit lay members to the trial steering committee.*

Conclusion: *The unique perspective offered by PPI has resulted in enhancements to the SELF study's design and a means of maintaining PPI throughout the conduct of the SELF study has been established.*

Key words: ■ Patient and public involvement (PPI) ■ Focus group ■ Research design

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INTRODUCTION

Patient and public involvement (PPI) in research has been defined as research undertaken with members of the public as partners in the process, rather than research being conducted on them (Thornton, 2008; INVOLVE, 2012). With the aim of creating world-class research that is focused upon the needs of patients and the public, PPI has become a key feature of UK National Health Service (NHS) Research and Development policy (Telford et al, 2004), and as a result its importance has become more recognized over recent years (Boote et al, 2006; Brett et al, 2010). Many funding bodies now expect to see PPI embedded within the research that they support (Staniszewska et al, 2008). Some observers suggest that PPI contributes to better quality research due to the unique perspective patients and the public can offer (Boote et al, 2002).

Benefits of PPI reported in the wider literature include: identification of more patient-centred research topics; improved feasibility of study design; more effective recruitment; more patient-centred data analysis; improved dissemination; and closer links to the community (Brett et al, 2010). Despite the apparent increase in uptake of PPI in research, a call has been made for better reporting of PPI to help develop our understanding of the difference it makes to research (Brett et al, 2010).

In relation to the physiotherapy, reporting of the extent and value of PPI is lacking. Such omissions or under-reporting mean that opportunities are not afforded to others to learn from these experiences and develop their own research programmes accordingly.

With the call for better reporting and the absence of literature relating to physiotherapy in mind, this paper describes a PPI event conducted to facilitate the development of the randomized controlled trial (RCT) aspect of a mixed-methods study, the SELF study. The SELF study evaluates the clinical and cost-effectiveness of a self-managed exercise programme vs. usual physiotherapy for chronic rotator cuff disorders (Littlewood et al, 2012a). We were aware of the general messages reported in the PPI literature, but in this paper we were specifically interested in consulting about the acceptability of the SELF study's proposed methods of blinding and on the intervention; this could not be gleaned from previous reports.

AIMS AND OBJECTIVES

The PPI event aimed to facilitate development of the SELF study by seeking lay consultation on the:

- Acceptability of the proposed methods of recruitment
- Acceptability of the proposed methods of blinding
- Acceptability of the intervention

- Measures to minimize loss to follow-up.

These objectives were set to reflect issues that are widely regarded as being problematic when conducting RCTs generally (Torgerson and Torgerson, 2008), but in relation to blinding and acceptability of the intervention these objectives were set to reflect specific issues relating to the SELF study.

To maintain ongoing PPI an additional objective was to recruit lay people to the SELF study trial steering committee with the remit of monitoring the progress of that study. This final objective reflects a move from consultative PPI where the control remains with the academic researchers, to a more equal partnership where decision-making is shared (Brett et al, 2010).

METHODS

In accordance with the National Research Ethics Service (NRES) guidance, ethical approval was not required for this involvement event.

While the protocol for the SELF study was under development, we undertook the focus group discussion. Posters advertized the focus group to potential lay members in the physiotherapy department of the host NHS institution where the SELF study was due to be conducted. The poster simply asked for volunteers who would be willing to contribute to a discussion about our proposed research. We invited adults (>18 years old) under the care of physiotherapy services to contact Chris Littlewood (CL) or John Ashton (JA) in person, via the telephone or by e-mail, to indicate their interest, and to discuss their potential role and extent of their involvement.

We used a convenience sampling approach for pragmatic reasons relating to recruitment and time available prior to the SELF study's RCT protocol submission for ethical approval. Most of the objectives of this study, with the possible exception of gauging the intervention's acceptability, might be regarded as generic and therefore relevant to any willing service user. However, it is unclear whether purposive sampling of potentially-eligible SELF study participants would have offered any further or contradictory information to that offered by patients currently attending physiotherapy for non-shoulder related disorders.

The focus group

When members consented to be involved they were invited to attend the focus group discussion led by CL and JA within the physiotherapy department of the host institution. To express gratitude for their involvement the participants received a £25 voucher and reimbursement of travel expenses.

The focus group commenced with introductions and all members were aware that CL and JA were researchers and physiotherapists by background. A structured topic guide was developed, with reference to the study's objectives, to facilitate discussion which was recorded and transcribed verbatim by CL. Member responses were anonymised.

We analysed the data using the framework approach, which incorporates the following stages:

- Familiarization—where key ideas and themes are identified
- Identification of a thematic framework by which the data can be examined
- Indexing—application of the thematic framework to all the data
- Charting—where the data is organized according to the defined thematic framework
- Mapping and interpretation—where the charts are used to define concepts and find associations with a view to providing explanations for the findings (Pope et al, 2000).

This approach is widely recognized as appropriate for applied research in which the objectives are set *a priori* (Pope et al, 2000). CL undertook the analysis and then JA reviewed and verified this analysis.

Subsequently, we produced a lay summary detailing key messages from the discussion and how the proposed research was to be developed as a result. The participants were sent a copy of this summary and invited to respond. Three out of the four members responded and approved the proposed changes. One member did not respond for unknown reasons, despite prompting.

RESULTS

Four patient members contributed to the focus group. Six initially volunteered but two, without explanation, did not attend on the day. All patients were female (age range 19–80 years) and currently attending physiotherapy for a range of musculoskeletal disorders, including past and present shoulder disorders.

The discussion began with the members briefly describing their previous involvement with research. Two of the four had previously participated in research: one as a patient and one as the partner of a patient. They were asked to consider if they would volunteer for future research and the factors that might motivate them to do so. All of the members described

personal benefit as a factor but also considered the benefits to the NHS and the wider population. This point was recognized by Member A:

'...anything that's gonna help me and other people is important...'

Acceptability of the proposed methods of recruitment

We proposed to make initial contact with potential SELF study participants by telephone. Upon receipt of the referral to the physiotherapy department, the information would be screened by a physiotherapist and then the call would be made to those who were potentially eligible. Although the members felt that this was appropriate, they suggested that it might not be the most effective way. The idea of a letter informing the potential participants of the study and the intention to contact them prior to a telephone call was suggested. Member A reflected:

'If you just get a random call then it's not very good for you. You might be out doing something and if you're busy or whatever and you're not expecting the call then you might just brush it off and not want anything to do with it, so I think the letter's a good idea.'

Following initial contact the participants would need to undergo a physical examination screening prior to recruitment. This means some of the invited participants would be subsequently excluded, and we were concerned that this might negatively impact upon willingness to volunteer. However, Member B, agreed with the others:

'No, it wouldn't because (the research physiotherapist) would have decided who were going to be the best people to do this. You would be allocated a physiotherapist anyway wouldn't you, so no.'

Acceptability of the proposed methods of blinding

The SELF study was designed to evaluate the clinical and cost effectiveness of a self-managed exercise programme vs. usual physiotherapy. A survey of current UK physiotherapy practice (Littlewood et al, 2012b) relating to rotator cuff disorders has identified that usual physiotherapy might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, and corticosteroid injection, at the discretion of the treating physiotherapist. However, a proportion of physiotherapists would engage with the philosophy of self-management and prescribe exercise within this framework. Hence in some instances, a programme of self-managed exercise might actually be termed usual physiotherapy.

We initially proposed to describe the intervention and control treatments within the SELF study participant information sheet simply as 'physiotherapy'. The rationale for this was to reflect usual care arrangements, where patients would not typically be aware of the exact content of their physiotherapy programme prior to attending, and also to introduce participant and outcome-assessor blinding, to maximize the proposed study's rigor. Unanimously, the group found this to be acceptable:

'It wouldn't bother me' (Member B)
'Well you don't know in the first place when you come for physio what it entails so personally it wouldn't bother me' (Member C).

'No, I don't think it's important to know exactly what you're going to be doing because you do trust them and you're going to physiotherapy to get your shoulder better. You don't go thinking what am I gonna be doing because you trust them to know what to do' (Member A).

However, some of the participants recognized that the perceptions some people hold regarding physiotherapy might contribute to resentful demoralisation:

'...he thought that physiotherapy was massage. He was gonna lay there, you were gonna lay your hands on him and he were gonna walk away and he'd be fine. And because he found out it was exercise he didn't want to come' (Member D).

With this stimulus, member A then reflected:

'Personally I like both, the massage and the exercise because the exercise... I don't think that I should just have one...'

Therefore, although the members initially responded favourably to this design feature,

they recognized that for some, including themselves, if participants were recruited without prior knowledge of the intervention, then retention might be more problematic than usual.

Acceptability of the intervention

The SELF study's proposed intervention was self-managed, loaded exercise. The exercise was to be prescribed by the physiotherapist but completed by the patient independently. It involved exercising the affected shoulder against gravity, a resistive therapeutic band, or a hand weight over three sets of 10–15 repetitions twice per day. We were concerned about resentful demoralisation affecting the intervention group if they were allocated to a self-managed programme. However, Member B recognised the role that participant blinding would play:

'I was just thinking about what (member D) said about people going to think that someone's going to have massage and they're going to have to do exercises but how would they know that other people are going to have massage because that's not what you're going to say are you?'

However, we recognized the contentious nature of our blinding proposal and were keen to seek lay opinion relating to the study if the ethics committee deemed blinding to be not ethically acceptable. The group raised concerns about the issue of participants maintaining motivation, and hence adherence to the exercise programme, if they weren't attending frequent clinic appointments. For different reasons Member C recognized this was a problem that she was currently encountering:

'... personally, this last time I've been coming with my knee each week she's sort of changed it and I've gone home and thought ooh I can't remember which exercise I'm supposed to be doing...I am an exercise person anyway, but it went.'

Member D suggested:

'...I would suggest people that are doing it (exercise) at home need encouragement so they would have to be seen more regularly for me than 3 weeks, because I think they will go home, perhaps do the exercise for a week, and then think um not bothered with this, they're having that done. You know, they do, people do that.'

The group were reassured that participants would be followed-up at a time convenient to them and which best met their needs. The group were also told the responsibility for carrying out the exercise would remain with the patient and it is not expected that they would return to the clinic to receive therapist-led interventions, e.g. mobilisations, electrotherapy, acupuncture.

We were proposing to provide patients with exercise diaries to monitor adherence, an idea the group felt was useful, and additionally, Member C suggested a modification to enhance the diary by including a picture of the prescribed exercise. Member A commented:

' I like the idea for the calendar because I think if I had that in my room and every day I looked at it and thought that's the exercise I need to do. I'd probably do it when I got up and do it before I went to bed, if I kept it in my bedroom...I think it's important to have a regular time when you do it and then when you get into a routine, you're not going to forget it.'

In the same way the literature recognizes the problem, the group identified a potential problem with exercise adherence. The group felt that the idea of an annotated exercise diary supplemented with intermittent clinic attendance, including a review of progress, exercise prescription, and further goal setting, might go some way to addressing this. All the participants were interested to hear that the intervention tends to include only one exercise at any one time, which they deemed to promote adherence. Member B had a different perspective on self-management, suggesting that for some it might be preferred:

'Yes, well the other thing is that some people are busier than others. You know I've been up there when some people are making an appointment and saying "Ooh no I can't come then." So that's something else that you've got to take into account isn't it?'

A further issue we identified relating to the intervention's acceptability is that the exercise intervention tends to be uncomfortable. It has been suggested that pain associated with exercise might be a barrier to adherence. However,

Member C stated:

'I would assume personally that it's gonna hurt...it's so easy not to do that because it hurts but if you do that then you're causing more problems so I would expect it to hurt to make it move.'

This view was shared by the group but came with the caveat that it was acceptable to undertake painful exercise providing there was a reasonable expectectation of a positive outcome, and providing progress could be measured by setting specific goals. Member B stated:

'And then thinking, well, at least I might be able to get that cup in that cupboard up there, then that's something to aim for.'

Member D offered another useful view point concerning an experience with her husband which highlights that even when an intervention is not regarded as acceptable initially, these barriers can be overcome with support:

'My husband badly damaged his shoulder cuff and he's not an exerciser, and course he came here and came home. "You'll never believe what they've given me." I said, "a rubber band" he said "yeah, how on earth is that going to sort anything?" (laughter). And I said "(husband), it will", and I made him do it every day and he's like "I don't wanna do it, it's hurting" and I'll say, "Well right keep pushing, keep pushing. No pain, no gain." And eventually his shoulder's fine now.'

Measures to minimize loss to follow-up

As with all studies, particularly with longer term follow-up, loss to follow-up is a significant problem. The group was aware of this issue and Member B again recognized:

'I don't know I think you're bound to get people not filling them in no matter what you do...'

The others recognized that a telephone prompt and stamped addressed envelopes for returning forms would provide a stimulus to them. They added that an incentive, particularly a monetary incentive, would significantly increase their chances of completing and returning follow-up data forms:

'There's got to be some carrot ... It doesn't have to be a big incentive, just an incentive' (Member D).

Participant reflection

To conclude the focus group discussion, we asked members to reflect upon their experience. They were pleased that research was being undertaken and keen to be involved in such a process. They felt they had contributed positively to the study's development and all wished to remain involved in some capacity and to understand how their input has influenced the research. Member A concluded:

'...if it helps other people, what we've done today, it's a good thing...and I've enjoyed being able to do that.'

DISCUSSION

The value of involving patients and the public in the design and conduct of research is now widely recognized. This study sought current physiotherapy attendees' opinion on the design and conduct of an RCT evaluating a self-managed exercise programme vs. usual physiotherapy for chronic rotator cuff disorders.

Throughout the focus group discussion the members found our proposals to be generally acceptable. However, in keeping with the wider body of literature (Brett et al, 2010), participants offered strategies with the potential to enhance the SELF study's design.

The group suggested the SELF study's initial recruitment proposal of 'cold calling' would be improved by approaching potential participants initially by letter. As this approach might enhance our recruitment strategy, we modified the proposed research to reflect it.

We were aware of the contentious nature of our proposal to blind participants to the exact content of the intervention and control arms of the SELF study. Interestingly, the participants did not express their concern on this matter. The participants recognized this was in line with usual clinical practice but also they trusted the physiotherapists responsible for their care. However, the participants offered other reasons for re-considering this feature. Participants raised the idea that potential study participants might have specific expectations of what physiotherapy might entail, including that physiotherapy should incorporate hands-on treatment. Therefore, if we enrolled participants with this perception and did not explain the interven-

tion's exact content, participants might withdraw from the study post-randomization. So, even though there are clear benefits associated with participant blinding there is an important consequence, i.e. attrition bias, which might compromize the validity of the SELF study. This was an issue we had not previously considered and when initial ethical concerns were raised about this feature, rather than defend it we opted to remove participant blinding from the study design and include a full description.

The group discussed two aspects about the intervention's acceptability. Firstly, the fact the intervention revolves around self-management, and secondly, the uncomfortable nature of the prescribed exercise.

Self-management was an approach the group valued, partly because they recognized the recurrent or chronic nature of musculoskeletal disorders and therefore the value of effective self-management as a tool. However, they did recognize the issue of exercise adherence as a potential problem. The group was reassured to know that the self-managed intervention would be supported through intermittent clinic attendance and would be facilitated through the use of an exercise diary. However, they felt this could be enhanced by including a visual illustration of the exercise as well as encouraging the patient and physiotherapist to set specific goals; both of these ideas were incorporated into the proposed research.

The uncomfortable nature of the exercise was not a concern, indeed there was almost an expectation that the exercise should be painful to be of value. The only caveat participants offered was that there should be a reasonable expectation that the intervention will be of benefit, which clearly would always be the case.

Loss to follow-up is a problem across RCTs. The group recognized this and acknowledged the potential value of the methods we were proposing to address this. However, the idea of including an incentive for participants to return all questionnaires seemed to be the most appealing and would apparently stimulate this group to return the questionnaires. Due to lack of funds, this idea was not incorporated into the SELF study but will be a feature of future funding applications.

Finally, we were keen to maintain and enhance PPI with the SELF study. We were hoping to recruit one or two lay members to the trial steering committee from this focus group. Surprisingly, when invited all four participants were very keen to maintain involvement and actively contribute to the conduct of the study. Two participants are currently fully engaged members of the SELF trial steering committee.

Implications

This PPI event has proven to be a useful component while designing the SELF study. The unique lay perspectives participants offered have resulted in changes to the proposed SELF study protocol, including:

- Initial approach by letter
- A full description of the content of the treatment arms
- An enhanced exercise diary incorporating a visual illustration of any prescribed exercise
- Enhanced recognition of the potential training needs of the physiotherapists involved.

In terms of the implications for other researchers, PPI is clearly valuable. Despite the increasing body of non-physiotherapy literature detailing the potential benefits of PPI, studies such as this enable exploration of possible study-specific contentious issues. Such study-specific explorations can facilitate enhancements to study design in ways that matter most to patients. Additionally, a platform upon which to maintain lay involvement throughout the design and conduct of a study has been developed.

Limitations

We conducted one focus group on one occasion with four members. This small number of participants was not a random sample of the population and might not be representative of the opinions that would be reported by the wider population. This small number partly reflects difficulties in recruiting lay members using the recruitment strategies described and also reflects the limited time frame in which to conduct and usefully apply the findings. It

KEY POINTS

- Patient and public involvement (PPI) is research undertaken with members of the public, as partners in the process, rather than research being conducted on them.
- PPI has the potential to contribute to better quality research due to the unique perspective that patients and the public can offer.
- Lay members recognize the potential for personal benefit when participating with research but also consider the benefits to the NHS and the wider population.
- In this context we consider that PPI resulted in suggestions and strategies with clear potential to enhance the design of our substantive study.
- What matters to the 'professionals' might not always matter to the patients and public.

is expected that a more expansive recruitment strategy along with an extended timeframe would enhance this work's value.

If this event were to be repeated with other groups of participants, e.g. men, at other times clearly the opinions expressed might be different.The focus group was an appropriate and convenient method of data collection but the potential influence of the group dynamic, including the role of the facilitators, on the discussion should be recognized. Data generated through individual interviews, where the influence of others is not as apparent, may result in different findings. Despite knowledge of the role and background of the facilitators, it is reassuring that the lay members were able to offer a critique of our proposals and offer alternative ideas. In the face of these limitations, we still feel that we were able to meet the objectives of the PPI event and ultimately that the process resulted in useful amendments to the SELF study.

CONCLUSION

We conducted a PPI event where the lay members found our proposals generally acceptable but were able to recognize the limitations of some aspects. The lay membes were also able to offer useful suggestions to enhance the design and conduct of the SELF study. The unique perspective offered has resulted in what we regard as positive changes to the proposed SELF study. IJTR

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ELSEVIER

Appendix 5

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Physiotherapy

Self-managed loaded exercise versus usual physiotherapy treatment for rotator cuff tendinopathy: a pilot randomised controlled trial

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Abstract

Objectives Rotator cuff tendinopathy is a common source of shoulder pain characterised by persistent and/or recurrent problems for a proportion of sufferers. The aim of this study was to pilot the methods proposed to conduct a substantive study to evaluate the effectiveness of a self-managed loaded exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy.
Design A single-centre pragmatic unblinded parallel group pilot randomised controlled trial.
Setting One private physiotherapy clinic, northern England.
Participants Twenty-four participants with rotator cuff tendinopathy.
Interventions The intervention was a programme of self-managed loaded exercise. The control group received usual physiotherapy treatment.
Main outcomes Baseline assessment comprised the Shoulder Pain and Disability Index (SPADI) and the Short-Form 36, repeated three months post randomisation.
Results The recruitment target was met and the majority of participants (98%) were willing to be randomised. 100% retention was attained with all participants completing the SPADI at three months. Exercise adherence rates were excellent (90%). The mean change in SPADI score was −23.7 (95% CI −14.4 to −33.3) points for the self-managed exercise group and −19.0 (95% CI −6.0 to −31.9) points for the usual physiotherapy treatment group. The difference in three month SPADI scores was 0.1 (95% CI −16.6 to 16.9) points in favour of the usual physiotherapy treatment group.
Conclusions In keeping with previous research which indicates the need for further evaluation of self-managed loaded exercise for rotator cuff tendinopathy, these methods and the preliminary evaluation of outcome offer a foundation and stimulus to conduct a substantive study.

Keywords: Randomised controlled trial; Rotator cuff tendinopathy; Exercise; Rehabilitation; Quality of life

Introduction

Rotator cuff tendinopathy is regarded as a common and burdensome source of shoulder pain with prevalence estimated to be as high as 14% in the general working-age population [1]. Impaired shoulder function impacts significantly upon activities of daily living, including eating, dressing and working [2]. The course of rotator cuff tendinopathy, for a significant proportion of sufferers, is characterised by persistent pain and/or disability and/or recurrent episodes [3]. Costs in the first 6 months following primary care contact have been estimated to be €690 per person which means that costs attributable to shoulder pain in the United Kingdom are in the region of €345 million or £310 million per year [4,5].

A range of interventions, both conservative and surgical, are currently used to treat this condition [5]. Although the mechanism of action is poorly understood [6], the potential

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benefits of loaded exercise, i.e. exercise against gravity or resistance, in comparison to other conservative or surgical treatment strategies have been reported in a systematic review [7]. However, this review, which included four studies regarded as presenting a low risk of bias, recognised the paucity of evidence and other methodological limitations of the evidence base, including no treatment control groups and a lack of use of validated outcome measures, when drawing this conclusion and subsequently recommended that further high-quality research should be conducted.

In keeping with the findings of the systematic review by Littlewood *et al*. [7], the purpose of this study was to pilot the methods proposed to conduct a substantive randomised controlled trial (RCT) to evaluate the effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for rotator cuff disorders/tendinopathy.

Methods

Aims and objectives

The aim of this study was to pilot the methods proposed to conduct a substantive study to evaluate the clinical and cost-effectiveness of a self-managed loaded exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. The objectives were to evaluate:

a. The process of recruitment and retention rates
b. Willingness of participants to be randomised
c. The extent of contamination between treatment groups
d. Participant adherence with treatment.

A secondary aim was to undertake a preliminary comparison of patient reported-outcomes and to estimate the variability of these outcomes in this patient population.

Design

A single-centre pragmatic unblinded parallel group RCT.

Setting

One private physiotherapy clinic in West Yorkshire, northern England.

Participants

Between January and June 2012 participants were recruited according to the following criteria: (i) Age > 18 years, (ii) Willing and able to participate, (iii) Primary complaint of shoulder pain with or without referral into the upper limb for >3 months, (iv) No/minimal resting shoulder pain, (v) Range of shoulder movement largely preserved, and (vi) Shoulder pain provoked consistently with resisted muscle tests, usually abduction or lateral rotation. Participants were excluded according to the following criteria: (i) Shoulder surgery within last 6 months, (ii) Reasons to suspect systemic pathology including inflammatory disorders, (iii) Cervical repeated movement testing affects shoulder pain and/or range of movement. Participants were recruited via posters, word of mouth and advertisements in the local press.

Potential participants were asked to contact the chief investigator via e-mail or telephone to express interest and undergo initial telephone screening, where appropriate, for inclusion criteria i to iv and exclusion criteria i to ii. If these criteria were met then the potential participant was sent a full participant information sheet and consent form. Upon receipt of the signed consent form the details of the participant were passed onto the physiotherapy clinic who subsequently arranged a mutually convenient appointment time to undertake a physical examination screening by one of the study physiotherapists for inclusion criteria v to vi and exclusion criteria iii.

Baseline/Outcome Assessment

Participants were initially assessed for eligibility and then consent was gained. Subsequently the patient-reported outcome measures were completed to establish baseline pain, function, quality of life and level of self-efficacy. After completion of the baseline measures, the participants were randomly allocated to the self-managed exercise or usual physiotherapy treatment groups. The measures of pain, function and quality of life were repeated three months post randomisation by the participants and returned by post.

The primary outcome measure was the Shoulder Pain and Disability Index (SPADI) [8]. The SPADI is a self-report measure specifically developed to evaluate pain and function in patients with shoulder pathology [9]. It is a commonly used and recommended measure that has been validated for use in this patient population and a minimally clinically important change of 10 points has been identified [9,10]. The SPADI includes 13 items divided into two sub-scales; pain (5 items), disability (8 items). The responses are indicated on a visual analogue scale where 0 = no pain/no difficulty and 10 = worst imaginable pain/so difficult it requires help. The items are summed and converted to a total score out of 100 where a high score indicates more pain.

The secondary outcome measure, the Short-form 36 (SF-36) is a generic measure of health related quality of life [11] and is the most widely used measure of this nature.

We expected that success of the self-managed exercise intervention was likely to be related to the level of exercise adherence and hence we were interested in evaluating this as well as exploring possible factors that might predict non-adherence in this context. A range of such factors have been identified including level of pain at baseline, levels of physical functioning, levels of well-being [12], all of which can be captured with the aforementioned measures. However, levels of self-efficacy appear to be an important determinant of adherence [12] and so the General Self-efficacy scale (GSES) [13] was completed at baseline. The GSES is a

10-item measure that has been developed to measure this construct and has been validated across different populations in different countries [14]. In the absence of objective measures of adherence, levels of treatment adherence were measured through the use of an exercise diary indicating the number and percentage of exercises completed as reported by the patient.

Randomisation

A computer generated randomisation sequence was produced by SJW in blocks of two and four to ensure an equal number of participants were randomised to each group. This was regarded as essential due to the small total sample size. The treating physiotherapists allocated participants to the self-managed exercise or usual physiotherapy treatment group by selecting the next consecutively numbered sealed opaque envelope, which concealed the group allocation. The participants name and study identification number were written on the envelope before it was opened.

The self-managed exercise intervention

The intervention, self-managed loaded exercise, was prescribed by the physiotherapist but completed by the patient independently. It involved exercising the affected shoulder against gravity, a resistive therapeutic band or hand weight over three sets of 10 to 15 repetitions completed twice per day. Exercise prescription was guided by symptomatic response requiring that pain was produced during exercise, but overall, symptoms were no worse upon cessation of that exercise [15,16]. The exercise was prescribed and operationalised within a self-managed framework which included focus upon knowledge translation, exercise/skill acquisition, self-monitoring, goal setting, problem solving and pro-active follow-up. The programme has been described in full elsewhere [17].

The comparator

Usual physiotherapy treatment might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection at the discretion of the treating physiotherapist [5].

Due to the private-practice setting in which the study was conducted, an agreement had to be reached prior to initiation of the study regarding how many sessions would be funded through the research for each of the trial arms respectively. Based upon the authors' prior clinical experience it was agreed that participants in the self-managed exercise arm could receive a maximum of four sessions funded by the research and based upon information from the clinic it was agreed that participants in the usual physiotherapy treatment arm could receive a maximum of eight funded sessions.

Sample size calculation

The primary aim of this study was to pilot the methods proposed to conduct a substantive study not to detect a true difference between treatment groups. In this context it was felt that a total of 24 participants would be sufficient for this purpose [18].

Data analysis

Recruitment, retention, adherence rates, proportion of participants randomised and GSES scores are presented descriptively as is description of the interventions offered in both treatment arms to enable an evaluation of contamination. The mean change in SPADI score from baseline to three months is calculated for each group along with its associated 95% confidence interval. For the primary outcome, the SPADI score after three months, the mean scores are presented for each group along with the mean difference in SPADI scores between the groups and its associated 95% confidence interval. Analysis of the SF-36 scores was undertaken in a similar way.

Results

Fig. 1 shows the study profile; 45 people were assessed for eligibility and 30 (67%) of these were potentially eligible for the study. Only one out of 45 (2%) declined to participate due to an unwillingness to be randomised. Twenty-four participants were randomly assigned to the self-managed exercise or usual physiotherapy treatment groups. The mean age at baseline of the participants was 63.2 years (range 44–79) and 50% (12/24) were male. The mean duration of symptoms was 38.6 months (range 3 to 168) and mean SPADI score was 42.2 (range 15.4 to 73.1); higher scores indicate higher pain and disability. The baseline characteristics of the participants by treatment group are presented in Table 1. The groups appeared well balanced at baseline except that the self-managed exercise group reported higher baseline shoulder pain and disability via the SPADI and the usual physiotherapy treatment group reported a longer mean duration of symptoms (49 versus 29 months). This estimate is influenced by one participant who reported duration of 168 months. When the influence of this outlier was removed the revised estimate of mean duration of symptoms was 37 months for the usual physiotherapy group.

Number and content of treatment sessions

The mean number of treatment sessions in the self-managed exercise group was less than the usual physiotherapy treatment group (3.9 versus 7.6 respectively). All participants in the self-managed exercise group received the intervention but two participants also received mobilisation

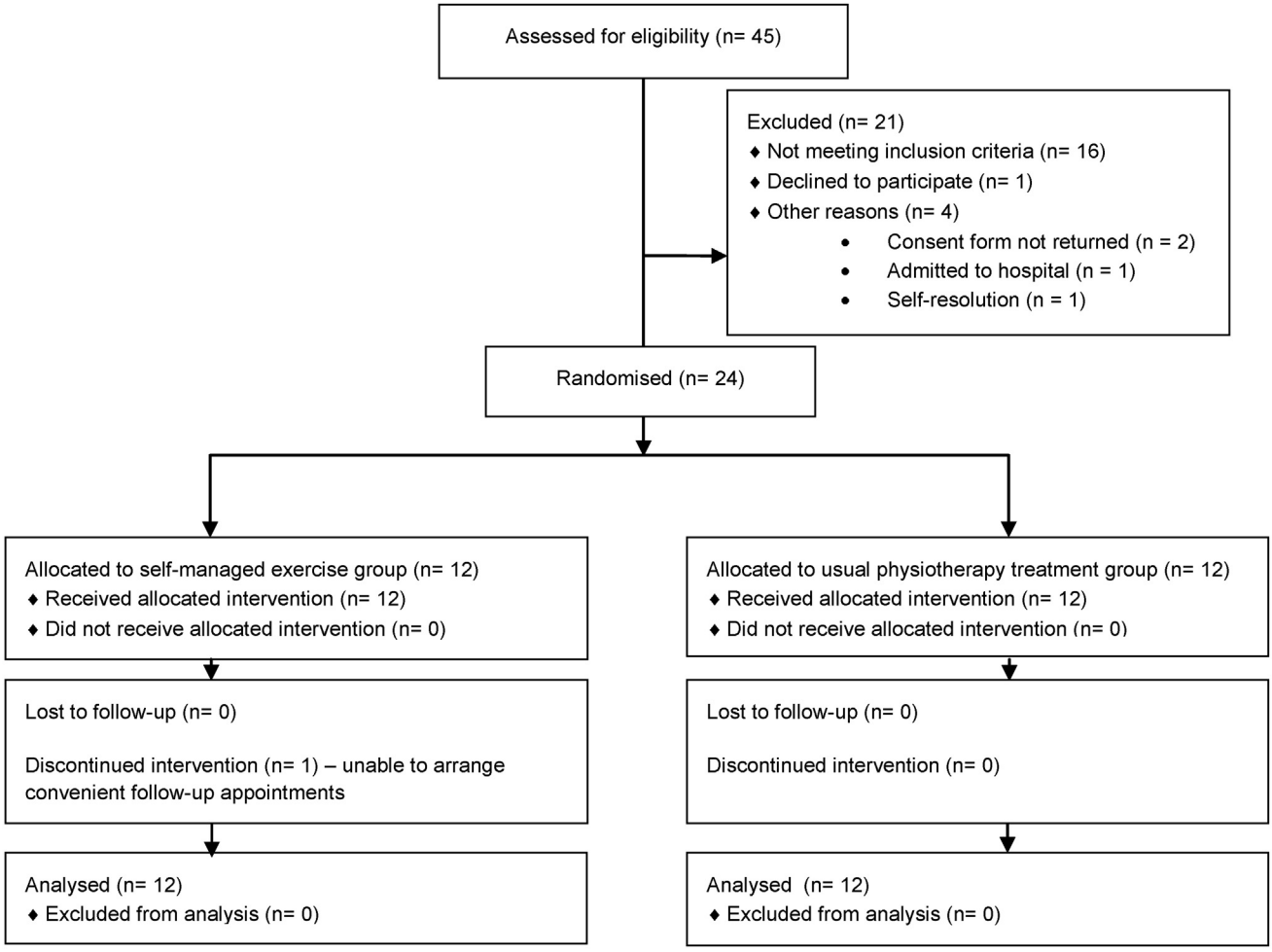

Fig. 1. Participant flow through the study.

and massage within their treatment packages. Participants in the usual physiotherapy treatment group received a range of treatments; described in Fig. 2.

Adherence

In the self-managed exercise intervention group, eleven out of 12 (92%) participants returned self-report exercise adherence data in the form of annotated exercise diaries. Of the eleven, seven participants returned complete data and four returned partial data. Complete data refers to the return of consecutive annotated diaries dated from initial assessment to final follow-up. According to the exercise protocol, the participants were required to exercise twice daily and so where this occurred 100% adherence was recorded for that day. Of

Table 1
Baseline characteristics of the participants by treatment group.

Characteristic	Treatment group			
	Self-managed exercise		Usual physiotherapy treatment	
	n	Mean or %	*n*	Mean or %
Age (years) (range)	12	62.6 (46 to 76)	12	63.9 (44 to 79)
Gender – male	12	5/12 (42%)	12	7/12 (58%)
Duration of shoulder symptoms (months) (range)	12	29 (3 to 120)	11	49 (3 to 168)
SPADI (SD)	12	44.6 (15.2)	12	39.7 (18.3)
SF-36 Bodily pain (SD)	12	51.4 (12.9)	12	49.4 (18.3)
SF-36 Physical functioning (SD)	12	71.9 (19.3)	12	72.9 (25.2)
GSES (SD)	12	33.5 (3.9)	11	35.3 (3.4)

For the SPADI (Shoulder Pain and Disability Index) higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100)/The Short Form (SF)-36 dimensions are scored on a scale of 0 to 100 and higher scores indicate better quality of life/The GSES (General Self-efficacy scale) is scored on a scale of 10 to 40 and higher scores indicates higher levels of self-efficacy.

Table 2
Outcome scores for the self-managed exercise and usual physiotherapy treatment groups at three months.

Outcome	Self-managed exercise			Usual physiotherapy treatment			Difference (95% CI)
	n	Mean	SD	*n*	Mean	SD	
SPADI[a]	12	20.9	19.2	12	20.7	20.3	+0.14 (−16.6 to +16.9)[c]
SF-36 Physical functioning[b]	12	78.2	17.7	12	73.3	29.3	+4.9 (−15.6 to +25.4)[d]
SF-36 Role-physical[b]	12	88.5	18.0	12	79.2	20.0	+9.4 (−6.7 to +25.5)[d]
SF-36 Bodily pain[b]	12	61.4	13.4	12	71.8	18.2	−10.3 (−23.9 to +3.2)[c]
SF-36 General health[b]	12	74.2	20.3	12	72.9	11.6	+1.2 (−12.7 to +15.2)[d]
SF-36 Vitality[b]	12	69.3	12.1	12	70.8	21.5	−1.6 (−16.3 to +13.2)[c]
SF-36 Social functioning[b]	12	45.8	11.1	12	50.0	10.7	−4.2 (−13.4 to +5.0)[c]
SF-36 Role emotional[b]	12	95.8	10.4	12	97.2	7.4	−1.4 (−9.0 to +6.2)[c]
SF-36 Mental health[b]	12	84.6	12.9	12	82.5	13.1	+2.1 (−8.9 to +13.1)[d]

[a] Higher scores indicates higher levels of pain and disability (scored on a scale of 0 to 100).
[b] Higher scores indicate better quality of life (scored on a scale of 0 to 100).
[c] Usual physiotherapy treatment group reports better outcomes
[d] Self-managed exercise group reports better outcomes.

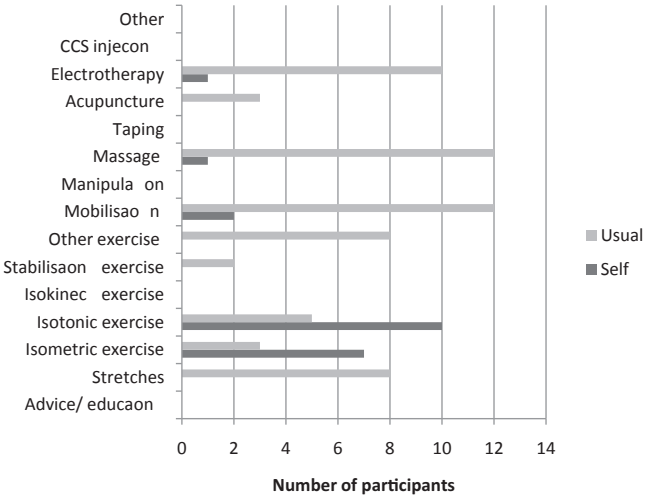

Fig. 2. Description of the interventions offered (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group).

the seven participants who returned completed data, the mean percentage adherence was 89% (range 77 to 99%). Of the four participants who returned partial data, the mean percentage adherence was 93% (range 83 to 100%). Overall self-report adherence was 90% (range 77 to 100%).

Self-efficacy

The mean GSES score at baseline for the self-managed exercise group was 33.5 (SD 3.9) and 35.3 SD 3.4) for the usual physiotherapy treatment group.

Clinical outcomes

All SPADI and SF-36 outcome measures were returned for the three month follow-up. The mean change in SPADI score from baseline to three months was −23.7 (95% CI −14.4 to −33.3) points for the self-managed exercise group and −19.0 (95% CI −6.0 to −31.9) points for the usual physiotherapy treatment group. These changes were regarded as clinically important.

Table 2 shows the differences in outcome scores between the self-managed exercise and usual physiotherapy treatment groups at three months. The mean SPADI score at 3 months was 20.9 (SD 19.2) points for the self-managed exercise group and 20.7 (SD 20.3) points for the usual physiotherapy treatment group. The difference in three month SPADI scores was 0.1 (95% CI −16. 6 to 16.9) points in favour of the usual physiotherapy treatment group. The 95% confidence interval includes a 10-point difference in SPADI scores between the groups which is a clinically relevant range confirming the value of progressing with the substantive study.

Discussion

The primary aim of this study was to pilot the research methods and self-managed exercise intervention proposed for a substantive study. With reference to the specific objectives of the pilot study; a) recruitment was to target and retention rates were excellent; b) the vast majority of participants were willing to be randomised; c) contamination was minimal, and; d) exercise adherence rates were excellent. Finally, the outcome measures used were acceptable, in terms of 100% completion at three months, and preliminary statistical analysis indicated an improvement in outcomes in both groups.

The process of recruitment and randomisation ran smoothly. The self-managed exercise intervention appears to have been delivered with minimal contamination and with recognition of the significant differences between what constitutes a self-managed exercise programme and usual physiotherapy treatment which is important in the context of planning further study so that an appropriate evaluation of different approaches can be undertaken. Our concern here was that the physiotherapists might gradually adopt the self-managed exercise into their usual treatment regimen as they became accustomed to working within this framework which would subsequently limit the value of any comparisons made.

Despite prior concerns relating to pain produced whilst exercising serving as a barrier to engagement, retention and reported levels of adherence were excellent which is in contrast to other exercise programmes [19]. Reasons for such high levels of adherence might relate to the minimal time requirement of undertaking a single-exercise, or might relate to aspects of the self-managed framework within which the exercise was prescribed. This framework included a focus upon knowledge translation meaning that participants had an understanding of why they were undertaking the specific exercise and also included goal setting, self-monitoring and proactive follow-up, all of which might enhance engagement [20,21]. Contrary to this, it is also possible that the self-report exercise diaries which were used as a measure of adherence were an inadequate measure of this construct and hence present an inaccurate picture of true levels of adherence. However, in the absence of alternative methods, such a self-report approach appears to be the most suitable means of gathering this data at this time.

In this underpowered pilot study, the patient reported outcomes in terms of the SPADI and SF-36 were comparable after three months but the patients in the self-managed group attended fewer follow-up sessions. However, this data does not provide adequate evidence of equivalence of the interventions but instead should be regarded as a stimulus to conduct a substantive RCT based upon the methods employed here.

Considerations and limitations

Although it is beyond the scope of any pilot study to claim findings that are generalisable, it should be recognised that this study was conducted in a private practice setting where the intervention was delivered by two highly experienced physiotherapists which might limit translation into more generalised settings. Additionally, the participants recruited to this study were not currently seeking healthcare for their shoulder problem which again is in contrast to other settings and hence the underlying characteristics of these participants might be different to those who were already actively seeking healthcare. The mean SPADI score at baseline in this group was 42.2 compared to 47.3 in a study recently conducted in the UK National Health Service where people with moderate to severe shoulder pain were sought [22]. Although the mean baseline SPADI score was less in this study, the difference would not be regarded as clinically significant and might actually be more reflective of the range of people who seek healthcare for this problem. To support this, a study recently conducted in Belgium that recruited a similar group of patient reported mean SPADI scores at baseline of 43.1 [23].

Similar to other RCTs of physiotherapy interventions, this trial was unblinded which introduces a potential source of bias. Although we initially proposed a double-blind study, i.e. patient and hence outcome assessor, this was regarded as unacceptable by the ethics committee.

Conclusion

Disorders of the rotator cuff are a burdensome problem and there is a clear evidence deficit in relation to conservative management and specifically self-managed loaded exercise. The research methods employed within this pilot RCT appear to offer a suitable foundation upon which to conduct a substantive study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy treatment for chronic rotator cuff disorders/tendinopathy.

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Conflict of interest: The authors report no conflicts of interest.

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Appendix 6

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05 December 2011

Chris Littlewood
ScHARR

Dear Chris

Loaded exercise for rotator cuff tendinopathy: A pilot study

Thank you for submitting the above research project for approval by the ScHARR Research Ethics Committee. On behalf of the University Chair of Ethics who reviewed your project, I am pleased to inform you that on 02 December 2011 the project was approved on ethics grounds, on the basis that you will adhere to the documents that you submitted for ethics review.

The research must be conducted within the requirements of the hosting/employing organisation or the organisation where the research is being undertaken.

If during the course of the project you need to deviate significantly from the documents you submitted for review, please inform me since written approval will be required. Please also inform me should you decide to terminate the project prematurely.

Yours sincerely

Cheryl Oliver
Ethics Committee Administrator

ELSEVIER

Appendix 7

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Physiotherapy

Patients with rotator cuff tendinopathy can successfully self-manage, but with certain caveats: a qualitative study

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Abstract

Objectives Evidence has emerged supporting the value of loaded exercises for rotator cuff tendinopathy but there are barriers that might prevent implementation of this intervention in the real-world. The purpose of this study was to explore these potential barriers with participants involved in a pilot randomised controlled trial (RCT) investigating a self-managed loaded exercise intervention.
Design A qualitative study within the framework of a mixed methods design. Data were collected using individual interviews and analysed using the framework method.
Setting One private physiotherapy clinic in northern England.
Participants Six patients and two physiotherapists were purposively sampled from those allocated to the self-managed exercise group within the RCT.
Results Three themes were generated: (1) Expectations and preferences, (2) characteristics of an unsuccessful outcome, (3) characteristics of a successful outcome. Most patients expressed expectations contrary to the philosophy of a self-managed approach. But this did not serve as a barrier when the intervention was offered within a positive and supporting environment where patients understood the reasons for undertaking the exercise, effectively self-monitored and engaged with pro-active follow-up. An early and appreciable response to therapy was also a key factor influencing continuing engagement with the exercise programme.
Conclusion With certain caveats including the need to recognise and respond to individual characteristics, implement effective knowledge translation strategies and the need to engage with appropriately timed pro-active follow-up, the potential to implement programmes of self-managed loaded exercise for patients with rotator cuff tendinopathy in the real-world and in further research studies appears feasible but challenging.

Keywords: Rotator cuff; Tendinopathy; Qualitative research; Self-management

Introduction

Over recent years evidence has emerged supporting the value of loaded exercises for the treatment of tendinopathy and more recently this has been applied to the rotator cuff [1–3]. However, such exercises are frequently painful to perform, require the patient to take responsibility for their management, and such exercise prescription does not align with the clinical reasoning processes of many physiotherapists [4]. Thus, although there is emerging empirical evidence to support this approach there are real and significant barriers that might serve to prevent implementation in the real world [5].

This paper presents a qualitative investigation of these potential barriers that was undertaken alongside a pilot randomised controlled trial (RCT) designed to compare a self-managed loaded exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy [6,7].

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Methods

Design

A qualitative study was undertaken within the framework of a mixed methods research design.

Setting

One private physiotherapy clinic in West Yorkshire, northern England.

Participants

A purposive sample of patients complaining of shoulder pain attributable to rotator cuff tendinopathy was recruited from the twelve patients who undertook a programme of self-managed loaded exercise within the pilot RCT. Patients were selected by the chief investigator (CL) to gain maximum variation in terms of age, gender and clinical outcome, as determined by change in Shoulder Pain and Disability Index (SPADI) from baseline to three month follow-up. As there were only two physiotherapists involved in the delivery of the intervention both were eligible for inclusion.

Initial recruitment to the pilot RCT included the procedure for gaining informed consent for taking part in a future related qualitative investigation. CL contacted patients by phone or e-mail to ask whether they would be willing to participate. If their response was favourable then a convenient time to undertake an interview was scheduled at the patient's home or physiotherapy clinic.

Data collection

Interviews were directed by semi-structured topic guides (Appendices 1 and 2, available from the author on request), recorded using a digital voice recorder and transcribed verbatim. All interviews were conducted by CL. The participants were aware that CL was a researcher undertaking the study and also a physiotherapist by background.

Data analysis

The qualitative data were analysed independently by CL using the framework method of analysis [8]. The framework method has been developed specifically for applied research in which the objectives of the investigation are set *a priori* [9]. Analysis began with data familiarisation which underpinned the development of a thematic framework. The framework formed the basis upon which key issues and themes were developed and by which the data were examined. Subsequently the data were indexed according to the framework before a charting process took place; where the data were organised according to the defined thematic framework. Finally the charts were used to define concepts and find associations to provide explanations for the findings [8,9]. The analysis was subsequently checked with reference to the original transcripts and verified by another researcher (PM) which did not result in significant amendment.

Results

Eight participants were recruited; six patients and two physiotherapists. Three of the patients were male (50%), age range was 51–74 years (mean 64.7 years) and the change in SPADI score ranged from +3.1, indicating worse status, to −42.3, indicating improved status (mean change −19.7). Both of the physiotherapists were female, each with greater than 20 years of experience working as physiotherapists in a variety of settings.

Three main themes were generated: (1) Expectations and preferences, (2) characteristics of a successful outcome, (3) characteristics of an unsuccessful outcome. Successful treatment outcome was determined by change in SPADI where a 10 point change is regarded as a minimal clinical important difference and hence was used as a cut-off point with greater change representing better outcome.

Expectations and preferences

The self-managed exercise programme required that patients took responsibility for the management of their condition and although they returned to the physiotherapist for follow-up, the focus of this return was to facilitate self-managed behaviour not to offer hands-on care [7]. However, at the outset it was evident that most of the patients expected physiotherapy to be therapist-led and include 'hands-on' intervention:

'*I expected a bit of a pummel actually and a bit of a tug about and somebody to go and make it all feel better.*' (ID 18)

This expectation was aligned to how the physiotherapists viewed their role:

'*I am very, very hands-on normally.*' (T2)

The patients' expectations appeared to be largely informed by previous experiences of physiotherapy. Prior to recruitment to the pilot RCT, patients were informed that they had an equal chance of being randomised to the self-managed exercise or usual physiotherapy treatment arm. However, when patients were allocated to undertake self-managed exercise these prior expectations appeared to contribute to resentful demoralisation:

'*I was quite sceptical I have to say when I went and we drew the envelope and it was, you've got, you know, self I thought ohh. . .that's not gonna do anything. . .I literally walked down the stairs of (the physiotherapy clinic thinking what av I signed up for!?*' (ID 29)

This perspective was in keeping with the experience of the physiotherapists:

'*. . .there were a few crestfallen faces when they got the self-managed side of it.*' (T2)

The clear exception to this was one patient who had previously received extensive physiotherapy, incorporating a range of therapist-led interventions, without benefit and entered the trial hoping to be randomised to the self-managed exercise intervention:

'*. . .exercises erm I think that worked much better than periodic injections and err weekly physiotherapy.*' (ID 15)

However, for the majority of patients and the physiotherapists it was clear that their expectations and preferences did not align with the philosophy of self-management.

Characteristics of an unsuccessful outcome

It would be reasonable to expect that where expectations are not met treatment outcome would be compromised. In this situation, this was not always the case and a more complex relationship between expectations and outcome arose. In addition to reporting alternative expectations of physiotherapy, patients regarded as having an unsuccessful outcome also expressed concerns about the nature of their problem and whether self-managed exercise was an adequate intervention. Additionally, the patients described the role of the physiotherapist which, in some situations, seemed to compound the negative nature of their prior beliefs:

'*. . . well I think (physiotherapist) felt more or less straight away that it was unfortunate that I'd drawn the short straw in terms of that. . .*' (ID 37)

This narrative from the patient perspective was in concordance with opinion expressed by one of the physiotherapists, where it can be seen that prior beliefs might impact upon their role in this environment:

'*I think there are some clients who from interviewing them, doing the examination, that you get an idea of whether they would be compliant and appropriate, and others you just think it's totally inappropriate and a waste of time.*' (T1)

Despite these adverse factors, all patients reported that they initially engaged with the self-managed exercise programme. However, a key barrier to on-going engagement appeared to be a lack of an early and appreciable response to the therapy:

'*. . .I think that when you find that they're not making a great deal of improvement, you're less inclined to erm continue it.*' (ID 37)

Conversely, when the symptoms improved to a certain point, although not resolved, the impetus to continue was also challenged:

'*. . .I would continue if it was still badly hurting. . .*' (ID 13)

Despite our initial concerns that pain provoked whilst undertaking the exercise programme might serve as a barrier, this was not a significant concern that was expressed by the patients during the individual interviews. Also, patients did not express any anxiety about what the pain response meant in terms of tissue damage.

'*. . . I suppose you expect to have a little bit of pain but erm I certainly wasn't worrying about any long-term erm, erm problems.*' (ID 37)

This perspective was not shared by one of the physiotherapists:

'*. . .but they weren't sold by that idea. They didn't like the idea of that.*' (T1)

The self-managed exercise programme was designed to be progressive. This requires that the patients understand how to progress the exercise when indicated or regress if necessary. Following some early reported benefit from the exercise programme, one patient indicated subsequent difficulty as the symptoms failed to respond as the programme progressed. Despite this, they did not consider regressing the programme or seeking advice, indicating an external locus of control as a potential barrier:

'*I just followed whatever the next one was. . .I just kept thinking I'll be glad when I go back and I might have something to do a bit easier or something.*' (ID 17)

The self-managed exercise programme was also designed to facilitate engagement in terms of minimal time needed to undertake and master the exercise. Despite this, some patients still expressed concern about attributes of the intervention:

'*. . .at first it seemed like a big task to do, because it was an additional thing to do through the day.*' (ID 18)

Unexpectedly, disquiet was expressed about the simplicity of the intervention and hence its lack of potential effectiveness:

'*. . .to cap it all it's such a simple exercise. . .I just came out thinking waste of time.*' (ID 29)

In summary, a range of factors can be identified which might be associated with an unsuccessful clinical outcome and hence serve as a barrier to implementation in the real world. These factors are wide ranging and include the role of prior beliefs, the role of the physiotherapist, attributes of the intervention, response to therapy and personal attributes, but they do not seem to act in isolation. Instead there appears to be a complex interplay between them which ultimately might impact upon the therapeutic response and experience.

Characteristics of a successful outcome

Although patients who regarded themselves as having a satisfactory experience still reported pre-treatment

expectations not aligned with a self-managed exercise approach, prior beliefs about the source and nature of their problem were not expressed during the interviews. One patient reflected upon a prior experience in a different way:

'*I'd experienced a year and a half of physiotherapy and it brought about a relatively limited improvement.*' (ID 15)

Also, the influence of the physiotherapist was framed in a more positive way:

'*. . . she explained it very well and said what the aim was and that if it did hurt what to do. . .I could ring her if I had problems, and she was very responsive, she rang me back the same day and said what to do. . .I felt very comfortable, very confident.*' (ID 18)

In addition to the support offered by the physiotherapist, one patient recognised the role of their partner in providing feedback and stimulating further engagement with the self-managed exercise programme during times when progress was slow:

'*My (partner) erm kept saying to me that (they) thought that I was complaining a lot less as time went on. I didn't feel that but she assured me that I was*' (ID 15)

The need for on-going support to facilitate successful engagement was also recognised by the physiotherapists. Patients also described personal traits that indicated self-efficacious individuals who took control of the programme:

'*. . .while I was waiting for the kettle to boil, I would do it. . .*' (ID 29)

'*. . .I kept my diary and I always wrote why I'd not done it so that I could think to myself well how can I fit that in then?*' (ID 18)

Other personal attributes were also described:

'*. . .I was driven to get rid of this pain really, so I thought I'm going to give this a really good go and do it properly.*' (ID 18)

'*I'm used to exercise and I know that repeated exercise improves strength and mobility.*' (ID 15)

In some circumstances the physiotherapists felt able to identify patients who they expected would successfully engage with the self-managed exercise programme:

'*. . .I think it's a certain type of person where you're going to be able to have success with a regime of exercises and no hands-on, I would say. . . People who were very positive about life. . . they were usually quite outgoing, quite confident in themselves and quite determined.*' (T1)

However, despite these inherent individual traits, one patient reflected upon a previous episode of physiotherapy when engagement with a prescribed exercise programme was limited:

'*I didn't do them. . .I don't know – because I thought they were doing it for me. So I came back with the booklet but I didn't do them. I thought oh well, I'm going back next week.*' (ID 18)

Other attributes of the intervention which facilitated engagement were also recognised. Whereas some patients had found aspects of the intervention difficult to implement, those patients who reported a successful outcome detailed different experiences:

'*. . .with it being such an easy exercise it. . .became part of a routine . . .I would do, it was short, short and sweet. So it wasn't a case of having to find time to do it, it just naturally fell into a little sort of routine that I have.*' (ID 29)

With reference to the exercise diary which is used as a key component of the programme as a means of self-monitoring, one patient reflected:

'*. . .I stuck the sheet that I was given on the fridge so it was there in the kitchen to remind me every day.*' (ID 29)

Additionally, with regards to the pro-active follow-up by the physiotherapist, another patient recognised:

'*. . .I knew I was seeing (physiotherapist) on those regular appointments; it was every four weeks wasn't it? So because I knew I was seeing her, I didn't want to go to her and say I've not done it. So that was a motivator to me. . .*' (ID 18)

Importantly, despite initial feelings of demoralisation, patients experienced a favourable therapeutic response that persuaded them of the potential value of the programme to them:

'*. . .when I started seeing the results. . .I was so pleased with it that that motivated me on more and more to keep going.*' (ID 18)

'*. . .it just carried on improving erm and it made me realise how weak the arm was . . .I was quite pleased that it came on so quickly.*' (ID 29)

Also, patients expressed an interesting opinion regarding pain and exercise:

'*. . .if it's not hurting it's not helping. . .*' (ID 13)

In summary, for some patients, expectations of what constitutes useful physiotherapy did not serve as a barrier to satisfactory treatment outcome with a self-managed exercise programme. This held true when the programme was offered within a positive and supporting environment where patients understood the reasons for undertaking the exercise and had means to self-monitor and return for pro-active follow-up. Response to therapy appeared to be a key factor influencing engagement. Individual traits, including self-efficacy, also appeared to play an important role in facilitating successful self-managed behaviour.

Discussion

The primary aim of this study was to explore participant experience and barriers that might serve to prevent implementation of the self-managed exercise intervention. Despite most patients expressing expectations of physiotherapy contrary to the philosophy of self-management, this did not serve as a barrier to successful treatment outcome when the intervention was offered within a positive and supporting environment where patients understood the reasons for undertaking the exercise, effectively self-monitored and engaged with pro-active follow-up. Additionally, an early and appreciable response to therapy appears to have been a key factor influencing continuing engagement with the exercise programme.

Within the context of this study, most patients expressed discontent when randomised to the self-managed exercise arm of the pilot RCT; a phenomenon recognised in other areas of research as resentful demoralisation [10]. The importance of recognising patient preferences and meeting patient expectations as a means of improving treatment outcome is not a new phenomenon. The influence of expectations in clinical practice has long been recognised and patient preference trials have been developed for evaluation in research settings [10]. In this context, if a self-managed intervention is to be successfully implemented, the relevance of expectations needs to be recognised and pro-actively addressed through open discussion.

Interestingly, despite negative initial feelings, the patients reported that they still engaged with the intervention, in terms of adhering to the exercise programme. However, a key feature of continuing engagement appeared to be an early and appreciable therapeutic response. Where this did not happen, the motivation of some patients waned. This is a concern because worthwhile response to therapeutic exercise is generally expected to take time [11]. This highlights the need for educational strategies to foster more realistic expectations of prognosis but also indicates that pro-active follow-ups by the physiotherapists, in the form of a telephone call or clinic appointment, should be offered.

Prior concerns relating to pain, produced whilst exercising, as a barrier to engagement were not apparent here in relation to the patients at least. However, it was evident that patients had a level of acceptable pain response which, if exceeded, had the potential to impact negatively. When delivering the self-managed exercise intervention, physiotherapists would need to be aware of this when progressing the programme and also when working with patients to help them adapt the programme to their individual capacity which includes an understanding of how to regress the exercise but maintain engagement if the pain response becomes unacceptable.

The influence of the prior beliefs of the patients was evident but so too were the prior beliefs of the physiotherapists, which might impact upon delivery of the intervention. In a profession where therapist-led 'hands-on' intervention is regarded as a vital and central intervention [4,12], a move towards a self-managed approach represents a seismic shift which would need to be managed appropriately through, among other things, education and training relating to the theory and application of self-management.

In addition to the role of the physiotherapist, personal attributes of the patients were important, particularly self-efficacy, defined as the confidence to perform a specific task or behaviour [13]. Self-efficacious individuals were able to organise themselves and their lifestyle to incorporate the exercise programme. However, it does appear that the programme has the capacity to enhance individual self-efficacy through processes including knowledge translation, exercise/skill acquisition, self-monitoring, goal setting, problem solving and pro-active follow-up and hence a self-managed approach in this context does not necessarily require wholly self-efficacious individuals at the outset.

Limitations

This study was conducted with eight participants recruited via their involvement in a RCT and the data were collected and analysed by one individual. Although most readers would now not judge qualitative research from the perspective of its capacity to generate data regarded as being generalisable, such a context might hamper the transferability, credibility and confirmability of the findings. However, it is reassuring to note that the patient recounted similar ideas and themes, both in the positive and negative whilst reflecting upon their experience which might actually enhance both the transferability and credibility. Furthermore, the participants were fully aware of the chief investigator's background and role in the research and in spite of this were not put off from relaying both positive and negative experiences. Finally, a transparent method of data analysis was adopted and the outcome of this was verified by a second researcher without the need for subsequent substantial amendment which does add to the confirmability of the output.

Conclusion

With certain caveats including the need to recognise individual traits, implement effective knowledge translation strategies for both patients and physiotherapists and the need to engage with appropriately timed pro-active follow-up the potential to implement programmes of self-managed loaded exercise for patients with rotator cuff tendinopathy in the real world and in further research studies appears feasible but challenging.

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Appendix 8

Interview Topic Guide - Patients

Thank you for agreeing to take part in this study and thank you for agreeing to discuss your experience.

Will you begin by briefly describing your shoulder complaint, how it affected you and whether it responded to the therapy?

Your treatment largely required you to undertake exercise independently. How did you feel about this?

Is this what you expected from physiotherapy treatment?

Did you encounter any problems completing the exercises?

In addition to completing the exercises independently, I also expect that at times they could be uncomfortable to do. Again, how did you feel about this?

Did you expect the exercises to be uncomfortable?

Did the discomfort associated with the exercise concern you?

Is there anything further you would like to mention or discuss?

Thank you for taking the time to discuss your experience.

Appendix 9

Interview Topic Guide – Physiotherapists

Thank you for agreeing to take part in this study and thank you for agreeing to discuss your experience.

Will you begin by briefly describing your background and experience in relation to shoulder disorders?

As part of the study, you were asked to deliver treatment as usual and treatment according to the research protocol. Did you find that the 2 approaches were significantly different from one another?

Did you encounter any problems delivering the loaded exercise intervention? For example, any concerns about prescribing exercises that were uncomfortable or any concerns about relying on the patient to self-manage their condition?

Did the patients report any concerns to you?

Is there anything further you would like to mention or discuss?

Thank you for taking the time to discuss your experience.

Appendix 10

BMC Musculoskeletal Disorders

STUDY PROTOCOL Open Access

A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: protocol for the SELF study

Chris Littlewood[1*], Jon Ashton[2], Sue Mawson[3], Stephen May[4] and Stephen Walters[1]

Abstract

Background: Shoulder pain is the third most common reason for consultation with a physiotherapist and up to 26% of the general population might be expected to experience an episode at any one time. Disorders of the shoulder muscles and tendons (rotator cuff) are thought to be the commonest cause of this pain. The long-term outcome is frequently poor despite treatment. This means that many patients are exposed to more invasive treatment, e.g. surgery, and/or long-term pain and disability.
Patients with this disorder typically receive a course of physiotherapy which might include a range of treatments. Specifically the value of exercise against gravity or resistance (loaded exercise) in the treatment of tendon disorders is promising but appears to be under-used. Loaded exercise in other areas of the body has been favourably evaluated but further investigation is needed to evaluate the impact of these exercises in the shoulder and particularly the role of home based or supervised exercise versus usual treatment requiring clinic attendance.

Methods/Design: A single-centre pragmatic unblinded parallel group randomised controlled trial will evaluate the effectiveness of a self-managed loaded exercise programme versus usual clinic based physiotherapy. A total of 210 study participants with a primary complaint of shoulder pain suggestive of a rotator cuff disorder will be recruited from NHS physiotherapy waiting lists and allocated to receive a programme of self-managed exercise or usual physiotherapy using a process of block randomisation with sealed opaque envelopes. Baseline assessment for shoulder pain, function and quality of life will be undertaken with the Shoulder Pain & Disability Index, the Patient Specific Functional Scale and the SF-36. Follow-up evaluations will be completed at 3, 6 and 12 months by postal questionnaire. Both interventions will be delivered by NHS Physiotherapist's.
An economic analysis will be conducted from an NHS and Personal Social Services perspective to evaluate cost-effectiveness and a qualitative investigation will be undertaken to develop greater understanding of the experience of undertaking or prescribing exercise as a self-managed therapy.

Trial registration number: ISRCTN84709751

Keywords: Mixed methods study, Randomised controlled trial, Rotator cuff tendinopathy, Exercise, Rehabilitation, Quality of life

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Background

Shoulder pain is one of the most common musculoskeletal symptoms with prevalence estimated at between 16 to 26% in the general population at any one time [1,2]. It is the third most common primary care musculoskeletal presentation [3] and the third most common reason for consultation with a physiotherapist [4]. Impaired shoulder function impacts significantly upon activities of daily living, including eating, dressing and working [5]. Disorders of the shoulder muscles and tendons (rotator cuff) are the commonest cause of this pain [6]. However long-term outcome is frequently poor for a significant proportion of patients which means that many are subsequently exposed to more invasive and costly treatment options, e.g. injections, surgery, and/or long-term pain and disability [7].

Shoulder pain, incorporating rotator cuff disorders, is a significant burden to the NHS and society. It has been identified that around 1% of adults in the UK consult their GP with a new presentation of shoulder pain each year. This amounts to over 500,000 adults. Costs in the first 6 months following primary care contact have been estimated to be €690 which means that costs attributable to this problem are in the region of €345 million or £310 million per year. Almost 50% of this cost is attributable to sick leave from paid employment [8]. Additionally, in 2005/6, 16,885 patients were admitted to hospital diagnosed with problems relating to the rotator cuff [9]. NHS costs associated with surgical procedures for such shoulder problems are estimated at £1,762 [10], which equates to a conservative estimate of almost £30 million per year. Clearly chronic rotator cuff disorders bring the associated health costs and economic burden, including loss of productivity, associated with other chronic conditions [5]. Therefore, this is an important health and social care problem for patients, clinicians, commissioners and researchers to consider.

Despite rotator cuff disorders being such a common shoulder problem there is a lack of high quality studies upon which to base practice [11]. Numerous systematic reviews have been undertaken in relation to subacromial impingement syndrome, an umbrella term encompassing rotator cuff disorders, investigating the various plausible interventions including physiotherapy, corticosteroid injections and surgery but all identify the insufficiency of the evidence base when attempting to draw conclusions [12-17]. Specifically in relation to the rotator cuff, a recent systematic review, which included 4 randomised controlled trials, suggested that loaded exercise, i.e. exercise against gravity or resistance, in the treatment of this disorder was promising [18] but due to the paucity of research and methodological limitations of the included studies further research is warranted. It was also recognised that home based or supervised exercise appears to confer similar outcomes to interventions, including therapist-led interventions, which were offered in a clinic-based setting. Additionally the benefits of loaded exercise have been reported in a particularly resistant patient group with long standing shoulder pain awaiting surgery due to a lack of response to previous conservative care [19]. Although small (n = 9), this uncontrolled pilot study reported that 56% responded to the point where they no longer required surgery despite a mean duration of pain of 41 months. Chronic rotator cuff tendon disorders have been shown to demonstrate similar pathological changes to tendon disorders in other areas of the body, e.g. the elbow, Achilles tendon, patellar tendon [20] where favourable results including reduced pain and improved function have been demonstrated in response to similar loaded exercise [21].

A recent survey of current practice suggests that physiotherapists usually offer a wide range of interventions for rotator cuff disorders including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection [22]. The majority of UK physiotherapists would expect patients to engage with some level of self-management but more than 58% would ask the patient to return for therapist-led interventions. The variability in the approach of physiotherapists might reflect the lack of high quality evidence upon which practice can be based.

It is hypothesised that self-managed loaded exercise has the capacity to reduce costs associated with rotator cuff disorders and improve treatment outcome which therefore reduces the need for work absenteeism and further expensive invasive interventions. There is a clear need for high quality research in this area to inform clinical practice and commissioning priorities. At a time when healthcare agendas are emphasising the need to encourage the self-management of long-term conditions this research would build upon the developmental work that has been undertaken so far and, based upon high quality research methods, will offer useful clinical and cost data upon which practice can be developed and future research can be based.

Methods/Design

Aims

The proposed study aims to answer the question: Is a self-managed exercise programme more effective than usual physiotherapy for chronic rotator cuff disorders?

The objectives are:

- To evaluate clinical effectiveness of loaded exercise in terms of pain, function and well-being.
- To evaluate cost-effectiveness of the interventions.
- To investigate patient adherence with treatment.
- To explore the perceptions and experience of the study participants.

Methods

The study design is a single-centre pragmatic unblinded parallel group randomised controlled trial (RCT) combined with qualitative investigation of patient and therapist experience. The study will be based at Doncaster & Bassetlaw Hospitals NHS Foundation Trust, UK.

The first part of the proposed study will be a RCT comparing self-managed loaded exercise versus usual physiotherapy.

The intervention

The intervention is self-managed loaded (against gravity or resistance) exercise. The exercise, prescribed by the physiotherapist but completed by the patient independently, involves exercising the affected shoulder against gravity, a resistive therapeutic band or hand weight over 3 sets of 10 to 15 repetitions completed twice per day. This exercise can be uncomfortable for the patient but is prescribed to ensure that the discomfort is manageable. Exercise prescription is guided by symptomatic response requiring that pain is produced during exercise that remains no worse upon cessation of that exercise [7,23]. Hence participants with more severe symptoms tend to commence a lighter regime to begin with. A typical programme is presented in Box 1.

To maintain the pragmatic value of the study, in both arms of the trial, the treating physiotherapists will determine the number of sessions, frequency and point of treatment cessation. However, the emphasis of the intervention arm is towards self-management with supervision and guidance only offered by the physiotherapist [7,23].

The comparator

Usual physiotherapy might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection at the discretion of the treating physiotherapist.

Prior to the recruitment of patients into the trial, the physiotherapists of Doncaster & Bassetlaw Hospitals NHS Foundation Trust who usually treat patients with rotator cuff disorders will be invited to participate in the study. A participant information sheet will be provided and explained via an initial information session delivered by the research team. If they wish to be included they will be asked to complete a consent form and return to the chief investigator within 2 weeks. During these training sessions the issue of contamination of the control arm and the implications will be discussed in an attempt to minimise contamination. The degree of any contamination will be evaluated via review of patient records and reported accordingly.

Recruitment

Inclusion criteria will be: (i) Age > 18 years, (ii) Willing and able to participate, (iii) Primary complaint of shoulder pain with or without referral into the upper limb for > 3 months, (iv) No/minimal resting shoulder pain, (v) Range of shoulder movement largely preserved, and (vi) Shoulder pain provoked consistently with resisted muscle tests, usually abduction or lateral rotation.

Exclusion criteria will be: (i) Shoulder surgery within last 6 months, (ii) Reasons to suspect systemic pathology including inflammatory disorders, (iii) Cervical repeated movement testing affects shoulder pain and/or range of movement. People who are unable to understand written and spoken English will be included in the study and NHS translation services will be accessed to accommodate their needs.

Potential trial participants will be identified from the NHS physiotherapy waiting list by a physiotherapist who usually has access to this information as part of their clinical role. Initial contact will be made through an introductory letter. Along with this letter the potential participants will also receive a participant information sheet and consent form. The letter will be followed up with a telephone call made by the physiotherapist one week later where further study information will be relayed as required and an enquiry about further participant involvement will be made. If the call recipient expresses interest in participating in the study the physiotherapist will then undertake initial telephone

Box 1 Typical loaded exercise progression

1. Week 0: Baseline assessment:
   - Resisted isometric (no movement) shoulder abduction (taking the arm out to the side) against a wall, or
   - Resisted shoulder abduction from 0 to 30° using moderate resistance from Theraband (resistive band used for training purposes).
2. Week 3: Initial follow-up:
   - Resisted shoulder abduction from 80 to 120° using light weight, e.g. tin of food.
3. Week 6: Second follow-up:
   - Resisted shoulder abduction from 80 to 120° with progressively increasing repetition and weight, e.g. heavy Theraband or dumbbell.
4. Week 12: Final follow-up/discharge.

screening for inclusion criteria i to iv and exclusion criteria i to ii. If these criteria are met then the potential participant will be invited to read the participant information sheet, ask any questions and sign the consent form prior to attending for physical examination screening for inclusion criteria v to vi and exclusion criteria iii. If the participant does not wish to pursue the discussion or does not meet the criteria they will be thanked for their time and told that their referral will continue to be treated as per usual arrangements.

Physical examination screening will also be carried out by an experienced clinical physiotherapist. The physical examination screening will take up to 30 minutes and will include assessment of neck and shoulder movements and any associated symptomatic responses as per a typical musculoskeletal examination. If potential participants do not meet inclusion criteria v to vi they will be thanked for their time, offered advice about their presenting problem in line with the physical examination screening, e.g. advice to keep the arm moving, offered a generic advice leaflet produced by the Physiotherapy department at the Doncaster & Bassetlaw Hospitals NHS Foundation Trust and told that their referral will continue to be treated as per usual arrangements. This research study will not interfere with the timing of receiving physiotherapy. The process of including or excluding participants will take place whilst the referral remains on the waiting list.

Informed consent

Prior to attending the physical examination screening a participant information sheet and consent form will be provided by post. The physiotherapist will offer an overview of the information sheet and answer any questions at the time of the initial telephone call. The potential participants will then be offered an appointment for a physical examination screening or, if more time is needed, will be offered a follow-up telephone call within the proceeding 2 weeks. If the participant does not wish to be considered for the study they will be thanked for their time and told that their referral will continue to be treated as per usual arrangements.

The potential participants will provide a signed consent form prior to the physical examination screening tests. Where consent is gained, the participants General Practitioner will also be informed of their inclusion in the study by letter. All potential participants who meet the criteria following physical examination screening will be eligible to be randomised. Those participants who do not meet the criteria will not be eligible to be randomised and will be informed of this along with the reasons. We expect only a small minority to be excluded at this stage and this aspect of the process is made clear in the information sheet.

Baseline/outcome assessment

After the participants have been assessed for eligibility and consent has been gained, prior to randomisation, they will complete a range of appropriate patient-reported outcome measures to establish baseline pain, function, quality of life and level of self-efficacy. Additionally, the participants' preference for one treatment or the other, if they had a free choice, will be noted to enable analysis of the effect of preference on outcome.

The primary aim of the proposed study is to evaluate the clinical and cost-effectiveness of self-managed loaded exercise versus usual physiotherapy for rotator cuff disorders. The primary outcome measure will be the Shoulder Pain & Disability Index (SPADI) [24] score at 12 weeks. SPADI is a self-report measure specifically developed to evaluate pain and function in patients with shoulder pathology [25]. It is a commonly used measure which has been validated for use in this patient population and a minimally clinically important change of 10 points has been identified [25]. The SPADI includes 13 items divided into 2 sub-scales; pain (5 items), disability (8 items). The responses are indicated on a visual analogue scale where 0 = no pain/no difficulty and 10 = worst imaginable pain/so difficult it requires help. The items are summed and converted to a total score out of 100.

The Short-form 36 (SF-36) is a generic measure of health related quality of life [26] and is the most widely used measure of this nature. The SPADI & SF-36 will be repeated at 12, 24 and 52 weeks and returned by post. These measures will be complemented by the patient specific functional scale (PSFS) which is a patient-specific outcome measure which investigates functional status and is intended to complement the findings of generic or condition-specific measures [27]. The PSFS has been shown to be valid and responsive in various musculoskeletal populations [28]. Due to the nature of the PSFS, this measure will be completed at baseline and then completed, until the end of the treatment episode, in the presence of the attending physiotherapist. Treatment duration is likely to be in the region of 3 months with the PSFS being completed at 1, 2 and 3 months post baseline.

We are interested in evaluating levels of adherence with treatment but also exploring possible factors that might predict non-adherence in this context. A range of such factors have been identified including level of pain at baseline, levels of physical functioning, levels of well-being [29], all of which can be captured with the aforementioned measures. However, levels of self-efficacy appear to be an important determinant of adherence [29] and so this will be captured via the General Self-efficacy scale (GSES) [30] at baseline. The GSES is a 10-item measure that has been developed to measure this construct and has been validated across different populations in different countries [31].

Due to the widely recognised limitations of clinical measures including range of movement and strength [32] these measures will not be undertaken as part of this study. In the absence of objectives measures of adherence, levels of treatment adherence will be formally measured through the use of an exercise diary including number and percentage of treatment sessions attended and percentage of exercises completed as reported by the patient.

Randomisation

Block randomisation will be carried out by an administrator based in the physiotherapy department but independent to the study. Following receipt of written informed consent and baseline assessment, a computer generated random number sequence indicating group allocation will be concealed in sealed opaque envelopes which will be consecutively numbered. The group allocation and baseline PSFS assessment will be attached to the patient referral for the attention of the treating physiotherapist in readiness for the programme of treatment.

Sample size calculation

The sample size calculation is based upon the primary outcome measure, the SPADI, where a 10-point change is regarded as a minimally clinically important change in shoulder function [24]. Assuming a standard deviation of 24 points, a power of 80% and a (two-sided) significance level of 5%, 91 participants per group will be required. We will allow for a 15% loss to follow-up and aim to recruit 105 participants per group. Data from the Physiotherapy department at Doncaster & Bassetlaw Hospitals NHS Foundation Trust indicates that 70 potentially suitable patients are referred for treatment each month. Hence a recruitment rate of 17 to 18 per month is felt to be realistic and manageable in the allotted timescale.

Data analysis

As the trial is a pragmatic parallel group RCT data will be reported and presented according to the revised CONSORT statement and statistical analyses will be performed on an intention-to-treat basis. All statistical exploratory tests will be two-tailed with $\alpha = 0.05$. Baseline demographic and health-related quality of life data (SF-36) will be assessed for comparability between the treatment groups. The primary aim is to compare the effect of loaded exercise versus usual physiotherapy. The mean SPADI total score at 12 weeks follow-up is the primary efficacy response variable. A two independent samples t-test will be used to compare mean SPADI total scores between the groups (loaded exercise and usual physiotherapy groups). In the event of differences between the groups with respect to baseline measurements, multiple regression or analysis of covariance (ANCOVA) will be used to adjust the treatment effect for these variables. Secondary outcomes will be analysed in a similar way. For the repeated PSFS assessments at baseline and termination of treatment and (SPADI, SF-36) assessments at baseline, 12, 24 and 52 weeks a summary measure such as the Area Under the Curve (AUC) will be calculated for each patient. A two independent samples t-test will be used to compare mean AUC between the groups (loaded exercise and usual physiotherapy groups).

Economic analysis

A cost-utility analysis will be undertaken using a NHS and Personal Social Services (PSS) perspective. The health outcomes will be expressed in terms of quality adjusted life years (QALYs). The QALY combines length and quality of life into a single index number between 0 and 1 where 0 corresponds to a health state judged to be equivalent to death and 1 corresponds to optimal health. The SF-6D will be used to calculate QALYs. The SF-6D is composed of six multi-level dimensions which describes 18,000 health states in all. The SF-6D will be derived from a selection of SF-36 items which will be completed at baseline and follow-up visits during the trial. Any patient who completes the SF-36 can be uniquely classified according to the SF-6D.

Data regarding resource utilisation will be collected via patient notes and patient questionnaire returned at 3, 6 and 12 months along with the other measures of clinical outcome. A range of costs will be considered including the number of physiotherapy sessions attended, medications (including steroid injections) and referrals to surgery (with associated follow-up). These and other unit costs will be taken from the most recent National Reference Costs, British National Formulary and PSSRU publication 'Unit costs of health and social care'. This will enable an estimation of the total cost for each participant as well as the average total cost for each treatment group.

As with the clinical outcomes, economic analysis will be on an intention-to-treat basis. The between groups differences will be compared using 2-independent samples t-tests. The QALY value will be estimated using straight line interpolation between data points. So, for example, if a patient reports quality of life (QoL) equal to 1 at each time point during the trial this will equate to a QALY of 1 and if they report QoL equal to 0.5 at each time point during the trial this will equate to a QALY of 0.5. Mean incremental costs and QALYs will be combined into an incremental cost effectiveness ratio (ICER) to enable assessment of the relative cost-utility. Sampling uncertainty will be represented by plots on the cost-effectiveness plane and associated cost-effectiveness acceptability curves (CEACs). To reflect uncertainty and to

enable valid inferences to be made, any missing data will be imputed using multiple imputation. This process will enable a decision about the acceptability of the intervention in terms of an effective use of NHS resources.

The qualitative investigation

The primary objective of the qualitative investigation is to explore perceptions and experience of the study participants. The intervention is largely self-managed and can be uncomfortable for patients which is in contrast to the majority view of usual physiotherapy [22]. Hence this aspect of the study is important to provide complementary data to the findings of the RCT because these factors might serve as barriers to successful outcome and/or real world implementation.

Recruitment

Participants for the qualitative aspect of the study will be purposively selected from the treating physiotherapists and those patients recruited to the intervention arm of the RCT. All patient participants randomised to the intervention arm of the RCT will be eligible to enter and will be selected to gain a balanced sample of male/female and treatment adherers/non-adherers. All therapists involved in the delivery of the intervention will be eligible to enter.

Information relating to this aspect of the study will be included in the initial participant information sheet. The chief investigator (CL) will identify potential patient participants from the data generated by the RCT and will initially contact them by telephone to discuss whether they would be able to discuss their experiences. If their response is favourable then a separate consent form will be posted to them and completed prior to being invited to attend an individual interview at their convenience. The interviews may be conducted at the patients' home or physiotherapy department.

The eligible physiotherapists will be approached as a group during the regular training sessions held throughout the duration of the trial, led by the chief investigator, and an open letter including a participant information sheet and consent form will invite them to contact CL with a view to discussing participation in this aspect of the study. If the physiotherapist wishes to participate then a mutually convenient individual interview at the physiotherapy department will be scheduled.

It is expected that interviews will last between 30 to 60 minutes. Purposive sampling will continue until data saturation. Data saturation is the point where on-going analysis reveals no new themes emerging from the data but it is estimated that 10 to 20 patient interviews will be required and up to 10 therapist interviews. Once it is thought that data saturation has been attained, 2 more interviews will be conducted to confirm this.

Data collection

Interviews will be directed by topic guides These discussions will be recorded using a digital voice recorder and subsequently transcribed verbatim.

Data analysis

CL and SM will analyse the data using the framework approach.

The framework approach has been developed specifically for applied research in which the objectives of the investigation are set *a* priori [33]. The 5 stages of data analysis associated with the framework approach are as follows:

1. Familiarisation – identifying key ideas and themes
2. Identifying a thematic framework – identifying all key issues, concepts and themes by which the data can be examined
3. Indexing – application of the thematic framework to all the data
4. Charting – Organisation of the data according to the defined thematic framework to which they relate to form common charts
5. Mapping and Interpretation – using the charts to define concepts, map the range and nature of phenomena, create typologies and find associations with a view to providing explanations for the findings.

One clear advantage of the framework method is the systematic and visible stages of the analysis process [34,35]. The patients and physiotherapists involved will be invited to inspect the outcomes of the analysis in an attempt to maximise validity of the interpretations.

Patient & public involvement

A formal patient and public involvement event was held with the aim of seeking lay opinion regarding the design and conduct of the SELF study. A focus group led by CL and JA was undertaken with a sample of volunteers currently attending for physiotherapy at Doncaster & Bassetlaw Hospitals NHS Foundation Trust. In summary, the lay group found our initial proposals acceptable but suggested that initial approach by letter, a full description of the content of the treatment arms, an enhanced exercise diary incorporating a visual illustration of any prescribed exercise and encouragement to the physiotherapists involved to help set specific treatment goals might improve the design and conduct of the SELF study. These features have been incorporated into this current version of the protocol.

Ethical approval

The protocol was approved by the National Research Ethics Service Committee Yorkshire & the Humber – Leeds West, UK on the 6th January 2012.

Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
CL was responsible for the conception of the idea and drafting of the initial manuscript. All authors were involved in the design, revisions to the manuscript and final approval of the version to be published.

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Appendix 11

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds West
First Floor
Millside
Mill Pond Lane
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Telephone: 0113 3050122
Facsimile: 0113 8556191

06 January 2012

Mr Chris Littlewood
Research Fellow
University of Sheffield
School of Health & Related Research
Regent Court, 30 Regent Street
Sheffield
S1 4DA

Dear Mr Littlewood

Study title:	**A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders (The SELF study).**
REC reference:	**11/YH/0443**
Protocol number:	**n/a**

Thank you for your letter of 05 January 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair and Professor Topping.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

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

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

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

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

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

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

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

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

Approved documents

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

Document	*Version*	*Date*
Evidence of insurance or indemnity		07 October 2011
Interview Schedules/Topic Guides	1.1 Patient	02 October 2011
Interview Schedules/Topic Guides	1.1 Physiotherapist	02 October 2011
Investigator CV	1.1	02 October 2011
Letter of invitation to participant	2.2	19 December 2011
Other: Baseline Assessment Pack- General Self- Efficacy Questionnaire	1.1	02 October 2011
Other: Follow-up Assessment Pack - Covering Letter	1.1	02 October 2011
Other: Follow-up Assessment Pack - Shoulder Pain and Disability Index	1.1	02 October 2011
Other: Follow-up Assessment Pack - Health Status Questionnaire	1.1	02 October 2011
Other: The Patient- Specific Functional Scale	1.1	02 October 2011
Other: CV - Sue Mawson	1.1	02 October 2011
Other: CV - Stephen Walters	1.1	02 October 2011
Other: CV - Stephen May	1.1	02 October 2011
Other: Baseline assessment pack	2.2	19 December 2011
Participant Consent Form	2.2	19 December 2011
Participant Consent Form: Physiotherapist-Qualitative	2.2	05 January 2012
Participant Information Sheet	2.2	19 December 2011
Participant Information Sheet: Physiotherapist-RCT	2.3	05 January 2012
Participant Information Sheet: Physiotherapist-Qualitative	2.2	05 January 2012
Protocol	1.1	02 October 2011
Questionnaire: Resource Utilisation Questionnaire	1.1	02 October 2011
Questionnaire: Shoulder pain and disability index	2.2	19 December 2011
Questionnaire: Patient specific function scale	2.2	19 December 2011

Questionnaire: Health status	2.2	
Questionnaire: General self efficacy	2.2	19 December 2011
REC application	3.2	18 October 2011
Referees or other scientific critique report		09 August 2011
Referees or other scientific critique report	Scientific Review 1	
Referees or other scientific critique report	Scientific Review 2	
Response to Request for Further Information		21 December 2011
Response to Request for Further Information		05 January 2012
Sample Diary/Patient Card	1.1	02 October 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

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

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

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

Feedback

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

Further information is available at National Research Ethics Service website > After Review

11/YH/0443	**Please quote this number on all correspondence**

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

Yours sincerely

pp **Dr Rhona Bratt**
Chair

Appendix 12

Patient Participant Information Sheet

Chief Investigator: Chris Littlewood

1. Study title

A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study

2. Invitation paragraph

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.

3. What is the purpose of the study?

Shoulder pain is the third most common reason for consultation with a physiotherapist and disorders of the shoulder muscles and tendons (rotator cuff) are thought to be the commonest cause of this pain. People with this disorder typically receive a course of physiotherapy, which might include a range of treatments, e.g. exercise, stretches, massage, ultrasound etc, but not enough is known about the relative effectiveness of these treatments.

The purpose of this study is to evaluate whether a self-managed exercise programme is more effective than usual physiotherapy in reducing pain and improving shoulder function in people with rotator cuff disorders. As part of this study we will also be inviting some people to discuss their experience of physiotherapy.

4. Why have I been invited?

You have been chosen based upon the details provided on your physiotherapy referral letter and the details that you have provided about yourself and your shoulder complaint. We intend to recruit 210 people with similar problems over a 12 month period.

5. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

6. What will happen to me if I take part?

Initially you will be invited to attend the physiotherapy department to undergo a physical examination by a chartered physiotherapist to see whether you are eligible to be included in the next phase of the study. This examination will last up to 30 minutes and will involve moving your shoulder, your neck and assessing the strength of the shoulder muscles. These tests will help us to decide if your shoulder complaint is caused by the muscles and tendons and if you meet these criteria you will be eligible to continue in the study. If you do not meet the criteria then you will not be eligible to take any further part in the research study and your next physiotherapy appointment will be scheduled in line with usual arrangements. We expect that only a small minority will not be eligible to continue in the study at this stage.

If you are eligible to continue, you will then be asked to complete some questionnaires to help us understand how your shoulder problem affects you now. This will take about 20 minutes.

Because we don't know which way of treating patients is best we need to compare the different treatments. To do this we carry out a randomised controlled trial which means that we put people into groups and offer each group a different treatment. The results are then compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). So, once you have completed the questionnaires you will be randomly assigned to receive a self-managed exercise programme under the guidance of a physiotherapist or usual physiotherapy which might include a range of treatments, e.g. exercise, stretches, massage, ultrasound treatment. There is an equal chance that you will be treated with one option or the other.

If you are asked to undertake some exercises at home you will also need to complete a very brief exercise diary to let us know how many exercises you managed to complete. The end of treatment will be determined by the physiotherapist you see in consultation with yourself. In our experience most people will have completed treatment by three months but you will be involved in the research for twelve months. If you agree to take part in this research we will send you copies of two of the questionnaires by post to complete after 3, 6 and 12 months as well as one further questionnaire to help us determine the resources needed to treat your shoulder problem. This will take about 15 minutes each time.

During the study we will also be inviting up to 20 people to attend an individual meeting with a member of the research team to discuss their experience of the treatment received. Such an interview would be quite informal and would last up to one hour in the comfort of your own home or in a private room in the physiotherapy department.

7. Will I be recorded and how will the media be used?

If you are invited to attend for an interview and agree to participate then the subsequent discussion will be recorded using a digital recorder. This recording will be converted into text and some quotes from the interview might be used when we write the study report. Any such quotations or references to the discussion will be anonymised so that no one else will know who made the comments. No other use will be made of the recordings of the interview.

8. What do I have to do?

We expect that you will make yourself available for the physiotherapy appointments, which will be scheduled at a mutually convenient time, as well as being prepared to follow the advice offered by the treating physiotherapist. We also expect that you will complete the questionnaires we send you and return them to enable us to evaluate the effectiveness of the treatment you receive.

9. Expenses & payments

Participants will not receive financial reward for taking part in this study but travel expenses can be claimed for cost incurred when travelling to the physiotherapy department for your initial assessment to see whether you were eligible to enter the study. Also, for those people who attend the interview travel expense can be claimed at usual NHS rates.

10. What are the possible disadvantages and risks of taking part?

Apart from the time taken to complete the questionnaires on four separate occasions, there are no disadvantages or risks to taking part in this research. Essentially you will be receiving a course of physiotherapy as you would expect following a referral to the physiotherapy department.

11. What are the possible benefits of taking part?

It is expected that you will gain benefit from the treatment that is prescribed. Furthermore, the information that we gain from this study will help inform future research and might also be of direct benefit to other people with similar shoulder complaints.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers and we will do our best to answer your questions. Please contact Chris Littlewood on 0114 222 0888. If you remain unhappy and wish to complain formally you can do this via the NHS complaints procedure. Further details can be obtained from Sharon Williams on 01302 553140 who is the contact for Patient Advice & Liaison Services (PALS) at Doncaster Royal Infirmary.

In the event that something does go wrong and you are harmed during this research and this is due to someone's negligence, then you may have grounds for a legal action against Doncaster & Bassetlaw NHS Foundation Trust but you may have to pay for your legal costs. The normal NHS and the University of Sheffield complaints mechanisms will still be available to you.

13. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. You will not be identifiable in any reports or publications. To enable the follow-up questionnaires to be sent out to you and to enable us to contact you to invite a selection of people to be interviewed the chief investigator, Chris Littlewood, will have access to your name and address. These details will be kept securely in a locked filing cabinet in the University of Sheffield and, where necessary, electronic files will be stored on a password protected computer.

As a matter of normal research practice, your own GP will be notified of your participation in the study. Your agreement to this notification will be sought prior to entering the study.

14. What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, the chief investigator, Chris Littlewood, will tell you and discuss whether you should continue in the study. If you decide not to continue your care will continue in line with usual arrangements. If you decide to continue in the study you may be asked to sign an agreement outlining the discussion.

15. What will happen if I don't want to carry on with the study?

You are free to withdraw from treatment or from the study at any time but if this is the case we would be grateful if you would still consider completing the questionnaires to let us know how your shoulder complaint progresses over time. The information we have about your shoulder complaint may still be used in a confidential manner.

16. What will happen to the results of the research study?

It is anticipated that the results of the study will be published in peer reviewed journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

17. Who is organising and funding the research?

The study is organised by a research team led by the chief investigator, Chris Littlewood, who is a chartered physiotherapist currently working as a Research Fellow in the School of Health & Related Research, University of Sheffield.

The study has been funded by the National Institute for Health Research.

18. Who has ethically reviewed the study?

The Leeds West Research Ethics Committee have reviewed the study and offered ethical approval. The Doncaster & Bassetlaw Hospitals NHS Trust Research and Development Committee has reviewed and approved the study.

19. Contact for further information,

Mr Chris Littlewood

School of Health & Related Research, Regent Court, 30 Regent Street, Sheffield, S1 4DA

Tel: 0114 222 0888

E-mail: c.littlewood@sheffield.ac.uk

You may keep this participant information sheet and one of the signed consent forms.

Thank you for considering taking part in this study

Appendix 13

Patient Consent Form - RCT

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study

Name of Researcher: Chris Littlewood

Please initial box

1. I confirm that I have read and understand the information sheet (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to my GP being informed of my participation in the study ☐
4. I understand that relevant sections of my physiotherapy notes and data collected during the study may be looked at by individuals from the University of Sheffield, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I understand that the lead researcher requires access to my personal contact details to send the postal questionnaires to me ☐
6. I understand that I might be contacted after completion of the treatment to see whether I would be willing to discuss my experience. ☐
7. If you agreed to question 4: I consent to audio-taping of the interview and agree that anonymous direct quotations may be used for the purpose of this research. ☐
8. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

When completed, 1 for participant; 1 for researcher site file; 1 (original) to be kept in notes

Appendix 14

Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds West
First Floor
Millside
Mill Pond Lane
Leeds
LS6 4RA

Tel: 0113 30 50116
Fax:

19 December 2012

Mr Chris Littlewood
Research Fellow
University of Sheffield
School of Health & Related Research
Regent Court, 30 Regent Street
Sheffield
S1 4DA

Dear Mr Littlewood

Study title:	**A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders (The SELF study).**
REC reference:	**11/YH/0443**
Protocol number:	**n/a**
Amendment number:	**2**
Amendment date:	**12 November 2012**
IRAS project ID:	**62692**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	1.2	12 November 2012
Notice of Substantial Amendment (non-CTIMPs)	2	12 November 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

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

11/YH/0443:	**Please quote this number on all correspondence**

Yours sincerely

p.p.

Dr Rhona Bratt
Chair

E-mail: marcneal@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Emma Hannaford, Doncaster & Bassetlaw Hospitals NHS Foundation Trust*
Trevor Rogers, Doncaster & Bassetlaw NHS Foundation Trust

NRES Committee Yorkshire & The Humber - Leeds West

Attendance at Sub-Committee of the REC meeting on 18 December 2012

Name	*Profession*	*Capacity*
Dr Martin Elliott	Consultant Paediatric Oncologist	Expert
Mr Marc Neal		None
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Expert

Appendix 15

Resource Use Questionnaire

The answers you give to the question on this questionnaire will help us to understand the costs associated with the treatment for your shoulder problem. Please complete the questions as accurately as possible.

(Please circle the appropriate response)

In the last three months…….

Have you seen your NHS Physiotherapist for anything related to your shoulder problem? Y/N

If yes, how many times have you seen them in total? _____

Have you seen your GP or practice nurse for anything related to your shoulder problem? Y/N

If yes, how many times have you seen them? _____

Have you seen any other NHS Health care professionals, e.g. consultant, surgeon, extended scope physiotherapist for anything related to your shoulder problem? Y/N

If yes, how many times have you had these visits? _____

Apart from NHS physiotherapy, have you received any other treatment provided by the NHS? Y/N

If yes, what has this been and how many times have you received it?

Injection _____

Surgery _____

Medication (please state) _____

Other (please state) _____

Other (please state) _____

Have you had any consultations with private therapists? Y/N

If yes, how many times has this been for:

Physiotherapy _____

Osteopathy _____

Chiropractic _____

Acupuncture (please state) _____

Other (please state) _____

Other (please state) _____

Have you incurred any costs due to your shoulder or any related treatment? Y/N

If yes, about how much has this been? _____

Have you had assistance from any family and friends? Y/N

If yes, about how many hours per week has this typically been? _____

Have you taken time off work due to your shoulder or any related treatment? Y/N

If yes, about how many hours per week has this typically been? _____

Have you taken time away from activities other than work due to your shoulder or any related treatment? Y/N

If yes, about how many hours per week has this typically been? _____

Thank you for taking the time to complete this questionnaire

Appendix 16

Patient Consent Form - Qualitative

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study

Name of Researcher: Chris Littlewood

	Please initial box
1. I confirm that I have read and understand the information sheet (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I consent to audio-taping of the interview and agree that anonymous direct quotations may be used for the purpose of this research.	☐
4. I agree to take part in the above study.	☐

_____	_____	_____
Name of Participant	Date	Signature
__		
_____	_____	_____
Name of person taking consent	Date	Signature

When completed, 1 for participant; 1 for researcher site file; 1 (original) to be kept in notes

Appendix 17

Physiotherapist Participant Information Sheet - Qualitative

Chief Investigator: Chris Littlewood

1. Study title

A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study

2. Invitation paragraph

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.

3. What is the purpose of the study?

As you are aware we have been conducting a clinical trial to evaluate the effectiveness of self-managed exercise for rotator cuff disorders. From the previous research that we have undertaken it seems that a majority of physiotherapists would offer a wide range of physiotherapy treatments and encourage their patients to return to their clinic to receive therapist-led interventions, e.g. mobilisation, massage, electrotherapy, acupuncture, corticosteroid injections, as opposed to self-managed exercise alone.

We expect that the prescription of self-managed exercise alone might have raised some issues for both patients and physiotherapists and hence we are keen to explore the experiences of a sample of the patients and physiotherapists involved in this aspect of the study. Through an investigation of your experience we will be able to offer context to the findings of the clinical trial as well as better understand any barriers to implementation of this method into real-world practice if the results of the study indicate that this would be appropriate.

4. Why have I been chosen?

You have been chosen because you kindly volunteered to deliver the self-managed exercise intervention during the clinical trial.

5. Do I have to take part?

It is 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 a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

6. What will happen to me if I take part?

The chief investigator, Chris Littlewood, will contact you to arrange a convenient time and location to meet to undertake an in-depth interview. Such an interview would be quite informal and would last up to one hour where you will be asked questions relating to your experience during the trial.

7. Will I be recorded and how will the media be used?

If you agree to participate then the interview will be recorded using a digital recorder. This recording will be converted into text and some quotes from the interview might be used when we write the study report. Any such quotations or references to the discussion will be anonymised so that no one else will know who made the comments. No other use will be made of the recordings of the interview.

8. What do I have to do?

All you have to do is make yourself available at the mutually convenient time that has been pre-arranged. Then, be prepared to discuss your ideas and thoughts as guided by the researcher. No further commitments are required.

9. Expenses & payments

Participants will not receive expenses or payments for taking part in this research.

10. What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to taking part in this research.

11. What are the possible benefits of taking part?

There is no intended benefit to you from taking part in this study. However, the information we get from this study may help us to implement knowledge generated from research into practice.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers and we will do our best to answer your questions. Please contact Chris Littlewood on 0114 222 0888. If you remain unhappy and wish to complain formally you can do this via the NHS complaints procedure. Further details can be obtained from Sharon Williams on 01302 553140 who is the contact for Patient Advice & Liaison Services (PALS) at Doncaster Royal Infirmary.

In the event that something does go wrong and you are harmed during this research and this is due to someone's negligence, then you may have grounds for a legal action against Doncaster & Bassetlaw NHS Foundation Trust but you may have to pay for your legal costs. The normal NHS and the University of Sheffield complaints mechanisms will still be available to you.

13. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Direct quotations from the discussion may be used when writing up the research however these quotes will be anonymous.

14. What will happen to the results of the research study?

It is anticipated that the results of the study will be published in peer reviewed journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish. At no time will any participants be identified in any report/publication.

15. Who is organising and funding the research?

The study is organised by a research team led by the chief investigator, Chris Littlewood, who is a chartered physiotherapist currently working as a Research Fellow in the School of Health & Related Research, University of Sheffield.

The study has been funded by the National Institute for Health Research

16. Who has ethically reviewed the study?

The Leeds West Research Ethics Committee have reviewed the study and offered ethical approval. The Doncaster & Bassetlaw Hospitals NHS Trust Research and Development Committee has reviewed and approved the study.

17. Contact for further information,

Mr Chris Littlewood

School of Health & Related Research, Regent Court, 30 Regent Street, Sheffield, S1 4DA

Tel: 0114 222 0888

E-mail: c.littlewood@sheffield.ac.uk

You may keep this participant information sheet and one of the signed consent forms.

Thank you for considering taking part in this study

Appendix 18

Physiotherapist Consent Form - Qualitative

Identification Number for this trial:

CONSENT FORM

Title of Project: A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders: the SELF study.

Name of Researcher: Chris Littlewood

Please initial box

1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

3. I consent to audio-taping of the interview and agree that direct quotations may be used for the purpose of this research ☐

4. I understand that data collected during the study may be looked at by individuals from the University of Sheffield, from regulatory authorities or from the NHS Trust. I give permission for these individuals to have access to this data. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of person Taking consent	Date	Signature

When completed, 1 for participant; 1 for researcher site file;