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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 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

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) and the research was conducted according to the Declaration of Helsinki.

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 operationalized 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**

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

**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 Statement
The authors report no conflicts of interest.

Role of the funding source
The funding body have played no role in the design, writing of the manuscript or decision to submit for publication.


Figure 1 Participant flow through the study

Assessed for eligibility (n= 45)

Excluded (n= 21)
- Not meeting inclusion criteria (n= 16)
- Declined to participate (n= 1)
- Other reasons (n= 4)
  - Consent form not returned (n = 2)
  - Admitted to hospital (n = 1)
  - Self-resolution (n = 1)

Randomised (n= 24)

Allocated to self-managed exercise group (n= 12)
- Received allocated intervention (n= 12)
- Did not receive allocated intervention (n= 0)

Lost to follow-up (n= 0)
Discontinued intervention (n= 1) – unable to arrange convenient follow-up appointments

Analysed (n= 12)
- Excluded from analysis (n= 0)

Allocated to usual physiotherapy treatment group (n= 12)
- Received allocated intervention (n= 12)
- Did not receive allocated intervention (n= 0)

Lost to follow-up (n= 0)
Discontinued intervention (n= 0)

Analysed (n= 12)
- Excluded from analysis (n= 0)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Self-managed exercise</td>
</tr>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Age (years) (range)</td>
<td>12</td>
</tr>
<tr>
<td>Gender - male</td>
<td>12</td>
</tr>
<tr>
<td>Duration of shoulder symptoms (months) (range)</td>
<td>12</td>
</tr>
<tr>
<td>SPADI (SD)</td>
<td>12</td>
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<td>SF-36 Bodily pain (SD)</td>
<td>12</td>
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<tr>
<td>SF-36 Physical functioning (SD)</td>
<td>12</td>
</tr>
<tr>
<td>GSES (SD)</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 1 Baseline characteristics of the participants by treatment group

For the SPADI (Shoulder Pain and Disability Index) higher scores indicate 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
Figure 2 Description of the interventions offered (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Self-managed exercise</th>
<th>Usual physiotherapy treatment</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>SPADI(^1)</td>
<td>12</td>
<td>20.9</td>
<td>19.2</td>
</tr>
<tr>
<td>SF-36 Physical functioning(^2)</td>
<td>12</td>
<td>78.2</td>
<td>17.7</td>
</tr>
<tr>
<td>SF-36 Role-physical(^2)</td>
<td>12</td>
<td>88.5</td>
<td>18.0</td>
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<tr>
<td>SF-36 Bodily pain(^2)</td>
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<td>61.4</td>
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<td>SF-36 Vitality(^2)</td>
<td>12</td>
<td>69.3</td>
<td>12.1</td>
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<td>SF-36 Social functioning(^2)</td>
<td>12</td>
<td>45.8</td>
<td>11.1</td>
</tr>
<tr>
<td>SF-36 Role emotional(^2)</td>
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<td>SF-36 Mental health(^2)</td>
<td>12</td>
<td>84.6</td>
<td>12.9</td>
</tr>
</tbody>
</table>

Table 2 Differences in outcome scores between the self-managed exercise and usual physiotherapy treatment groups at three months

\(^1\) Higher scores indicate 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