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1 Self-managed loaded exercise versus 2 usual physiotherapy treatment for 3 rotator cuff tendinopathy: a pilot 4 randomised controlled trial

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30 **Abstract**

31 **Objectives:** Rotator cuff tendinopathy is a common source of shoulder pain characterised by
32 persistent and/or recurrent problems for a proportion of sufferers. The aim of this study was to pilot
33 the methods proposed to conduct a substantive study to evaluate the effectiveness of a self-
34 managed loaded exercise programme versus usual physiotherapy treatment for rotator cuff
35 tendinopathy.

36 **Design:** A single-centre pragmatic unblinded parallel group pilot randomised controlled trial.

37 **Setting:** One private physiotherapy clinic, northern England.

38 **Participants:** Twenty-four participants with rotator cuff tendinopathy.

39 **Interventions:** The intervention was a programme of self-managed loaded exercise. The control
40 group received usual physiotherapy treatment.

41 **Main outcomes:** Baseline assessment comprised the Shoulder Pain and Disability Index (SPADI) and
42 the Short-Form 36, repeated three months post randomisation.

43 **Results:** The recruitment target was met and the majority of participants (98%) were willing to be
44 randomised. 100% retention was attained with all participants completing the SPADI at three
45 months. Exercise adherence rates were excellent (90%). The mean change in SPADI score was -23.7
46 (95% CI -14.4 to -33.3) points for the self-managed exercise group and -19.0 (95% CI -6.0 to -31.9)
47 points for the usual physiotherapy treatment group. The difference in three month SPADI scores was
48 0.1 (95% CI -16.6 to 16.9) points in favour of the usual physiotherapy treatment group.

49 **Conclusions:** In keeping with previous research which indicates the need for further evaluation of
50 self-managed loaded exercise for rotator cuff tendinopathy, these methods and the preliminary
51 evaluation of outcome offer a foundation and stimulus to conduct a substantive study.

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54 **Keywords:** Randomised controlled trial, rotator cuff tendinopathy, exercise, rehabilitation, quality of
55 life

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62 **Introduction**

63 Rotator cuff tendinopathy is regarded as a common and burdensome source of shoulder pain with
64 prevalence estimated to be as high as 14% in the general working-age population [1]. Impaired
65 shoulder function impacts significantly upon activities of daily living, including eating, dressing and
66 working [2]. The course of rotator cuff tendinopathy, for a significant proportion of sufferers, is
67 characterised by persistent pain and/or disability and/or recurrent episodes [3]. Costs in the first 6
68 months following primary care contact have been estimated to be €690 per person which means
69 that costs attributable to shoulder pain in the United Kingdom are in the region of €345 million or
70 £310 million per year [4,5].

71 A range of interventions, both conservative and surgical, are currently used to treat this condition
72 [5]. Although the mechanism of action is poorly understood [6], the potential benefits of loaded
73 exercise, i.e. exercise against gravity or resistance, in comparison to other conservative or surgical
74 treatment strategies have been reported in a systematic review [7]. However, this review, which
75 included four studies regarded as presenting a low risk of bias, recognised the paucity of evidence
76 and other methodological limitations of the evidence base, including no treatment control groups
77 and a lack of use of validated outcome measures, when drawing this conclusion and subsequently
78 recommended that further high-quality research should be conducted.

79 In keeping with the findings of the systematic review by Littlewood et al [7], the purpose of this
80 study was to pilot the methods proposed to conduct a substantive randomised controlled trial (RCT)
81 to evaluate the effectiveness of a self-managed exercise programme versus usual physiotherapy
82 treatment for rotator cuff disorders/ tendinopathy.

83 **Methods**

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

87 **Aims and objectives**

88 The aim of this study was to pilot the methods proposed to conduct a substantive study to evaluate
89 the clinical and cost-effectiveness of a self-managed loaded exercise programme versus usual
90 physiotherapy treatment for rotator cuff tendinopathy. The objectives were to evaluate:

- 91 a. The process of recruitment and retention rates
- 92 b. Willingness of participants to be randomised
- 93 c. The extent of contamination between treatment groups
- 94 d. Participant adherence with treatment.

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

97 **Design**

98 A single-centre pragmatic unblinded parallel group RCT.

99 **Setting**

100 One private physiotherapy clinic in West Yorkshire, northern England.

101 **Participants**

102 Between January and June 2012 participants were recruited according to the following criteria: (i)
103 Age > 18 years, (ii) Willing and able to participate, (iii) Primary complaint of shoulder pain with or
104 without referral into the upper limb for > 3 months, (iv) No/ minimal resting shoulder pain, (v) Range
105 of shoulder movement largely preserved, and (vi) Shoulder pain provoked consistently with resisted
106 muscle tests, usually abduction or lateral rotation. Participants were excluded according to the

107 following criteria: (i) Shoulder surgery within last 6 months, (ii) Reasons to suspect systemic
108 pathology including inflammatory disorders, (iii) Cervical repeated movement testing affects
109 shoulder pain and/ or range of movement. Participants were recruited via posters, word of mouth
110 and advertisements in the local press.

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

118 **Baseline/ Outcome Assessment**

119 Participants were initially assessed for eligibility and then consent was gained. Subsequently the
120 patient-reported outcome measures were completed to establish baseline pain, function, quality of
121 life and level of self-efficacy. After completion of the baseline measures, the participants were
122 randomly allocated to the self-managed exercise or usual physiotherapy treatment groups. The
123 measures of pain, function and quality of life were repeated three months post randomisation by
124 the participants and returned by post.

125 The primary outcome measure was the Shoulder Pain and Disability Index (SPADI) [8]. The SPADI is a
126 self-report measure specifically developed to evaluate pain and function in patients with shoulder
127 pathology [9]. It is a commonly used and recommended measure that has been validated for use in
128 this patient population and a minimally clinically important change of 10 points has been identified
129 [9,10]. The SPADI includes 13 items divided into two sub-scales; pain (5 items), disability (8 items).
130 The responses are indicated on a visual analogue scale where 0 = no pain/no difficulty and 10 =

131 worst imaginable pain/so difficult it requires help. The items are summed and converted to a total
132 score out of 100 where a high score indicates more pain.

133 The secondary outcome measure, the Short-form 36 (SF-36) is a generic measure of health related
134 quality of life [11] and is the most widely used measure of this nature.

135 We expected that success of the self-managed exercise intervention was likely to be related to the
136 level of exercise adherence and hence we were interested in evaluating this as well as exploring
137 possible factors that might predict non-adherence in this context. A range of such factors have been
138 identified including level of pain at baseline, levels of physical functioning, levels of well-being [12],
139 all of which can be captured with the aforementioned measures. However, levels of self-efficacy
140 appear to be an important determinant of adherence [12] and so the General Self-efficacy scale
141 (GSES) [13] was completed at baseline. The GSES is a 10-item measure that has been developed to
142 measure this construct and has been validated across different populations in different countries
143 [14]. In the absence of objective measures of adherence, levels of treatment adherence were
144 measured through the use of an exercise diary indicating the number and percentage of exercises
145 completed as reported by the patient.

146 **Randomisation**

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

154 **The self-managed exercise intervention**

155 The intervention, self-managed loaded exercise, was prescribed by the physiotherapist but
156 completed by the patient independently. It involved exercising the affected shoulder against gravity,
157 a resistive therapeutic band or hand weight over three sets of 10 to 15 repetitions completed twice
158 per day. Exercise prescription was guided by symptomatic response requiring that pain was
159 produced during exercise, but overall, symptoms were no worse upon cessation of that exercise
160 [15,16]. The exercise was prescribed and operationalized within a self-managed framework which
161 included focus upon knowledge translation, exercise/ skill acquisition, self-monitoring, goal setting,
162 problem solving and pro-active follow-up. The programme has been described in full elsewhere [17].

163 **The comparator**

164 Usual physiotherapy treatment might include a range of interventions including advice, stretching,
165 exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection
166 at the discretion of the treating physiotherapist [5].

167 Due to the private-practice setting in which the study was conducted, an agreement had to be
168 reached prior to initiation of the study regarding how many sessions would be funded through the
169 research for each of the trial arms respectively. Based upon the authors' prior clinical experience it
170 was agreed that participants in the self-managed exercise arm could receive a maximum of four
171 sessions funded by the research and based upon information from the clinic it was agreed that
172 participants in the usual physiotherapy treatment arm could receive a maximum of eight funded
173 sessions.

174 **Sample size calculation**

175 The primary aim of this study was to pilot the methods proposed to conduct a substantive study not
176 to detect a true difference between treatment groups. In this context it was felt that a total of 24
177 participants would be sufficient for this purpose [18].

178 **Data analysis**

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

186 **Results**

187 Figure 1 shows the study profile; 45 people were assessed for eligibility and 30 (67%) of these were
188 potentially eligible for the study. Only one out of 45 (2%) declined to participate due to an
189 unwillingness to be randomised. Twenty-four participants were randomly assigned to the self-
190 managed exercise or usual physiotherapy treatment groups. The mean age at baseline of the
191 participants was 63.2 years (range 44-79) and 50% (12/24) were male. The mean duration of
192 symptoms was 38.6 months (range 3 to 168) and mean SPADI score was 42.2 (range 15.4 to 73.1);
193 higher scores indicate higher pain and disability. The baseline characteristics of the participants by
194 treatment group are presented in table 1. The groups appeared well balanced at baseline except
195 that the self-managed exercise group reported higher baseline shoulder pain and disability via the
196 SPADI and the usual physiotherapy treatment group reported a longer mean duration of symptoms
197 (49 versus 29 months). This estimate is influenced by one participant who reported duration of 168
198 months. When the influence of this outlier was removed the revised estimate of mean duration of
199 symptoms was 37 months for the usual physiotherapy group.

200 **Number and content of treatment sessions**

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

204 massage within their treatment packages. Participants in the usual physiotherapy treatment group
205 received a range of treatments; described in figure 2.

206 **Adherence**

207 In the self-managed exercise intervention group, eleven out of 12 (92%) participants returned self-
208 report exercise adherence data in the form of annotated exercise diaries. Of the eleven, seven
209 participants returned complete data and four returned partial data. Complete data refers to the
210 return of consecutive annotated diaries dated from initial assessment to final follow-up. According
211 to the exercise protocol, the participants were required to exercise twice daily and so where this
212 occurred 100% adherence was recorded for that day. Of the seven participants who returned
213 completed data, the mean percentage adherence was 89% (range 77 to 99%). Of the four
214 participants who returned partial data, the mean percentage adherence was 93% (range 83 to
215 100%). Overall self-report adherence was 90% (range 77 to 100%).

216 **Self-efficacy**

217 The mean GSES score at baseline for the self-managed exercise group was 33.5 (SD 3.9) and 35.3 SD
218 3.4) for the usual physiotherapy treatment group.

219 **Clinical outcomes**

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

224 Table 2 shows the differences in outcome scores between the self-managed exercise and usual
225 physiotherapy treatment groups at three months. The mean SPADI score at 3 months was 20.9 (SD
226 19.2) points for the self-managed exercise group and 20.7 (SD 20.3) points for the usual
227 physiotherapy treatment group. The difference in three month SPADI scores was 0.1 (95% CI -16.6
228 to 16.9) points in favour of the usual physiotherapy treatment group. The 95% confidence interval

229 includes a 10-point difference in SPADI scores between the groups which is a clinically relevant range
230 confirming the value of progressing with the substantive study.

231 **Discussion**

232 The primary aim of this study was to pilot the research methods and self-managed exercise
233 intervention proposed for a substantive study. With reference to the specific objectives of the pilot
234 study; a) recruitment was to target and retention rates were excellent; b) the vast majority of
235 participants were willing to be randomised; c) contamination was minimal, and; d) exercise
236 adherence rates were excellent. Finally, the outcome measures used were acceptable, in terms of
237 100% completion at three months, and preliminary statistical analysis indicated an improvement in
238 outcomes in both groups.

239 The process of recruitment and randomisation ran smoothly. The self-managed exercise
240 intervention appears to have been delivered with minimal contamination and with recognition of
241 the significant differences between what constitutes a self-managed exercise programme and usual
242 physiotherapy treatment which is important in the context of planning further study so that an
243 appropriate evaluation of different approaches can be undertaken. Our concern here was that the
244 physiotherapists might gradually adopt the self-managed exercise into their usual treatment
245 regimen as they became accustomed to working within this framework which would subsequently
246 limit the value of any comparisons made.

247 Despite prior concerns relating to pain produced whilst exercising serving as a barrier to
248 engagement, retention and reported levels of adherence were excellent which is in contrast to other
249 exercise programmes [19]. Reasons for such high levels of adherence might relate to the minimal
250 time requirement of undertaking a single-exercise, or might relate to aspects of the self-managed
251 framework within which the exercise was prescribed. This framework included a focus upon
252 knowledge translation meaning that participants had an understanding of why they were
253 undertaking the specific exercise and also included goal setting, self-monitoring and proactive

254 follow-up, all of which might enhance engagement [20,21]. Contrary to this, it is also possible that
255 the self-report exercise diaries which were used as a measure of adherence were an inadequate
256 measure of this construct and hence present an inaccurate picture of true levels of adherence.
257 However, in the absence of alternative methods, such a self-report approach appears to be the most
258 suitable means of gathering this data at this time.

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

264 **Considerations and limitations**

265 Although it is beyond the scope of any pilot study to claim findings that are generalisable, it should
266 be recognised that this study was conducted in a private practice setting where the intervention was
267 delivered by two highly experienced physiotherapists which might limit translation into more
268 generalised settings. Additionally, the participants recruited to this study were not currently seeking
269 healthcare for their shoulder problem which again is in contrast to other settings and hence the
270 underlying characteristics of these participants might be different to those who were already
271 actively seeking healthcare. The mean SPADI score at baseline in this group was 42.2 compared to
272 47.3 in a study recently conducted in the UK National Health Service where people with moderate to
273 severe shoulder pain were sought [22]. Although the mean baseline SPADI score was less in this
274 study, the difference would not be regarded as clinically significant and might actually be more
275 reflective of the range of people who seek healthcare for this problem. To support this, a study
276 recently conducted in Belgium that recruited a similar group of patient reported mean SPADI scores
277 at baseline of 43.1 [23].

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

281 **Conclusion**

282 Disorders of the rotator cuff are a burdensome problem and there is a clear evidence deficit in
283 relation to conservative management and specifically self-managed loaded exercise. The research
284 methods employed within this pilot RCT appear to offer a suitable foundation upon which to
285 conduct a substantive study to evaluate the clinical and cost-effectiveness of a self-managed
286 exercise programme versus usual physiotherapy treatment for chronic rotator cuff disorders/
287 tendinopathy.

288

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301 **Conflict of Interest Statement**

302 The authors report no conflicts of interest.

303 **Role of the funding source**

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

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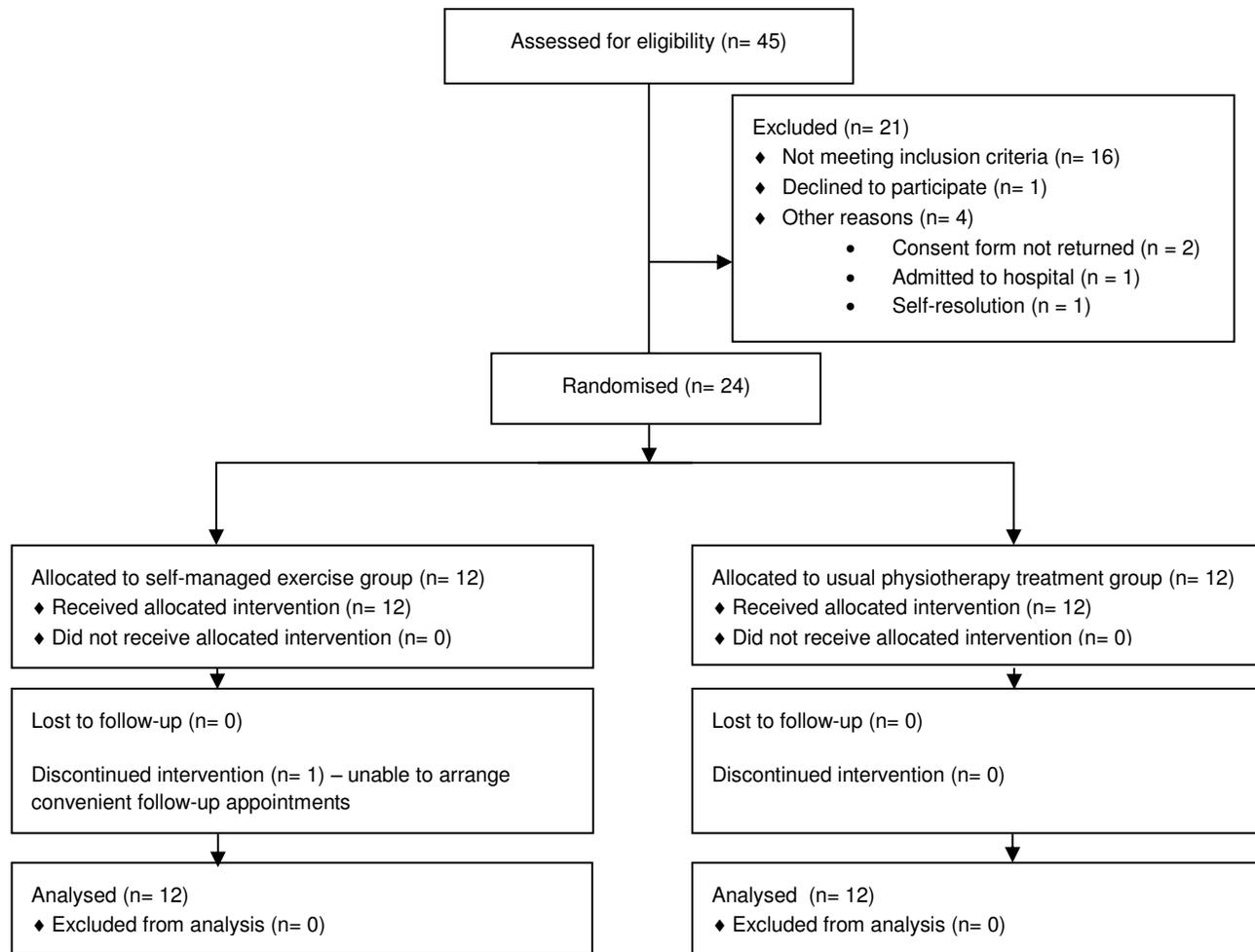


Figure 1 Participant flow through the study

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)

Table 1 Baseline characteristics of the participants by treatment group

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

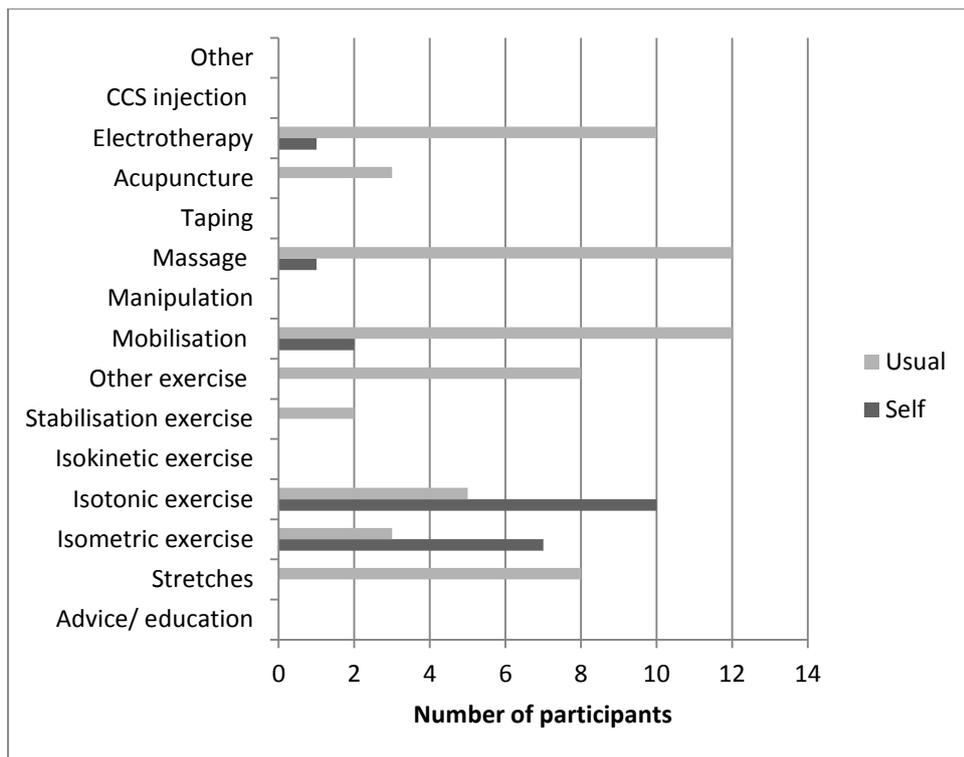


Figure 2 Description of the interventions offered (SELF refers to self-managed exercise group; Usual refers to usual physiotherapy treatment group)

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

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

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