A self-managed single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy: a randomised controlled trial (the SELF study)

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Abstract

Objectives: To evaluate the clinical effectiveness of a self-managed single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy.

Design: Multi-centre pragmatic unblinded parallel group randomised controlled trial.

Setting: UK National Health Service.

Participants: Patients with a clinical diagnosis of rotator cuff tendinopathy.

Interventions: The intervention was a programme of self-managed exercise prescribed by a physiotherapist in relation to the most symptomatic shoulder movement. The control group received usual physiotherapy treatment.

Main outcome measures: The primary outcome measure was the Shoulder Pain & Disability Index (SPADI) at three months. Secondary outcomes included the SPADI at six and twelve months.

Results: 86 patients (self-managed loaded exercise n=42; usual physiotherapy n=44) were randomised. 26 patients were excluded from the analysis because of lack of primary outcome data at the 3 months follow-up, leaving 60 (n=27; n=33) patients for intention to treat analysis. For the primary outcome, the mean SPADI score at three months was 32.4 (SD 20.2) for the self-managed group, and 30.7 (SD 19.7) for the usual physiotherapy treatment group; mean difference adjusted for baseline score: 3.2 (95% Confidence interval -6.0 to +12.4 p = 0.49).

By six and twelve months there remained no significant difference between the groups.

Conclusions: This study does not provide sufficient evidence of superiority of one intervention over the other in the short-, mid- or long-term and hence a self-management programme based around a single exercise appears comparable to usual physiotherapy treatment.

Trial registration number: ISRCTN84709751

Keywords: Rotator cuff tendinopathy, exercise, rehabilitation, quality of life, self-management

Introduction

Rotator cuff tendinopathy is a common and burdensome source of shoulder pain with prevalence estimated to be as high as 14% in the general working-age population (1). For a significant proportion of sufferers, it is characterised by persistent pain and/or disability and/or recurrent episodes (1).

A range of interventions, conservative and surgical, are currently used to treat this condition (2–4). Systematic reviews have reported comparable effects of surgical and conservative approaches, including physiotherapy (3) but there is a range of potential conservative approaches for rotator cuff tendinopathy and the optimal treatment strategies remain unclear (4). However, the potential benefits of loaded exercise i.e. exercise against gravity or resistance, have been reported (3,4) but concerns relating to the paucity of evidence and other methodological limitations of the evidence base have limited the inferences that can be drawn.

Furthermore, the potential superiority of single or multiple exercises is unknown. The potential benefits of a single exercise approach include pragmatic, time saving reasons to facilitate exercise adherence. Also, the assumption that incremental benefit is gained by adding more exercises that are theoretically stressing the same tissue might not be valid and the extra burden possibly unnecessary (5).

Hence, there is a need for research to be conducted to inform the optimal conservative management of rotator cuff tendinopathy. The aim of this study was to evaluate the effectiveness of a self-managed loaded single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy.

Methods

The protocol was approved by the National Research Ethics Service Committee Yorkshire & the Humber (Ref 11/YH/0443) and published online (6).

A multi-centre pragmatic unblinded parallel group randomised controlled trial was conducted in three UK National Health Service centres; one in northern England, one in the midlands and one in the south. The initial protocol (6) described a single-centre randomised controlled trial but when the recruitment rate fell behind the anticipated rate, two further centres were opened.

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 (> 50% external rotation), 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 [3].

Participants were identified from UK National Health Service physiotherapy waiting lists by a local physiotherapist assigned to undertake this task independently of treatment. Contact was made through an introductory letter and followed up with a telephone call. If the call recipient expressed interest in participating the same physiotherapist undertook initial telephone screening for inclusion criteria i to iv and exclusion criteria i to ii. If these criteria

were met the participant was invited to attend a physical examination for inclusion criteria v to vi and exclusion criterion iii.

Physical examination screening was carried out by local physiotherapists assigned to undertake this task independently of treatment. Baseline range of shoulder movement and response to resisted shoulder tests were examined before the cervical spine was assessed using a repeated movement approach according to the protocol described by McKenzie & May (7).

Basic demographic detail was collected by the physiotherapist before the participant completed a range of patient reported outcomes prior to randomisation including, the Shoulder Pain and Disability Index (SPADI) and Short Form-36. The primary outcome was the SPADI at three months post-randomisation. Secondary outcomes included the SPADI at six and twelve months and Short Form-36 at three, six and twelve months.

The SPADI is a self-report measure which 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 SPADI has been validated for use in this patient population and a minimally clinically important change of 10 points has been identified (8–10).

The secondary outcome measure, the Short Form-36 is a generic measure of health related quality of life (11) and is acceptable to patients, internally consistent and a valid measure of health status across a wide range of patients (12–14).

In addition, the Patient Specific Functional Scale, a patient-specific outcome measure which has been shown to be valid and responsive in various musculoskeletal populations, investigates functional status as determined by the patient (15), and exercise adherence data in the form of an exercise diary were completed during the intervention period.

A computer generated randomisation sequence was produced in blocks of two and four. Group allocation was concealed in consecutively numbered sealed opaque envelopes and the name of the patient and study identification number were written on the next consecutive envelope before being opened to reveal group allocation.

The intervention and comparator

Prior to commencing the study, the treating physiotherapists attended two 2 hour training sessions led by CL. The intervention comprises a single exercise, prescribed by the physiotherapist within the context of a self-managed framework. The affected shoulder is exercised against gravity, a resistive therapeutic band or hand weight over three sets of 10 to 15 repetitions twice per day. Exercise prescription is guided by symptomatic response requiring that pain is produced during exercise that remains no worse upon cessation of that exercise. In the absence of evidence to suggest that prescribing painful exercise is harmful, such an approach was taken to facilitate self-monitoring of symptoms over time which is regarded as a cornerstone of successful self-management (5).

Typically the exercise programme might commence with isometric abduction and progress to isotonic abduction. Exercise might also be progressed through increased repetitions and load. If, for example, abduction exercise provoked symptoms that were worse upon cessation of exercise then other planes of movement, for example lateral rotation or flexion, were explored. Participants were offered follow-up appointments as required to facilitate

self-management and discuss exercise progression. The intervention, including further justification, has been described in full previously (5).

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 (2).

A total of 31 physiotherapists with a wide range of experience were involved in delivering the intervention and comparator treatments and at times an individual physiotherapist might have delivered both treatments.

Sample size calculation

The original calculation was based upon the primary outcome measure, the SPADI where a 10-point change was regarded as a minimally clinical important change (16). We assumed a standard deviation of 24 points (17), a power of 80% and a (two-sided) significance level of 5% meaning that 91 participants per group were required. Allowing for a 15% loss to follow-up, we aimed to recruit 210 participants. However, in light of new information from our pilot study (18) we undertook a revised sample size calculation which was approved by the ethics committee. 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 (18) and, additionally, we identified a correlation between baseline and three-month SPADI scores of 0.5. Julious (19) 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. Taking into account adjustment for baseline SPADI scores and the narrower standard deviation, it was

estimated that 34 participants per group were required. To account for 15% loss to follow-up, we aimed to recruit a total of 78 participants.

Data analysis

The data are reported and presented according to the revised CONSORT statement (20) and statistical analyses were performed on an intention-to-treat basis. All statistical exploratory tests are two-tailed with $\alpha = 0.05$.

Analysis of Covariance was used to compare outcome scores between the groups at three, six and twelve months post-randomisation adjusting for baseline SPADI score. Within group changes in mean SPADI score between baseline and three, six and twelve months post randomisation were compared using a paired *t*-test.

Results

Figure 1 shows the study flow diagram; 86 patients were randomly assigned; 20 in the northern centre; 39 in the midlands and 27 in the south. 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 still in the recruitment system.

The groups appear well balanced at baseline (table 1) except that the usual physiotherapy treatment group reported a longer mean duration of symptoms. However, the data are positively skewed 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 difference might be more readily explained as a product of the summary measure used rather than a true difference between groups.

Table 2 shows the baseline characteristics of those patients who provided follow-up data at three months compared to those who did not. From table 2, it can be seen that the mean age and SPADI score of participants who completed follow-up compared to participants who did not across the treatment groups is different where it seems that participants who completed follow-up are more likely to be older and are more likely to report lower levels of pain and disability than participants who did not complete follow-up. However, the mean age of participants who did not complete follow-up and SPADI score are similar in both the self-managed exercise group and the usual physiotherapy treatment group suggesting that the effects of randomisation have been maintained.

The mean total 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.

The content of the treatment sessions is described in table 3.

By six months post-randomisation, six of the participants in the self-managed exercise group reported receiving 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 by a physiotherapist. Five of the participants in the self-managed exercise group reported medication use, including analgesics and non-steroidal anti-inflammatories, compared to eight in the usual physiotherapy treatment group. Four of the participants in the self-managed exercise group reported 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.

Participants in the intervention arm only completed self-report exercise adherence diaries and 29% (12/42) returned them. Of the twelve, five participants returned complete data and seven returned partial data. 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%).

The mean General Self-Efficacy Scale 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).

Clinical outcomes

The SPADI and Short Form-36 outcomes at three, six and twelve month follow-up are presented in table 4.

Paired *t*-test analysis demonstrated statistically significant and clinically important within group changes on the SPADI from baseline to all three follow-up points; 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) by three months; 29.1 point change (95% CI 21.0 to 37.1; $p < 0.01$) for the self-managed exercise group (n =

23) and 23.5 point change (95% CI 15.1 to 31.9; $p < 0.01$) for the usual physiotherapy treatment group (n = 24) by six months; and 31.0 point change (95% CI 20.8 to 41.3; $p < 0.01$) for the self-managed exercise group (n = 20) and 25.2 (95% CI 14.3 to 36.1; $p < 0.01$) for the usual physiotherapy treatment group (n = 21) by twelve months.

There were no statistically significant differences between the groups across all the outcomes at three, six or twelve months (table 4).

We also initially proposed to analyse the Patient Specific Functional Scale scores collected during the intervention periods (6). 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 described in figure 2; 14 participants described limitations with activities above shoulder level; eight described limitations with activities below shoulder level; 27 described limitations related to self-care activities; nine described limitations with recreational activity; six with working and nine participants described difficulty sleeping.

Discussion

The aim of this study was to evaluate the clinical effectiveness of a self-managed single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy. The results provide insufficient evidence to reject the null hypothesis that there is no difference between the two treatment approaches at three, six or twelve months.

The findings of this current study are in keeping with other similar studies where superiority of one approach over an active comparator is not apparent [20,21]. 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 minimally clinical important change of 10 points (16), the changes reported by other studies, for example Engebretsen et al. (21), Kromer et al. (22) and Yiasemides et al. (23), in excess of 20 points on the SPADI, are greater. Such a difference might be explained by contextual factors, such as the patient population, the treating physiotherapist and the content of the treatment package, but this is difficult to substantiate. One relevant factor though is the time required to 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, due to UK National Health Service waiting times, and for a minority treatment had not commenced by the three month follow-up point. This is an important consideration particularly with reference to an exercise programme which might require a minimum intervention period of twelve weeks to achieve a therapeutic dose (24).

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 further intervention.

To the authors knowledge, this is the first study to evaluate the effectiveness of a single exercise approach for rotator cuff tendinopathy. This is in contrast to much of current physiotherapy practice and other studies where a range of exercises, and other modalities, tend to be prescribed (2,18). Notwithstanding the limitations of this current study, it is suggested that the data presented here in tandem with that of the pilot randomised controlled trial (18) might serve to challenge the idea that a range of exercises are needed to effect a worthwhile 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 outcomes (25). The pragmatic benefits of a single exercise and the comparability of the single exercise approach and multi-modal or multi-exercise approach might suggest that a single exercise approach is a valid and worthwhile prescription for certain patients, at least as a first line rehabilitation intervention.

The strengths of this randomised controlled trial 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.

In addition to the lack of blinding, which was not possible in this current study due to ethical guidance, one clear limitation to this randomised controlled trial is the loss-to-follow up. By three months 70% of patients had returned primary outcome data and this diminished further to 56% by six months and 49% by twelve months. 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. (26,27), Despite this, it is reassuring to note that comparable between group treatment effects were also found in the pilot study (18) which was conducted in a different context.

Clinical Message

- A self-management programme based around a single exercise appears comparable to usual physiotherapy treatment

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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) Median = 7 months	43	17.5 (3 to 120) Median = 6 months
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)

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)

Characteristic	Treatment group			
	Self-managed exercise (n =42)		Usual physiotherapy (n = 44)	
	Completed follow-up (n = 27)	Did not complete follow-up (n = 15)	Completed follow-up (n = 33)	Did not complete follow-up (n = 11)
	Mean or count	Mean or count	Mean or count	Mean or count
Age (years)	58.3	45.7	58.5	46.9
Gender - male	12	5	18	8
Gender – female	15	10	15	3
Duration of shoulder symptoms (months)	11.8	11.5	18.1	15.6
SPADI	44.8	56.9	47.4	53.6
GSES	32.9	31.9	32.4	32.6

Table 2 Baseline characteristics of participants who completed and did not complete follow-up at three months

Range of possible interventions	Number of times each intervention was offered by treatment group	
	Self-managed exercise	Usual physiotherapy
Advice/ education	19	15
Stretches	2	13
Isometric exercise	9	5
Isotonic exercise	33	32
Isokinetic exercise	0	0
Stabilisation exercise	2	24
Other exercise	0	4
Mobilisation	1	13
Manipulation	0	0
Massage	0	2
Taping	0	1
Acupuncture	1	0
Electrotherapy	0	1
CCS injection	0	1
Other	0	0

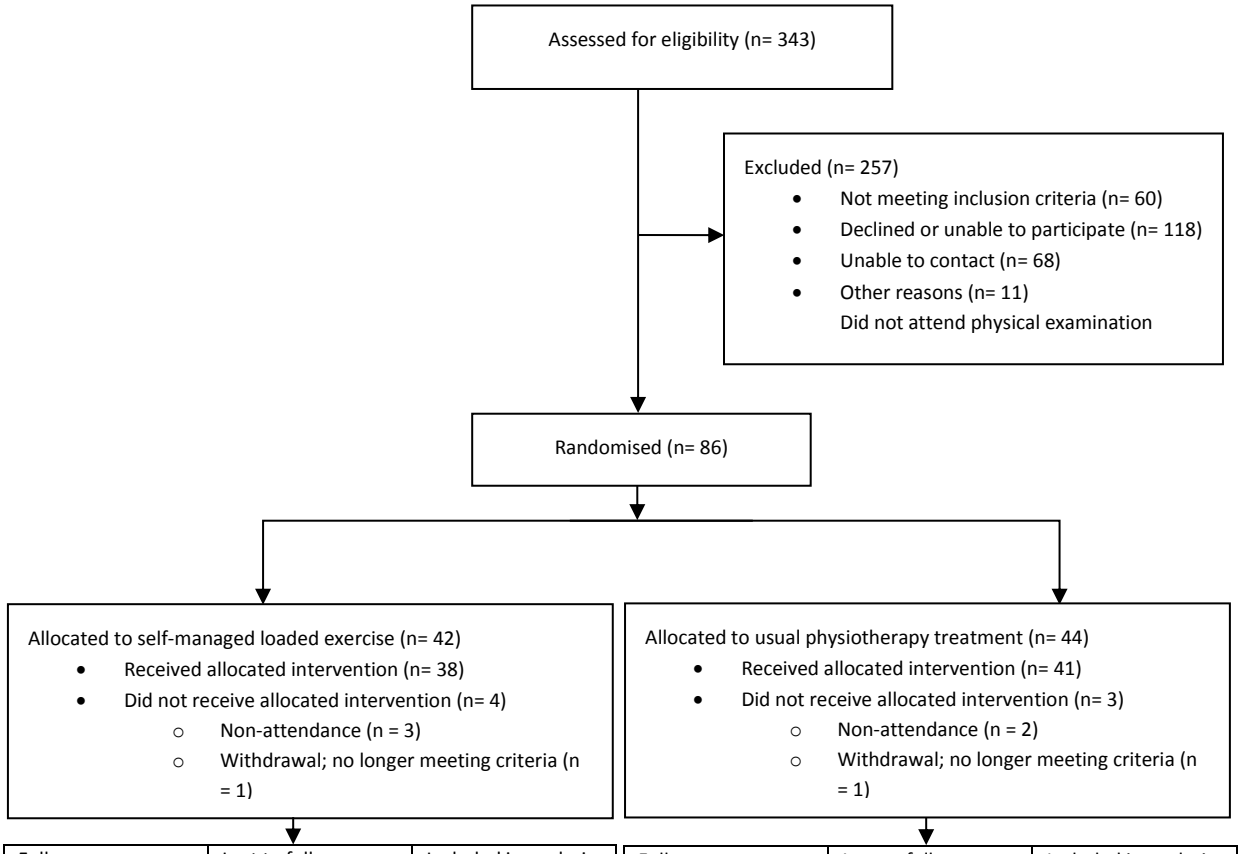
Table 3 Interventions offered by treatment group

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[1] (12 months)	20	14.2	20.0	22	21.4	25.4	-7.1 (-21.5 to +7.2)[7]	0.32	-6.0 (-19.7 to +7.6)[7]	0.38
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 Physical functioning[2] (12 months)	21	62.2	34.2	21	72.6	22.4	-10.4 (-28.4 to +7.6)[6]	0.25	-5.6 (-15.6 to +4.3)[6]	0.26
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 Role-physical[2] (12 months)	20	71.3	30.9	21	75.6	23.7	-4.3 (-21.7 to +13.0)[6]	0.62	-3.5 (-17.8 to +10.7)[6]	0.62
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 Bodily pain[2] (12 months)	21	62.4	28.5	21	59.3	19.0	+3.0 (-12.1 to +18.2)[7]	0.69	+8.1 (-6.9 to +23.2)[7]	0.28
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 General health[2] (12 months)	21	59.4	22.4	21	62.1	24.3	-2.8 (-17.3 to +11.8)[6]	0.70	-8.0 (-18.2 to +2.1)[6]	0.12
SF-36 Vitality[2] (3 months)	27	59.8	18.0	33	52.1	19.6	+7.7 (-2.1 to +17.5)[7]	0.12	+4.9 (-2.8 to +12.7)[7]	0.21
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 Vitality[2]	21	56.6	20.3	21	54.5	22.5	+2.2 (-11.2	0.74	+1.1 (-8.9 to	0.82

(12 months)							to +15.5)[7]		+11.1)	
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 Social functioning[2] (12 months)	21	48.2	12.0	21	47.6	6.4	+0.6 (-5.4 to +6.6)[7]	0.84	+0.72 (-5.5 to +7.0)[7]	0.82
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 Role emotional[2] (12 months)	20	85.8	26.1	21	92.9	13.0	-7.0 (-19.9 to +5.9)[6]	0.28	-5.7 (-17.3 to +5.9)[6]	0.33
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
SF-36 Mental health[2] (12 months)	21	74.3	18.5	21	75.2	13.1	-0.9 (-10.9 to +9.1)[6]	0.86	-0.2 (-8.2 to +7.8)[7]	0.95

Table 4 Unadjusted and adjusted differences in outcome scores between the self-managed exercise and usual physiotherapy groups at three, six and twelve 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] 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 / [6] Usual physiotherapy group reports better outcomes / [7] Self-managed exercise group reports better outcomes)



Follow-up	Lost to follow-up	Included in analysis
3 months	15	27
6 months	19	23
12 months	22	20

Follow-up	Lost to follow-up	Included in analysis
3 months	11	33
6 months	19	25
12 months	22	22

Figure 1 Study flow diagram

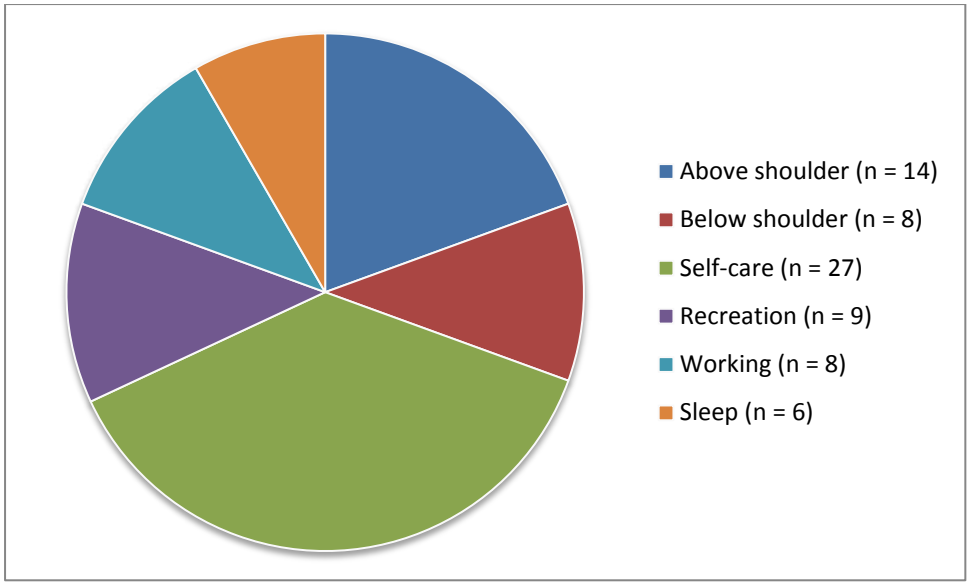


Figure 2 Description of the primary functional limitations reported by the participants on the patient specific functional scale (data available for 72/86 participants)