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ORIGINAL REPORT

GUIDED EXERCISES WITH OR WITHOUT JOINT MOBILIZATION OR NO TREATMENT IN PATIENTS WITH SUBACROMIAL PAIN SYNDROME: A CLINICAL TRIAL

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Background: **Graded resistance training is the recommended treatment for patients with subacromial pain syndrome. It is debated whether adding joint mobilization will improve the outcome. The aim of this study was to evaluate the clinical outcome of guided exercises with or without joint mobilization, compared with controls who did not receive any treatment.**

Methods: **A 3-armed controlled trial in a primary care setting. A total of 120 patients, with clinically diagnosed subacromial pain syndrome, were randomized into guided exercise groups with and without additional joint mobilization, and a control group that did not receive any treatment. Data were analysed at baseline, 6 weeks, 12 weeks and 6 months. Primary outcome was the Constant-Murley score, and secondary outcomes were pain and active range of motion.**

Results: **Shoulder function improved in all groups, as measured with the Constant-Murley score. At 12 weeks and 6 months the exercise groups improved significantly compared with the control group ($p \leq 0.05$). Add-on joint mobilization resulted in decreased pain in active range of motion at 6 and 12 weeks compared with guided exercise or no treatment ($p \leq 0.05$). Range of motion increased over time in all 3 groups.**

Conclusion: **In patients with subacromial pain syndrome guided exercises improved shoulder function compared with no treatment. Add-on joint mobilization decreased pain in the short-term compared with exercise alone or no treatment.**

Key words: Constant-Murley score; manual therapy; resistance training; shoulder pain.

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LAY ABSTRACT

To determine treatment efficacy in patients with shoulder pain treated with a combination of joint mobilization and guided training or guided training alone, and compare this with a control group who received no treatment. The study was a randomized controlled trial in Swedish primary care. A total of 120 patients aged between 20 and 59 years were recruited from general practice in Stockholm. Guided exercises, with or without joint mobilization, improved shoulder function compared with no treatment. In the short term, add-on joint mobilization decreased pain, and may thus serve as a substitute for non-steroidal anti-inflammatory drugs (NSAIDs) or other painkillers at the start of a treatment period.

Subacromial pain syndrome (SAPS) is a clinical diagnosis and one of the most common reasons for seeking physical therapy in primary care (1). The aetiology is known to be multi-factorial and includes several rotator cuff pathologies, such as increased tendon thickness (e.g. tendinopathies), bursitis, and tears affecting the rotator cuff or the long head of the biceps tendon (2). No single examination test has the specificity and sensitivity to alone set the diagnosis. A combination of different tests has been suggested (3). There is little knowledge about the natural history and treatment of patients with SAPS. This syndrome is believed to consist of inflammatory cells, and therefore patients with SAPS are often treated with non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroid injection (4). Even if current evidence suggests that the inflammatory response is a key component, the presence of inflammation has not been confirmed in those with tendinopathy (5).

A consensus on physical therapy treatment for patients with SAPS was reached in 2015 (6). This was after the start of the current clinical trial. However, the current trial followed the guiding principles for implementing exercise therapy for shoulder pain recommended by the consensus. Namely, a limited number of exercises, performed with appropriate scapulo-humeral coordination and humeral head alignment, in a gradually progressed manner.

A common reason for using joint mobilization is to reduce hypomobility and improve shoulder function, but it has also been used to decrease pain (7, 8). The main mechanism for joint mobilization discussed is neurophysiological, and includes stimulating mechanoreceptors, releasing endorphins, and reducing the cytokine concentration (9). Whether joint mobilization evokes pain relief, which then provides suitable conditions for resisted exercises, is inconclusive (10, 11). However, the joint mobilization according to Kaltenborn used in the current study is a theory, and was used in order to decrease pain and increase relaxation (8).

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The aim of the current study was to evaluate the clinical outcome, in terms of shoulder function and pain, of guided exercises with or without the addition of joint mobilization compared with no treatment, in patients diagnosed with SAPS. The hypothesis was that the addition of joint mobilization of the gleno-humeral joint would be superior to guided exercises alone or no treatment in patients with SAPS.

METHODS

Design

The current study protocol was approved by the regional ethics committee in Stockholm (Dnr 2009/1197-31/2) and is reported in accordance with the template for intervention description and replication (TIDier) checklist and guide (12). No methodological changes have been made to the study plan since approval in 2009. This parallel, 3-armed clinical trial was registered retrospectively in connection with the data analysis in June 2017 (ISRCTN67469356).

Subjects

Between August 2010 and December 2015, 120 patients with SAPS were recruited from 5 primary care clinics in the general community of Stockholm. (The final patient had his/her final follow-up in June 2016). Oral and written information about the study was provided at the first visit by the physiotherapist performing all the examinations. If the patient consented to participate in the study, written consent was obtained.

Inclusion criteria were: patients aged 20–59 years, who had had SAPS for between 4 weeks and 1 year, and presented with a full passive range of motion (PROM) of the glenohumeral joint, a positive painful arc (13), and at least 2 positive clinical tests of those listed.

Exclusion criteria were: bilateral shoulder pain; previous treatment with corticosteroid injection; diabetes mellitus; thoracic or cervical spine syndromes; and a positive drop-arm test; clinical signs of full thickness/total rotator cuff rupture (e.g. lag signs (14)); earlier surgery and dislocations of the shoulder joint; rheumatoid arthritis; severe arthroses; frozen shoulder; and fibromyalgia.

Clinical tests

The examiner (AE) followed a predetermined study protocol, and all the tests followed the same order for each patient, at baseline and at the follow-ups at 6 weeks, 12 weeks and 6 months.

To clinically exclude full-thickness tears (FTT) or total tears of the rotator cuff, possible weakness (e.g. total "give-away") was observed when performing the following clinical tests:

- Jobe's test/empty can test (15);
- Drop arm test (16);
- Lag signs (14).

Neurological testing of the upper extremities was always performed. Excluded from the trial were those patients who presented with significant upper extremity weakness, active range of motion (ROM) deficits, reduced or altered sensation and reduced tendon reflexes.

Tests to further identify pain or weakness during resisted flexion, abduction, external and internal rotation were performed (17), as well as the lift off test (18), and the palm-up test (19). The adduction test (cross-body test) and the Hawkins-Kennedy test were used to identify possible impingement (20).

These clinical tests were carried out by the same physical therapist (AE) with more than 20 years of experience. Furthermore, AE was blinded to group allocation at baseline and at all the evaluation occasions. In order not to reveal their group affiliation the patients were instructed not to discuss their physical activities with this examiner (AE).

Randomization process

If a patient was eligible to participate in the current trial, a second physical therapist, not otherwise involved in the study, performed the inclusion to the present study according to Fig. 1. This resulted in the following sample sizes at inclusion: intervention group 1 (IG1: joint mobilization + guided exercises, $n=29$); intervention group 2 (IG2: guided exercises, $n=52$); and control group (CG: no treatment, $n=39$) (Table I). The intervention started within 1 week after allocation and was guided by 2 experienced independent physical therapists with 12–15 years of experience in physical therapy.

Radiological and ultrasound examinations

Radiological and ultrasound (US) examinations were performed on the symptomatic shoulder within 5 weeks from allocation, in order to rule out malignity and detect other pathologies. If the patient did not attend the scheduled US, he or she was further excluded from the study. The results of the radiological and US examinations were blinded to both the patient and the physical therapist (AE), as well as to the physical therapists guiding the exercise. All US examinations were performed by the same expert of US methodology.

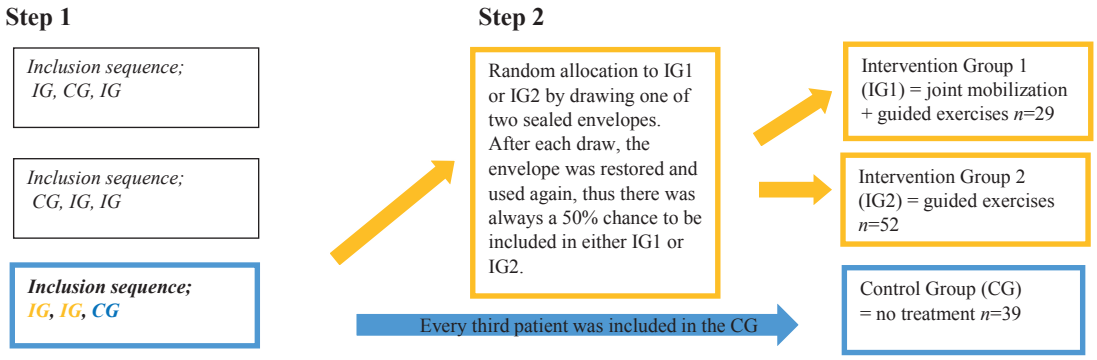

Fig. 1. Two step randomization process. Step 1; one of three sequence lists were drawn to decide upon inclusion to control group (CG) and Step 2; randomization to Intervention groups (IG1, IG2)

Table I. Patient characteristics at baseline

Variable	IG 1 (*n* = 29)	IG 2 (*n* = 52)	CG (*n* = 39)
Male/Female, *n*	14/15	26/26	19/20
Age, mean (SD)	43.2 (9.8)	45.5 (8.3)	46.0 (10.2)
Physical activity, times/week, mean (SD)	1.7 (1.6)	1.9 (1.6)	1.7 (1.7)
Dominant arm, right, *n* (%)	27 (93)	47 (90)	38 (97)
Symptomatic arm, dominant, *n* (%)	20 (69)	26 (50)	26 (67)
Duration of pain, weeks, mean (SD)	23 (15)	21 (15)	24 (17)
Slow debut, *n* (%)	24 (86)	45 (87)	35 (90)
Beighton score, mean (SD)	3.4 (2.1)	3.1 (2.0)	3.4 (2.2)
Hand-strength, symptomatic arm, mean (SD)	400 (128.2)	384 (131.8)	361 (115.8)
Pain at rest, *n* (%)	19 (66)	33 (63)	24 (62)
Pain at movement, *n* (%)	29 (100)	52 (100)	39 (100)
Pain at compression, *n* (%)	22 (76)	46 (88)	32 (82)
Analgesics, *n* (%)	18 (64)	37 (71)	26 (67)
Tendinosis, *n* (%)	10 (29)	13 (38)	11 (32)
Partial rotator cuff rupture, *n* (%)	11 (29)	16 (36)	18 (40)

IG1: intervention group 1: joint mobilization + guided exercises; IG2: intervention group 2: guided exercises; CG: control group; SD: standard deviation.

Physical therapy protocol

The guided training in the intervention groups consisted of 20 sessions at one of the clinics, twice a week over a period of 12 weeks. IG1 received 8 sessions with joint mobilizations, during the first 6 weeks (1–2 times/week) as add-on treatment to the guided exercises. IG1 and IG2 also performed home exercises twice a day (only once a day on days with guided training). The guided exercise protocol and the home training programme were progressed gradually. The patients performed each exercise 10 times in 3 sets. Some pain (VAS 10–40 mm) was allowed during the exercise (20). If the pain did not "wear off" between training sessions, a reduction of sets, repetitions and loading, was carried out. More information about the training programme is provided in Appendix I.

The patients in the CG did not receive any treatment and were informed to live as usual. Some pain (VAS 10–40 mm) was allowed during daily activities. If the pain did not "wear off", a reduction in activity level was advised (this information was given to all participants).

An addition of low-speed joint mobilization according to Kaltenborn (8) was performed in IG1, where grade 1 often is referred to as a "piccolo" traction that decreases the compressive forces and is suggested to reduce pain (7), and grade 2 traction tightening the shoulder tissues. Mobilization of a posterior tight capsule is thought to give the humerus an improved resting position within the glenoid fossa. A description of the guided exercises and the home training programme is shown in Appendix I, and a description of the joint mobilization is shown in Appendix II.

Outcome measures

The primary outcome measure (see Appendix III), was the original Constant-Murley shoulder assessment score, (C-M) (22) modified for muscle force, where dumbbells were used instead of a dynamometer (23). The strength was measured in a standardized way, using weights of 0.5, 1, 2 up to 12 kg, until the patient felt any pain. For familiarization, the patients started by testing their non-symptomatic arm. The arm was elevated to 90º in the humeroscapular plane (30–45º abduction) with the hand and forearm pronated. An intra-rater reliability test of the C-M score was conducted by the same physical therapist (AE). An independent physiotherapist was also present in order to complete the results. Eleven patients with SAPS were tested with 3–4 days in between tests resulting in an intraclass correlation (ICC) of 0.987.

The secondary outcome measures were pain using the visual analogue scale (VAS), and active range of motion (AROM). Pain at rest, pain at movement and compression pain (pain when lying on the affected shoulder) was answered yes or no, at each evaluation time-point. Furthermore, pain and AROM were measured in flexion and abduction with the VAS and a universal goniometer. A Myrin inclinometer (24) was used to measure external rotation. Internal rotation was measured as the distance between C7 and the patients thumb on the columna (25). All measurements were carried out according to a standardized protocol.

Sample size estimation

The sample size was calculated with 80% power to show a clinically important difference of 10%, based on the C-M score. The calculation of effect size was based on descriptive statistics from a preliminary study by Haahr et al. (26). It was estimated that 33 patients per group were required. To account for loss to follow-up, the current study aimed to recruit a total of 120 patients.

Data analysis

All variables were summarized using standard descriptive statistics. Compliance with the guided exercises and the add-on joint mobilization were registered by the treating physiotherapists. Shapiro–Wilk was used for normality test. Non-parametric or skewed distribution was analysed with Kruskal–Wallis analysis of variance (ANOVA) and pairwise differences with Mann–Whitney *U* test or χ^2 test or Fishers' exact test for yes/no answers. The total C-M score, and a change score to adjust for baseline, was analysed with ANOVA repeated measures and planned comparisons. The change score was calculated as the improvement from baseline to the 3 evaluation times, 0–6 weeks, 0–12 weeks and 0–6 months. The Levene's test for homogeneity of variances between groups was violated at 6 weeks when analysing the total score and Kruskal–Wallis ANOVA and Mann–Whitney *U* tests were applied. The total C-M score, the subscore pain and the change score, are presented with means and 95% confidence intervals (95% CI) and the mean differences between groups. Pain at rest, in movement and at compression is presented with the proportion of yes answers, with 95% CI, at the different evaluation times. All continuous data were analysed per protocol (PP), and with intention to treat (ITT) using the mean or median by randomized groups. There were no differences with respect to outcome between PP and ITT, and the ITT analysis was used in the results section. The level of significance was set at $p \leq 0.05$ (2-tailed).

RESULTS

Subjects

A total of 120 patients were included in the present study. A flow-chart of the patients throughout the entire trial is presented according to the Consolidated Standards of Reporting Trials (CONSORT) (27). Patients who did not attend the scheduled visit were reminded

by a phone call, according to clinical practice, and thereafter were withdrawn from the study (Fig. 2). IG1 and IG2 had a high (>80%) compliance with the guided exercise and joint mobilization visits. In the study plan a "last date" was set for closing the project, and starting statistical analyses.

Shoulder function

Based on the C-M score the shoulder function improved for all groups over time and the 2 intervention groups (IG1, IG2) were significantly improved compared with the control group (CG) (Table II, Fig. 3 and Fig. 4). IG1 and IG2 reached a clinical important change of 17 points or more at the 12 weeks' follow-up (28) (Table II, Fig 4). A significant linear increase in AROM over time was shown in all 3 groups during flexion, abduction, external and internal rotation of the glenohumeral joint ($p \leq 0.05$). No group differences were found.

Shoulder pain

According to the subscore "Pain" in the C-M score the intervention groups were significantly improved

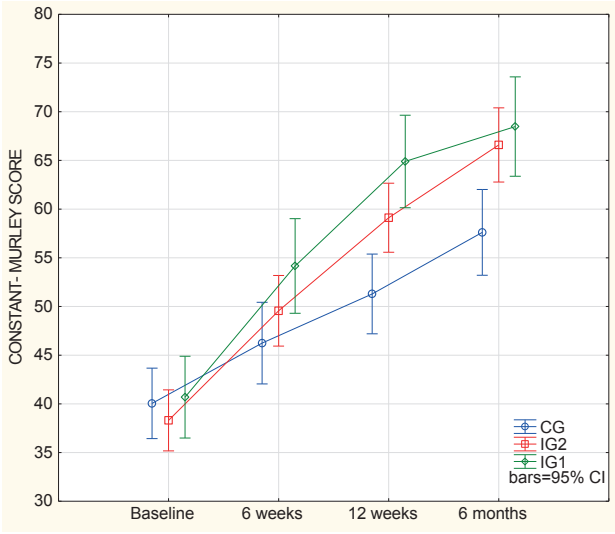

Fig. 3. The Constant-Murley score at baseline, 6 weeks, 12 weeks and 6 months. The intervention group 1 (IG1) was significantly improved compared to the Control Group (CG) at 6 weeks, 12 weeks and 6 months and intervention group 2 (IG2) was improved at 12 weeks and 6 months. Exact values and mean differences with 95% confidence intervals are presented in Table II.

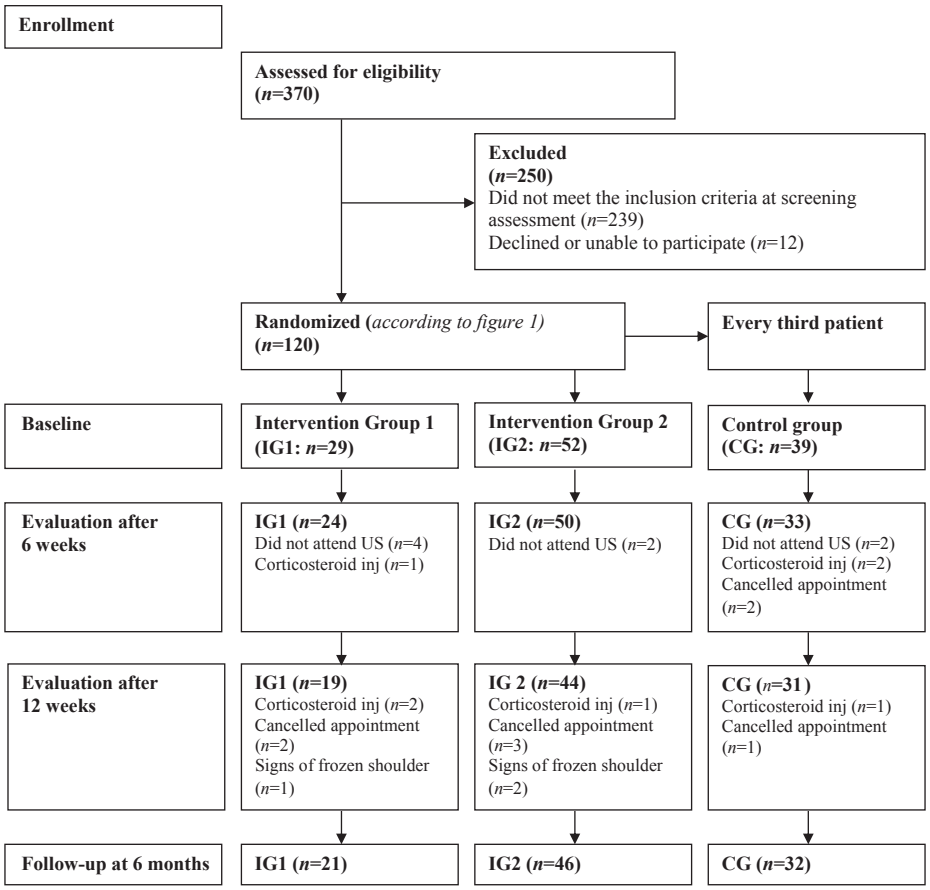

Fig. 2. Flow-chart of the patients throughout the entire study reported following the recommendations of the Consolidated Standards of Reporting Trials (CONSORT).

Table II. Shoulder function measured with Constant-Murley (C-M) score in patients with subacromial pain syndrome.

Total C-M Score						Mean difference between groups					
Group	Baseline	6 weeks	12 weeks	6 months	Group	6 weeks	*p*-value	12 weeks	*p*-value	6 months	*p*-value
IG1	40.7 (36.0–45.4)	54.2 (48.7–59.7)	64.9 (58.8–71.0)	68.5 (62.1–74.9)	IG1-CG	7.9 (1.5–14.3)	0.0006	13.6 (7.3–19.9)	0.00004	10.9 (4.1–17.6)	0.0018
IG2	38.3 (35.0–41.7)	49.6 (45.6–53.6)	59.1 (55.4–62.8)	66.6 (62.9–70.3)	IG2-CG	3.3 (–8.9–2.2)	n.s.	7.8 (2.4–13.2)	0.005	9.0 (3.2–14.8)	0.0028
CG	40.1 (36.9–43.2)	46.2 (42.9–49.6)	51.3 (48.2–54.4)	57.6 (53.7–61.6)	IG1-IG2	4.6 (–1.5–10.7)	n.s.	5.8 (–0.1–11.7)	n.s.	1.9 (–4.5–8.3)	n.s.
Change score		0–6 weeks	0–12 weeks	0–6 months	Group	0–6 weeks	*p*-value	0–12 weeks	*p*-value	0–6 months	*p*-value
IG1		13.5 (10.2–17.4)	24.2 (10.7–18.2)	27.8 (11.5–19.6)	IG1-CG	7.3 (2.3–12.3)	0.0047	13.0 (7.0–18.9)	0.00003	10.7 (4.8–16.6)	0.0005
IG2		11.2 (8.2–12.1)	20.8 (11.4–16.8)	28.3 (12.9–19.1)	IG2-CG	5.1 (0.7–9.4)	0.022	9.6 (4.5–14.7)	0.0003	10.2 (3.4–17.1)	0.00377
CG		6.2 (7.2–11.4)	11.2 (7.2–11.3)	17.6 (9.7–15.3)	IG1-IG2	2.2 (–7.0–2.5)	n.s.	3.4 (–2.2–9.0)	n.s.	0.5 (–6.0–7.0)	n.s.

The total score and the improvement from baseline to the 3 evaluation times, called the change-score, is presented with mean values and 95% confidence intervals (95% CI) and mean differences between groups. C-M: Constant-Murley; IG1: intervention group 1; joint mobilization + guided exercises; IG2: intervention group 2; guided exercises, CG: control group.

Table III. Subscore Pain in Constant-Murley score, presented as mean and 95% confidence intervals.

Sub Score Pain					Mean difference between groups						
Group	Baseline	6 weeks	12 weeks	6 months	Group	6 weeks	*p*-value	12 weeks	*p*-value	6 months	*p*-value
IG1	2.4 (1.1–3.7)	6.6 (5.3–7.8)	8.6 (7.2–10.0)	10.5 (9.0–12.1)	IG1–CG	2.9 (1.0–4.5)	0.002	3.2 (1.4–5.1)	0.0009	3.3 (1.3–5.2)	0.002
IG2	1.6 (1.0–2.3)	5.8 (4.8–6.8)	8.3 (7.1–9.4)	9.7 (8.6–10.8)	IG2–CG	2.1 (0.5–3.4)	0.01	2.9 (1.3–4.5)	0.001	2.5 (0.8–4.2)	0.005
CG	2.3 (1.2–3.5)	3.7 (2.6–4.9)	5.4 (4.3–6.5)	7.2 (5.9–8.6)	IG1–IG2	0.8 (–0.8–2.4)	n.s.	0.3 (–1.4–2.1)	n.s.	0.8 (–1.0–2.6)	n.s.

IG1: intervention group 1; joint mobilization + guided exercises, IG2: intervention group 2; guided exercises, CG: control group. Group differences were analysed with Kruskal–Wallis analysis of variance (ANOVA) and where differences found compared with Mann–Whitney *U* test.

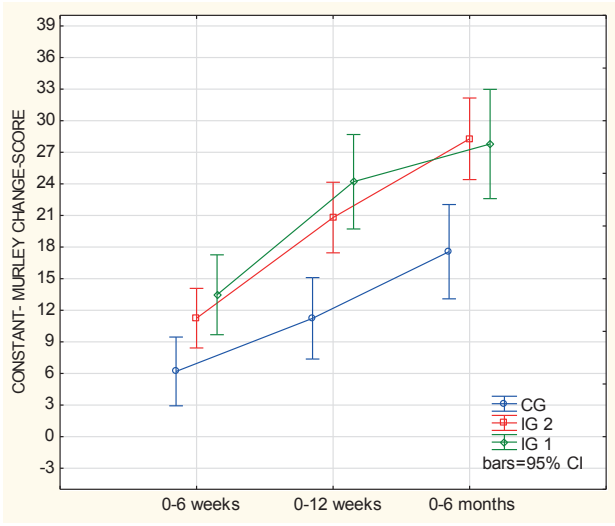

Fig. 4. The improvement in Constant-Murley score from baseline expressed as a change-score. The vertical bars denote 95% confidence interval (CI), and the mean differences between the control group (CG) and the intervention groups (IG1 and IG2) are significant at all points of measurement. Exact values and mean differences with 95% confidence intervals are presented in Table III. The intervention groups reaches clinically important change at 3 months (≥ 17p on C-M score) (28).

compared with the CG at 6 and 12 weeks as well as at 6 months (Table III).

"Pain at rest", "pain in movement" and "pain at compression" were registered as yes or no at the different evaluation times. The answers are presented as the proportion of yes answers (Table IV, Fig. 5). Pain measured with VAS during AROM in flexion, abduction, external and internal rotation is presented in Table V. A short-term effect was evident in the IG1 compared with IG2 and the CG. VAS 14 mm (29), is considered

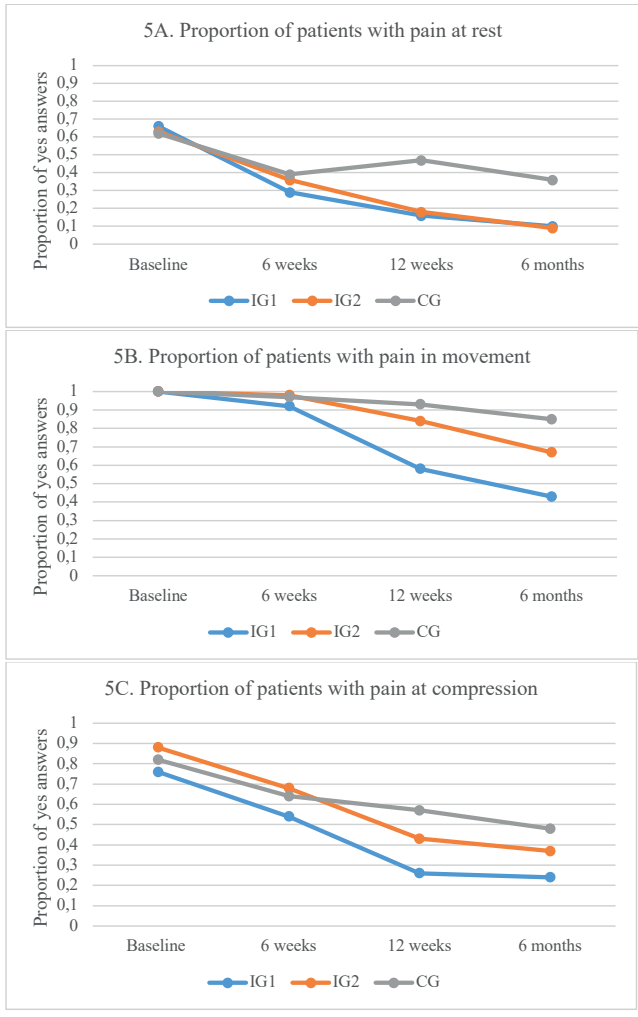

Fig. 5. Proportions of patients with pain at rest, in movement and at compression at the different evaluation times

Table IV. Proportions of yes-answers with 95% confidence intervals for pain at rest, pain in movement and pain at compression at the different evaluation times.

	Baseline	6 weeks	12 weeks	6 months
Pain at rest				
IG1	0.66 (0.49–0.83)	0.29 (0.11–0.47)	0.16 (0.00–0.49)	0.10 (–0.03–0.23)
IG2	0.63 (0.50–0.76)	0.36 (0.23–0.49)	0.18 (0.07–0.29)	0.09 (0.01–0.17)
CG	0.62 (0.47–0.77)	0.39 (0.22–0.56)	0.47 (0.29–0.65)	0.36 (0.20–0.52)
Kruskal Wallis ANOVA		$p=0.03$	$p=0.01$	$p=0.004$
Differences found between		IG1 - CG	IG2 - CG	IG2 - CG
Pain in movement				
IG1	1.00	0.92 (0.81–1.03)	0.58 (0.36–0.80)	0.43 (0.22–0.64)
IG2	1.00	0.98 (0.94–1.02)	0.84 (0.73–0.95)	0.67 (0.53–0.81)
CG	1.00	0.97 (0.91–1.03)	0.93 (0.84–1.02)	0.85 (0.73–0.97)
Kruskal Wallis ANOVA		n.s.	$p=0.007$	$p=006$
Differences found between			IG1 - CG	IG1 - CG
Pain at compression				
IG1	0.76 (0.61–0.91)	0.54 (0.34–0.74)	0.26 (0.06–0.46)	0.24 (0.06–0.42)
IG2	0.88 (0.79–0.97)	0.68 (0.55–0.91)	0.43 (0.28–0.58)	0.37 (0.23–0.51)
CG	0.82 (0.70–0.94)	0.64 (0.56–0.72)	0.57 (0.39–0.75)	0.48 (0.31–0.65)
Kruskal Wallis ANOVA		n.s.	n.s.	n.s.

IG1: intervention group 1, joint mobilization + guided exercises; IG2: intervention group 2, guided exercises; CG: control group; ANOVA: analysis of variance; n.s.: not significant.

Table V. Pain measured with a visual analogue scale (VAS) in active range of motion (Active ROM) from baseline to the evaluation time at 6 weeks, 12 weeks and 6 months.

Active ROM		IG1 VAS pain Md (range)	IG2 VAS pain Md (range)	CG VAS pain Md (range)	IG1 vs IG2	IG1 vs CG	IG2 vs CG
Flexion	baseline	28 (0–73)	30 (0–74)	30 (0–74)	n.s.	n.s.	n.s.
	6 weeks	10* (0–76)	27 (0–72)	26 (0–70)	0.008	0.005	n.s.
	12 weeks	2*(0–55)	9*(0–66)	15*(0–69)	n.s.	0.000	0.017
	6 months	0*(0–40)	0*(0–45)	0*(0–90)	n.s.	n.s.	n.s.
Abduction	baseline	31 (0–79)	44 (0–83)	45(9–76)	n.s.	n.s.	n.s.
	6 weeks	13.5*(0–76)	25* (0–84)	27*(0–85)	0.020	0.039	n.s.
	12 weeks	0*(0–40)	13* (0–71)	15*(0–70)	0.000	0.000	n.s.
	6 months	0*(0–50)	1.5*(0–70)	4.5*(0–92)	n.s.	n.s.	n.s.
External rotation	baseline	25 (0–83)	36 (0–86)	22(0–71)	n.s.	n.s.	n.s.
	6 weeks	14 (0–88)	19.5 (0–76)	24 (0–89)	0.023	0.004	n.s.
	12 weeks	1*(0–25)	10.5*(0–68)	10 (0–77)	0.005	0.003	n.s.
	6 months	0*(0–55)	2*(0–81)	4*(0–87)	n.s.	n.s.	n.s.
Internal rotation	baseline	25 (0–70)	45 (0–91)	33 (0–87)	n.s.	n.s.	n.s.
	6 weeks	11.5 (0–61)	29*(0–90)	30 (0–90)	0.017	0.001	n.s.
	12 weeks	6*(0–60)	10*(0–89)	22 (0–65)	n.s.	0.004	n.s.
	6 months	0.0*(0–70)	2*(0–87)	9 (0–88)	n.s.	0.015	n.s.

Data are analysed with Kruskal–Wallis analysis of variance (ANOVA) and when significant pairwise compared with Mann–Whitney U test. *p*-values for the between-group differences are presented, when significant. IG1: Intervention Group 1: joint mobilization + guided exercises, IG2: Intervention Group 2: guided exercises, CG: Control Group, ROM: range of motion, VAS: Visual Analog Scale: 0–100mm *VAS ≥ 14mm: Minimal clinical important improvement (MCID) (29) Md: median: n.s: not significant.

a minimal clinical important difference (MCID) and is marked with a * in Table IV.

DISCUSSION

Twelve weeks of physiotherapeutically guided exercises showed significant improvements in shoulder function in patients with SAPS, as evaluated with the C-M score. This result is in line with earlier findings by Holmgren et al. and Hallgren et al. (30, 31). However, in contrast to the present study their SAPS patients had been treated with corticosteroid injections prior to the physical exercise period. According to the present trial, treatment with corticosteroids is not necessary for a good clinical outcome in patients with SAPS. Previous studies also concluded that corticosteroids should not be the first treatment of choice in patients with SAPS (32, 33).

Ruling out partial tears with clinical tests is difficult, while diagnosing FTT or total tears seem to be more accurate (13), which also was the case in the present trial (Table I). Only one patient with a FTT was found after the clinical examinations, while as many as 40% of the patients were diagnosed with a partial tear, where corticosteroids should not be the first treatment of choice (34).

An increase of 17–18 points in the C-M score between baseline and 12 weeks is of clinical importance in patients with SAPS (28, 35). Haahr et al. (26) reported a clinical improvement with a mean change of approximately 20 points in the C-M score after 12 weeks as well as after 6 months of guided exercises. In the present trial, guided exercise with or without joint mobilization led to between 20.8 (IG2) and 24.2 (IG1) points of improvement compared with 11.2 points in the CG after 12 weeks, measured with the C-M score (Table II and III, Fig. 4). This confirms the importance of physical therapy as the treatment of choice in patients with SAPS.

The current study found a short-term effect on pain reduction with add-on joint mobilization compared with exercises alone or no treatment. An early effect on reduced pain in patients with add-on joint mobilization is in agreement with the findings by Kromer et al (36). There are very few studies on joint mobilization as add on treatment to exercise in patients with SAPS. Reviews and meta-analysis have analysed the mixed effect of manual mobilization including a combination of different mobilization techniques in different joints (glenohumeral joint, acromioclavicular joint, scapulae and the cervical and thoracic spine), manipulations and other treatments, such as massage and acupressure, without coming to any firm conclusion (9, 37). The current study showed that joint mobilization, early in rehabilitation has an impact on pain reduction. The results could be of clinical interest, since there is currently no justification to support the use of NSAIDs (38), and many patients want pain relief before starting a rehabilitation period. These findings have to be further evaluated in future clinical trials.

Study limitations and strengths

A limitation of the current trial was the retrospective registration. In 2008–09 when the present study was planned, registration of physiotherapy research was not customary. However, according to Swedish health and medical care law, all patients have a medical journal, in which all test results are documented. Ethics approval for the study was obtained prior to the start of the study, and nothing was changed from the original approval. Today there is international consensus on the importance of prospective registration to enhance transparency and quality of reporting trials. To improve compliance with trial registration in the future, it has been suggested that all ethics committees added a clause to their standard approval letter and then electronically link the ethics form to the trial registration interface (39).

A further limitation was the different group sizes due to the randomization, with its "simple random allocation method" (40) and a control group, where every third patient seeking care was included. Today there are better computerized methods easily accessed online for clinical trials in primary care, where it is difficult to get resources for computer programs other than those used in daily care.

Lack of a longer follow-up is another limitation. Evaluations after 1 or 2 years would have been interesting, especially since the patients showed improvement at 6 months after the start of the study. On the other hand, the short-term result on pain reduction imply that more frequent evaluation times, at the beginning of the trial, could be of interest.

Trials including a control group with patients with SAPS who do not receive any treatment is unusual and should be considered a strength. The clear definition of SAPS, the thorough examination performed according to a standardized protocol and the blinding to group allocation of the patients are other strengths of the present trial.

Conclusion

Guided exercises, with or without joint mobilization, improve shoulder function in patients with SAPS without prior corticosteroid injections, compared with no treatment. In the short-term, add-on joint mobilization decreases pain and could be a substitute for NSAIDs or other painkillers at the start of a treatment period.

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The authors have no conflicts of interest to declare.

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Appendix I. Exercise programme.

Each exercise is held for 2–5 s and repeated 10 times in 3 sets, when possible. Pain 10–40 according to visual analogue scale (VAS) is allowed, but has to wear off between sessions in order to maintain the same load and amount of repetitions. (A–C) Retraction of the scapulae while lifting the arms to the hip (the subject is instructed to not lift too high). (A) and (C) can also be performed prone on the floor. (D–F) Retraction and loading of the shoulder stabilizers in a standing position: (E) adduction, (F) abduction. (G) Outward rotation with fixated elbow (small movement). (H) A progression of G. (I) Retraction of the scapulae while lifting the arms away from the back. (J) Loaded elevation and depression of the shoulder. (K) Stretching of the upper trapezius by depressing/lower the shoulder (with the subject keeping the arm close to the body and the hand flexed). (L) Stretching of the pectorals by moving the feet away from the arm. (H–J are held for 18–20 s and repeated twice). (M) Pendulum. Both the supervised exercise and the home training programme were divided into 4 levels for gradual progression. Level 1: exercise A–C, I, J, M. Level 2: exercise A–E, G, and I–K, M. Level 3: exercise A-G, I-M. Level 4: A–M, I–M. The cut-off level to move on to the next programme was clearly defined to the physiotherapist guiding the training: the patient had to be able to keep the scapulae retracted during the exercise, pain level (VAS 10–40) and training time (a maximum of 1 h). The home training programme consisted of exercises D–E, (with the addition of exercise H in level 4). Material: dumbbells or rubber bands for resistance. The photographs have been approved for publication by the model, who is a physiotherapist.

Appendix II. Joint mobilization.

Three different joint mobilizations of the caput humerus were given during the first 6 weeks of the intervention (1–2/week). The patients were offered a total of 8 sessions. Each mobilization was repeated 3 times and held for 30 s.

1. A lateral mobilization of the head of the humerus for pain reduction or restoring restricted extension from zero position.
2. Dorsal mobilization of the head of the humerus for pain reduction or restoring restricted flexion and medial rotation. Starting position: abduction and medial rotation.
3. Ventral mobilization of the head of the humerus for pain reduction or restoring restricted elevation. Starting position: prone with elevated, lateral rotated arm.

Appendix III. Constant-Murley score.

CONSTANT SCORE (100 P)

PAIN (15)

No pain	15
Slight pain	10
Moderate pain	5
Severe pain	0

Activities of daily living (10)

Work, unaffected	4	(All can be marked)
Sports/ leisure, unaffected	4	
Undisturbed sleep	2	

Working without problems to (10)

Waist	2
Sternum/Chest	4
Collarbone	6
Up to head (top of the head)	8
Above head	10

Active movement (20)	Flexion	Abduction
0-30°	0	0
31-60°	2	2
61-90°	4	4
91-120°	6	6
121-150°	8	8
151-180°	10	10

OUTWARD ROTATION (10)

Hand does not reach head	0	(All can be marked)
Hand behind neck, elbow forward	2	
Hand behind neck, elbow back	2	
Hand on top of head, elbow forward	2	
Hand on top of head, elbow back	2	
Full elevation med armbåge bakåt	2	

INWARD ROTATION (10)

Back of hand reaching:	Lateral aspect of tigh	0
	Buttoc	2
	Sacroiliac joint	4
	L3 (waist)	6
	Th 12	8
	Interscapular level (Th 7)	10

FORCE (25)

Isometric strength with arm abducted to 90 degrees in the scapular plane, elbow is straight, wrist pronated, palm facing down.
1 Point /½ KG

Sum:_____