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Original Article

Home training with or without joint mobilization compared to no treatment: a randomized controlled trial

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Abstract. [Purpose] To investigate if joint mobilization in patients with subacromial pain syndrome has additional benefits to a home training program on shoulder function and pain, and to compare home training to no physical therapy. [Participants and Methods] Eighty-nine primary care patients (mean age 45 years) with subacromial pain syndrome during an average of 23 weeks. Home training was performed twice a day during a 12 week period. One of the intervention groups received add-on shoulder joint mobilization to the home training. A third group did not receive any physical therapy. Constant-Murley score, pain and active range of motion was evaluated at baseline, 6 weeks, 12 weeks and 6 months. [Results] The total Constant-Murley score revealed no significant differences between groups at any time point. All groups improved over time. The add-on joint mobilization group reached clinical important change at 12 weeks. The subscale pain showed that both intervention groups reported less pain after 12 weeks compared to the reference group. [Conclusion] Home training is not superior to no treatment evaluated with the total Constant-Murley score. However, home training with or without add-on joint mobilization may decrease pain compared to no treatment.

Key words: Constant-Murley score, Joint mobilization, Shoulder pain

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INTRODUCTION

Subacromial pain syndrome (SAPS) is a common multifactorial condition[1)] including several rotator cuff pathologies ranging from increased tendon thickness [e.g. tendinopathies], bursitis to partial or full thickness tears. However, what causes the pain in patients with SAPS is yet not fully understood. Neer found that shoulders without rotator cuff pathologies have the same symptoms as those presenting with[2)]. On the other hand, shoulders with rotator cuff pathologies may be asymptomatic[3)]. In a recent study Nordqvist et al. found that rotator cuff dysfunction is seen in almost all patients with SAPS, while limited active range of motion (AROM) and scapular dyskinesia is found in almost half of the patients[4)] without any correlation between these findings.

A combination of tests such as painful arc test, external rotation resistance test, Hawkin test and the Jobe test have been recommended as diagnostic tools to confirm SAPS[5)]. The accuracy of these tests have been criticized regarding lack of validity and reliability. Therefore, it has been suggested abandoning the pathological model when setting the diagnosis[6)], and instead emphasizing the dysfunction[7)]. Compared to non-operative treatments, surgical interventions may not be beneficial for patients with SAPS[8, 9)]. Graded loaded exercises have been suggested as the optimal rehabilitation[10)], and should there-

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fore be chosen as the first line treatment option[11, 12]. These recommendations include patients with full-thickness tears[13]. Whether home training or physical therapist guided training is the best choice is still under debate and previous research is inconclusive. Some studies have shown home training or supervised training equally effective for SAPS patients[14, 15], while a recent large study reported that supervised training was superior to home training[16].

The evidence of exercise combined with manual therapy for treating SAPS are conflicting and only a few systematic reviews have reported significant results supporting the effect of manual treatment, and if so, the clinical importance has not been stated[17]. Manual therapy interventions such as joint mobilization techniques, are often used by physical therapists when treating patients with SAPS. Joint mobilization have been defined by the International Federation of Orthopaedic Manipulative Physical Therapists as skilled hand movements performed by a therapist. Kaltenborn[18], identified a scale in 3 levels to describe the joint mobilization amplitude. Grade 1 of this scale is "loosen up the slack", where a small piccolo-traction eliminating the compressive forces on the joint is believed to relieve pain. Grade 2 and 3 introduce a glide to one joint surface relative to another while maintaining the joint traction. Adding joint mobilization to an exercise program may decrease pain and thereby improve function, but this is not yet fully established[19].

To the best of our knowledge joint mobilization as an addition to home training has not previously been studied. Therefore, the objective of the present trial was to investigate if joint mobilization could have any additional effect on a home training program on shoulder function and pain, and to compare the effect of home training to no physical therapy in patients with SAPS. The hypothesis was that an addition of joint mobilization to the glenohumeral joint would be superior to home training alone or no treatment in patients with SAPS.

PARTICIPANTS AND METHODS

A randomized controlled trial was conducted at Karolinska Institutet, Stockholm, Sweden. The trial was approved by the Regional Ethics committee in Stockholm, 2009 (Dnr2009/1197-31/2) and registered in International Standard Randomised Controlled Trial Number (ISRCTN67469356). Fifty SAPS patients (22 males and 28 females) mean 45 years were randomized to a home training + joint mobilization group (MG) or a home training group (HG). A reference group (RG) of 19 male and 20 female patients with the same inclusion and exclusion criteria from a previous study[20] served as a reference group. This is in accordance with a study by Ludewig et al.[21], where asymptomatic subjects were assigned to a second control group without randomization. SAPS was defined as subacromial pain with ruled out restricted passive movement of the shoulder joint and no referred pain from the cervical or thoracic spine.

The patients were identified during visits to physicians and physical therapists in four primary care clinics in Stockholm, Sweden between October 2012 and February 2016. They were recruited according to the following criteria: age between 20 and 59 years, complaints of shoulder pain between four weeks and one year, positive painful arc during flexion and/or abduction of the shoulder joint. Patients with two positive findings of the following tests to indicate SAPS[22]: Hawkin-Kennedy Test[23], Jobe Test[24], painful resisted shoulder abduction, external or internal rotation, or a positive lift off test[25].

Exclusion criteria were bilateral shoulder problems, diabetes mellitus, prior corticosteroid injection and referred pain from the cervical or thoracic spine and clinical findings of full-thickness rotator cuff tear. Patients with shoulder joint instability, restricted passive movement (frozen shoulder, severe arthroses and arthritis, earlier surgical procedures) and difficulties in understanding the Swedish language were also excluded.

At the first consultation, patients who met the inclusion criteria were informed about the study, and patients who agreed to participate in the study signed a written informed consent. These patients were randomly allocated into two groups (MG and HG) using a sealed envelope consisting of two smaller envelopes, one for MG and one for HG. The group allocation was randomly performed by an independent physical therapist by drawing one of the two smaller envelopes. The smaller envelope was replaced and used again. Consequently, there was always a 50% chance for entering each group[26] which may explain the difference in group size. MG (n=20), HG (n=30). The RG (n=39) did not receive any physical therapy or training advices. Radiological and ultrasound (US) examinations were performed within the first five weeks after recruitment, in order to rule out malignity or detect other pathologies.

The experienced physiotherapist (Specialist in Orthopaedic Manual Therapy) conducting all the examinations at baseline, 6 weeks, 12 weeks and 6 months after the intervention was blinded to the randomization and the patients were blinded to the different intervention groups within the study, meaning the patients were not aware of other interventions offered. Baseline characteristics are presented in Table 1.

The home training program[20], was instructed to MG and HG at baseline and after six weeks by the one physiotherapist performing all the examinations. The home training protocol consisted of circulation exercises, gradually loaded exercises of the scapulae stabilizers and stretch. It was performed twice a day during 12 consecutive weeks. The patients were then encouraged to continue with their home training program 2–3 times a week until the 6 month follow-up. The home training program was gradually progressed and somewhat individualized due to pain, motivation and learning capacity. In the beginning, the patients were instructed to perform the exercises isometrically and then progress to more eccentric and dynamic load. The patients performed each exercise 10 times in 3 sets. Some degree of pain, 10–40 out of 100 mm, measured with a Visual Analogue Scale (VAS) or pain accepted by the patient was allowed during training. This pain had to wear off between training sessions. If pain was maintained after an activity, it was instructed that a reduction of that activity should be carried out.

Table 1. Patient characteristics at baseline

Variable		MG (n=20)	HG (n=30)	RG (n=39)
Male/Female	n	7/12	14/16	19/20
Age (years)	m (SD)	43 ± 11	43 ± 12	46 ± 10
Physical activity (times/week)	m (SD)	1.6 ± 1.5	1.1 ± 1.3	1.7 ± 1.7
Dominant arm, right	n (%)	18 (90)	27 (90)	38 (97)
Symptomatic arm=dominant	n (%)	12 (60)	20 (67)	26 (67)
Duration of pain (weeks)	m (SD)	24 ± 13	22 ± 14	24 ± 17
Slow debut	n (%)	18 (90)	27 (90)	35 (90)
Pain at rest	n (%)	11 (55)	19 (66)*	24 (62)
Pain at movement	n (%)	20 (100)	29 (100)*	39 (100)
Pain at compression	n (%)	16 (80)	26 (90)*	33 (85)
Analgesics (NSAID's)	n (%)	11 (55)	22 (76)*	26 (67)

MG: joint mobilization and home training group; HG: home training group; RG: reference group.
*n=29 (one missing answer).

The patients in MG, received joint mobilizations at the clinic, 8 sessions during the first 6 weeks, as add-on treatment to home training. One physiotherapist at each clinic was instructed in how to perform the low speed joint mobilization therapy according to Kaltenborn[18]. Every glide was held for about 30 sec and repeated 3 times.

1: A lateral mobilization of the head of the humerus for pain reduction or restoring restricted extension from zero position. Starting position: supine.

2: Dorsal mobilization of the head of the humerus for pain reduction or restoring restricted flexion and medial rotation. Starting position: supine, with arm in 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.

HG performed the 12 weeks home training program and RG was informed to live as usual. The pain management was equally instructed to the groups. All three groups were allowed to take prescribed drugs, though they were encouraged to decrease the intake if they were feeling better or if they did not have any effect of the medicine. Some pain (VAS 10–40) or pain accepted by the patient was allowed in daily life activities.

Primary outcome was the original Constant-Murley score (C-M)[27] after 6 weeks, 12 weeks and 6 months. The score has been validated by Roy et al.[28] and recommended to be used in shoulder research by the European Society for Surgery of the Shoulder and Elbow. The score has a maximum of 100 points which represent a pain free shoulder without any functional problems. The C-M score includes four subscales: pain (15 points), activities of daily living (20 points), range of motion (40 points) and strength (25 points). Secondary outcomes were active range of motion (AROM) and pain, evaluated with a VAS 0–100 mm.

Sample size calculation was based on a study by Haahr et al[29]. At that time, the minimal important change of the C-M score was not known[30]. Sample size calculations, (power 80%, p=0.05), indicated 22 patients per group. TIBCO Statistica® version 13.4 was used for statistical analysis[31, 32]. All variables were summarized with standard descriptive statistics such as frequency, mean and standard deviation (m(SD)) or median and range (md(min–max)). Yes/no-answers were presented as proportions of yes-answers and presented with 95% confidence intervals (95%CI). The total C-M score, the change score (C-M score adjusted for baseline) and different movement directions were analysed with repeated measures ANOVA. The subscale pain and pain at different movement directions evaluated with the Visual Analog Scale 1–100 mm (VAS) were analysed with Kruskal Wallis ANOVA and where significant, pairwise compared with Mann Whitney U test. All continuous data was analyzed with intention to treat (ITT) using the mean or median by randomized groups. The significance level in all analyses was set at $p \leq 0.05$ (two-tailed).

RESULTS

The flow of patients is presented according to the Consort Statement (Fig. 1). Patients who did not attend the scheduled visit were reminded by a phone call, according to clinical practice, and thereafter withdrawn from the study. MG and HG had a high (>80%) compliance with the home training and joint mobilization visits.

The total C-M score and change in score revealed no differences between groups at any time point (Table 2). All groups improved over time ($p<0.0000$). The add-on joint mobilization group reached clinical important change (≥17–18)[30] at 12 weeks (Table 2). The subscale pain in the C-M score showed that both the MG and HG reported less pain after 12 weeks compared to RG ($p<0.001$). The MG also reported less pain after six months compared to RG ($p<0.001$).

Pain in movement, during compression and pain at rest as well as medication (NSAID's) at the different evaluation times

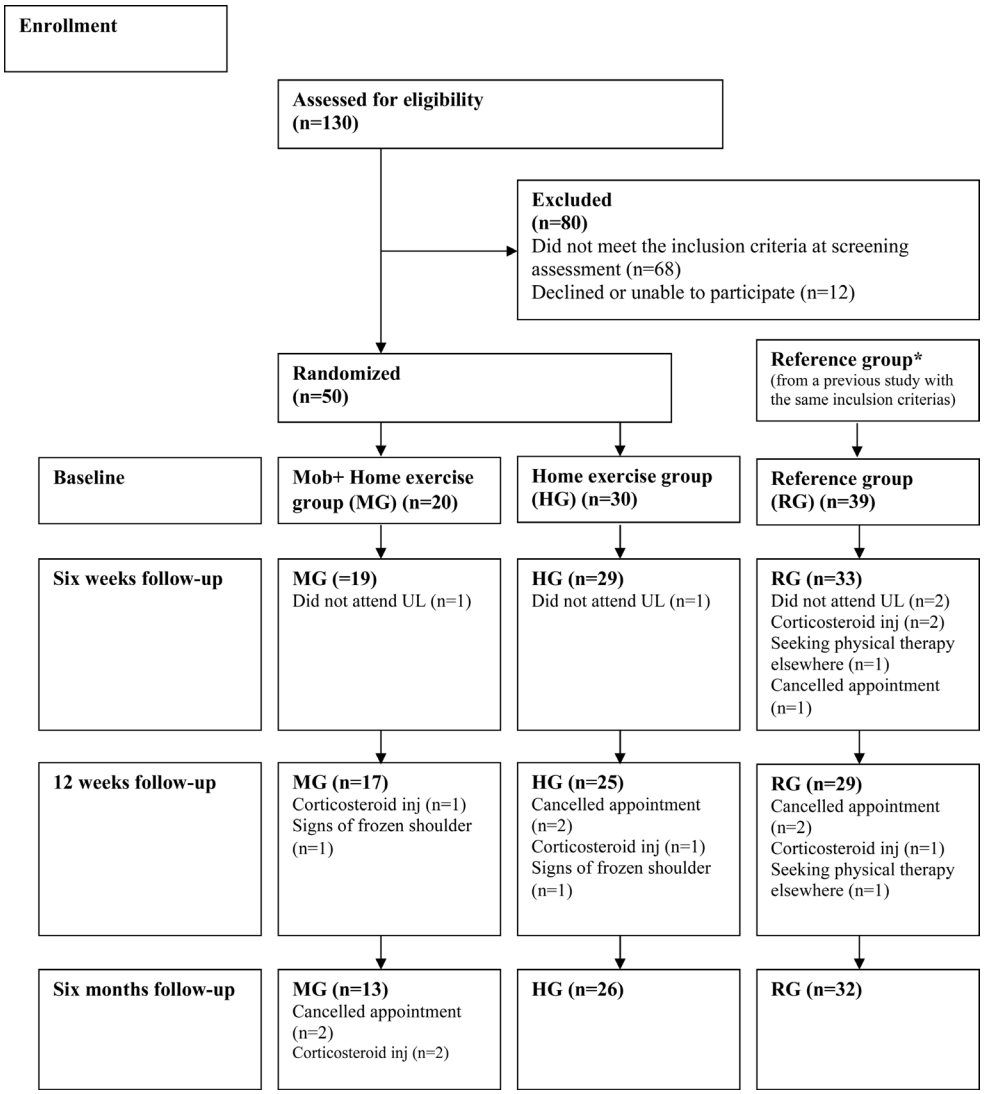

Fig. 1. Flow-chart of the patients throughout the entire study reported following the recommendations of the Consolidated Standards of Reporting Trials (CONSORT).
Inj: Injection, *ref[18].

Table 2. Shoulder function measured with Constant-Murley score in patients with subacromial pain syndrome

Total C-M Score:				
group	Baseline	6 weeks	12 weeks	6 months
MG	36.4 (30.1–42.8)	45.6 (38.3–52.8)	57.3 (49.7–64.9)	65.2 (59.3–71.1)
HG	39.1 (36.2–42.0)	45.3 (41.4–49.2)	55.0 (50.0–60.0)	58.8 (53.4–64.2)
RG	40.1 (36.9–43.2)	46.2 (42.9–49.6)	51.3 (48.2–54.4)	57.6 (53.7–61.6)
	Change score:	0–6 weeks	0–12 weeks	0–6 months
MG		9.2 (8.2–10.0)	20.9*(19.6–22.1)	28.8 (29.2–28.3)
HG		6.2 (5.2–7.2)	15.9 (13.8–18.0)	19.7 (17.2–22.2)
RG		6.2 (7.2–11.4)	11.2 (7.2–11.3)	17.6 (9.7–15.3)

The total score and the improvement from baseline to the three evaluation times, called the change-score, is presented with mean values and 95% confidence intervals (CI).
C-M: Constant-Murley; MG: Joint-mobilization + Home exercise group; HG: Home training group; RG: Reference group.
*: Clinical important change ≥17–18 points[28, 32].

are presented in Table 3. Pain estimated with VAS in different movement directions is presented in Table 4, and minimal important change in VAS (≥14 mm)[33] is marked with an Asterix. Pain in AROM decreased over time. Both MG and HG reported significantly less pain in most directions (AROM) at 12 weeks and 6 months compared to the RG (Table 4). Significant differences between MG and HG, in favor of MG, were also found in all movement directions, except for internal rotation at 12 weeks, where it was the other way around (Table 4).

AROM improved significantly in all three groups over time in terms of flexion, abduction, internal and external rotation ($p<0.001$) and in flexion there was a significant difference at 12 weeks between the intervention groups and RG ($p<0.001$).

DISCUSSION

In contrast to our hypothesis, patients from all groups significantly improved their shoulder function over time as measured with the C-M score. At 12 weeks follow-up a clinical important change in the C-M score has been estimated to ≥17–18 points[30, 34], and only the add-on joint mobilization group (MG) reached this level of change (20.9 points). Previous reports on home training using C-M score show similar results. Walther et al.[35] found a mean improvement of 9 points after six weeks from baseline and a mean improvement of 16 points after 12 weeks, which is similar to the HG in the present trial (15.9 points). Giombini et al.[36] showed a mean improvement of only 3.8 points after six weeks. However, their home program only consisted of passive exercises, which might explain their small improvement. The patients in the RG in the present study reached a somewhat higher score than the participants in the study of Giombini.

The clinical important change in MG in the present study might be due to pain relief. In a previous study we found short term pain relief during joint mobilization[20]. When analyzing the C-M subscore pain, both MG and HG reported less pain after 12 weeks compared to the RG. This result together with the finding that the intervention groups reported significantly less pain during flexion and an increase in active flexion compared to RG after 12 weeks, could encourage patients to keep up their home training.

A high pain threshold is believed to improve the adherence to prescribed exercises[37]. This knowledge may be useful as an indication for which patients a home training program could be successfully prescribed. In the present trial, patients who had been treated with corticosteroid injections were excluded, though NSAID treatment was allowed, since this is one of the most conservative interventions[38, 39]. Corticosteroid injections may be a valid alternative only when exercise is not possible, while NSAIDs can be helpful in the short term[40], in order to reduce pain and encourage activity. Participants in the present trial were informed to stop their intake of NSAID when pain management could be performed without medication, since NSAID has a negative effect on the structural healing of degenerative tendons[38, 39].

Our results, though small, show that home training and, even better, home training with joint-mobilization, is more effective in decreasing pain compared to no treatment, although no statistical differences were found when evaluated with the total C-M score. One reason for similar results in all three groups may be due to that some patients did not follow the recommended home program. Another reason may be that some patients in RG continued to be physically active or found suitable exercises on their own. It may also be that some patients benefit more from home training than others. Considering

Table 3. Proportions of yes-answers and 95% CI for pain at rest, pain in movement, pain at compression and medicine at the different evaluation times

Pain at rest	Baseline	6 weeks	12 weeks	6 months
MG	0.58 (0.36–0.80)	0.32 (0.11–0.53)	0.24 (0.04–0.44)	0.08 (0.65–0.94)
HG	0.66 (0.49–0.83)	0.34 (0.17–0.51)	0.28 (0.10–0.46)	0.23 (0.07–0.39)
RG	0.62 (0.47–0.77)	0.39 (0.22–0.56)	0.47 (0.29–0.65)	0.36 (0.20–0.52)
Pain in movement	Baseline	6 weeks	12 weeks	6 months
MG	1.00	1.00	0.76 (0.04–0.44)	0.54 (0.27–0.81)
HG	1.00	0.97 (0.90–1.04)	0.84 (0.70–0.98)	0.69 (0.51–0.87)
RG	1.00	0.97 (0.91–1.03)	0.93 (0.84–1.02)	0.85 (0.73–0.97)
Pain at compression	Baseline	6 weeks	12 weeks	6 months
MG	0.84 (0.68–1.00)	0.68 (0.47–0.89)	0.41 (0.18–0.64)	0.24 (0.06–0.42)
HG	0.90 (0.80–1.00)	0.76 (0.61–0.91)	0.56 (0.36–0.76)	0.46 (0.27–0.65)
RG	0.82 (0.70–0.94)	0.64 (0.56–0.72)	0.57 (0.39–0.75)	0.48 (0.31–0.65)
NSAID	Baseline	6 weeks	12 weeks	6 months
MG	0.55 (0.33–0.77)	0.21 (0.19–0.23)	0.12 (–0.03–0.27)	0.00
HG	0.73 (0.57–0.89)	0.34 (0.17–0.34)	0.24 (0.07–0.41)	0.04 (–0.03–0.11)
RG	0.90 (0.84–0.95)	0.24 (0.09–0.39)	0.10 (–0.01–0.21)	0.19 (0.05–0.32)

MG: joint mobilization and home training group; HG: home training group; RG: reference group; NSAID: Non-Steroidal Anti-inflammatory Drugs.

Table 4. Pain measured with a Visual Analog Scale (VAS) in active range of motion from baseline to the evaluation time at 6 weeks, 12 weeks and 6 months

Active ROM		MG VAS pain MD (range)	HG VAS pain MD (range)	RG VAS pain MD (range)	MG vs. HG	MG vs. RG	HG vs. RG
Flexion	Baseline	30 (0–70)	26.5 (0–70)	31 (0–72)			
	6 weeks	24 (0–60)	32 (0–76)	26 (0–70)			
	12 weeks	0* (0–36)	0* (0–50)	20 (0–69)	0.000	0.002	0.000
	6 months	0* (0–30)	10* (0–82)	0* (0–90)			0.000
Abduction	Baseline	36 (0–70)	38 (0–95)	45 (9–76)			
	6 weeks	22.5 (0–62)	30 (0–95)	27* (0–85)			
	12 weeks	10* (0–65)	18* (0–66)	15* (0–70)			
	6 months	0* (0–70)	15* (0–65)	5* (0–92)	0.037	0.002	0.050
External rotation	Baseline	18 (0–64)	28.5 (0–81)	22 (0–71)			
	6 weeks	21 (0–70)	26 (0–70)	24 (0–89)			
	12 weeks	0* (0–45)	4* (0–76)	10 (0–77)	0.005		0.047
	6 months	0* (0–37)	8* (0–71)	4* (0–87)	0.025	0.008	
Internal rotation	Baseline	39 (0–88)	42.5 (6–75)	33 (0–87)			
	6 weeks	28 (0–76)	28* (0–82)	30 (0–90)			
	12 weeks	17* (0–50)	0* (0–5)	22* (0–65)	0.000		0.000
	6 months	0* (0–26)	13* (0–79)	9* (0–88)	0.012	0.008	

Data is analyzed with ANOVA and, when significant, pairwise compared with the Mann-Whitney U test.
p-values for the between group differences are presented when significant.
MG: joint mobilization and home training group; HG: home training group; RG: reference group; VAS: Visual Analog Scale=0–100 mm. *VAS ≥14 mm=Minimal clinical important improvement (MCID)[31].

the results from the present trial, home training does not seem to be much more effective than no treatment at all. Other authors have concluded that physiotherapist supervised exercises result in greater improvements compared to home training in patients with SAPS[16]. This is important knowledge not only to physiotherapists and patients, but also to decision makers when planning future health care.

A limitation with the present study was the uneven group sizes. A possible reason for this may be the methodology with a 50% chance to be included in either group at all times[26]. Another limitation was that the patients in the RG were borrowed from one of our previous trials, though included from primary care, with the same inclusion and exclusion criteria[20].

A strength with the present study was that both the examiner and the patients were blinded to group as well as intervention offered to others. Other strengths were the clear definition of SAPS and the thorough examination performed according to a standardized test-protocol.

In future trials, new outcome scores with higher sensitivity and specificity to better detect changes in pain and function is welcomed. The individual patient's previous experience and expectations may influence the treatment response, which has to be addressed in future trials. The results should also focus on clinical importance, before we fully can recommend passive treatments to an exercise regimen.

In conclusion, there is no significant difference between home training, home training with add-on joint mobilization or no treatment for patients with SAPS, evaluated with the total C-M score. Measuring pain as a single variable, home training and home training with add-on joint mobilization showed decreased pain compared to no treatment. To fully understand who benefits from home training, add-on joint mobilization or physiotherapist led treatment, we suggest that future research emphasize more on the individual patient.

Funding and Conflicts of interest

No funding sources or conflicts of interest were reported for this study.

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