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Primary Results From an Investigator-Blinded, Randomized, Controlled Trial**

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ORIGINAL RESEARCH

Effect of Psychomotricity in Combination With 3 Months of Active Shoulder Exercises in Individuals With Chronic Shoulder Pain: Primary Results From an Investigator-Blinded, Randomized, Controlled Trial

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Abstract

Objective: To evaluate whether psychomotor therapy (PMT) in combination with usual care active exercise (AE) rehabilitation for the shoulder is superior to merely AE.

Design: The trial was a single-center, stratified (by corticosteroid injection [yes or no]), randomized, and controlled superiority trial.

Setting: Shoulder unit of the orthopedic department at Hospital Lillebaelt, Vejle Hospital.

Participants: Eligible participants (N=87) were adults aged 18-75 years with shoulder complaints lasting for at least 3 months, in addition to a score equal to or below 3 on the Multidimensional Assessment of Interoceptive Awareness score. Furthermore, patients had at least a visual analog scale pain score of 2 at rest, 3 at night, and 5 in activity (range: 0-10).

Interventions: Patients were randomized to 12 weeks of AE (control group) or in combination with 5 PMT sessions (intervention group).

Main Outcome Measure: The primary outcome was the patient-reported outcome score Disability of the Arm, Shoulder and Hand questionnaire. The primary endpoint was 12 weeks after baseline.

Results: There was no between-group difference in function between the intervention group and control group.

Conclusions: Our results showed no additional benefit on patient-reported function and pain from PMT over usual care in patients with long-lasting shoulder pain and low body awareness. This finding suggests that PMT adds no additional benefit to patients' recovery in relation to pain and active function in comparison to standard care.

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Shoulder pain is a frequent complaint in primary and secondary care.¹⁻³ Patients often experience long-lasting pain and decreased function due to their shoulder disorder, with high risk of pain becoming chronic.⁴ National clinical guidelines recommend active exercises (AEs) as primary treatment.⁵ However, several clinical trials have shown only moderate effects after exercise

interventions.⁶⁻⁹ Therefore, mainly focusing on active exercises is not always sufficient to significantly improve patients' pain and function. Multimodal intervention strategies, have shown to improve the results for patients having chronic pain.¹⁰ In shoulder patients, pain self-efficacy has been shown to be a strong predictor for continued pain and disability, why education and focus on self-efficacy is recommended as part of a rehabilitation program.^{11,12} Psychomotor therapy (PMT), based on a biopsychosocial approach, combines pedagogic and manual therapeutic approaches, and encompasses aspects of self-awareness and self-efficacy education, and could therefore potentially in combination with an AE strategy improve standard treatment. However, evidence for the effect of psychomotor therapy is lacking, and to

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our knowledge, no prior study has investigated the supplemental effect of psychomotor therapy, when applied with an AE strategy among patients with chronic shoulder pain.

The primary aim of the current trial was to evaluate whether PMT in combination with usual care consisting of AE rehabilitation for the shoulder is superior to merely active exercise rehabilitation for the shoulder. We hypothesized that the intervention group (PMT+AE) would have a significantly larger decrease in the primary endpoint from the Disability of the Arm, Shoulder and Hand (DASH) questionnaire.¹³

Methods

Trial design

The trial was a single-center, stratified (corticosteroid injection [yes or no]), randomized, controlled superiority trial. The primary endpoint of disability was 12 weeks after baseline. Patients were randomized to either the PMT+AE group or the AE group.

Participants

Between March 2016 and March 2017, we recruited participants with long-lasting shoulder pain and decreased body awareness from the shoulder unit of the orthopedic department at Hospital Lillebaelt, Vejle Hospital. Eligible participants were adults aged 18-75 years with shoulder complaints lasting for at least 3 months. To be included, patients had to score equal to or below 3 on the Multidimensional Assessment of Interoceptive Awareness (MAIA) score, which measures 8 different aspects of patients' bodily awareness, including the ability to regulate psychological distress by attention to body sensations, tendency not to ignore or distract oneself from sensations of pain or discomfort, and awareness of the connection between body sensations and emotional states.^{14,15} Furthermore, patients should have at least a visual analog scale pain score of 2 at rest, 3 at night, and 5 in activity (range: 0-10).¹⁶

Exclusion criteria were as follows: (1) patients scheduled for surgery; (2) fractures or glenohumeral osteoarthritis verified by radiograph; (3) shoulder surgery within the last 6 months; (4) clinically symptomatic osteoarthritis in the glenohumeral or acromioclavicular joint; (5) frozen shoulder or symptoms derived from the cervical spine; (6) suspected competing diagnoses (eg, rheumatoid arthritis, cancer, neurologic disorders, fibromyalgia, psychiatric illness, posttraumatic stress disorder); (7) use of psychopharmacy drugs; (8) current substance abuse; (9) pregnancy; or (10) inability to understand spoken or written Danish.

List of abbreviations:

AE	active exercise
CI	confidence interval
DASH	Disability of the Arm, Shoulder and Hand
GPE	Global Perceived Effect
IQR	interquartile range
ITT	intention to treat
MAIA	Multidimensional Assessment of Interoceptive Awareness
NRS	Numerical Rating Scale
PMT	psychomotor therapy
SMS	short message service

Interventions

Prior to randomization, all patients were given an initial exercise instruction with a physiotherapist, who planned a patient-specific AE program to be performed at home. Patients randomly assigned to follow AE (control group) intervention, received subsequently up to 4 individual sessions with the physiotherapist. Specific exercises were based on the individual participants' pain and movement restrictions, but consisted mostly of strengthening and stabilization exercises for the glenohumeral joint with focus on the rotator cuff muscles, and the scapula-thoracic muscles. The usual care AE regime for patients with shoulder pain at the physiotherapy department advocate 3 sets of 15-20 repetitions every second day, allowing for some increase in pain during and in the subsequent 12 hours after exercise. Secondly, posture correction and stretching exercises were applied if deemed relevant by the physiotherapist. Patients were advised to seek further advice on progression of exercises at a private practice physiotherapy clinic, and continue exercises for at least 3 months. The treating physiotherapists were all experienced therapists with more than 5 years of experience in treating patients with shoulder pain.

The PMT+AE (intervention group) received the same active exercise rehabilitation intervention as the AE group and furthermore received 5 sessions with a psychomotricity therapist within the first 8 weeks after inclusion. These sessions were founded on the phenomenology theory base, which states that you are and act out of your body, and therefore an increased knowledge of your body, and an increased self-efficacy in relation to different symptoms, is essential to go through different and maybe critical periods of life and respond constructively. The PMT sessions included different therapeutic techniques, including soft manual palpation of muscles, with a focus on shoulder, arm, and neck muscles, in order to improve consciousness and understanding of signals from the sensory and kinesthetic system. Through this improved consciousness, the goal of PMT is that, patients become able to sense muscle tonus in daily life, how the muscle tension reacts to different situations in daily living, and how it affects psychology, behavior, and pain experience. Recognition of patterns and changes was used to give the patients a toolkit they could use, to guide them through the day in a less painful way. The sessions also consisted of breathing and bodily awareness exercises in an effort to emphasize mental calmness and to balance the sensory system in order to calm the sympathetic nervous system. The psychomotricity therapist performing all PMT procedures was an experienced therapist with 4 years of experience in working with patients with shoulder pain. Patients were seen for a 3-month follow-up evaluation at the shoulder unit.

An orthopedic specialist based concomitant administration of corticosteroid injection on evaluation of pain level and presence of inflamed subacromial bursae or calcifications. The corticosteroid injections were administered to patients after baseline assessment, but before randomization.

Outcomes

Primary outcome was change in DASH questionnaire scores (scores of 0-100, 100=no problems) from baseline to week 12.¹³ The DASH questionnaire is a patient self-reported outcome measure, measuring pain and function in the upper extremity. It is considered valid and reliable,^{17,18} with a minimal clinically relevant difference of 10.2.¹⁸

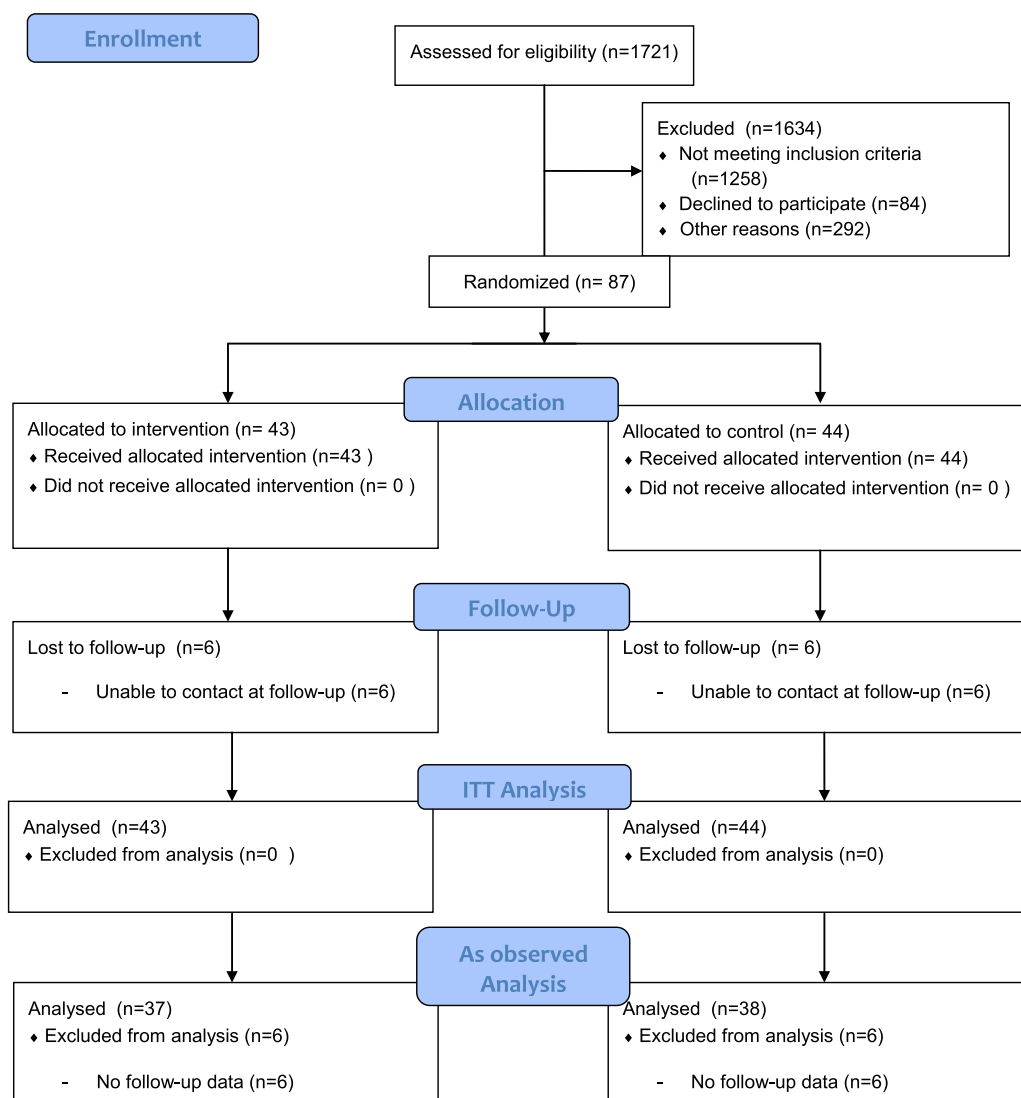


Fig 1 CONSORT flowchart. Abbreviation: CONSORT, Consolidated Standards of Reporting Trials.

The numeric rating scale (NRS) for pain was measured by asking patients to score their pain from 0 (no pain) to 10 (extreme pain) at rest, during sleep, and during activity over the last 24 hours. NRS was measured at baseline and 12 weeks of follow-up. The short message service (SMS) tracking system^a was applied with a weekly question regarding pain, to which patients could answer with an SMS including a number between 0 and 10, corresponding to the NRS for pain.¹⁹⁻²¹

Demographic and patient-reported data were obtained, covering pain and socioeconomic variables such as age, gender, body mass index, history of injury (accident, overload, or unknown), duration of current symptoms, education level, and Hospital Anxiety and Depression Scale scores (scores of 0-21, 0=no problems).²² Furthermore, a Global Perceived Effect (GPE) score ("How are your shoulder complaints today in comparison to prior to your participation in the trial?") Likert scale 1-7, with 1=better, an appreciable improvement; 7=worse, an appreciable worsening) at 12 weeks' follow-up.

Data collection

Baseline and 12 weeks' follow-up assessments were performed through patient self-reporting on tablets in the shoulder unit.

From weeks 1-12, the patients received an SMS once a week, asking the patient to grade the present shoulder pain level from 0-10 (NRS).

Sample size and power calculations

Based on studies from patients with shoulder pain,^{6,7,23-27} we expected a mean baseline of 40 points in the DASH questionnaire with an SD of 16, and a 50% change (change from 40 to 20 DASH points) in the PMT+AE group and a 25% change (change from 40 to 30 DASH points) in the AE group. For a 2-sample, pooled *t* test of a normal mean difference with a 2-sided significance level of .05 ($P \leq .05$), assuming a common SD of 16 DASH points, we found that a sample size of 42 patients per group was required to obtain a power of at least 80% for detecting a mean difference of 10 DASH points between the 2 groups.

Table 1 Demographic and baseline values for PMT+AE and AE

Variable	PMT+AE (n=43)	AE (n=44)
Sociodemographic measurements		
Mean age (y) ± SD	50.8±12.0	50.0±13.4
Sex, female, n (%)	22 (51.2)	30 (68.2)
Mean BMI (kg/m ²) ± SD*	28.9±7.9	27.3±5.5
Education, n (%)*		
Low	29 (70.7)	30 (69.8)
Medium	10 (24.4)	8 (18.6)
High	2 (4.9)	5 (11.6)
Duration of symptoms (mo), median (range)*	11 (3-168)	12 (3-252)
Symptom history, n (%)*		
Accident or acute incidence	10 (24.4)	12 (27.9)
Slow consistent development (overload)	14 (34.2)	16 (37.2)
Unknown	17 (41.5)	15 (34.9)
Corticosteroid injection at baseline, n (%)	22 (51.1)	23 (52.3)
Mean HAD ± SD [†]		
Depression	4.3±3.5	3.7±2.8
Anxiety	7.2±3.8	6.1±3.8
Mean MAIA score ± SD	2.4±0.4	2.3±0.4

NOTE. The Hospital Anxiety and Depression Scale range is 0-21. The Psychomotor Therapy Group (Intervention Group) is represented by PMT+AE.

Abbreviations: BMI, body mass index; HAD, Hospital Anxiety and Depression Scale.

* n = 84 (PMT+AE = 41; AE = 43).

[†] n = 86 (PMT+AE = 42; AE = 44).

Randomization and allocation concealment

Patients were randomly assigned to PMT+AE or AE with a 1:1 allocation, stratified by administration of concomitant corticosteroid injection. A computer-generated randomization schedule with permuted blocks of random sizes (2-6) was used to prepare opaque, sealed, sequentially numbered envelopes placed accordingly in 2 separate ring binders (corticosteroid: yes or no). A secretary at the hospital prepared the sequentially numbered envelopes, while secretaries at the shoulder units performed the allocation procedure by taking the next prepared, sequentially numbered, opaque, sealed envelope. The study investigators were kept blinded from group allocation until primary analysis had been performed and conclusion had been written.

Statistical analysis

To evaluate the empirical distribution of continuous outcomes, visual inspection was used to suggest whether the assumption of normality and variance homogeneity was reasonable.

For primary efficacy analysis in the intention-to-treat (ITT) population (all randomized patients independent of compliance and withdrawals), the between-group difference in the change from baseline to 12 weeks in the DASH score was calculated. The baseline observation carried forward technique was used in case of missing data (eg, patients who did not complete the study).

For the primary analyses, analysis of covariance was used to compare mean changes from baseline to 12 weeks' follow-up in DASH scores. The primary model included change from baseline as the dependent variable, with treatment group (PMT+AE or AE) and corticosteroid status (yes or no) as main effects. The baseline score was an additional covariate. For these analyses, results are expressed as the difference between-group means and 95% confidence intervals (CIs) with associated *P* values, based on the general linear model.

To analyze the longitudinal element of time effects on the NRS pain score, recorded by SMS tracking (repeated measures design at 1-12 wk), a mixed linear model approach was used, where the "patient" was applied as a random effects variable, to take into account the clustering on individuals due to highly significant intraclass correlation in individuals. Assessment of treatment and time effects was exploratory for the primary outcome in testing for a possible interaction. Treatment and time were used as systematic factors, using baseline values as covariates to reduce random variation and increase power.

All analysis based on the ITT population were performed blinded to group allocation (groups named A and B in the dataset).

In the "per protocol" population, the GPE score was analyzed with a chi-square test, for analysis of differences in perceived effect between the 2 groups from baseline to 12 weeks' follow-up.

Before unblinding of group allocation, the primary conclusion was written and approved by all authors. Analyses were performed using Stata^b version 14. A *P* value <.05 was considered statistically significant.

Results

A total of 1721 patients were assessed for eligibility. Eighty-seven patients fulfilled the eligibility criteria and provided informed

Table 2 Analysis of changes in ITT population for primary outcomes 12 weeks after baseline for PMT+AE and AE

	Baseline		12 Weeks' Follow-Up		Within-Group Change		Adjusted* Between-Group Difference on Change	<i>P</i> Value
	PMT+AE (n=43)	AE (n=44)	PMT+AE (n=43)	AE (n=44)	PMT+AE (n=43)	AE (n=44)		
DASH	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	
Primary	35.9±12.9	38.1±15.3	28.2±17.0	29.4±18.1	7.7 (4.2-11.2)	8.8 (5.1-12.4)	-0.9 (-5.8 to 4.1)	.73
Hobby [†]	46.5±28.5	39.6±25.9	37.5±27.7	32.1±28.2	9.0 (-0.5 to 18.6)	7.5 (-1.0 to 16.0)	1.0 (-12.0 to 14.1)	.87
Work [‡]	34.2±24.3	35.4±25.4	29.1±24.2	26.6±25.6	5.1 (-0.5 to 10.7)	8.9 (2.3-15.6)	-3.7 (-14.7 to 7.3)	.50

NOTE. The Psychomotor Therapy Group (Intervention Group) is represented by PMT+AE. The DASH questionnaire range is 0-100.

* Adjusted for baseline value and corticosteroid (yes/no).

[†] n = 33 (PMT+AE = 18; AE = 15).

[‡] n = 67 (PMT+AE = 32; AE = 35).

Table 3 Analysis of changes in ITT population for NRS Pain outcomes 12 weeks after baseline for psychomotor PMT+AE and AE

	Baseline				Within-Group Change		Adjusted* Between-Group Difference on Change	P Value
	PMT+AE (n=43)	AE (n=44)	PMT+AE (n=43)	AE (n=44)	PMT+AE (n=43)	AE (n=44)		
NRS Pain	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	
Rest	5.6±1.7	5.9±1.7	4.1±2.8	3.8±2.6	1.5 (0.9-2.2)	2.1 (1.4-2.7)	-0.6 (-1.5 to 0.4)	.24
Activity	7.1±1.4	7.2±1.6	5.4±2.8	4.8±2.9	1.7 (1.0-2.5)	2.4 (1.7-3.2)	-0.7 (-1.7 to 0.4)	.20
Night	7.0±2.0	7.0±2.0	4.9±3.1	4.3±2.8	2.1 (1.3-2.8)	2.7 (2.0-3.4)	-0.6 (-1.7 to 0.4)	.23

NOTE. The Psychomotor Therapy Group (Intervention Group) is represented by PMT+AE. The NRS range is 0-100.

* Adjusted for baseline value and corticosteroid (yes/no).

consent to participate. Forty-three patients were randomized to PMT+AE and 44 to AE.

All patients in the PMT+AE group received the allocated intervention, as they attend at minimum the first PMT session, and received the AE intervention. Patients received a median of 1 (PMT+AE interquartile range [IQR]=1; AE IQR=0) physiotherapist-guided instructions at the hospital, and the PMT+AE group received a median of 5 sessions (IQR=0) with the psychomotricity therapist. Four patients in the PMT+AE group and 7 in the AE group sought treatment at a private practice after initial exercise instruction at the hospital. Five patients received between 0-4 sessions; 5 between 5-9 sessions; and 1 more than 10 sessions. Twelve patients (6 in the PMT+AE group and 6 in the AE group) could not be reached for follow-up evaluation. Therefore, the baseline observation carried forward technique was performed on these 12 patients, corresponding to an ITT population of 87 patients (fig 1). A total of 75 patients (PMT+AE=37; AE=38), constituted the “per protocol” population.

Demographic and clinical characteristics of the participants who did not complete the follow-up tests were not different from those with a complete data set (data not shown), except from the Hospital Anxiety and Depression Scale in which patients who dropped out scored significantly ($P=.02$) worse (5.8 ± 2.1) than those who completed the follow-up assessment (3.7 ± 2.9).

At baseline, demographic and clinical characteristics were not different between the groups (table 1). There was no difference in DASH baseline score in patients who received a concomitant corticosteroid injection (37.2 ± 16.2) compared to those who did not (36.9 ± 12.0 , $P=.92$).

Efficacy analysis

In the ITT population at week 12, there was no significant group difference in the adjusted change in DASH score (table 2). Both groups had a significant within-group improvement in DASH scores (see table 2). A significant difference in mean DASH change score was found between patients who received a concomitant corticosteroid injection (10.9 [95% CI, 7.4-14.3]) compared to those who did not receive a concomitant corticosteroid injection (5.4 [95% CI, 1.8-8.9]) ($P=.03$).

Secondary analyses

There were no between-group differences at baseline in NRS pain at rest, during activity, or at night. Significant within-group improvements were found for all NRS measurements in both groups,

but no significant differences between groups from baseline to 12 weeks' follow-up (table 3).

The repeated measure of NRS scores showed no difference between the groups from baseline to 12 weeks' follow-up (fig 2).

In the “per protocol” population, 39 patients experienced an appreciable improvement, 37 patients reported no relevant improvement, and 1 patient experienced an appreciable worsening from baseline to 12 weeks' follow-up reported on the GPE. No significant difference was found between the 2 groups ($P=.5$) (table 4).

Discussion

We found no additional benefit of PMT in primary or secondary outcomes. In both groups, we found significant within-group improvement in primary outcome (DASH scores). Overall, 51% of the patients experienced an appreciable improvement from baseline to 12 weeks' follow-up.

Explanation of results

Several supplemental interventions have been evaluated for additional effects in combination with exercise (manual therapy, corticosteroid injections, laser, acupuncture, therapeutic ultrasound, etc). So far, there seems to be no additional clinical relevant effect of these supplemental interventions when combined with exercises.²⁸⁻³² The same is seen in this study, as we found no additional effect of PMT when combined with exercise, even

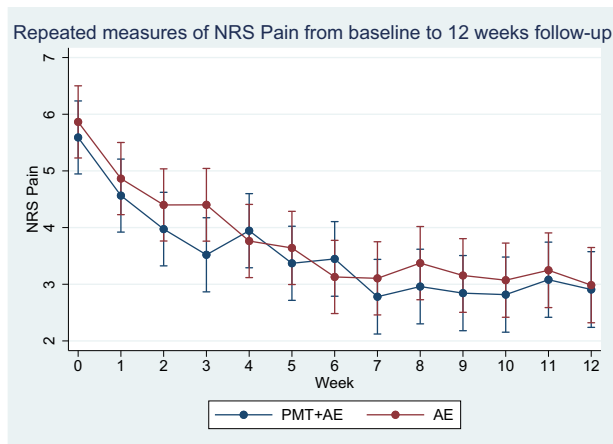


Fig 2 NRS pain measured by SMS from baseline to 12 weeks' follow-up.

Table 4 GPE score measured at 12 weeks' follow-up

GPE: How are your shoulder complaints today in comparison to prior to your participation in the trial?	PMT+AE (n=38)	AE (n=39)	Total
Better, an appreciable improvement, n (%)	10 (26)	7 (18)	17 (22)
A little better, enough to be an appreciable improvement, n (%)	12 (31)	10 (26)	22 (29)
A little better, but not appreciably improved, n (%)	10 (26)	11 (28)	21 (27)
Unchanged, n (%)	4 (11)	10 (26)	14 (18)
A little worse, but not appreciably worsened, n (%)	1 (3)	1 (2)	2 (3)
A little worse, enough to be an appreciable worsening, n (%)	1 (3)	0 (0)	1 (1)
Worse, an appreciable worsening, n (%)	0 (0)	0 (0)	0 (0)

though our target population was included based on the MAIA score. This could be because AE interventions are the optimal treatment strategy for the majority of patients with shoulder pain, as, several exercise interventions have shown positive effects on patients with shoulder pain.³³ However, often a large proportion of the participants do not reach a clinically relevant improvement following the interventions tested,^{7,8,34} which also was the case in the current trial. Furthermore, previous studies have shown that exercise compared to placebo or “wait and see” is not clinically superior.^{34,35} Thus, our results might show the “natural course” in patients with shoulder pain or it might be due to 12 weeks not being a sufficient amount of time to observe clinically relevant change in the patients' function and pain.

Another explanation for our results could be the choice of primary outcome. The DASH questionnaire measures pain and activity limitations. As PMT focuses on body awareness, there might be aspects of PMT that will not be reflected in the DASH score. A qualitative study on 12 patients from the PMT+AE group was performed as part of this study, evaluating the participants experience with PMT.³⁶ This study found that, in general, PMT resulted in a tendency to experience an increased focus on body awareness,³⁶ which might not be reflected in the DASH score. This is why additional questions regarding body awareness could possibly have highlighted differences between the 2 groups of this randomized, controlled trial on these aspects.

Comparison with previous studies

We were unable to find previous studies evaluating PMT in patients with shoulder pain. One study assessed the effect of 3 sessions of PMT after lumbar fusion and found that PMT significantly improved functional disability, self-efficacy, outcome expectancy and fear of movement or reinjury.³⁷ This is in contrast to the findings of this study. It could partly be explained by a much more comprehensive AE rehabilitation intervention in the PMT group than an effect of the actual PMT sessions (3 sessions). Van der Maas et al³⁸ evaluated the additional effect of PMT in treatment of chronic pain. They found no effect on their primary outcomes of health-related quality of life, disability, or depression after 6, 9, or 12 months. In a secondary paper, the authors investigated the role of body awareness, and concluded that PMT seems to provide benefit by improving body awareness, and might have the largest effect in patients with low body awareness.³⁹

Study limitations

A limitation of the current study was the lack of blinding of the treating physiotherapists, which could have influenced administration of exercise. However, 75% of patients only received 1

exercise instruction, which was given prior to randomization. This is why such an influence is considered minimal. Secondly, the choice of primary outcome could potentially have caused some uncertainty in relation to the interpretation of the results. However, as pain and decreased function are the primary concerns patients' presents in the clinic, these were considered the most representative outcomes.

The strengths of the current study were the inclusion of an active control group, a priori study registration in a registry of clinical trials, a blinded outcome analysis, and interpretation of the results a priori to unblinding.

Conclusions

Our results showed no additional benefit on patient-reported function and pain from PMT over usual care exercise therapy in patients with long-lasting shoulder pain and low body awareness. This finding suggests that PMT adds no additional benefit to patients' recovery in relation to pain and active function in comparison to standard care. In general, patients significantly improved from baseline to 3 and 6 months' follow-up, with the largest effect seen in patients receiving a corticosteroid injection, and 51% of the participants report a clinically relevant improvement.

Suppliers

- SMS-tracking system; SMS-Track ApS.
- Stata version 14; StataCorp.

Keywords

Exercise; Pain; Rehabilitation; Shoulder

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