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CLINICAL TRIAL REPORT

Exercise into Pain in Chronic Rotator Cuff-Related Shoulder Pain: A Randomized Controlled Trial with 6-Month Follow-Up

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Purpose: Exercise therapy is the first-line treatment in rotator cuff-related shoulder pain (RCRSP), and diverse types of exercise seem effective. However, it is not still clear if painful exercise should be allowed or avoided during exercises. The objective of this study was to investigate if exercise into pain is more effective than no pain in RCRSP.

Patients and Methods: A randomized controlled trial was conducted in a physiotherapy clinic in Belgium. Forty-three participants with chronic RCRSP were randomly allocated to G1 (exercising into pain) or G2 (exercising without pain) in a 12-week intervention with 6-month follow-up. Primary outcome was the Shoulder Pain and Disability Index (SPADI); secondary outcomes were pain intensity, fear-avoidance beliefs, fear of pain, quality of life, strength, and range of motion. Outcomes were measured at baseline (T0), after 9 weeks (T1), 12 weeks (T2), and 6 months (T3) from the first session and analysed with linear mixed models.

Results: No between-group difference in SPADI (time-by-group interaction, p = 0.25) up to 6 months was found, with mean difference (G1-G2) at T1 = 5.78 (CI95%: −3.43,14.59; p = 0.33), at T2 = 0.93 (CI95%: −7.20,9.05; p = 0.82), at T3 = 4.15 (CI95%: −2.61,10.92; p = 0.33). No between-group differences were found for any other outcomes.

Conclusion: Pain provocation seems not to be necessary in RCRSP for achieving successful treatment effect in pain and disability reduction, fear-related beliefs, and quality of life up to 6 months.

Trial Registration: ClinicalTrials.gov NCT04553289.

Keywords: shoulder pain, rehabilitation, physical therapy modalities, shoulder impingement syndrome, exercise therapy

Introduction

Shoulder pain is commonly reported as a musculoskeletal disorder in primary care, with a median prevalence of 16% in community settings, and higher estimates in women and high-income nations.[1] Rotator cuff-related shoulder pain (RCRSP) refers to pain and limitations typically experienced during shoulder elevation and external rotation. It is an umbrella term encompassing rotator cuff tendinopathy, subacromial impingement syndrome, and symptomatic rotator cuff tears, whether partial or full-thickness.[2]

Exercise therapy is recommended as the first choice of treatment in RCRSP. However, there is currently no evidence to support the superiority of one exercise program over another.[3] Various exercise types, from scapular-focused[4] to motor control exercises,[5] and various delivery modalities, from home to supervised interventions,[6] seem effective. There is low evidence regarding whether a high dose (in terms of load and volume) of exercise provides greater functional benefits

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over a low dose.[7] As different types, modalities or doses seem beneficial, the focus of research might be in other therapeutic parameters, such as pain avoidance or tolerance during exercise.

It is not clear whether pain should be avoided or allowed during exercise.[8,9] Protocols involving exercise that elicit pain may be more beneficial in short term for chronic musculoskeletal disorders,[10] and painful exercises can help address fears associated with movements perceived as threatening.[11] Furthermore, exercise has a hypoalgesic effect, and protocols including painful exercises often involve a higher dose of exercise, resulting in increased exercise-induced hypoalgesia.[10,11] Lastly, pain can serve as a triggering stimulus during the conditioned pain modulation response, which is also known as "pain inhibits pain" mechanisms.[11] Conversely, pain aggravation during exercise might indicate tissue overload, hamper motor relearning, and decrease patient's motivation.[12]

Exercise into pain remains under debate with conflicting indications regarding the acceptable level of pain.[9] The pain monitoring model, which has been frequently used in previous studies, involves patients experiencing pain during exercise but no more than 5/10 on a Visual Analogue Scale (VAS) or Numeric Pain Rating Scale (NPRS).[13,14] However, other studies used different thresholds, such as resting pain at 3/10,[15] or different monitoring timings, such as pain reverting to initial levels or subsiding directly after an exercise session,[16] before the next session[14] or by the next morning.[13] Although the pain monitoring model is widely used in research, the original low (0–2 on VAS scale), acceptable (2–5), and high (5–10) risk-zone levels were based on the clinical experience of Thomee in 1997.[17] Moreover, studies usually do not report a minimal VAS or NPRS scale for treatment, even when explicitly comparing painful and non-painful eccentric exercises in RCRSP.[18] These discrepancies are also evident in clinical practice, where the tolerance for pain during exercise in RCRSP varies from being acceptable to experiencing no pain or maintaining pain below a certain threshold in different countries.[19–21]

Consequently, the objective of this randomized controlled trial was to investigate if exercising into pain (4–7 NPRS) was more effective than non/slightly painful (0–2 NPRS) exercises on pain and disability in RCRSP. The findings could impact exercise prescription in RCRSP, and they are relevant for both health-care professionals and their patients.

Materials and Methods

Design

This study is presented following the CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments,[22] and it was registered in ClinicalTrials.gov (NCT04553289). The Ethics Committee of Antwerp University Hospital approved this study (ref: B300201837376) and the study complies with the Declaration of Helsinki. All participants gave written informed consent before data collection began.

It consisted of a single-center, double-blinded (outcome assessor and patients), controlled study with a 1:1 allocation ratio, where participants were randomized into two groups (G1: exercise into pain, G2: exercise without pain). They underwent nine sessions of physiotherapy over a 12-week period, with measurements taken at 4 time points: baseline (T0), after 9 weeks (T1), 12 weeks (T2), and 6 months (T3) from the first physiotherapy session.

An independent researcher generated the randomization list with www.randomization.com (2 groups, permuted block randomization of sizes 2, 4, and 6) and prepared sequentially numbered sealed opaque envelopes, which were opened by the physiotherapist only at the first treatment session. There was a single outcome assessor (CC), who remained blinded to the group allocation until the end of data collection. Patients were informed that two treatments involving exercise therapy were compared, but they were kept unaware to the main research hypotheses. They were specifically instructed not to describe their exercises to the assessor to ensure the blinding. The physiotherapists applying treatments were aware of the group allocation, but they did not disclose it to patients or the outcome assessor to limit bias.

Participants and Setting

Adults with RCRSP were recruited at a private physiotherapy clinic in Hove (Belgium), where three physiotherapists (GW, LB, TV) included patients with: shoulder pain for minimum 3 months elicited in the antero-lateral shoulder region, age 18–65 years, resting pain at 2/10 maximum on verbal NPRS, at least 3 out of 5 provocative tests positive (Neer test, Hawkins–Kennedy test, Jobe test, painful arc between 60° and 120°, external rotation resistance test).[23] The exclusion

criteria were: bilateral shoulder pain, corticosteroid injections 6 weeks prior to the study, pregnancy, inability to understand spoken or written Dutch, clinical signs of full-thickness rotator cuff tears (positive external and internal rotation lag tests and drop arm test), evidence of frozen shoulder (reduction of 50% or above 30° of loss in passive external rotation),[24] previous cervical, thoracic or shoulder surgery, recent fractures or dislocations on the painful shoulder, symptoms of cervical nerve root involvement, reproduction of shoulder pain with cervical rotation or axial compression, primary diagnosis of acromioclavicular pathology or shoulder instability, previous medical imaging confirming the presence of fracture or calcification larger than 5 mm, presence of competing pathologies (inflammatory arthritis, neurological disorders, fibromyalgia, malignancy, mental health illness, osteoporosis, hemophilia, rheumatic polymyalgia), more than 4 h of training in sport overhead shoulder activities per week. Upon patients' interest, the principal assessor CC confirmed their eligibility using the same criteria and collected data on demographics (age, sex, e-mail address) and other patients' characteristics (BMI, duration of symptoms, hand dominance, working status, sport, previous treatments) one or two weeks before the first treatment session.

Intervention

Patients sought treatment for shoulder pain with a prescription for 9 or 18 sessions, as standard procedure of care in Belgium. The intervention consisted of four progressively loaded exercises conducted over a period of 12 weeks, with nine sessions supervised by two physiotherapists (GW, LB). At the end of the 12th week, additional sessions were added if deemed necessary, and they were registered as additional treatment at the end of the 6-month follow-up. All patients attended one supervised session per week and two additional unsupervised exercises per week. The first five sessions were typically planned within the first five weeks, depending on the patient's availability. The remaining four sessions were spread out over the following seven weeks. During the unsupervised weeks, patients were instructed to exercise at home three times per week. Each supervised session was divided into 10–15 minutes of manual therapy (stretching of the posterior tissues of the shoulder performed by the physiotherapist) and 15–20 minutes of exercise therapy consisting of four exercises. The stretching of the posterior shoulder tissues was based on the presence of posterior shoulder tightness in RCRSP,[25] which can create scapular maladaptations contributing to shoulder symptoms.[26] Moreover, it was delivered in line with the treatment applied in the previous feasibility phase.[27] There were two groups: G1 (exercising into pain) and G2 (exercising with no pain).

We previously investigated the compliance and feedback of patients and physiotherapists regarding exercise in pain (4–7 on verbal NPRS) in a feasibility study.[27] A considerable proportion of patients did not adhere to exercising into pain, and compliance with home exercise was low. Therefore, we decreased the number of exercises into pain from 4 to 1, and we decided to use the rate of perceived exertion (RPE)[28] in case the physiotherapists could not find exercises that provoked pain at a certain point in the treatment. G1 performed one exercise that induced pain within the range of 4–7 on the NPRS, along with three loaded exercises that caused minimal pain within the range of 0–2 on the NPRS, up until the 9th week. In the last 3 weeks, all exercises in G1 were performed within the 0–2 NPRS range. G2, on the other hand, performed all exercises without pain (max 2/10 on NPRS) throughout the entire 12-week treatment period. The choice of 4–7 and 0–2 as range reference was to make a clear distinction between exercise with or without pain, respectively, giving also a minimal value of 4 on NPRS in G1. As pain perception is rather subjective and it might fluctuate during exercise, we decided to indicate a range instead of only one number on NPRS, consistent also with the ranges given in the feasibility study.[27] As neuromuscular adaption supposedly occurred in the first phase,[27] all patients performed pain-free exercises after 9 weeks.

The physiotherapists selected four exercises from a predefined list of categories: two exercises in a closed kinetic chain (category 1), two exercises with an elastic band or with dumbbells/weights (category 2 and 3 respectively). Stretching exercises (category 4) were applied only if necessary. The exercises were individualized for each patient in terms of progression and repetitions to keep the pain within the predetermined range. Details on exercises are reported in Supplementary Table 1 and in Supplementary Information 1 (in Supplementary Material A), following the Consensus on Exercise Reporting Template guidelines.[29] Patient education, lifestyle, and ergonomics recommendations were provided equally to both groups, following current practices in Belgium.[19]

Outcome Measures

Primary Outcome

The Dutch Shoulder and Pain Disability Index (SPADI) was the primary patient-reported outcome measure (PROM), as it is a highly reliable, valid, and responsive shoulder-specific questionnaire.[30,31] It consists of two subscales: pain (5 items) and disability (8 items).[30] Each item ranges from 0 (no pain/no difficulty) to 10 (worst imaginable pain/so difficult that it requires help) on NPRS. The total score is the average of the two subscales, where a higher score indicates more pain or disability. The minimal clinically important difference (MCID) of SPADI between groups previously reported was 10 points,[32] while the minimal important change (MIC) was 20 points.[30]

Secondary Outcomes

Pain was also evaluated with the VAS% scale, which was registered during movement on the day of completing the questionnaire, in the past night, and maximal pain over the last 24 hours.[33] As this RCT was comparing pain tolerance versus pain avoidance in terms of, respectively, high or low NPRS ranges during exercise, it was essential to evaluate the between-groups differences on pain-related beliefs. Therefore, fear of pain was assessed as a total score (FPQ-9 total) and as subscales (severe, minor, medical),[34] together with fear-avoidance beliefs concerning physical activity (FABQ-PA) and work (FABQ-W).[35] Health-related quality of life was evaluated with the EQ-5D-5L questionnaire,[36] which resulted in an EQ-5D index and a VAS score. PROMs were administered via an online survey using Qualtrics (Qualtrics software, Version [2020–2022], Qualtrics, Provo, UT, USA. https://www.qualtrics.com).

Strength was also measured because we hypothesized that G1 would develop greater strength due to higher dose or difficulty of exercise to make it painful. The maximum voluntary isometric contraction was assessed in external rotation, internal rotation, and scaption using a hand-held dynamometer (MicroFet, Hoggan Health Industries Inc.) in Newtons.[37] In order to evaluate the flexibility acquired during treatment, range of motion (ROM) was assessed for passive and active internal rotation, external rotation, and scaption using a gravity-referenced inclinometer (Plurimeter, Dr. Rippstein, Medidevice) in degrees.[37] Details for reliability and MCID for secondary outcomes and measurement protocols of physical outcomes are reported in Supplementary Information 2. All PROMs and secondary outcomes were measured at T0, T1, T2, T3. Ultrasonographic outcomes (acromiohumeral distance, coracohumeral distance, rotator cuff tendon thickness) and scapular dyskinesis were also measured, but they are not presented in the current manuscript for the sake of clarity and brevity.

Other outcome measures were adherence, adverse effects, additional treatments, patient's satisfaction, and recovery. Adherence was assessed separately for physiotherapy and home exercise sessions. Co-interventions were registered throughout the 12-week treatment period and between the end of the treatment at 12 weeks and the 6-month follow-up. The global perceived effect (GPE) was assessed as the amount of recovery or satisfaction after one week, nine weeks, and twelve weeks from the first physiotherapy session. Details on adherence, additional treatments, and GPE are described in Supplementary Information 2. Deviations from trial registration were present, concerning outcomes, intervention, and sample size calculation. Details are described in Supplementary Information 3.

Data Analysis

The sample size was calculated using the Edland method, R package longpower 1.0–11 considering a mixed regression model for repeated measures,[38] and it was based on the following data: 10% points as MCID in SPADI at 6 months (considered as moderate effect size),[32] 30% for adjustment for non-linearity of the data (because of the higher decrease in SPADI in the first three months compared to six months), alpha = 5%, power = 80%. The required total sample size was 38 subjects, considering 15% drop-out rate. The variance of the residuals cannot be estimated from previous studies, but it has an extremely limited effect on the sample size. It does not change the result of the power calculation, and therefore it was not included in this analysis. The original sample size calculation did not account for inflation due to therapist effect, but therapist effect was included as a random effect in the analysis.

The difference in SPADI score as a primary outcome was estimated over a period of 6 months with 4-time points measurement (T0, T1, T2, T3). A linear mixed model was fitted with participants and physiotherapists as random effects, and group, time (as categorical variable), and group-by-time as fixed effects. Group-by-time was the primary focus of the

analysis for every outcome, and significant p-values were set at 0.05. Covariates of interest were age, sex, and durations of symptoms, and they were added to the initial model for every outcome. Group-by-time and covariates were eliminated using a stepwise backwards approach starting from the least significant variable, and intention-to-treat analysis was used. Linear mixed models do not need complete cases, as long as missing data are missing at random.[15] If a significant effect of time was present in the primary outcome SPADI, post-hoc analysis was conducted with Tukey HSD correction to find at which timepoint the differences were significant, also in relation to the MIC of 20 points in SPADI.[30]

Between-group differences were investigated with Standard Least Square Methods for every outcome of interest at T1, T2, and T3, considering significant covariates for every specific outcome. P-values were corrected for False Discovery Rate (FDR), and Effect Cohen's d was calculated at T1, T2, T3 and considered as follows: very small if $d < 0.2$, small if $0.2 \leq d < 0.5$, medium if $0.5 \leq d < 0.8$ and large if $d > 0.8$.[39] For all models fitted, the assumptions of normality of residuals and homoscedasticity were checked using a QQplot and a plot of residuals versus fitted values. Dichotomous outcomes were compared between groups with chi-square test or Fisher's exact test. All statistical analyses were completed using JMP® (JMP Pro, Version 17, SAS Institute Inc., Cary, NC).

Results

Participants and Therapists

Between July 2020 and June 2022, 43 participants were included in the trial, while 281 were excluded (Figure 1). In G2, one participant dropped out of the study before T3. Two patients from G2 were excluded in the final analysis due to reporting exclusion criteria after their initial inclusion (mental illness condition and calcification > 5 mm). Missing data for both PROMs and physical outcomes are presented in Supplementary Table 2 (in Supplementary Material B).

There was no delay between randomization and the initiation of the intervention, as the physiotherapists opened the allocation envelopes for each patient just before the start of their first session. Two physiotherapists performed the intervention: GW treated 33 patients, LB treated 8 patients. Two patients were treated by both physiotherapists because of the unavailability of one therapist due to holidays. In six patients from G1, the physiotherapists used the RPE instead of the NPRS at one or more sessions during therapy, as they could not find a successful provocative exercise for these patients. Demographic characteristics are shown in Table 1. Scores for all PROMs and physical outcomes (strength, active and passive ROM) at different time points for both groups are presented in Supplementary Tables 3 and 4 (in Supplementary Material B).

Patient-Reported Outcome Measures

There was no significant group-by-time interaction in the primary patient-reported outcome measure SPADI, while the treatment group did not have a significant effect (Table 2). Participants improved their function and pain (represented by SPADI total) at the end of the treatment, irrespectively of the treatment group (Figure 2). Between-group differences were not significant at any timepoint (T1, T2, T3) (Table 3). Although the effect size was medium at T1 and G1 showed higher SPADI than G2 (Table 3), this difference was not significant (FDR adjusted p-value=0.33) and the score 5.78 was inferior to the MCID of 10. Moreover, the percentage of patients who reached a significant and clinically relevant change over time in SPADI was not different between groups (n = 14, 70% in G1 and n = 16, 84% in G2, Fisher's exact test p = 0.45). Patients showed significant improvement in time irrespectively of the group, and every pairwise comparison between different time points was significant ($p < 0.005$). The mean differences between T0-T1 (20.71, CI95%: 14.91; 26.51), T0-T2 (26.42, CI95% 20.71; 32.12) T0-T3 (33.21, CI95% 27.45; 38.96) exceeded the MIC of 20 points.

Similarly, SPADI subscales (pain, function), VAS% (movement, 24 h, night), FPQ-9 (total score and subscales severe, medical, minor), quality of life (EQ-5D index, EQ-5D VAS) did not show a significant time-by-group interaction, nor a group effect. Time showed a significant effect irrespectively of the group in all PROMs, expect FPQ-9 (total score and all subscales) and FABQ-W. Duration of symptoms was a relevant covariate in FPQ-9 (total score, severe and minor subscales) (Table 2).

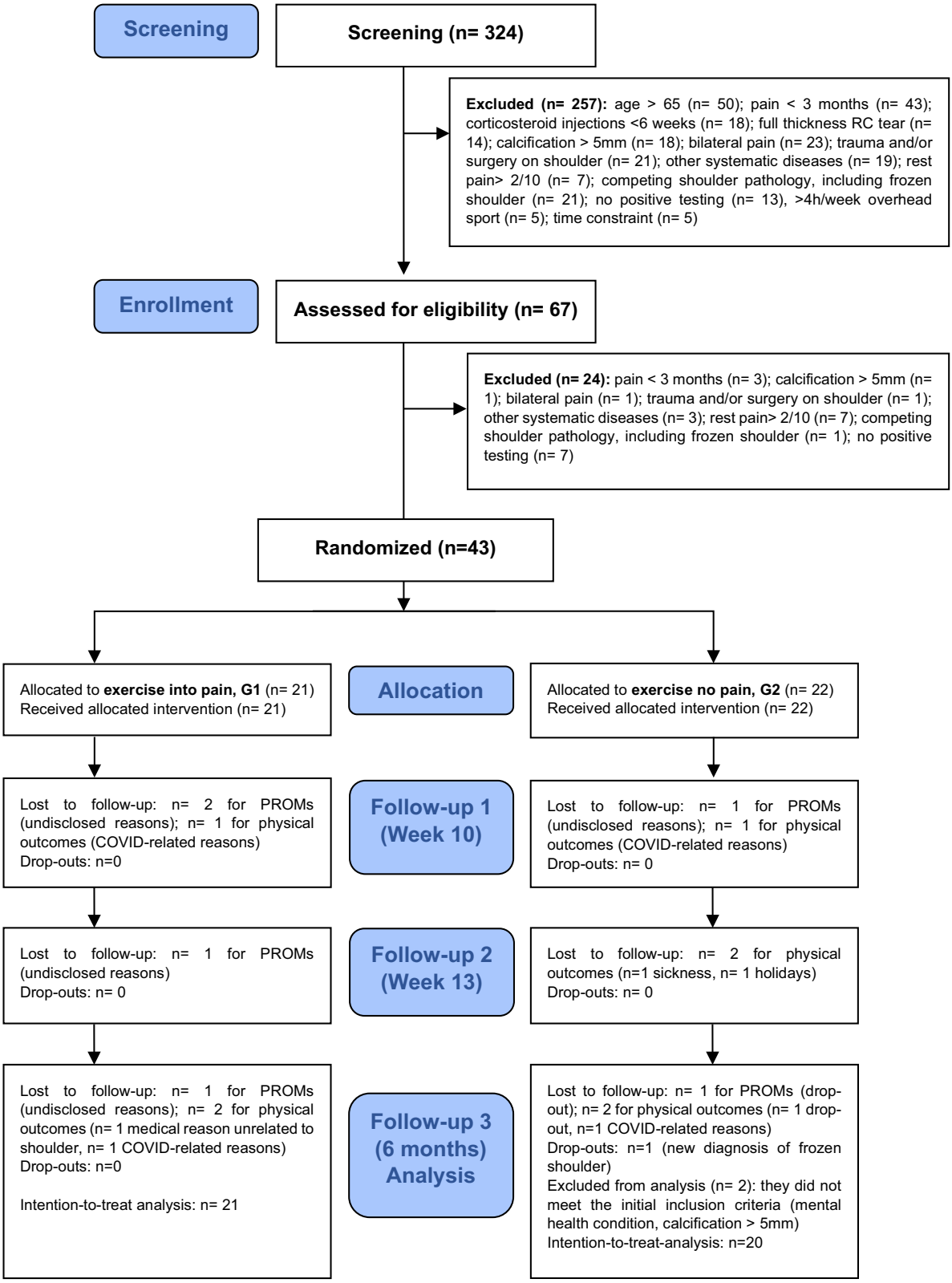

Figure 1 Flowchart diagram (modified CONSORT flowchart 2010). PROMs outcomes included: SPADI total, SPADI subscale pain, SPADI subscale function, VAS% in movement, VAS% at night, VAS% in the last 24h, FPQ-9 total, FPQ subscale severe, FPQ subscale medical, FPQ subscale minor, FABQ subscale physical activity, FABQ subscale work, EQ-5D index and EQ-VAS. Physical outcomes included: strength in external and internal rotation, strength in scaption, active ROM in external and internal rotation, active ROM in scaption, passive ROM in external and internal rotation, passive ROM in scaption. The data from a patient was considered lost at a specific time point for PROMs or physical outcomes if: 1) the data set was entirely missing for all the scores at that specific time point 2) if the patient partially filled in the questionnaire and this resulted in a more than three missing final scores for PROMs.

Table 1 Baseline Characteristics

	Exercise into Pain G1 (n=21)	Exercise No Pain G2 (n=20)	Total (n=41)
Age (years), mean (SD)	47 (8.8)	48 (11.0)	47 (9.8)
Sex, n female (%)	8 (38%)	14 (70%)	22 (54%)
BMI (kg/m^2), mean (SD)	26 (3.9)	24 (3.9)	25 (3.9)
Duration of symptoms (months), mean (SD)	32 (50)	24 (28)	28 (41)
Dominant side affected, n (%)	14; 67%	14; 70%	28; 68%
Working, n (%)	19[a]; 90%	20; 100%	39; 95%
If currently working:			
High workload, n (%)	5 (26%)	3 (15%)	8 (21%)
Pain during work, n (%)	12 (63%)	12 (60%)	24 (62%)
Sport activities, n (%)	20 (95%)	16 (80%)	36 (88%)
If recently playing sport:			
Overhead sport, n (%)	8 (40%)	7 (44%)	15 (42%)
Pain during sport, n (%)	10 (50%)	14 (88%)	24 (69%)
Previous treatment, n (%)	11 (52%)	11 (55%)	22 (54%)

Notes: "previous treatment" included any treatment for shoulder pain prior to enrolment (such as physiotherapy, injections, osteopathy, excluding drugs); [a]=2 subjects were retired at the time of enrolment.
Abbreviation: BMI, Body mass index.

Table 2 Results (p-values) of All Outcomes from Linear Mixed Models

	Time*Group	Group Effect	Time Effect	Other Covariates
PROMs				
SPADI total	0.62	0.35	<0.0001	NS
SPADI pain	0.36	0.27	<0.0001	NS
SPADI function	0.48	0.51	<0.0001	NS
VAS% night[a]	0.90	0.89	<0.0001	NS
VAS% movement	0.47	0.93	<0.0001	NS
VAS% 24hours	0.82	0.65	<0.0001	NS
FPQ-9 total	0.61	0.40	0.44	Duration of symptoms (p=0.02)
FPQ-9 severe	0.94	0.85	0.67	Duration of symptoms (p=0.03)
FPQ-9 minor	0.17	0.12	0.92	Duration of symptoms (p=0.03)
FPQ-9 medical	0.37	0.98	0.14	NS
FABQ-PA	0.40	0.31	<0.0001	NS
FABQ-W	0.67	0.39	0.07	NS
EQ-5D index	0.84	0.18	<0.0001	NS

(*Continued*)

Table 2 (Continued).

	Time*Group	Group Effect	Time Effect	Other Covariates
EQ-5D VAS[b]	0.87	0.18	=0.0004	NS
Physical outcomes				
Strength external rotation[b]	0.23	0.51	<0.0001	Sex (p<0.0001)
Strength Internal rotation[b]	0.75	0.75	<0.0001	Sex (p<0.0001)
Strength Scaption[b]	0.68	0.80	<0.0001	Sex (p<0.0001)
Passive ROM external rotation	0.27	0.65	<0.0001	NS
Passive ROM internal rotation[b]	0.19	0.79	<0.0001	NS
Passive ROM scaption	0.63	0.38	<0.0001	NS
Active ROM external rotation	0.52	0.52	<0.0001	NS
Active ROM internal rotation[c]	0.35	0.84	<0.0001	NS
Active ROM scaption	0.25	0.35	<0.0001	Age (p=0.03)

Notes: [a]data were transformed in logarithmic values because of not normal distribution of conditional residuals in original data; [b]non-significant covariates were included in the final model, otherwise the model was not valid due to non-convergence; [c]therapist was excluded as random effect in the final model, otherwise the model was not valid due to non-convergence.
Abbreviations: NS = non-significant.

Physical Outcomes

There were no significant group-by-time interactions or group effects were observed for any of the strength or ROM measures (external rotation, internal rotation, scaption). All participants improved over time irrespectively of the treatment group (Table 2).

There were no significant between-groups differences in adverse effects, use of additional treatments, adherence, GPE-recovery, or GPE-satisfaction ($p > 0.05$). Adverse effects after physiotherapy-led sessions were similar in both groups: 10% (n = 2) had 4–7 episodes of persistent pain or fatigue. Concerning adverse effects after home-exercises, 4–7 episodes occurred in 14% (n = 3) in G1 and in 5% (n = 1) in G2. Details are presented in Supplementary Information 4.

Discussion

The findings of this RCT indicate that exercising into pain does not result in greater benefits compared to exercising without pain in RCRSP. No significant between-group differences were detected for pain or disability, fear-avoidance beliefs, fear of pain, quality of life, and for ROM. Interestingly, no between-group differences were found also in adherence, the use of additional treatments, occurrence of adverse effects, patients' satisfaction, or perception of recovery. However, there was a substantial improvement in pain and function over time, irrespectively of the group.

Two previously randomized controlled trials were conducted in similar RCRSP population: Maenhout et al investigated the addition of a heavy-load eccentric program dosed on pain-monitoring model to a usual rotator-cuff training in a 12-week intervention,[13] while Valles-Carrascosa et al compared two exercise protocols with or without painful eccentric exercise of the rotator cuff in a 4-week intervention.[18] In agreement with our results in SPADI at 12 weeks, no between-group differences were found in either SPADI at 12 weeks[13] or in VAS at 4 weeks[18] in previous studies, although their frequency of treatment was higher, going from daily exercises[13] to 5x/week.[18]

The physiotherapists involved in the current study adjusted the load or resistance for the exercise that induced pain in the group that exercised into pain, aiming to make it provocative. However, both groups progressed in terms of repetitions or loads in the non-provocative exercises throughout the treatment period. This suggests that the difference in treatment may not have been sufficient to produce a significant between-group difference. However, six patients in G1 (exercise into pain group) transitioned from NPRS to the RPE scale, meaning that fatigue during exercise may be a more viable option for certain patients. Moreover, based on low adherence observed in a previous feasibility study,[27] increasing the number of painful exercises is not recommended.

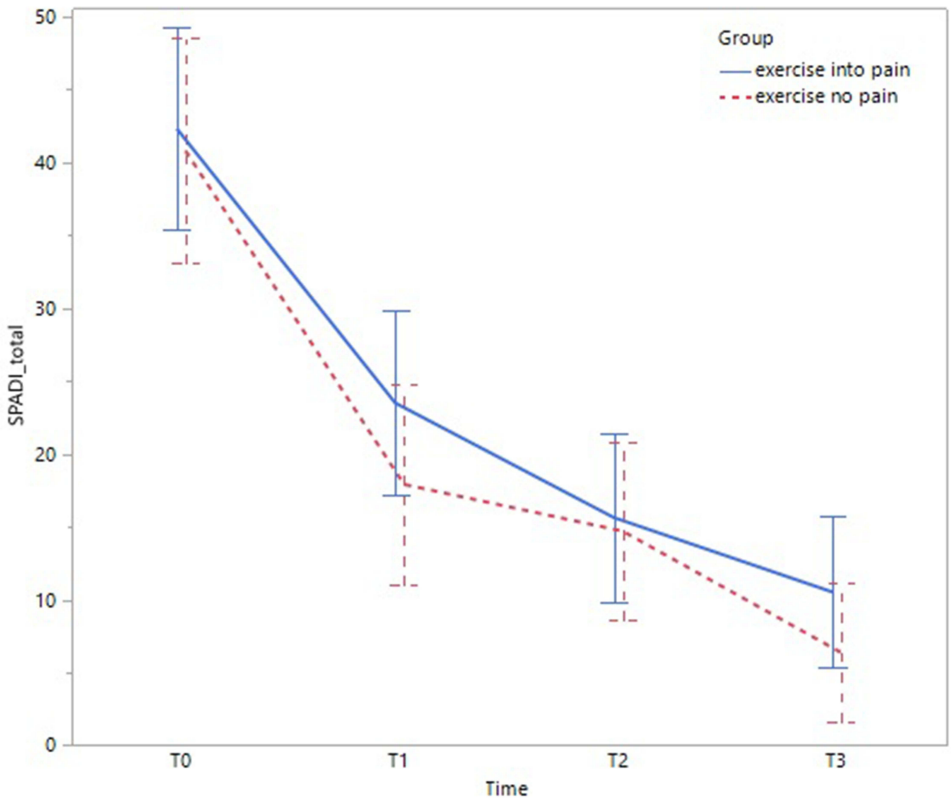

Figure 2 SPADI over time. T0= baseline, T1= after 9 weeks, T2= after 12 weeks, T3= after 6 months from the first physiotherapy session. Time was considered as categorical variable in the statistical analysis and therefore the difference between time points is equal between T0-T1, T1-T2, T2-T3. Each error bar was constructed using a 95% confidence interval of the mean.

This study aimed to improve pain and disability with one painful exercise by inducing higher exercise hypoalgesia and by enhancing fear-related beliefs while also restoring muscular strength through the other three exercises against gravity or resistance. The physiotherapists gave different types of exercises, two in a closed kinetic chain and two in an open kinetic chain (with dumbbells or elastic bands), as diverse exercises seem effective in RCRSP (ie scapular-focused, motor control, eccentric exercises).[3,4,6,40] Quality and good performance were sought in all exercises and, in particular, for the three non-painful exercises,

Table 3 Differences Between Groups at T1, T2, T3 for All Outcomes

	Difference Between Groups, Mean (CI 95%)	FDR p-value adj.	Cohen's d (CI 95%)
PROMs			
SPADI total			
T1	5.78 (−3.43; 14.59)	0.33	0.54 (−0.31; 1.38)
T2	0.93 (−7.20; 9.05)	0.82	0.09 (−0.67; 0.84)
T3	4.15 (−2.61; 10.92)	0.33	0.40 (−0.24; 1.03)
SPADI pain			
T1	7.47 (−2.32; 17.27)	0.31	0.51 (−0.15; 1.15)
T2	3.60 (−6.49; 13.69)	0.47	0.24 (−0.42; 0.91)
T3	6.05 (−3.53; 15.63)	0.31	0.41 (−0.23; 1.04)

(*Continued*)

Table 3 (Continued).

	Difference Between Groups, Mean (CI 95%)	FDR p-value adj.	Cohen's d (CI 95%)
SPADI function			
T1	3.68 (−5.76;13.13)	0.63	0.53 (−0.79; 1.83)
T2	−1.75 (−9.00; 5.50)	0.63	−0.25 (−1.25; 0.76)
T3	2.25 (−2.29;6.78)	0.63	0.32 (−0.31; 0.95)
VAS% night			
T1	−4.03 (−16.05; 7.99)	0.75	−0.22 (−0.86; 0.42)
T2	−4.34 (−16.66; 7.97)	0.75	−0.24 (−0.89; 0.42)
T3	−1.09 (−8.68; 6.50)	0.77	−0.06 (−0.46; 0.34)
VAS% movement			
T1	3.56 (−3.97; 11.09)	1.00	0.40 (−0.42; 1.21)
T2	−0.02 (−9.96; 9.93)	1.00	0.00 (1.07; −1.07)
T3	0.93 (−4.90; 6.75)	1.00	0.10 (−0.53; 0.73)
VAS% 24 hours			
T1	5.06 (−9.56; 19.68)	0.78	0.25 (−0.46; 0.96)
T2	−1.87 (−14.66; 10.92)	0.78	−0.09 (−0.71; 0.53)
T3	1.35 (−8.29; 11.00)	0.78	0.07 (−0.40; 0.53)
FPQ-9 total[a]			
T1	0.90 (−3.09; 4.89)	0.82	0.17 (−0.55; 0.89)
T2	0.76 (−3.32; 4.84)	0.82	0.14 (−0.60; 0.88)
T3	0.41 (−3.18; 4.00)	0.82	0.08 (−0.57; 0.72)
FPQ-9 severe[a]			
T1	0.47 (−1.52; 2.46)	0.89	0.16 (−0.49; 0.80)
T2	−0.15 (−2.07; 1.78)	0.89	−0.05 (−0.67; 0.57)
T3	0.13 (−1.68; 1.93)	0.89	0.04 (−0.54; 0.63)
FPQ-9 minor[a]			
T1	0.22 (−1.11; 1.54)	0.74	0.11 (−0.54; 0.76)
T2	1.00 (−0.45; 2.45)	0.51	0.51 (−0.21; 1.22)
T3	0.60 (−0.73; 1.92)	0.55	0.30 (−0.35; 0.95)
FPQ-9 medical			
T1	0.22 (−1.15; 1.58)	0.88	0.12 (−0.62; 0.86)
T2	−0.10 (−1.42; 1.22)	0.88	−0.05 (−0.77; 0.67)
T3	−0.37 (−1.53; 0.78)	0.88	−0.21 (−0.84; 0.42)

(*Continued*)

Table 3 (Continued).

	Difference Between Groups, Mean (CI 95%)	FDR p-value adj.	Cohen's d (CI 95%)
FABQ-PA			
T1	−0.53 (−4.31; 3.26)	0.78	−0.09 (−0.73; 0.55)
T2	−2.30 (−6.50; 1.90)	0.41	−0.40 (−1.11; 0.32)
T3	−2.67 (−7.27; 1.93)	0.41	−0.46 (−1.24; 0.32)
FABQ-W			
T1	−2.47 (−7.68; 2.73)	0.43	−0.33 (−0.95; 0.33)
T2	−2.15 (−7.65; 3.35)	0.43	−0.27 (−0.95; 0.41)
T3	−2.28 (−7.87; 3.31)	0.43	−0.29 (−0.97; 0.40)
EQ-5D index			
T1	0.01 (−0.03; 0.05)	0.49	0.19 (−0.35; 0.73)
T2	0.03 (−0.02; 0.09)	0.49	0.44 (−0.32; 1.19)
T3	0.02 (−0.03; 0.06)	0.49	0.22 (−0.41; 0.85)
EQ-VAS			
T1	−3.08 (−9.12; 2.95)	0.68	−0.29 (−0.84; 0.26)
T2	−2.45 (−9.75; 4.85)	0.68	−0.23 (−0.90; 0.44)
T3	−1.43 (−8.33; 5.47)	0.68	−0.13 (−0.76; 0.50)
Physical outcomes			
Strength External Rotation, N[b]			
T1	3.14 (−8.30; 14.58)	0.58	0.17 (−0.42; 0.75)
T2	6.49 (−6.31; 19.28)	0.45	0.34 (−0.32; 1.00)
T3	5.68 (−7.13; 18.49)	0.45	0.30 (−0.36; 0.96)
Strength Internal Rotation, N[b]			
T1	7.23 (−8.32; 22.79)	0.53	0.24 (−0.26; 0.73)
T2	5.62 (−14.04; 25.29)	0.68	0.18 (−0.44; 0.81)
T3	0.75 (−21.02; 22.51)	0.95	0.02 (−0.67; 0.71)
Strength Scaption, N[b]			
T1	−3.06 (−20.41; 14.30)	0.95	−0.16 (−1.01; 0.70)
T2	−0.50 (−15.67; 14.67)	0.95	−0.03 (−0.77; 0.72)
T3	1.24 (−12.81; 15.29)	0.95	0.06 (−0.63; 0.75)
Passive ROM External Rotation,°			
T1	9.03 (−11.98; 30.04)	0.58	0.33 (−0.41; 1.06)
T2	11.98 (−7.75; 31.72)	0.58	0.43 (−0.27; 1.12)

(*Continued*)

Table 3 (Continued).

	Difference Between Groups, Mean (CI 95%)	FDR p-value adj.	Cohen's d (CI 95%)
T3	0.65 (−17.90; 19.21)	0.94	0.02 (−0.62; 0.67)
Passive ROM Internal Rotation,°			
T1	3.91 (−11.30; 19.12)	0.89	0.19 (−0.52; 0.89)
T2	−3.37 (−15.30; 8.57)	0.89	−0.16 (−0.71; 0.39)
T3	−0.94 (−14.91; 13.04)	0.89	−0.04 (−0.69; 0.60)
Passive ROM Scaption,°			
T1	9.97 (−3.73; 23.66)	0.45	0.37 (−0.13; 0.87)
T2	7.09 (−7.15; 21.33)	0.48	0.26 (−0.26; 0.78)
T3	0.61 (−17.26; 18.47)	0.95	0.02 (−0.62; 0.67)
Active ROM External Rotation,°			
T1	5.24 (−14.72; 25.20)	0.89	0.21 (−0.56; 0.97)
T2	8.83 (−9.14; 26.80)	0.89	0.35 (−0.35; 1.04)
T3	−1.21 (−18.11; 15.69)	0.89	−0.05 (−0.69; 0.60)
Active ROM Internal Rotation,°			
T1	−3.02 (−15.46; 9.41)	0.63	−0.15 (−0.75; 0.45)
T2	−3.89 (−14.69; 6.91)	0.63	−0.20 (−0.72; 0.33)
T3	−3.53 (−16.86; 9.79)	0.63	−0.18 (−0.82; 0.47)
Active ROM Scaption,°[c]			
T1	7.28 (−6.33; 20.88)	0.51	0.34 (−0.28; 0.95)
T2	6.78 (−7.34; 20.91)	0.51	0.31 (−0.33; 0.95)
T3	−1.63 (−16.57; 13.30)	0.83	−0.08 (−0.74; 0.59)

Notes: Differences and effect sizes displayed as: "exercise into pain" – "exercise no pain".[a]= difference between groups was calculated accounting for duration of symptoms as covariate; [b]= difference between groups was calculated accounting for sex as covariate; [c]= difference between groups was calculated accounting for age as covariate.
Abbreviation: FDR: False Discovery Rate adjusted p-values (Benjamini-Hochberg adjustment) to decrease Type I error.

the aim was to re-train force couples in the shoulder (ie lower activity of serratus anterior and over-activation of the upper trapezius during arm elevation[41]), improve the function of rotator cuff muscles to center the humeral head in the glenoid, preventing excessive superior humeral head translation caused by contraction of the deltoid.[42] Nevertheless, the bursal impingement under the coracoacromial arch and the status of the synovial bursa were not evaluated. However, it might give potentially useful indications (ie the presence of synovial hypertrophy with hypervascularization, exudative bursitis, adhesive bursitis),[43] and it is suggested as an additional ultrasonographic measure for future studies.

As there were no between-group differences for all the outcomes but a significant effect of time up to 6 months, we can hypothesize that exercise had a hypoalgesic effect in both groups, with restored strength in three different shoulder positions and substantial decrease in FABQ-PA, perhaps mediated by a reconceptualization of pain and improved self-efficacy.[44] Similarly, FABQ-PA was not different at 6 months when comparing progressive home exercises (16 weeks, up to six sessions) with best practice advice (one session),[45] or when adding three additional group meetings to control

intervention in RCRSP.[46] This suggests that fear-avoidance beliefs on physical activity might have marginal importance in order to achieve successful treatment outcomes.

In contrast, fear-avoidance related to work and fear of pain did not seem to change over time, and the latter was significantly influenced by duration of symptoms. A combination of various factors, from neuromuscular, neuro-endocrine-immune, and psychosocial mechanisms, may have played a role.[47] However, we cannot draw conclusions on the effect of exercise based on the current study, because we did not include a control group. Nevertheless, we can conclude that pain provocation during one exercise seems not to be necessary in the treatment of chronic RCRSP to achieve beneficial results.

Patients were equally reassured and motivated in both groups, and this may also explain the absence of difference in perception of recovery or satisfaction between the groups. Interestingly, the number of adverse effects, use of additional treatments, and adherence did not differ between groups. One would expect that patients training with pain in one exercise would be less compliant or experience more pain or fatigue after exercises, but this was not the case in the current study. However, closer monitoring of symptoms flares-up during home-exercises is suggested in future studies, as four patients in total had 4 to 7 episodes of increased pain after 24 h from the unsupervised exercises.

Limitations

Although we found clinical improvements over time, we did not include a control group to assess the natural course of the RCRSP. Moreover, the sample size was calculated on the primary outcome SPADI. Consequently, the results on the other outcomes should be considered exploratory in nature because type II error might be present due to a possible lack of power for the analysis of these outcomes. The research team decided to not provide a fixed set of exercises because different types of exercises seem equally effective in RCRSP.[3,4,6] On the one hand, this increased the variability of exercises and progression between different patients, on the other hand, it aligns well with current clinical practice.[19] Furthermore, the blinding of outcome assessors and patients decreased the risk of performance and detection bias. Only one assessor evaluated the patients using the mean of three measures, increasing the internal consistency of physical measures. The assessor was blinded to group allocation but, as being part of the research team leading the project, this could have introduced biases. Therefore, an external outcome assessor is suggested for future studies.

Only two physiotherapists working in one physiotherapy clinic participated in the study, which limits the external validity of the results but reduces variations of the intervention. Moreover, the presence of two different therapists was considered as a random effect in the statistical analysis. Lastly, only 13% of all screened patients were included. Consequently, our conclusions are limited to patients with chronic RCRSP with minimal resting pain (verbal NPRS < 2), and findings might be different in a population with higher initial irritability or in an acute phase.

Conclusion

Interventions including one exercise into pain or not are both effective in pain and disability reduction, fear-related beliefs, and quality of life up to 6 months in chronic RCRSP. This study suggests that there is a substantial improvement in pain and function over time, whether the patients with RCRSP exercise into pain or not. Increases in strength and range of motion were also present over time, irrespectively of group. Therefore, pain provocation during shoulder exercises does not seem to be necessary in the treatment of chronic RCRSP for achieving successful results.

Abbreviations

BMI, Body Mass Index; CERT, Consensus on Exercise Reporting Template; CI, Confidence Interval; CONSORT, Consolidated Standards of Reporting Trials; EQ-5D-5L, 5-level EQ-5D by EuroQol Group; FABQ-PA, Fear-Avoidance Beliefs on Physical Activity; FABQ-W, Fear-Avoidance Beliefs on Work; FDR, False Discovery Rate; GPE, Global Perceived Effect; MCID, Minimal Clinically Important Difference; MIC, Minimal Important Change; NPRS, Numeric Pain Rating Scale; NS, Non Significant; QQplot, Quantile Quantile plot; RCRSP, Rotator Cuff-Related Shoulder Pain; RCT, Randomized Controlled Trial; ROM, Range Of Motion; RPE, Rate of Perceived Exertion; SPADI, Shoulder and Pain Disability Index; VAS, Visual Analogue Scale.

Data Sharing Statement

The data used during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Informed Consent

The Ethics Committee of Antwerp University Hospital approved this study (ref: B300201837376). All participants gave written informed consent before data collection began.

Consent for Publication

The person appearing in the Supplementary Information has given her written consent for publication.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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