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Exercise into pain in chronic rotator cuff related shoulder pain: a prospective single-group feasibility study

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ABSTRACT

Objectives This study evaluated the feasibility of exercising into pain in rotator cuff related shoulder pain (RCRSP), data collection procedures, feedback from physiotherapists and patients, and clinically important changes in patient-reported outcome measures (PROMs).

Design Unblinded non-randomised single-group study.

Setting Physiotherapy clinic in Belgium.

Participants Twelve patients with unilateral RCRSP for minimum 3 months, aged 18–65 years.

Interventions Twelve weeks of four individualised exercises, with nine physiotherapist-led sessions with pain ratings 4–7 out of 10 on a verbal Numeric Pain Rating Scale for 9 weeks and then pain ratings 0–2 for 3 weeks. Every physiotherapy session included 15 min of manual therapy. Non-supervised exercises were: 2×/week in weeks with physiotherapy session, 3×/week in weeks without physiotherapy session.

Outcome measures Primary: adherence, where patients were considered adherent with 78% (7/9 sessions) attendance for supervised sessions and 81% (22/27 sessions) completion for non-supervised exercises, and Shoulder Pain and Disability Index (SPADI); secondary: fear-avoidance behaviour, fear of pain, physical outcomes (strength, range of motion, scapular dyskinesis); others: ultrasound (US) imaging outcomes (acromionhumeral distance, supraspinatus tendon thickness, occupation ratio), global perceived effect (GPE). PROMs were collected via online survey, except for the GPE (via closed envelope). US measures were taken after physical measures.

Results Adherence and adverse effects were analysed in patients who had the possibility to attend minimum seven supervised sessions (n=8): 88% of them adhered to supervised sessions, 50% to non-supervised exercises; none of them withdrew from the study, three of them obtained individual clinically important improvements in SPADI score above 20 points. The measurement protocol of physical and ultrasonographic outcomes took around 60 min.

Conclusions Adherence to supervised sessions was satisfactory, the adherence to non-supervised exercises must be improved. Data collection procedures were feasible to perform, but some changes are recommended.

Trial registration number NCT04154345.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Satisfactory adherence to non-supervised exercises if patients completed 22/27 (81%) of sessions.
⇒ Satisfactory adherence to supervised sessions with attendance of 7/9 (78%) physiotherapy sessions.
⇒ An intensive collection of patient-reported outcome measures on pain, function, fear-related behaviours and objective measures.
⇒ The intake of analgesic drugs was not registered, but it might be relevant as non-planned cointervention.
⇒ Absence of blinding (no control for detection or performance biases) or randomisation (no assessment of willingness to randomisation or group allocation).

INTRODUCTION

Shoulder pain is the third most frequent musculoskeletal complaint,[1] with a yearly prevalence ranging between 5% and 47%.[2] Physiotherapy accounted for 60% of the mean healthcare costs in a Swedish cost-of-illness study.[3] Rotator cuff related shoulder pain (RCRSP) is the most reported shoulder disorder encompassing impingement, subacromial pain, rotator cuff tendinopathy, tendinosis, tendinitis and partial or non-traumatic full-thickness rotator cuff tears.[4] Different structures might be involved in the aetiology of RCRSP, such as subacromial bursa, acromion, rotator cuff tendons and muscles,[5] as well as different mechanisms, going from tendon overload to central sensitisation,[6] and therefore, various types of treatment have been proposed.[7] A non-operative intervention is the first option for the management of RCRSP, with a strong recommendation for exercise.[7] Loaded exercises are considered safe[8] and higher repetitions and sets seem to have superior effect compared with low dosage.[9] However, questions remain regarding what is the best exercise modality and approach and whether pain should be elicited or avoided during exercise.[10] Indeed, it is suggested that 'exercising into pain' can give small but significant benefits in the short term in chronic musculoskeletal disorders and should not be considered an obstacle to positive outcomes.[11]

The theoretical rationale behind the concept of 'exercise into pain' is based on the

positive impact on the central nervous system (CNS),[11 12] in which exercise induces endogenous hypoalgesia due to a release of endogenous opioids and the activation of spinal inhibitory mechanisms.[13] Protocols using exercise into pain usually included higher loads or levels of resistance, which eventually gave greater improvements in pain reduction following a dose-response effect.[10 11] Therefore, painful exercise may offer greater benefits in short term because of a greater exercise-induced hypoalgesia.[11 14] Furthermore, painful exercises may serve as painful conditioning stimulus to initiate the conditioned pain modulation (CPM) response, which activates descending pain inhibitory responses decreasing pain-related fear and the activity of the amygdala.[14] Therefore, temporary reproduction of patient's symptoms within a framework of 'hurt not equalling harm' might help to address fear avoidance and catastrophising beliefs in chronic musculoskeletal pain.[11 12]

When we consider the literature relating to painful exercise, strength training for rotator cuff and scapular stabilisers which allowed pain during exercise was better than non-specific shoulder or neck exercises, with considerably more patients in the specific exercise group withdrawing from the waiting list for surgery.[5] A pilot study using painful eccentric exercises showed significant results in nine patients awaiting surgery, with five patients choosing to not undergo surgical treatment.[15] However, when heavy load eccentric training allowing pain during exercise was added to a rotator cuff strengthening programme,[16] this did not result in superior reduction of pain or functional improvement. When comparing one painful self-managed exercise to usual physiotherapy, which included manual therapy, massage or other interventions, there were no significant between-group differences in clinical outcomes.[17]

Tissue irritability is also an essential factor in exercise therapy, and it might be especially important when prescribing exercises into pain. Although tissue irritability has been included in different clinical models or classifications systems for shoulder rehabilitation,[4 18] it has not been specifically addressed in clinical trials. The threshold of pain that was allowed during exercise varied in previous studies. Patients should feel some pain during exercises,[15–17] but no more than 5 out of 10 on Visual Analogue Scale[16] or on Numerical Rating Scale (NRS),[5] with the pain subsiding by the next exercise session,[5] by the next morning[16] or directly after the exercises.[17] Although pain was allowed or even recommended during exercises, studies usually do not indicate a minimal amount of pain in VAS or NRS, even when comparing specifically painful and non-painful treatments in RCRSP.[19]

There are various possible mechanisms why a resisted exercise programme into pain may induce pain reduction and bring about functional improvement, including changes in CNS processing, reconceptualisation of fear-related movement, and strengthening of deconditioned muscle tissue. Since different modalities of exercises have been found equally effective in RCRSP, we hypothesise that different exercises prescribed with high range of pain (4–7 on verbal NRS), could give better results than non/slightly painful modality (0–2 on verbal NRS scale). However, before testing this hypothesis in a randomised controlled trial, we conducted a feasibility study. Hence, the objectives of this study were as follows: (1) to assess the rate of adherence and adverse effects for patients receiving the intervention; (2) to describe data collection procedures; (3) to report feedback from both patients and physiotherapists and (4) to analyse the effect of exercise into pain on shoulder pain and disability, fear of pain or fear-avoidance beliefs.

METHODS

Study design and participants

This feasibility study was reported according to the Consolidated Standards of Reporting Trials 2010 statement: extension for pilot and feasibility studies[20] (online supplemental additional files 1 and 2). It was designed as prospective single-group study with three time points of measurement: before (T0), during (6 weeks—T1), at the end (12 weeks—T2) of the intervention. The eligibility criteria are presented in table 1.

Procedure

Two physiotherapists recruited the participants in a private physiotherapy practice in Belgium between November 2019 and February 2020. Patients who expressed an interest in participating were given an appointment with the principal assessor. The first assessment session (T0) included: project explanation (informed consent, exercise diary, online survey), screening, assessment of physical (strength, range of motion, scapular dyskinesis) and US outcomes (acromiohumeral distance, supraspinatus tendon thickness, occupation ratio). The order of measurements was standardised, with US measures taken after the physical outcome measures. The physical and US measures were evaluated again at 6 (T1) and at 12 weeks (T2). The time planned was approximately 90 min for T0 and 60 min for T1 and T2. The patient-reported outcome measures (PROMs) were sent through online platform Qualtrics (Qualtrics, Provo, Utah (USA), versions 2019, 2020).[21] They had to be completed within 2 days from the assessment day, whereafter an email reminder was sent if necessary.

Intervention

Patients followed a 12-week intervention with nine supervised physiotherapy sessions which included one supervised session per week and two non-supervised home exercise sessions per week. The first five supervised sessions were scheduled on the initial 5 weeks of treatment. The other four supervised sessions were spread over the following 7 weeks. During the unsupervised weeks, the patient had to practice home-based exercises three times per week at home.

Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
► Age 18–65 years ► Pain for at least 3 months ► Pain in the anterolateral shoulder region ► Pain at rest maximum 2 out of 10 on verbal NRS ► Patient had to test positive at least 3 out of 5 symptoms-provoking tests: pain during Neer test, Hawkins-Kennedy test, Jobe test, painful arc between 60° and 120°, pain or weakness during external rotation resistance test.[36] ► All types of occupations were included: students, workers (including overhead workers or heavy duty workers), people on sick leave and retired people.	► Bilateral shoulder pain ► Corticosteroid injections less than 6 weeks prior to the enrolment ► Participants who were pregnant, not able to understand Dutch ► Clinical signs of full-thickness rotator cuff tears (positive external and internal rotation lag tests or drop arm test) ► Evidence of adhesive capsulitis (50% or more than 30° loss of passive external rotation)[37] ► Previous cervical, thoracic or shoulder surgery; recent fractures or dislocations on the painful shoulder ► Symptoms of cervical radiculopathy as primary complaint (tingling, radiating pain in the arm associated with neck complaints) ► Primary diagnosis of acromioclavicular pathology, shoulder instability ► Previous medical imaging confirming full-thickness rotator cuff tears or calcifications larger than 5 mm ► Patients with competing pathologies (inflammatory arthritis, neurological disorders, fibromyalgia, malignancy) ► Participants performing overhead sport activities for more than 4 hours/week

NRS, Numerical Rating Scale.

Every physiotherapy session lasted about 30 min and included 15–20 min of exercise therapy (exercising into pain) and 10–15 min of manual therapy (focusing on stretching of the posterior soft tissues of the shoulder). The manual treatment of posterior shoulder soft tissues was based on two main reasons. First, the presence of posterior capsular tightness has been detected in RCRSP and other shoulder disorders when comparing healthy and affected shoulders.[22] Second, restoring flexibility deficits might help to adjust scapular malpositioning, which is often present in RCRSP.[23] Moreover, the manual stretching of posterior shoulder tissues was embedded in the routine treatment of shoulder pain in the recruited private practice and therefore its implementation was expected by treating physiotherapists to be part of the intervention protocol. Guidelines were given to the physiotherapists concerning pain intensity, direction of movement, frequency of exercises. A list of possible exercises was proposed and discussed, which included closed kinetic chain exercises, exercises with elastic bands or weights. However, the physiotherapists were free to choose the type of exercises as long as the patient could reproduce it at home.

Each patient had four individualised exercises, reported according to the Consensus on Exercise Reporting Template[24] in online supplemental additional file 3. The physiotherapists targeted both rotator cuff and periscapular strength with a set of four exercises. Lifestyle advice, ergonomics advice, patient education regarding exercise in RCRSP were provided, in line with current physiotherapy practice in Belgium.[25]

The patient performed four exercises chosen by the physiotherapist and the pain had to be between 4 and 7 on verbal Numeric Pain Rating Scale (NPRS) in every exercise. One exercise was in a specific painful direction, meaning in flexion, abduction or external/internal rotation or a combination of these directions. The other three exercises elicited pain between 4 and 7 but not in the same painful direction of movement. However, the pain might fluctuate between different exercises but the session was considered into pain when the average of the four exercises recorded by the physiotherapist was between 4 and 7 on NPRS. In the last 3 weeks of the treatment the pain during exercise ranged between 0 and 2 on NPRS to allow the patient to exercise in a less painful range after neuromuscular adaptations occurred in the previous phase. The pain range was set at the physiotherapy session, but it could decrease or increase during home exercises. The physiotherapist checked and adjusted the exercises at the correct pain range at every session.

Objectives and outcomes

This study had four main objectives to investigate: rate of adherence and adverse effects (objective 1), data collection procedures (objective 2), feedback from patients and physiotherapists (objective 3), effect on PROMs (objective 4).

Objective 1: rate of adherence and adverse effects

Every patient filled in an exercise diary, specifying the number of sets and repetitions for every exercise and the level of pain before, during and after 1 hour of each exercise session. The physiotherapists were also instructed to fill in a questionnaire covering attendance of patients, and for each patient the type of exercises, number of sets and repetitions, intensity (weight or colour of elastic band) and level of pain before, during and after 1 hour of each exercise session. The pain after 1 hour during the physiotherapy session was asked to the patient at every following session. The outcomes related to objective 1 are presented in box 1.

Box 1 Outcome measures for objectives 1, 2, 4

Outcomes for objective 1

⇒ Adherence to physiotherapy treatment (primary outcome): when patients attended at least 7 of 9 (78%) sessions.

⇒ Adherence to non-supervised exercises (primary outcome): when patients completed at least 22 of 27 (81%) sessions. One session of non-supervised (home) exercise was considered completed when at least 80% of the total amount of sets and repetitions were executed as prescribed by the physiotherapist.

⇒ Adverse effects: when patients were leaving the study because of treatment-related reasons. Increased pain after 1 h hour of the exercise compared with baseline level was registered but not considered as an adverse effect in the final analysis, since the intervention was deliberately provocative.

Outcomes for objectives 2 and 4

⇒ Patient-reported outcome measures (PROMs) (primary outcome): Shoulder Pain and Disability Index; PROMs (secondary outcomes): Fear-Avoidance Beliefs Questionnaire (with subscale of physical activity FABQ-PA and subscale of work FABQ-W), Fear of Pain Questionnaire-9 items; other PROMs: global perceived effect on recovery (GPE) and GPE on satisfaction.

Outcomes for objective 2

⇒ Physical outcomes (secondary outcomes): passive range of motion in external rotation, internal rotation, scaption; active range of motion in external rotation, internal rotation, scaption; strength in scaption, external rotation, internal rotation; scapular dyskinesis (at rest, unloaded and loaded, with scapular correction tests).

⇒ US outcomes (other outcomes): acromionhumeral distance at rest, supraspinatus tendon thickness, occupation ratio.

Objective 2: data collection procedures

The time needed to collect the data was tested for screening and objective measures (physical and US measures). The clinical questionnaires were sent via online survey Qualtrics before the treatment, at 6 and 12 weeks, except for the global perceived effect (GPE), which was collected as a measure of treatment effect in a closed envelope by the physiotherapist after 1 week of treatment, at 6 and at 12 weeks. The outcomes related to objective 2 are presented in box 1 in the order of measurement. Details on PROMs and on the measurement protocol of physical and US measures are described in online supplemental additional file 4.

Objective 3: feedback from patients and physiotherapists

The patients who attended at least seven sessions out of nine were interviewed in a face-to-face meeting at 6 and 12 weeks by the first author to evaluate their experience with the intervention and the adherence to both the supervised and non-supervised sessions. If a face-to-face meeting was not possible, the patient was interviewed by phone. The exercise and pain diary were filled out by the patient and explored during the assessments. Feedback from the physiotherapists was explored at the end of the study period.

Objective 4: effect on PROMs

The PROMs are indicated in box 1 and relative details are reported in online supplemental additional file 4. Concerning the primary patient-reported outcome Shoulder Pain and Disability Index (SPADI),[26] the Minimal Important Change (MIC) was calculated for each patient as a change of at least 43% of the individual baseline scores, as proposed by Thoomes-de Graaf *et al*.[27] A change of less than 20 points might be due to measurement error.[27]

Sample size

For the primary objective, a sample size of 12 patients was calculated to test 80% of compliance rate, ranging between 0.78 and 0.84 within a 95% of CI, obtained with the 'score method incorporating continuity correction' reported by Newcombe *et al*.[28] We considered in this calculation 36 sessions (9 supervised and 27 non-supervised sessions), 12 exercises in total (4 different exercises, 3 sets for each exercise) for a total of 432 observations.

Randomisation and blinding

No control group was present, and randomisation or blinding was not implemented.

Patient and public involvement

Patient involvement was important in the intermediate (at 6 weeks) and final (at 12 weeks) analysis of the project as one of the reasons we conducted the feasibility study was to obtain patient feedback on the acceptability of the exercise protocol. Patients who could attend at least seven out of nine sessions were interviewed at 6 or 12 weeks follow-up in person or, when this was not possible, by phone. They were asked about the reasons why they could not exercise at home or why they did not attend a physiotherapy session. They were not involved in results dissemination.

Data analysis

Demographics, patient characteristics and recruitment time were analysed with Microsoft Excel (2016) and JMP Software (V.15.2.1, SAS Institute). Feedback from patients and physiotherapists was noted down and reported in short interviews, but no formal registration or transcription were conducted. The PROMs, physical and US outcomes were reported quantitatively. Change in the primary patient-reported outcome (SPADI) was described in relation to the individual MIC: patients with change scores of at least 43% of their baseline SPADI were considered clinically improved.[27]

The physical and US outcomes were included for evaluating data collection procedures and only pretreatment data are presented. The continuous variables were described as median, minimum or maximum values or IQRs due to the small sample size.

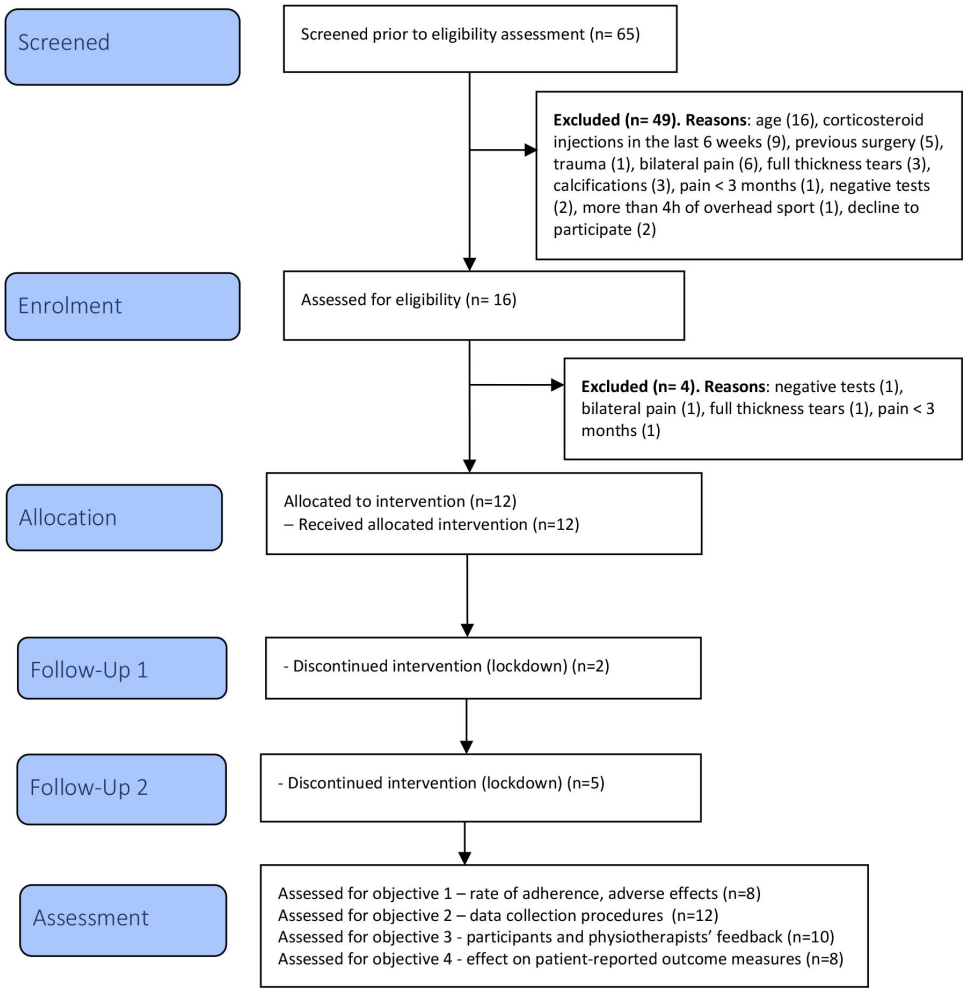

Figure 1 **Flow chart adapted from CONSORT flow chart**. CONSORT, Consolidated Standards of Reporting Trials.

RESULTS

Participant flow and recruitment

Two physiotherapists screened 65 patients with RCRSP, excluding 49 patients in a first assessment (figure 1), while the principal assessor excluded 4 extra patients in the final assessment for eligibility. However, the follow-up measurements and the physiotherapy sessions during the pandemic of COVID-19 were stopped in March and April 2020, and therefore, physiotherapy treatments and measurements of physical and US outcomes were lost for seven patients at 6 or 12 weeks. In the analysis of adherence and adverse effects, we considered only the patients who had the possibility to attend a minimum of seven supervised sessions (n=8). They continued to exercise at home also during the period of lockdown and two patients completed their sessions during the lockdown and they were monitored by the physiotherapist by phone. The data on PROMs were also analysed (n=8). The time and order of data collection for US and physical outcomes were analysed for all patients (n=12), but only pretreatment data are reported as part of the feasibility of the measurement protocol. Feedback from physiotherapists (n=2) and patients analysed (n=8) was elaborated in face-to-face meetings or by phone.

Twelve subjects participated in the study and their baseline characteristics are reported in table 2. Although only 2 participants had heavy workload, identified as full-time occupation demanding frequent overhead activities, 8

Table 2 Baseline characteristics

Variable	n=12
Gender, female	7 (58.3%)
Age, years	50.5 (16.5)
Body mass index, kg/m^2	23.2 (3.4)
Working status	
Working	11 (91.7%)
Student	1 (8.3%)
Duration of symptoms, months	6.5 (11.3)
Dominant side affected	7 (58.3%)
Previous treatments	8 (66.7%)

Data are presented as median (IQR) or n (%). 'Previous treatments' included any treatment for shoulder pain (such as physiotherapy, injections more than 6 weeks ago, osteopathy) conducted before the enrolment.

of them had some pain during work, while 10 had pain during sport and/or leisure activities. The PROMs, physical and US outcomes for 12 patients at baseline are reported in online supplemental additional file 5. The GPE of recovery and satisfaction was collected separately in a closed envelope after 1 week of treatment for the first time. Data at this time point are presented in online supplemental additional file 5.

Objective 1: rate of adherence and adverse effects

Eighty-eight per cent (7/8) of patients fulfilled the criteria of attending at least 7/9 of the supervised sessions. Only 50% (4/8) completed at least 22/27 of the non-supervised exercises, as prescribed by the physiotherapists in terms of repetitions and sets. One patient did not attend three times the physiotherapy sessions because of work-related reasons, while five patients could not exercise at home as prescribed, because of sickness (n=1), increased pain related to return to sport (n=2), lack of time (n=1) and misunderstanding with the physiotherapist concerning the number of repetitions and sets (n=2). None of the patients considered in this analysis withdrew from the study.

Considering the mean of pain in four exercises for every supervised session in the first 9 weeks, four patients (57%) trained between 4 and 7 on verbal NRS, while three (43%) did not reach this range. The questionnaire for one patient was not completely filled in by the physiotherapist, and therefore, not considered in this analysis. The number of sessions of these patients varied between 4 and 8 sessions in the first 9 weeks, depending on the availability of the patients.

Objective 2: data collection procedures

Enrolment and screening for eligibility criteria took around 30 min while the measurements for all the physical and US measures took 60 min. Filling out the online questionnaires took on average 6 min at the first time, 7 min the second time and 4 min the last time. Reminders were sent out a maximum of two times per person. The online survey was more effective than closed envelope as modality of data collection, since 5 data were lost at baseline with the envelope modality for GPE (online supplemental additional file 5). Patients forgot to give the envelope back to the physiotherapists, especially during period of restrictions due COVID-19 pandemic. Concerning the loaded scapular tests, the weight of 1 kg was very provocative in two patients. Since the movement was repeated five times in abduction and five times in flexion, these patients performed the tests with 0.5 kg instead.

Objective 3: feedback from patients and physiotherapists

Physiotherapists had difficulties in providing four painful exercises for 9 weeks for different reasons. First, there was an increase in pain during the four exercises, which was becoming unbearable for some patients at the fourth exercise, especially in the first sessions. Consequently, there was a motivational issue for these patients who had high initial pain levels. Other patients had fast recovery and it was not possible to provoke pain adding more loads in four different exercises already at the third or fourth week. Furthermore, some issues during home exercises which could have influenced the pain perception occurred. For example, some patients trained one extra session during the week, or they did not wait 24 hours between sessions. Two patients increased their sport activities during the treatment period, influencing the pain during home exercises. Moreover, one patient had an extra physiotherapy session during the study period and another patient performed additional stretching exercises. Although the return to sport could influence the level of pain during exercise, some patients were willing to engage into sport while some others were too afraid. Therefore, the physiotherapists did not give limitations on this matter but they let the patients decide based on their willingness.

Objective 4: effect on PROMs

Of those patients who had the possibility to attend at least seven out of nine supervised sessions (n=8) before the pandemic of COVID-19, results of PROMs are shown in online supplemental additional file 5 and figure 2. Considering the SPADI change for each individual patient, three patients had a significant individual change which was also superior to the measurement error of 20 points, while one patient had a significant change but it was inferior to 20 points (see online supplemental additional file 5). In figure 2, improvement in pain and function is seen in all patients, as indicated by decreased SPADI score, while other PROMs showed different trends over time depending on the patient.

DISCUSSION

This feasibility study showed that a significant proportion (43%) of patients did not adhere to a programme of exercise into pain of 4–7/10 for nine consecutive weeks. The rate of attendance of physiotherapy was satisfactory, but the rate of adherence to non-supervised exercises was not. The time for data collection complied with the prespecified time frame, and the delivery of the clinical questionnaires via online survey was both practical and achievable. The order of physical outcome measures and modalities of scapular testing should be adjusted in future studies.

According to the feedback of the physiotherapists, it was not possible to prescribe four painful exercises for 9 weeks for all patients. Physiotherapists encountered problems in motivating the patients to exercise into pain or could not find painful exercises for some patients. This suggests that ‘exercise into pain’ might not be applicable to all patients. This was not the case in a similar study conducted by Vallés-Carrascosa *et al*,[19] as they did not report any drop-out in both painful and non-painful exercise groups. However, patients in the painful group trained below 40 mm on VAS scale carrying out only one

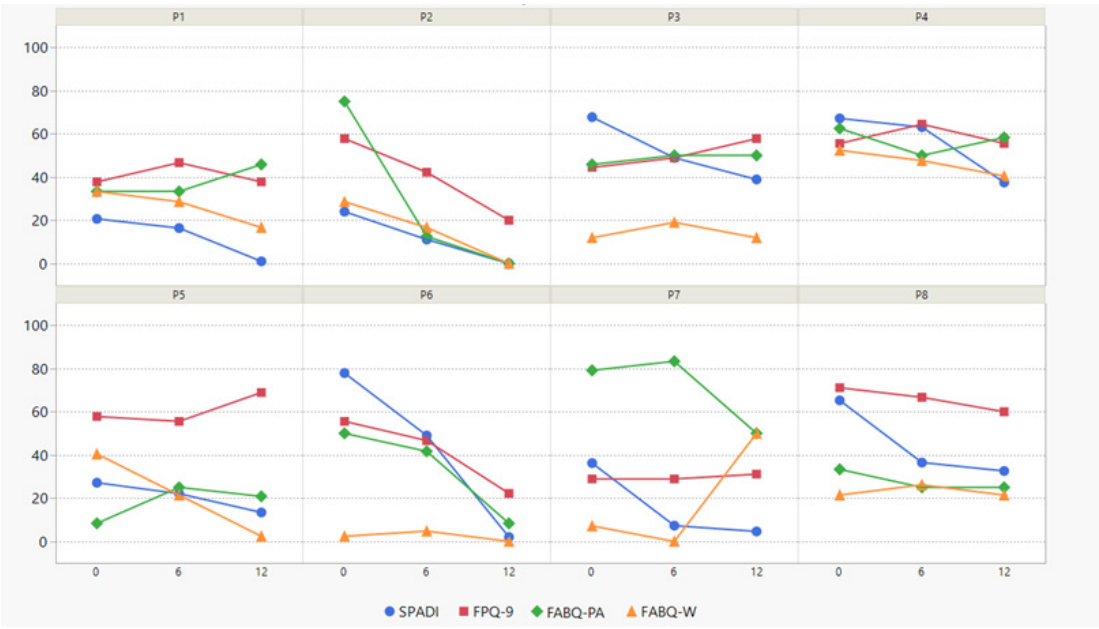

Figure 2 **SPADI, FPQ-9, FABQ-PA, FABQ-W at 0, 6 and 12 weeks follow-up**. Data of SPADI, FPQ-9, FABQ-PA, FABQ-W for eight patients are converted to a value from 0 to 100, where 100 identifies a worse score. FABQ-PA, Fear-Avoidance Beliefs Questionnaire-Physical Activity; FABQ-W, FABQ-Work; FPQ-9, Fear of Pain Questionnaire; P1–P8, ID Patient; SPADI, Shoulder Pain and Disability Index.

painful eccentric exercise of the supraspinatus out of six exercises. Between-group differences in pain or function were not found at the end of the treatment. One might argue that the difference in VAS during training between groups was not sufficient to elicit significant differences, or maybe that different pain levels were not a relevant factor in the study. Since it was not possible to maintain four painful exercises for 9 weeks in the current study, we propose that exercise into pain should be limited to one exercise in the painful direction with clear limits during training (4–7 on NRS), while the remaining three exercises could be performed at a pain level between 0 and 2 on NRS. On the other hand, it is possible that this exercise protocol could work only in a subgroup of patients continuously supervised by the physiotherapist and who are very motivated to exercise, even into pain, as self-efficacy has shown to be an important predictive factor during therapy.[29] Moreover, a qualitative analysis is suggested for future studies to understand the barriers and beliefs around the concept of 'exercise into pain' for both patients and physiotherapists.

Second, adherence to home exercises was lower than expected. Closer monitoring and discussion of exercises and expectations between physiotherapists and patients during future studies is recommended. Images and videos of exercises might enhance adherence and help the patient in the performance of the home exercises. To deal with the low rates of patient adherence, telerehabilitation may be a good approach. It has shown good results (92%) combined with usual care when applied in people with RCRSP, compared with usual care alone (67%).[30] Moreover, the intake of analgesic medication during treatment should be registered in future feasibility or pilot studies as the flare-ups of pain inducing a patient to take analgesic drugs after training session might be considered as a non-planned cointervention and a medication use may be a significant variable that could impact on results.

Considering the individual SPADI changes, only three patients had a significant MIC which was also above the measurement error of 20 points. However, the median change in SPADI score for all patients was 29 points, which was higher than previous estimated values (8–13.2 points)[31] and also higher than another recent feasibility study with similar RCRSP population (17 points) by Major *et al*.[32] Although patients were similar in terms of age (around 50 years old) and gender distribution (higher prevalence of women), other differences may have influenced the results, such as previous (failed) treatments in the study by Major *et al*.[32] Moreover, our population presented higher SPADI at baseline compared with Major *et al*, which could have led to greater changes during time.

The choice of the research team to not use a specific set of exercises but rather to use a list of possible exercises was motivated by two main reasons: to allow the physiotherapist to prescribe individualised exercises and to adapt the exercises in the provocative range. We believe that this approach to chronic shoulder pain is more applicable to routine clinical practice rather than only one specific modality of exercise, which will not fit all patients. This feasibility study suggests that challenging patients with chronic RCRSP into pain-provoking exercises in frequent supervised physiotherapy sessions may bring significant individual results in pain and function (SPADI score) in some patients, but not in all of them. After all, this type of exercises might work only on a subgroup of patients who

are highly motivated and we cannot estimate causation in a single-arm non-randomised study. We have to be very cautious as these effects could be obtained by the natural course of the intervention and/or by the placebo effect as we did not specifically analyse contextual (ie, patient–therapist relationship) or non-specific (ie, natural course) effects.[33] Moreover, low adherence to non-supervised exercise indicates that not all patients wanted or could exercise into pain. As we included patients with chronic symptoms and low tissue irritability at rest, our results could be generalised only to patients with similar characteristics. Adherence to painful exercises could have been lower in patients with acute symptoms and/or highly irritable tissues, but we could only speculate on that as we did not test it.

A standardised order of US measurements at the beginning of the testing is suggested for future studies. The reason is that some physical outcome measures, in particular the measurements of maximal strength, were provocative and therefore 1 hour of testing could affect both supraspinatus tendon thickness and acromio-humeral distance on the US image. A significant increase in supraspinatus tendon thickness has been previously detected after 1 hour of fatigue loading exercises in patients with rotator cuff tendinopathy, although it did not reach the minimal detectable change.[34] The acromio-humeral distance also reduced significantly 1 hour after the fatigue loading in the same study. Since both these US parameters can be significantly affected after 1 hour of exercise, it is suggested that US measurements should be carried out at the beginning of the testing procedure. Regarding loaded scapular tests, the weight used for the testing was reduced for two patients because of high pain reported during repetitive testing. Therefore, it is suggested to set the provocative load at the first assessment at 0.5 kg for all patients and gradually increase the load.

LIMITATIONS

This feasibility study had some limitations. First, we aimed to recruit patients with potentially low tissue irritability, excluding participants with resting pain higher than 2 out of 10 on verbal NRS. However, tissue irritability can be rated in more detail (ie, absence of night pain, minimal pain with overpressure) as part of the Staged Approach for Rehabilitation Classification: Shoulder Disorders (STAR-Shoulder).[18] This system of rating tissue irritability in low, medium and high levels recently showed acceptable reliability and strong relationship with patient-reported outcomes,[35] and it is suggested for future studies. Based on the level of tissue irritability, this approach can help the clinicians in the choice of training intensity and treatment strategy.[18] Second, the US outcomes were measured after the other physical tests, but this can be a limitation as the measures of acromio-humeral distance and supraspinatus tendon thickness might be affected after 1 hour of fatigue loading exercises.[34] Although the measurement protocol was not addressing specifically fatigue loading exercises, it is suggested to measure first the US outcomes and then the other physical tests to avoid that measures such as repetitive strength testing influence US measures. Moreover, feedback from patients was not registered or transcribed and the interview was performed by a researcher who was involved in the inclusion and assessment of patients. A more in-depth and well-structured interview performed by a person not involved directly in the research could give better insight on the qualitative value of this type of study. Lastly, the sample size of this study was small and the number of lost measures was high, but this was mainly due to unforeseen consequences of the COVID-19 pandemic and related restrictions.

CONCLUSION

This feasibility study showed that not all patients were adherent to exercise into pain for 9 weeks and that the adherence to non-supervised exercises should be improved. However, there was an acceptable rate of attendance to the physiotherapy sessions and no patients withdrew from the study. Data collection procedures were feasible and achievable, but the order of measurement in the protocol and modalities of scapular testing should be adjusted in future trials.

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Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by the Ethics Committee of the Antwerp University Hospital approved this study (ref:

B300201837376). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. The datasets used during the current study are available from the corresponding author on reasonable request.

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	33-34
Authors *	Contact details for the corresponding author	Title page
Trial design	Description of pilot trial design (eg, parallel, cluster)	40
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	41,42
Interventions	Interventions intended for each group	43-47
Objective	Specific objectives of the pilot trial	37-39
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	48-54
Randomization	How participants were allocated to interventions	NA
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	40
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	55-59
Recruitment	Trial status†	NA
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	55-59
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	55-59
Harms	Important adverse events or side effects	57
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	60-62
Trial registration	Registration number for pilot trial and name of trial register	63
Funding	Source of funding for pilot trial	Mentioned in the article

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*
†For conference abstracts.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4,5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5, 6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6,7, additional file 3
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8,9,additional file 4
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	11, 12
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9, 10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10, figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	10, figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11, additional file 5
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11, figure 1
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11, 12, additional file 5
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	12-15
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	12-15
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	12-15
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	12-15
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	6
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16
	26	Ethical approval or approval by research review committee, confirmed with reference number	16

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

ADDITIONAL FILE 3 - CONSENSUS ON EXERCISE REPORTING TEMPLATE (CERT)

1 Detailed description of the type of exercise equipment	The exercises were performed with elastic band, in closed kinetic chain (push out on the wall, overhead roll over, press up, external rotation against the wall), or with dumbbells. If extra material was used (i.e. physiotherapy roll for rollover exercise), it was indicated as in the paragraph of "List of exercises" below.
2 Detailed description of the qualifications, expertise and/or training	Two physiotherapists delivered the intervention in a private outpatient clinic. One physiotherapist had a special interest in shoulder and worked for more than 20 years only on shoulder patients, while the other physiotherapist had 1 year of clinical experience.
3 Describe whether exercises are performed individually or in a group	The exercises were performed individually.
4 Describe whether exercises are supervised or unsupervised; how they are delivered	The exercises were supervised in 9 sessions. The physiotherapists adjusted the level of load (dumbbell) or resistance (elastic band) or bodyweight (in closed kinetic chain exercises) in order to set the level of pain between 4 and 7 on NPRS for every exercise. The exercise session was considered "training into pain" for the average of 4 exercises. The physiotherapists also corrected the exercise performance before increasing the load. They also motivated the patient to exercise at home with the same load and number of repetitions demonstrated during the physiotherapy session. The patients were provided with the necessary material (elastic band or dumbbell).
5 Detailed description of how adherence to exercise is measured and reported	Adherence to exercises was reported using an exercise and pain diary. Patients were considered adherent to physiotherapy if they attended at least 7 out 9 (78%) sessions and adherent to home exercises if they completed 22 out of 27 (81%) days of home-exercises. The home exercise was deemed complete if the sets of repetitions were completed at (at least) 80% of the total amount prescribed.
6 Detailed description of motivation strategies	The physiotherapists strengthened the therapeutic alliance encouraging the patient to exercise at home; they explained the diagnosis (with anatomical model) and emphasized the necessity to re-train the shoulder and the role of the physiotherapist as a coach for the patient during the training.
7a Detailed description of the decision rule(s) for determining exercise progression 7b Detailed description of how the exercise program was progressed	When an exercise was performed correctly, the physiotherapists passed to the next level of difficulty (see "List of exercises" below). The physiotherapists progressed each exercise in order to obtain 4 to 7 on NPRS during each exercise. The average pain of 4 exercises during the entire exercise session had to be between 4 and 7 on NPRS. The physiotherapists found first an exercise in the most provocative direction and then 3 exercises in other directions. The patient started with 3 sets of 10 repetitions at the first session and the physiotherapists increased the load/resistance when the exercise was correctly executed but maintaining the pain level between 4 and 7 during exercise session in the first nine weeks and between 0 and 2 in the last three weeks. Exercises were progressed in terms of repetitions over time. The physiotherapists usually increased in one session the load and in another session they added a set of the same exercise.
8 Detailed description of each exercise to enable replication	The physiotherapists instructed the patient at every session on how to perform the exercises. The exercises are described in "List of exercises" below.
9 Detailed description of any home programme component	The patient repeated the exercises at home twice per week if it was the week with physiotherapy session, and three times per week if it was the week without physiotherapy session. The pain level during home exercises could increase or decrease but it was adjusted at the correct range (4-7 on verbal NPRS in first nine weeks and 0-2 in the last three weeks) by the physiotherapist at every session.
10 Describe whether there are any non-exercise components	The two physiotherapists applied manual treatment on the posterior soft tissues on every physiotherapy session (10-15 minutes). The experienced physiotherapist trained extensively the novice in the manual therapy technique before the start of the feasibility study.

11 Describe the type and number of adverse events that occur during exercise	Since the exercises were deliberately provocative, pain after exercise was not considered an adverse effect. Withdraw from the study was considered an adverse effect.
12 Describe the setting in which the exercises are performed	The exercises were performed in a private clinical practice and at home. Patients were provided with the equipment (i.e. elastic band, dumbbell) if necessary. If dumbbell was not available, a water bottle of equivalent weight was used for home exercises.
13 Detailed description of the exercise intervention	A list of exercises is presented below.
14a Describe whether the exercises are generic (one size fits all) or tailored 14b Detailed description of how exercises are tailored to the individual	The exercises are adapted to each individual. The patient started with 10 repetitions repeated in 3 sets. The exercises are tailored in difficulty and load during the physiotherapy session with pain between 4 and 7 on NPRS in the first nine weeks and between 0 and 2 in the last three weeks for each patient.
15 Describe the decision rule for determining the starting level	The physiotherapist started with 3 sets of 10 repetitions and adapted the exercise to 4-7 on NPRS using the load (body weight or dumbbell) or resistance (elastic band).
16a Describe how adherence or fidelity is assessed/measured 16b Describe the extent to which the intervention was delivered as planned	The physiotherapists filled in a questionnaire indicating the exercises and the pain level for every exercise and for the overall exercise session. They contacted the principal assessor if further explanation was necessary. The physiotherapists found difficult to give four painful exercises and the diaries of the physiotherapists were checked verifying if an average session was between 4 and 7 on NRS in the first nine weeks. The low percentage of compliance to exercise into pain (57%) might be influenced not only by the physiotherapists but also by different factors discussed in the manuscript.

LIST OF EXERCISES

The physiotherapists instructed the patient to perform four exercises from the following list. They progressed the exercises at every supervised session. Once the exercise was deemed correctly performed, the patient could progress in terms of difficulty (and load). Only one exercise was performed in the specific painful direction (external rotation, abduction, flexion or combined movements). The pictures of the exercises are presented as follows:

- Exercises in closed kinetic chain, where the first image is the starting position and the following images are the first three or four progressions of the exercise
- Exercises with elastic band are presented in this sequence: starting position, mid-position, final position.
- Exercise with weights is presented in this sequence: starting position, mid-position 1, mid-position 2, final position.

EXERCISES IN CLOSED KINETIC CHAIN

Press up

1. Press up on a chair, arms in extension and external rotation, knees flexed at 90°, full bilateral foot support
2. Press up on a chair, bilateral tip toe support
3. Press up on a chair, unilateral foot support (e.g. 1 leg extended)
4. Press up on a chair, unilateral tip toe support
5. Press up on a table, bilateral tip toe support
6. Press up on a table, unilateral tip toe support
7. Press up on a table, no foot support
8. Press up on kitchen counter, bilateral tip toe support
9. Press up on kitchen counter, unilateral tip toe support
10. Press up on kitchen counter, no foot support

Push out

1. Push out on the wall with both arms
2. Push out on the wall with the affected arm (not shown in the picture)
3. Push out on the wall with the affected arm, with controlateral leg extended
4. Push out on the kitchen counter with both arms
5. Push out on the kitchen counter with the affected arm
6. Push out on the kitchen counter with the affected arm, with controlateral leg extended
7. Push out on the table/desk with both arms
8. Push out on the table/desk with the affected arm

9. Push out on the table/desk with the affected arm, with controlateral leg extended
10. Push out on lower height/stairs
11. Push out on the floor

External rotation against the wall

1. External rotation on side plank, standing against the wall (distance 1 foot)
2. Same exercise as 2, support on one foot
3. Increase foot distance to the wall (2 feet)
4. Same exercise as 3, support on one foot
5. External rotation side plank on kitchen counter/back of a sofa
6. Same exercise as 5, support on one foot
7. External rotation side plank on table/desk
8. Same exercise as 7, support on one foot
9. External rotation side plank in horizontal position (floor, bed…)
10. Same exercise as 9, support on one foot

Overhead rollover

1. Glide on the wall with both arms, little distance from the wall (not shown in the picture)
2. Glide on the wall with both arms, little distance from the wall, one leg extended (not shown in the picture)

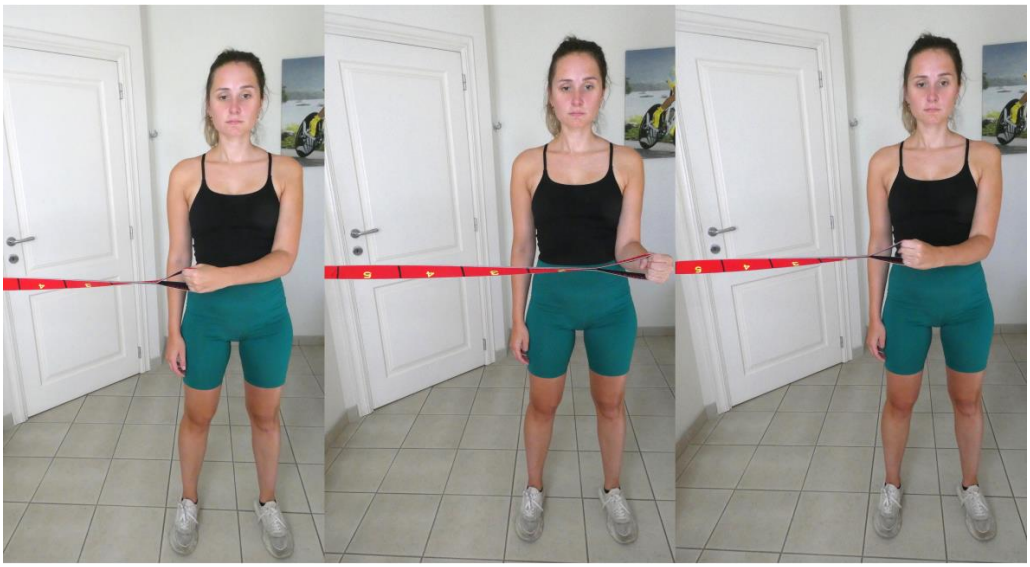
3. Glide on the wall with both arms, bigger distance from the wall
4. Glide on the wall with both arms, bigger distance from the wall, one leg extended
5. Glide on the wall with the affected arm, little distance from the wall
6. Glide on the wall with the affected arm, little distance from the wall, one leg extended
7. Glide on the wall with the affected arm, bigger distance from the wall
8. Glide on the wall with the affected arm, bigger distance from the wall, one leg extended
9. Glide on the kitchen counter with both arms
10. Glide on the kitchen counter with the affected arm
11. Glide on the table/desk with both arms
12. Glide on the table/desk with the affected arm
13. Glide on the floor from knee support with both arms
14. Glide on the floor from knee support with the affected arm

Same progressions can be made using a foam roll on the wall (or a pillow cover at home)
Little distance corresponded to 1 foot, bigger distance corresponded to 2 feet

Exercise with graded elastic band

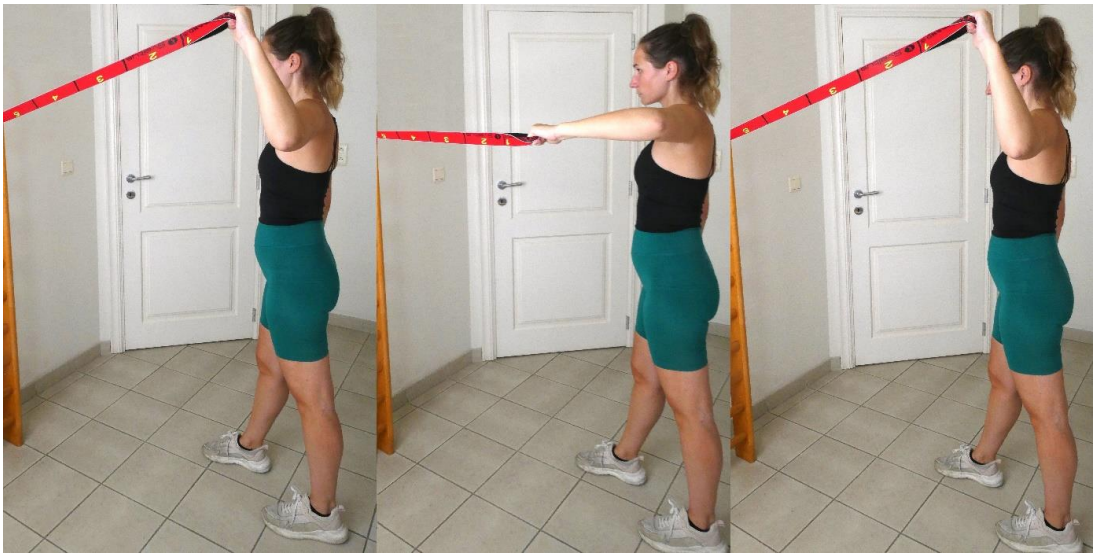
External rotation at 0° of abduction

1. External rotation with graded elastic band (10 kg), elbow flexed
2. External rotation with graded elastic band (15 kg), elbow flexed
3. External rotation with graded elastic band (20 kg), elbow flexed
4. External rotation with graded elastic band (25 kg), elbow flexed



External rotation at 90° of abduction

1. External rotation in overhead position with graded elastic band (10 kg), elbow flexed
2. External rotation in overhead position with graded elastic band (15 kg), elbow flexed
3. External rotation in overhead position with graded elastic band (20 kg), elbow flexed
4. External rotation in overhead position with graded elastic band (25 kg), elbow flexed



Horizontal adduction

1. Horizontal adduction with graded elastic band (10 kg), elbow flexed
2. Horizontal adduction with graded elastic band (15 kg), elbow flexed
3. Horizontal adduction with graded elastic band (20 kg), elbow flexed
4. Horizontal adduction with graded elastic band (25 kg), elbow flexed

(no pictures)

Exercises with weights

First, the physiotherapist checks if flexion in scapular plane in full concentric phase (going up) and eccentric (going down) can be performed in the selected pain range. If yes, progressions in weights is made. If no, the patient begins with only going up with the weight close to the body and then performing only the eccentric phase down (see picture). In this case, the exercise is firstly progressed in weights and eventually the concentric phase is added at the following session. An example of the progression from only eccentric phase to concentric-eccentric phase is explained below:

1. flexion in scapular plane with water bottle/weight (0.5liter/dumbbell 0.5kg), only eccentric phase
2. flexion in scapular plane with water bottle/weight (1liter/dumbbell 1kg), only eccentric phase
3. flexion in scapular plane with water bottle/weight (0.5liter/dumbbell 0.5kg), both eccentric and concentric phases
4. flexion in scapular plane with water bottle/weight (1liter/dumbbell1kg), both eccentric and concentric phases

ADDITIONAL FILE 4

PATIENT-REPORTED OUTCOME MEASURES

The primary subjective outcome was the change in Shoulder and Pain Disability Index (SPADI).(1) It contains 13 items, divided in two subscales: pain (5 items) and disability (8 items). Each item is scored from 0 (no pain/no difficulty) to 10 (worst imaginable pain/so difficult it requires help) on a Numeric Rating Scale (NRS). The total final score is the mean of the two subscales, where a higher score indicates worse outcome. Patients with change scores of 43% or more of their baseline SPADI can be considered clinically improved, while scores of less than 20 points in individual patients might be due to measurement error.(2) The Dutch SPADI is a valid and reliable questionnaire for evaluating shoulder pain.(3,4)

The secondary patient-reported outcomes were Fear-Avoidance Beliefs Questionnaire (FABQ) and Fear of Pain Questionnaire - 9 items (FPQ-9). The FABQ consists of 16 items on a scale 0 to 6 evaluating fear avoidance beliefs and behaviours.(5,6) The physical activity subscale (FABQ-PA, range: 0-24) is the sum of items 2-5, while the work subscale (FABQ-W, range: 0-42) is the sum of the items 6,7,9-12,15. The FABQ was originally created for patients with low back pain,(7) but in this study it was adjusted for shoulder complaints, as done in previous studies.(5,8) The Fear of Pain Questionnaire (FPQ-9 items, range: 9-45) is the shortened version of the Fear of Pain Questionnaire-III (30 items) and it was deemed psychometrically sound for brief screening of fear and anxiety in patients with chronic pain.(9) Since each item has the same wording of the original longer version, the shortened Dutch version relied on the previous translation of the FABQ-30 items in Dutch, which is valid and reliable.(10)

The Global Perceived Effect (GPE) was measured after 1 week of treatment, at 6 week and at 12 weeks with two questions: “To what extent do you feel recovered compared to the beginning of the treatment?” (from 1=very much better to 7=very much worse) as a measure of treatment outcome, and “To what extend are you satisfied about your treatment?” (from 1=absolutely satisfied to 7=absolutely dissatisfied) as a measure of care satisfaction.(11) These two questions were collected in a closed envelope separately from the rest of the measures, since they indicate levels of recovery and satisfaction which can be assessed only after the start of the treatment.

PHYSICAL OUTCOME MEASURES

Range of motion and strength

Range of Motion (ROM) was measured with an inclinometer (Plurimeter, Dr. Rippstein, Medidevice) in active and passive pain-free internal rotation, external rotation and scaption. Internal and external rotations were measured with the patient in supine position, shoulder abducted at 90°, elbow flexed at 90° and the inclinometer fixed on dorsal side of the forearm close to the wrist. For internal rotation, the assessor checked if the scapula was fixed on the table during the movement. For scaption, patients were standing against the wall with a towel between the lumbar spine and the wall and they were asked to keep a constant pressure against the wall to avoid compensations during testing.(12) The arm was straight and the inclinometer was placed along the shaft of the radius and proximal to the elbow, with the thumb up. The assessor checked visually if the movement was performed in the scapular plane, between 30 to 45° from the frontal plane. After a test trial, the mean of 3 measures was taken.

Maximum Voluntary Contraction (MVC) was measured in isometric internal rotation, external rotation and scaption with a hand-held dynamometer (HHD) (MicroFet, Hoggan Health Industries Inc.). For external and internal rotation, the patient was placed in sitting position with the back straight, elbow flexed to 90°, holding a towel between elbow and chest.(12) For scaption, patients were in standing position with the arm straight and flexed at 90° in the scapular plane (between 30-45° from frontal plane, determined visually by the assessor). The HHD was placed at the distal forearm for all

measurements. After a test trial, patients had to perform a maximal contraction for 5 seconds in 3 consecutive trials. Three approved MVCs were registered and the mean was used in the final analysis.

Scapular dyskinesis

It was evaluated by one assessor at rest, during shoulder movement and with scapular correction tests. The rest position was evaluated in the frontal plane from dorsal view, with the subject standing and both arms relaxed. The visual observation of winging, tilting, excessive elevation or depression, protraction determined the judgement of altered scapular resting position (yes/no).(13) The presence of winging or dysrhythmia during flexion and abduction (loaded and unloaded, 5 repetitions for each movement) indicated the presence of scapular dyskinesis (yes/no) during shoulder movement.(13,14) The load depended on the body weight: if the patients weighted less than 70 kg, a dumbbell of 0.5 kg was used, if they weighted more than 70 kg, a dumbbell of 1 kg was used. For two patients the weight was lowered from 1 to 0.5 kg because 10 consecutive repetitions (5 in abduction and 5 in flexion) with weights were deemed too provocative. The scapular retraction test (SRT) and modified scapular assistance test (mSAT) were used as symptom modification tests to detect scapular dyskinesis provoking shoulder complaints. The SRT was performed during Jobe test,(15) which was repeated with manual assistance of the examiner in scapular retraction or posterior tilting and external rotation.(13) The mSAT was conducted in the most painful direction (choosing between abduction, scaption or flexion), with the examiner assisting posterior tilting and upward rotation of the scapula during the movement.(16) If symptoms were reduced with the manual assistance of at least 2 points on NPRS,(17) the association of scapular dyskinesis to symptoms was confirmed.

ULTRASOUND OUTCOMES

The Ultrasound images were taken with GE Logiq-V2 and a 4.2-13 MHz linear-array transducer (GE Healthcare). All the measurements were in millimetres. Two measures were conducted: acromiohumeral distance (AHD) at rest and supraspinatus tendon thickness (STT). The occupation ratio (OR) was also calculated as percentage of the AHD occupied by the supraspinatus tendon using the following formula: OR = [(STT/AHD)*100].(18)

Acromiohumeral distance at rest

The subject was seated with the feet flat on the ground, the back straight and the arm examined on the lap in neutral position. The US probe was placed on the most anterior part of the acromion, with the long axis in the direction of the scapular plane.(19) AHD was identified as the shortest distance between the humerus and the antero-inferior aspect of the acromion.(18) When the AHD was visualized, the US screen was frozen and the measurement taken.

Supraspinatus tendon thickness

The subject was positioned in the modified Crass position, with the palmar side of the hand placed on the superior aspect of the iliac wing with the elbow flexed and directed posteriorly.(20,21) The STT was examined only in the transverse plane, as this view was previously used to compute the OR.(18) The transducer was placed anteriorly on the shoulder and perpendicular to the supraspinatus tendon.(20) Keeping the tendon in view, the probe was moved until the long head of the biceps (LHB) appeared and the image was taken.(22) The measurement of the STT was conducted between 10 and 15mm from the LHB.

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ADDITIONAL FILE 5 – RESULTS

Table. PROMs, physical and US outcome measures at baseline.

	n=12
Patient-reported outcome measures	
SPADI pain (0-100)	48.0 [43.5]
SPADI function (0-100)	43.1 [39.1]
SPADI total (0-100)	47.6 [39.0]
FPQ – 9 (9-45)	23.0 [12.0]
FABQ - PA (0-24)	12.5 [8.5]
FABQ – W (0-42)	10.5 [15.8]
Physical outcome measures	
Strength, N	
Strength ER	76.84 [53.40]
Strength IR	83.36 [57.59]
Strength SC [a]	42.17 [65.02]
Range of motion, °	
PROM ER	61 [41]
PROM IR	62 [44]
PROM SC	141 [17]
AROM ER	63 [38]
AROM IR	73 [48]
AROM SC	136 [23]
Scapular Dyskinesis, positive, n (%)	
SD rest	4 (33.3%)
SD FL [b]	5 (41.7%)
SD ABD [a]	5 (41.7%)
SD FLw [b]	5 (41.7%)
SD ABDw [b]	5 (41.7%)
mSAT	8 (66.7%)
SRT	7 (58.3%)
Ultrasound outcome measures	
Acromiohumeral distance, mm	10.85 [1.76]
Supraspinatus tendon thickness, mm	4.17 [0.63]
Occupation Ratio, %	42.11 [6.57]

Data are presented as median [IQR], and n (%); [a]data for 11 patients, [b]data for 10 patients. Abbreviations: AROM=Active Range of Motion; ER=External Rotation; IR=Internal Rotation; FABQ-PA=Fear of Avoidance Beliefs Questionnaire-Physical Activity; FABQ-W=Fear of Avoidance Beliefs Questionnaire-Work; FPQ-9= Fear of Pain Questionnaire-9 items; IQR=Interquartile range; mSAT=modified Scapular Assistance Test; N=Newtons; n=number of subjects; PROM=Passive Range of Motion; SC=Scaption (Scapular plane elevation); SD Abduction=Scapular Dyskinesis in Abduction; SD ABDw=Scapular Dyskinesis in Abduction with Weight; SD FL=Scapular Dyskinesis in Flexion; SD FLw= Scapular Dyskinesis in Flexion with Weight; SD rest=Scapular Dyskinesis at rest; SRT= Scapular Retraction Test; SPADI=Shoulder Pain and Disability Index.

Table. Global perceived effect after 1 week.

Variable	Level	n (% of 12)
GPE-Recovery		
	1=very much better	0 (0%)
	2=much better	0 (0%)
	3=somewhat better	1 (8.33%)
	4 =same	6 (50.00%)
	5=somewhat worse	0 (0%)
	6=much worse	0 (0%)
	7=very much worse	0 (0%)
	Missing data	5 (41.67%)
GPE- Satisfaction		
	1=absolutely satisfied	1 (8.33%)
	2=very satisfied	4 (33.33%)
	3=somewhat satisfied	2 (16.67%)
	4=not satisfied, not dissatisfied	0 (0%)
	5=somewhat dissatisfied	0 (0%)
	6=very dissatisfied	0 (0%)
	7=absolutely dissatisfied	0 (0%)
	Missing data	5 (41.67%)

Legend*. GPE= Global Perceived Effect*

Table. Patient-reported outcome measures.

ID	SPADI 0;6;12	SPADI change (0-12)	SPADI MIC	FPQ-9 0;6;12	FABQ–PA 0;6;12	FABQ–W 0;6;12	GPE-R 0;6;12	GPE-S 0;6;12
P1	20.6; 16.4; 1.0	19.6*	11.8	17; 21; 17	8; 8; 11	14; 12; 7	4; 3; 1	2; 2; 1
P2	24.0; 11.1; 0.0	24.0**	13.7	26; 19; 9	18; 3; 0	12; 7; 0	4; 2; 1	2; 2; 1
P3	67.8; 48.9; 38.9	28.9	38.6	20; 22; 26	11; 12; 12	5; 8; 5	3; 4; 4	3; 4; 4
P4	67.1; 63.1; 37.5	29.6	38.3	25; 29; 25	15; 12; 14	22; 20; 17	4; 3; 3	3; 2; 2
P5	27.1; 22.1; 13.4	13.8	15.5	26; 25; 31	2; 6; 5	17; 9; 1	-; 2; 2	-; 1; 1
P6	77.9; 49.0; 2.0	75.9**	44.4	25; 21; 10	12; 10; 2	1; 2; 0	4; 3; 1	2; 1; 1
P7	36.3; 7.3; 4.6	31.6**	20.7	13; 13; 14	19; 20; 12	3; 0; 21	4; 2; -	1; 1; -
P8	65.3; 36.5; 32.6	32.6	37.2	32; 30; 27	8; 6; 6	9; 11; 9	-; 3; -	-; 1; -
Median (range)	50.8 (20.7-77.9); 29.3 (7.3-63.1); 9.0 (0-38.9)	/	/	25.0 (13.0-32.0); 21.5 (13.0-30.0); 21.0 (9.0-31.0)	11.5 (2.0-19.0); 9.0 (3.0-20.0); 8.5 (0.0-14.0)	10.5 (1.0-22.0); 8.5 (0.0-20.0); 6.0 (0.0-21.0)	4 (3-4); 3 (2-4); 2 (1-4)	2 (1-3); 2 (1-4); 1 (1-4)
Median Diff (0-12)	29.3 (13.8-75.9)	/	/	0.0 (-6.0 to 17.0)	1.5 (-3.0 to 18)	3.0 (-18.0 to 16.0)	3 (-1 to 3)	1 (-1 to 1)

***Legend**: Results are presented as 0;6;12 weeks for SPADI total, FPQ-9, FABQ-PA, FABQ-W, and as 1;6;12 weeks for GPE-R and GPE-S. The SPADI MIC was calculated for each patient as: SPADI_T0-43%SPADI_T0, where SPADI_T0= SPADI measured at week 0. If SPADI change was > than SPADI MIC, this was considered a significant change for that patient, indicated by *; if SPADI change was also > 20 points of measurement error, it was indicated by **. **Abbreviations**: FABQ–PA= Fear-Avoidance Beliefs Questionnaire – Physical Activities; FABQ-W= Fear-Avoidance Beliefs Questionnaire – Work; FPQ-9= Fear of Pain Questionnaire – 9 items; GPE-R= Global Perceived Effect – Recovery; GPE-S= Global Perceived Effect – Satisfaction; Median Diff= Median Difference (0-12weeks); MIC= Minimal Important Change; SPADI= Shoulder Pain and Disability Index*