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# Specific versus general exercise programme in adults with subacromial impingement syndrome: a randomised controlled trial

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# ABSTRACT

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**Objectives** Current evidence on the clinical effectiveness about the different types of exercises in the subacromial impingement syndrome (SIS) remains controversial. This study aims to compare the short-term (at 5 weeks) effects of a specific exercise programme with a general exercise programme on shoulder function in adults with SIS. Methods In total, 52 adults with SIS were randomly allocated to 5 weeks to perform specific exercises (experimental group, n=26) or general exercises (control group, n=26). The primary outcome was change in shoulder function, it was assessed using the Shoulder Pain and Disability Index (SPADI) from baseline to 5 weeks. Secondary end points included changes in upper limb function (Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire), pain intensity (Visual Analog Scale (VAS)) and kinesiophobia (Tampa Scale of Kinesiophobia (TSK)).

**Results** All participants completed the trial. The between-group differences at 5 weeks were: SPADI, 13.5 points (95% CI: 4.3 to 15.6;  $\eta^2$ =0.22; p=0.001); DASH, 10.1 points (95% CI: 5.6 to 15.2;  $\eta^2$ =0.27; p<0.001); VAS at rest, 0.2 cm (95% CI: 0.1 to 0.3;  $\eta^2$ =0.07; p=0.553); VAS on movement, 1.7 cm (95% CI: 0.9 to 2.2;  $\eta^2$ =0.24; p<0.001); and TSK, 16.3 points (95% CI: 13.2 to 15.3;  $\eta^2$ =0.33; p<0.001). All differences favoured the experimental group and effect sizes were medium to large for most outcomes. Mediation analyses showed that the effect of the specific exercises on shoulder function was mediated by kinesiophobia ( $\beta$ =2.800; 95% CI: 1.063 to 4.907) and pain on movement ( $\beta$ = -0.690; 95% CI: -1.176 to -0.271).

**Conclusion** In adults with SIS, specific exercises may have a larger effect than general exercises. However, most differences did not reach the minimum threshold to be considered clinically important and the evidence to support exercise as standard treatment warrant further study. **Trial registration number** Brazilian Registry of Clinical Trials UTN number U111-1245-7878. Registered on 17 January 2020 (https://ensaiosclinicos.gov.br/rg/RBR-4d5zcg).

## INTRODUCTION

Subacromial impingement syndrome (SIS) is the most common diagnostic label for

### WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Subacromial impingement syndrome (SIS) is associated with impairments of the rotator cuff and the scapular muscles.
- ⇒ Exercise therapy improves pain, range of motion and shoulder function; however, no exercise protocol has been identified as a reference standard for the nonsurgical treatment of SIS.
- ⇒ The effectiveness of a specific exercise strategy focused on reducing muscle impairments in people with SIS is unclear.

# WHAT THIS STUDY ADDS

- ⇒ In people with SIS, a 5-week specific exercise programme improved function and reduced pain and fear of movement more than general exercises.
- $\Rightarrow$  However, the differences did not reach the minimum threshold to be considered clinically important.
- ⇒ Decreasing fear of movement through exercise therapy could be an effective strategy to improve shoulder function in people with SIS.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our findings should guide future research to determine if subgroups of people with SIS and kinesiophobia benefit more from specific than general exercises.

shoulder pain.<sup>1</sup> Neer defined SIS as mechanical shoulder dysfunction causing mechanical stress to the rotator cuff tendons and/or the long head of the biceps tendon in the subacromial space.<sup>2</sup> However, this pathoanatomic model is now controversial because recent evidence suggests that it does not fully explain the mechanisms related to SIS.<sup>3 4</sup>

SIS has been found to be associated with biomechanical factors, such as alterations in glenohumeral and scapulohumeral kinematics, and impairment of the rotator cuff and the scapular muscles.<sup>5–8</sup> Electromyographic studies of the intensity and timing



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of muscle activity of the shoulder muscles in people with SIS have found increased upper trapezius activity with reduced serratus anterior and inferior trapezius activity, associated with a delay in the activation time of these latter two muscles.<sup>5</sup> <sup>9-11</sup> At the glenohumeral level, the activity and coactivation of the rotator cuff muscles, especially the infraspinatus and subscapularis, was found to be reduced during the first phase of arm elevation.<sup>5 8 11</sup>

These findings led to a change in the approach to physiotherapy for SIS, with the new focus on biomechanical or movement-related mechanisms.<sup>3 12 13</sup> Exercise programmes for the treatment of SIS frequently include different types of exercises,<sup>14–16</sup> such as scapular stabilisation exercises, resistance exercises for the rotator cuff muscles, exercises to improve range of motion and stretching.<sup>16 17</sup> However, no particular type of exercise protocol has emerged as a reference for the non-surgical treatment of SIS.<sup>14-17</sup> A consensus decision algorithm for physical therapists based on clinical reasoning for the assessment and treatment of people with shoulder pain has been proposed.<sup>18</sup> In this algorithm, the type of exercises are determined from the clinical findings and not the structural pathology, and specific exercises are the fundamental basis of the treatment.<sup>18</sup> The exercises are performed according to the following principles: the exercises should not produce pain, they should selectively activate weak muscles without activating overactive muscles and they should be performed in a graduated manner with appropriate scapulohumeral coordination and humeral head alignment.<sup>18</sup> Several clinical trials have evaluated the effectiveness of this specific exercise programme in people with SIS.<sup>19-21</sup>

However, a systematic review found insufficient evidence to support or refute the clinical effectiveness of a specific exercise programme for the treatment of SIS.<sup>22</sup> The most common cause for downgrading the quality of the evidence was the lack of an adequate sample size; this was an issue in all included studies. Additionally, the high risk of selection bias (unclear randomisation and allocation concealment) and poor descriptions of the interventions limit the transferability of protocols to clinical practice.<sup>22</sup> Due to inconsistencies and lack of high-quality evidence, it is not currently possible to determine whether implementing specific exercises in a rehabilitation programme for people with SIS is relevant. Therefore, high-quality clinical trials with clear methodological design that report the type, frequency, dose and progression of specific exercise programmes is needed.

Regarding prognostic factors in people with shoulder pain. A systematic review found strong evidence that high levels of pain intensity, concomitant neck pain and a longer duration of symptoms predicts worst clinical outcomes.<sup>23</sup> Additionally, two systematic reviews showed that psychological factors such as catastrophizing, depression, anxiety and kinesiophobia had no predictive value on functional outcomes in people with musculoskeletal shoulders disorders and non-traumatic shoulder pain treated conservatively.<sup>24</sup> <sup>25</sup> Despite this, psychological factors such as catastrophizing and kinesiophobia play an important role in the shaping of the physiological responses to pain, and therefore the development and maintenance of chronic pain.<sup>26</sup> In this sense, a recent study provides preliminary evidence of an association between kinesiophobia, pain intensity and shoulder disability in people with chronic shoulder pain.<sup>27</sup> To our knowledge, no studies have determined if the clinical effectiveness of an exercise programme is mediated by variables such kinesiophobia or pain intensity in people with SIS.

The primary aim of this randomised controlled trial was to compare the short-term effectiveness of a specific exercise programme with that of a general exercise programme on shoulder function. The secondary aim was to compare the effects of both programmes on upper limb function, pain intensity and kinesiophobia in people with SIS. The tertiary aim was to determine if the effect of the specific exercise programme on shoulder function was mediated by other variables, such as kinesiophobia, pain intensity (at rest or during movement) or upper limb function. We hypothesised that the difference in the effect of a specific exercise programme and a general exercise programme on shoulder function would be larger than the minimum clinically important difference (MCID). We also hypothesised that improvement in shoulder function would be mediated by a decrease in kinesiophobia or pain intensity.

## METHODS

# **Design/setting**

We conducted a single-blind, randomised controlled trial with two parallel groups. This research was prospectively registered in the Brazilian Registry of Clinical Trials (UTN number U111-1245-7878). The study is reported according to the Consolidated Standards of Reporting Trials Statement for Randomized Trials of Nonpharmacologic Treatments.<sup>28</sup>

#### **Participants**

Participants were recruited from the Physiotherapy Department of the Clinical Hospital San Borja Arriaran among individuals diagnosed by physicians as SIS according to the WHO International Classification of Diseases-10 criteria (Code M75.4). To be eligible for participation, people with SIS had to meet the following conditions: aged≥18 years; pain located on the anterolateral side of the shoulder for  $\geq 3$  months; and  $\geq 3$  positive clinical signs of SIS, such as the Neer or Hawkins-Kennedy test, a painful arc, pain on resisted external rotation, or the Empty Can test. The sensitivity and specificity of these clinical signs is >74% for the diagnosis of SIS.<sup>29</sup> The exclusion criteria were a diagnosis of cervical radiculopathy, osteoarthritis in the acromioclavicular or glenohumeral joint, calcific tendinitis, adhesive capsulitis, glenohumeral instability or a partial or full-thickness rotator cuff tear; radiographs and MRI were performed to confirm the absence of these pathologies.<sup>30</sup> Other exclusion

criteria were a clinical history of acute trauma, previous surgery or previous fracture in the affected shoulder; or corticosteroid injection into the shoulder joint in the previous 12 months.

#### **Randomisation and blinding**

Two coordinating researchers were responsible for managing the entire process of each participant from inclusion until the end of the exercise programmes. They were blinded to the allocated intervention and treatment provided by the treating physiotherapists. One of the coordinating researchers (JV-F) was responsible for enrolling the participants in the study, verifying that they met the eligibility criteria. Another of the coordinating researchers (HJGE) was responsible for generating the randomisation sequence: eligible participants were randomly assigned to participate in a specific or general exercises programme using a validated web-based randomisation programme (Sortition). The randomisation method was in blocks with randomly selected block sizes of four participants.

The group to which each participant was assigned was kept in a sealed envelope with the objective of concealing the assignment from the researcher who decided the entry of the participants in the study. Given the nature of the therapeutic interventions studied, blinding of the treating physiotherapists and participants was not possible; however, the evaluators and statistician were blinded to group allocation. Two external evaluators performed a clinical examination before and after the exercise programmes, they were blinded to the treatment provided by the treating physiotherapist.

## Intervention

Participants continued to receive their usual care throughout the trial as prescribed by their physician; 500 mg of oral naproxen two times per day for 14 days and a supervised home exercise programme. The usual care and the experimental and control interventions were delivered by two physiotherapists with a master's degree in manual therapy and more than 15 years of experience in musculoskeletal physiotherapy. Both physiotherapists were external to the research team; they never expressed their predilection for one treatment or another to the participants.

The usual care included a session of advice during which individuals were taught an exercise programme to perform at home. The programme consisted of four exercises for the neck and shoulder with no external load: pain-free active movements of shoulder elevation, shoulder retraction, shoulder abduction in the scapular plane and neck retraction. Each exercise was repeated 10 times, 2 times per day at home. To promote adherence to the home exercise programme, the participants reviewed the exercise programme with the physiotherapist once a week. Additionally, adherence and adverse events were monitored during a weekly phone call by a physiotherapist and recorded in the data collection notebook of each participant.

### Experimental group

In addition to the usual care, the experimental group participated in a 5-week, two times per week, supervised, specific exercise programme based on the clinical decision algorithm proposed by a panel of experts.<sup>18</sup> In the initial stage, 'scapular orientation' was trained to improve proprioception and normalise the resting position of the scapula. Then, three scapular control exercises were performed: bilateral shoulder flexion up to 60°; a closed kinetic chain exercise (the 'unilateral bench press'); and a scapular control exercise with bilateral shoulder retraction and extension in the prone position. The final stage included two glenohumeral control exercises to restore centralisation and prevent superior translation of the humeral head: isometric external rotation performed with shoulder adduction; and isometric adduction of the shoulder in the scapular plane at  $30^{\circ}$  and  $60^{\circ}$  of elevation (see online supplemental table S1). The exercises were performed without pain, and a maximum of four exercises were performed per session. The dose and progressions were related to the goal of each exercise; 8-10 repetitions of each exercise with a 5-10 s hold and 30 s to 1 min of rest between each repetition.<sup>19-21</sup>

## Control group

In addition to the usual care, participants in the control group participated in a 5-week, two times per week, supervised, general exercise programme based on a previous clinical trial.<sup>31</sup> This programme consisted of physiotherapy sessions involving mainly strengthening, stretching and mobility exercises (see online supplemental tables S2 and S3). The aim was to restore strength, mobility and coordination between the rotator cuff and the shoulder girdle, to unload the subacromial space and to centre the humeral head in the glenoid fossa during active movements.<sup>31 32</sup>

Finally, the duration and periodicity of the treatment was similar, the difference between both therapeutic interventions was in the duration of the treatment sessions, for the experimental group it was 1 hour on average, while for the control group it was 1 hour 30 min.

#### **Outcome measures**

Two blinded evaluators assessed the outcomes at baseline and the end of the 5-week intervention. No changes were made to the outcome measures after trial beginning. The evaluators were external to the research team, they were masked of the type of treatment that the participants received and to which group they belonged. Both blinded evaluators assessed the same proportion of participants in each group.

#### Primary outcome

The primary outcome was shoulder function, assessed using the Spanish version of the Shoulder Pain and Disability Index (SPADI) questionnaire.<sup>33</sup> Scores for this questionnaire range from 0 to 100 points, with higher scores representing greater levels of pain and disability.<sup>33</sup> The MCID is 20 points.<sup>34</sup>

# Secondary outcomes

# Upper limb function

The Spanish version of the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire was used to measure upper limb function.<sup>35</sup> Scores range from 0 to 100 points, with higher scores indicating poorer function.<sup>35</sup> The MCID is 11 points.<sup>36</sup>

#### Pain

Pain intensity was measured at rest and during movement on the Visual Analog Scale (VAS), with scores ranging from 0 ('*no pain*') to 10 ('*the worst imaginable pain*').<sup>37</sup> The MCID is 1.4 cm in people with rotator cuff disease.<sup>38</sup>

#### Kinesiophobia

The original 17-item Tampa Scale of Kinesiophobia (TSK) was used to assess pain-related fear of movement.<sup>39</sup> The scores range from 17 to 68 points, with higher scores indicating greater fear of movement and/or (re-)injury. The MCID for people with chronic pain is 5.6 points<sup>39</sup>; however, the MCID for people with SIS or rotator cuff disease has not been established.

#### **Data analysis**

The sample size calculation was based on the MCID of 20 points for the SPADI Questionnaire.<sup>34</sup> The assumed mean for the calculation was 26.8, with an SD of 17.8 points, based on the results of a previous clinical trial.<sup>31</sup> To detect this difference between the two exercise programmes with an alpha ( $\alpha$ ) value of 0.05 and a statistical power ( $\beta$ ) of 95%, a minimum of 21 participants per group was needed. This minimum sample size estimate was increased by 20% after considering potential dropouts or withdrawals, giving a final total of 26 participants in each group.

Since all the participants in each arm received the allocated treatment and there were no dropouts, intention-to-treat and per-protocol analyses yielded the same results. Descriptive statistics were used to describe the demographic and clinical characteristics of the participants in each group. Continuous variables are presented as mean and SD, and categorical variables are presented as number and percentage. The normality of the distribution was evaluated using both statistical (Shapiro-Wilk test) and graphical (normal probability plot) methods. When the distribution was not normal, non-parametric tests were used.

Outcomes were compared between groups to provide estimates of the effect of the experimental intervention relative to the control intervention. The distribution was determined with bootstrap sampling (5000 samples) and bias corrected and accelerated CIs. Each of these estimates was reported as a mean difference with a 95% CI, calculated using the method of Campbell and Gardner.<sup>40</sup> The 95% CI can be further interpreted to indicate the significance of within-group changes if the upper or lower limits do not cross zero. Furthermore, raincloud plots were produced using estimation statistics for data visualisation.<sup>40</sup> We performed an analysis of covariance for between-group differences in primary and secondary outcomes at 5 weeks using continuous scales, with adjustment for baseline levels of outcomes. Group×time interaction effects were examined, and partial eta squared ( $\eta^2$ ) group×time interaction effect sizes were calculated as the between-group sum of squares divided by the total sum of squares, considering the effect as small (0.0–0.13), substantial (0.13–0.26) or large (>0.26).<sup>41</sup>

Additionally, to evaluate whether the effect of the specific exercise programme on shoulder function (primary outcome) was mediated by other variables such as kinesiophobia, pain intensity (at rest or during movement) or upper limb function, linear regression models were fitted using bootstrapped (5000 samples) mediation techniques with the PROCESS SPSS macro (V.4.0). All the analyses were adjusted for the following variables: age, sex, duration of symptoms, affected dominant shoulder, education level and body mass index. Our mediation analyses are in line with the A Guideline for Reporting Mediation Analyses statement. The statistical analyses were performed using IBM SPSS Statistics for Windows (V.26) and p<0.05 was set as the limit for statistical significance.

## RESULTS

## **Compliance with the trial protocol**

A total of 52 participants was recruited, as planned. All enrolled participants met the eligibility criteria. All primary and secondary outcomes were reported according to the registered protocol.

#### Flow of participants through the study

Inclusion of patients started in February 2020 and the last patient completed the trial in February 2022. In total, 64 people were screened and 52 fulfilled the eligibility criteria and were randomised to 1 of the 2 groups. All enrolled participants met the eligibility criteria. All primary and secondary outcomes were reported according to the registered protocol. Figure 1 displays a flowchart of the participants.

#### **Characteristics of the trial participants**

The baseline characteristics of each group are presented in table 1. Regarding treatment adherence, 1 participant (3.8%) in the intervention group and 2 participants (7.7%) in the control group did not attend 1 rehabilitation session. These absences were all because of health problems not directly related to SIS. Regarding the adherence to the home exercise programme, one participant in the experimental group and one in the control group did not perform the prescribed frequency and dose of the home exercises; all other participants performed the home exercise programme as prescribed. Regarding adverse events associated with both treatments,

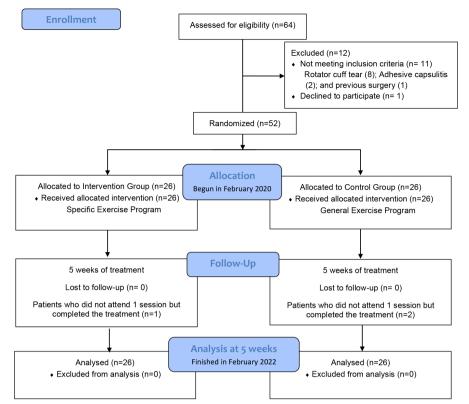


Figure 1 Consolidated Standards of Reporting Trials flow diagram of participants through the phases of the study.

1 participant (3.8%) in the intervention group reported increased pain at the end of the sessions during the first week of treatment. In the control group, 4 participants (15.4%) reported increased pain at the end of the first 2 weeks of treatment. Research staff reported at ethics committee all adverse events reported by the participants.

## Effects of the intervention Primary outcome

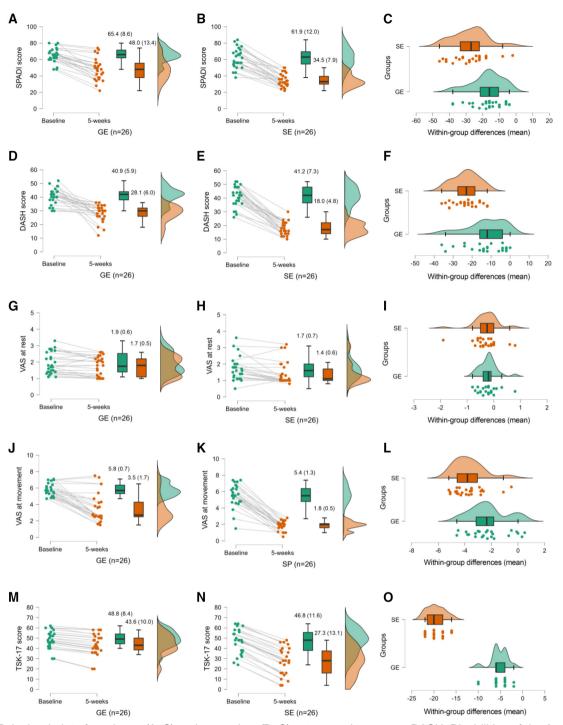
Shoulder function improved in both groups, but more so in the experimental group (figure 2A–C). At week 5, the mean between-group difference in the amount of improvement in SPADI Score was 13.5 points (95% CI: 4.3 to 15.6;  $\eta^2$ =0.22, p=0.001), indicating that the experimental

Characteristics	Specific exercises group (n=26)	General exercises group (n=26)	P value
Sex, male, n, (%)	18 (69.2)	19 (73.1)	0.843*
Age (years), mean (SD)	45.7 (4.9)	45 (4.3)	0.634†
Duration of symptoms (months), mean (SD)	4 (1)	3.8 (1)	0.501†
Affected dominant shoulder, n, (%)	21 (88.8)	22 (84.6)	0.629*
Education level, n, (%)			0.064*
Primary	9 (34.6)	7 (26.9)	
Middle	11 (42.3)	16 (61.5)	
University	6 (23.1)	3 (11.6)	
Height (m), mean (SD)	1.67 (0.08)	1.67 (0.07)	0.925†
Weight (kg), mean (SD)	76.4 (6.8)	77.7 (6.7)	0.496†
Body mass index ( $kg/m^2$ ), mean (SD)	27.4 (2.1)	27.9 (2.3)	0.402†

\*P value: obtained with the  $\chi^2$  test.

†P value: obtained with the Student's t-test.

SIS, subacromial impingement syndrome.



**Figure 2** Raincloud plots for primary (A–C) and secondary (D–O) outcomes by groups. DASH, Disabilities of the Arm, Shoulder, and Hand questionnaire; GE, general exercise group (control group); SE, specific exercise group (intervention group); SPADI, Shoulder Pain and Disability Index; TSK-17: Tampa Scale of Kinesiophobia; VAS, Visual Analog Scale. P value\*: p value obtained with analysis of covariance.

intervention improved shoulder function significantly more than the control intervention (see table 2).

#### Secondary outcomes

#### Upper limb function

Upper limb function improved in both groups (figure 2D–F). At week 5, the mean between-group difference in the amount of improvement in the 100-point DASH Scale was 10.1 points (95% CI: 5.6 to 15.2;

 $\eta^2$ =0.27, p<0.001). The large effect size indicated that the experimental intervention improved upper limb function more than the control intervention (see table 2).

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# Pain

On average, pain intensity at rest tended to decrease in both groups (figure 2G–I). The mean between-group difference was 0.2 cm (95% CI: 0.1 to 0.3;  $\eta^2$ =0.07,

	Specific exercises (n=26)		General exercises (n=26)		Difference					
Outcome	Baseline Mean (SD)	5 weeks Mean (SD)	Difference within group Mean (SD)	Baseline Mean (SD)	5 weeks Mean (SD)	Difference within group Mean (SD)	between groups after 5 weeks treatment Mean (SD)	95% CI	Effect size for mean difference between groups (η <sup>2</sup> )	
SPADI	61.9 (12)	34.5 (7.9)	27.4 (10.5)	65.4 (6.6)	48.0 (13.4)	17.4 (9.5)	13.5 (3.0)	4.3 to 15.6	0.22	0.001
DASH	41.2 (7.3)	18.0 (4.8)	23.2 (6.7)	40.9 (5.9)	28.1 (6.0)	12.8 (10.2)	10.1 (1.5)	5.6 to 15.2	0.27	<0.001
VAS at rest	1.7 (0.7)	1.4 (0.6)	0.3 (0.4)	1.9 (0.6)	1.7 (0.5)	0.2 (0.3)	0.2 (0.1)	0.1 to 0.3	0.07	0.553
VAS at movement	5.4 (1.3)	1.8 (0.5)	3.6 (1.1)	5.8 (0.7)	3.5 (1.7)	2.3 (1.4)	1.7 (0.3)	0.9 to 2.2	0.24	<0.001
TSK-17	46.8 (11.6)	27.3 (13.1)	19.5 (1.9)	48.8 (8.4)	43.6 (10.0)	5.2 (1.8)	16.3 (3.2)	13.2 to 15.3	0.33	<0.001

Table 2 Comparison of mean differences within and between groups at end of 5 weeks of treatment in participants with SIS

Boldface indicates a p-value < 0.05

\*P value obtained with analysis of covariance adjusted for baseline scores.

DASH, Disabilities of the Arm, Shoulder, and Hand Questionnaire; SIS, subacromial impingement syndrome; SPADI, Shoulder Pain and Disability Index; TSK-17, Tampa Scale of Kinesiophobia; VAS, Visual Analog Scale.

p=0.553), indicating that the experimental intervention did not reduce pain more than the control intervention. Pain intensity during movement decreased in both groups (figure 2J–L). The mean between-group difference was 1.7 cm (95% CI: 0.9 to 2.2;  $\eta^2$ =0.24, p<0.001), indicating that the between-group difference in pain during movement was larger than the MCID, in favour of the experimental group (see table 2).

#### Kinesiophobia

Kinesiophobia reduced in both groups (figure 2M–O). At week 5, the mean between-group difference was 16.3 points (95% CI: 13.2 to 15.3;  $\eta^2$ =0.33, p<0.001), The large effect size indicated that the experimental intervention reduced fear to movement more than the control intervention (see table 2).

## Mediation analyses

The mediation analyses showed that the effects of the specific exercise programme on shoulder function were significantly mediated by improvements in Kinesiophobia levels ( $\beta$ =2.800; 95% CI: 1.063 to 4.907) and the VAS on movement ( $\beta$ = -0.690; 95% CI: -1.176 to -0.271) see online supplemental figure S1. Thus, the specific exercise programme appeared to reduce kinesiophobia and pain (on movement), which in turn increased shoulder function.

## DISCUSSION

The results of this study showed that a specific exercise programme improved shoulder function and reduced pain on movement and fear of movement significantly more than a general exercise programme in people with chronic SIS. However, in contrast with our hypothesis, most between-group differences did not reach the minimum threshold to be considered clinically important. Additionally, mediation analyses showed that kinesiophobia and pain on movement were the most important factors related to the improvement in shoulder function in these participants.

A systematic review found no evidence to support the use of specific exercises over general exercises in rehabilitation programmes for people with SIS with regard to pain, function, range of motion or muscle strength.<sup>22</sup> Similarly, another systematic review showed that both specific and non-specific exercise programmes were effective for short-term pain reduction in people with neck or shoulder pain, with no clinically important differences between the two approaches.<sup>42</sup> Additionally, another systematic review showed low to very low certainty and conflicting evidence regarding the clinical effectiveness of a higher exercise dose in people with rotator cuff tendinopathy.<sup>43</sup> However, the studies included in those reviews were mostly of moderate to low quality with unclear descriptions of the method of randomization, allocation concealment, blinding, and inclusion criteria for the diagnosis of SIS; and lack of reproducible and transparent interventions and co-interventions.

Although therapeutic exercise has been described as an important component of non-surgical treatment for SIS, its effectiveness remains controversial.<sup>16</sup> <sup>17</sup> <sup>43</sup> <sup>44</sup> Several systematic reviews with or without meta-analysis have analysed the effectiveness of therapeutic exercise for the management of people with SIS, showing a decrease in pain and an increase in shoulder function.<sup>14-17 43-45</sup> However, no reference standard exercise protocol has been defined, although a network metaanalysis concluded that general exercises plus other therapies such as specific exercises, manual therapy, kinesiotaping and acupuncture are effective treatments for adults with SIS.<sup>43</sup> In our study, the control group exercises were based on the findings of a systematic review that synthesised an evidence-based exercises protocol for the treatment of SIS.<sup>14</sup> Other important criteria for the selection of the exercises was their practicability, and the possibility to perform all exercises with a rubber band.<sup>32</sup>

Current evidence shows that the central nervous system may undergo plastic reorganisation in the presence of musculoskeletal disorders, contributing to alterations in motor control and thereby modulating chronic pain.<sup>46</sup> Accordingly, neuroplastic changes have been reported in people with chronic rotator cuff disorders.<sup>47</sup> In this sense, studies using transcranial magnetic stimulation have found that the deficits associated with chronic shoulder pain are related to reorganisation of the motor and somatosensory cortex, with a decrease in corticospinal excitability and an increase in the active motor threshold of the representations of the rotator cuff and scapular muscles.<sup>48</sup> <sup>49</sup> We therefore hypothesised that specific exercises would more effectively improve function than general exercises. Our specific exercise programme involved controlled, graduated corticomotor retraining to stimulate task learning and selective motor skills. Some neurophysiological effects attributed to low-load isometric exercises have been described in the literature. These exercises induce plastic cortical changes.<sup>46 50-52</sup> as well modification of the excitability and active motor thresholds of the areas of the primary motor cortex that are altered in people with chronic pain.<sup>46 53</sup> This could partly explain the positive effects of these exercises on function, pain and fear of movement.

Interestingly, the mediation analyses showed that kinesiophobia and pain on movement were important factors relating to the improvement in shoulder function. A possible explanation for this finding is that high levels of kinesiophobia could alter motor control and impair the performance of shoulder movements.<sup>46 54</sup> General exercises may result in increased joint compression and increased mechanosensitivity to loading, with early fatigue. This may be perceived as a threat, inducing fear of movement to avoid generating more pain.55 56 Conversely, a specific exercise programme without pain, based on physiological hypoalgesia induced through low-load isometric exercises,<sup>51</sup> without the abnormal mechanical loads that potentially fatigue or irritate the tissues, could reduce fear and pain on movement and thus improve shoulder function.<sup>46 55 56</sup>

#### **Clinical implications**

These results suggest there may be subgroups of people with SIS with high levels of kinesiophobia and pain on movement for whom a specific exercise programme is particularly beneficial. However, no previous studies have established the characteristics that identify such individuals. Indeed, kinesiophobia can occur and develop during the treatment and/or rehabilitation of musculoskeletal disorders, surgical interventions and other traumas.<sup>57</sup> Kinesiophobia is known to be a barrier to rehabilitation adherence in different chronic pain conditions.<sup>58</sup> Therefore, clinicians and physiotherapists should identify the presence of kinesiophobia prior to defining an intervention for a given individual, since its presence may require a different and more specific approach than standard rehabilitation programmes.<sup>59</sup> This is supported by the results of a recent network meta-analysis that showed that the use of general exercises to keep individuals active

may be inappropriate in the presence of kinesiophobia induced by musculoskeletal pain.<sup>60</sup>

## Limitations

The main limitation of this study is the lack of a follow-up to determine the long-term effects of both exercise programmes and the persistence of the between-group differences. Other sources of potential bias were the fact blinding of the physiotherapists and participants was not possible because of the nature of the interventions studied, and self-report questionnaires were used for the assessment; these are prone to subjectivity and recollection bias.

This study also has several strengths. We used an adequate randomisation method, the assessors and the statistician were blinded to group allocation, and the study was adequately power to detect intergroup differences. Furthermore, the use of mediation analyses to explain the results is novel and provided useful information.

# CONCLUSION

In adults with SIS, specific exercises may have a larger effect than general exercises. However, most differences did not reach the minimum threshold to be considered clinically important and the evidence to support exercise as standard treatment warrant further study. The mediation analysis showed that decreasing fear of movement through exercise could be an effective therapeutic strategy for the improvement of shoulder function. Further studies are needed to determine if subgroups of people with SIS and kinesiophobia benefit more from specific than general exercises, as well as to determine the medium-term and long-term clinical effectiveness of specific exercises in people with chronic SIS.

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