Struyf F, Nijs J, Mollekens S, and et al. Scapular-focused treatment in patients with shoulder impingement syndrome: a randomized clinical trial. Clinical Rheumatology 2013; 32:73–85.

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Design: Randomized controlled trial

Objective: To evaluate the effectiveness of a scapular-focused treatment protocol with a control treatment in patients with shoulder impingement syndrome.

Population /sample size/setting:

- 22 consenting participants were recruited through physicians, orthopedic surgeons, and physical therapists working in private medical clinics or private physiotherapy practices in Antwerp, Belgium (10 men, 12 women, mean age 46). Twenty patients completed the trial.
- Eligibility criteria included a prescription from their physician for impingement symptoms, informed consent, age 18 years or older, ability to complete questionnaires, shoulder impingement symptoms lasting at least 30 days, negative full can test, and release test for anterior shoulder instability had to be negative for apprehension.
  In addition, they had to have 2 out of 3 tests positive from the following: Neer, Hawkins, Jobe.
- Exclusion criteria included previous fractures or dislocation in the shoulder complex or shoulder surgery, pain onset due to trauma, cervical radiculopathy, degenerative joint disease of the shoulder, inflammatory arthropathy, biceps tendinopathy, infiltration of the shoulder in the previous 3 weeks, non-steroidal anti-inflammatory drug use, or shoulder treatment including physical therapy within the past year.

Interventions:

- All participants were randomized to one of two exercise protocols; the experimental group (n = 12), and the control group (n = 10).
- All patients were treated by the same physiotherapist (unblinded). All assessments were conducted by a blinded assessor. For both treatment groups, load was increased in terms of gravity, range of motion, number of repetitions, speed, and resistance. All patients were treated for 9 sessions of 30 minutes. Treatment frequency was between one and three times per week.
- The treatment protocol for the experimental group was individually tailored and consisted of passive manual mobilization of the scapula, stretching of the levator scapulae, rhomboid and pectoralis minor muscles, and motor control training of the scapula with an emphasis on a scapular orientation exercise for stability and positioning. External resistance exercises using resistance bands and other materials were added once scapular control improved for training the trapezius and serratus anterior muscles. The exercises and stretching were also performed once per day at home, except that the scapular orientation exercise (10 repetitions) was performed as many times as possible in a day.

- The treatment protocol for the control group included exercise focusing on an eccentric muscle strength training program of the rotator cuff muscles using elastic bands, manual passive glenohumeral mobilization, muscle friction massage therapy, and ultrasound therapy. The exercises were 3 series of 15 repetitions each of flexion, extension, medial rotation, and lateral rotation of the shoulder. Once daily home exercises were the same as performed under supervision.

Main outcome measures:

- The primary outcome was the Shoulder Disability Questionnaire (SDQ) score, a self-reported questionnaire, evaluating shoulder function. Scores range between 0 and 100 (severe disabled). A lower score indicates better shoulder function. The minimal clinically important difference is 18.75.
- Secondary outcomes were visual analog scale (VAS; 100 mm) scores used for the assessment of the severity of shoulder pain both at rest and during shoulder activity. The minimal clinically important difference in VAS pain scores has been reported to be 17 mm. Many other unimportant secondary outcomes were also reported.
- Evaluations of all outcome measures were carried out at baseline, immediately post-treatment after 9 therapy sessions, and 3 months post-treatment. All assessments were performed by the same examiner blinded for group allocation.
- There were no significant differences in the background variables at baseline, and no statistical differences between the groups in any of the outcome measures at baseline, except that the experimental group reported 11% higher pain levels during the Hawkins test.
- The mean change in the SDQ score decreased 20.9 points in the experimental group showing improved function and only 2.2 points in the control group from baseline to post-treatment. Only the scapular-focused experimental group showed a significant effect on the SDQ scores after nine sessions of exercise treatment (Cohen's $d = 0.93$; $p=0.006$) which represents a large effect size. An improvement of 20.9 points on the SDQ in the experimental group also exceeds the minimum clinically importance difference (18.75 points) needed to demonstrate a clinically important improvement in shoulder function on this outcome measure.
- The experimental group had significantly greater improvement than the control group in the primary outcome of self-reported shoulder function evaluated with the SDQ score. The mean difference between groups was 18.7 points after treatment completion. This mean difference of 18.7 points in the SDQ score between the 2 groups does demonstrate a clinically important difference. This mean difference is not only statistically significant ($p = 0.025$), but it equates to a medium to large effect size as defined by Cohen (Cohen's $d = 0.73$).
- The experimental group had significantly greater improvement than the control group in the secondary outcome of self-reported shoulder pain during movement evaluated with the VAS score. For pain during movement, the experimental group demonstrated an effect size that was both large and statistically significant (Cohen's $d=1.19$; $p= 0.004$), and was also clinically important (2.7 cm). For pain during movement, the control group did not demonstrate a statistically significant or clinically important improvement from baseline to post-treatment (1.2 cm). There was a statistically significant difference

between groups (p=0.046) in favor of the scapular-focused experimental group demonstrating a large effect size (Cohen's d = 1.04) for pain during movement.
- The experimental group demonstrated a moderate (Cohen's d = 0.67; p=0.26 within experimental group) improvement in self-experienced pain at rest, though not statistically significant, whereas in the control group, almost no improvement was noted (Cohen's d = 0.04; p=0.71 within control group). The improvement of 1.5 cm on the VAS scale for the experimental group and 0.1 cm for the control group from baseline to post-treatment does not demonstrate a clinically important difference in pain for either group.

Authors' conclusions:

- A scapular focused exercise treatment protocol that includes motor control exercises, scapular mobilizations, and stretching is effective for reducing pain and disability in patients with shoulder impingement syndrome.
- The scapular-oriented exercise treatment protocol showed clinically important beneficial effects on self-reported disability, since the improvement on the SDQ exceeded the 18.75 cutoff value for minimal clinical improvement.
- Patients in the experimental group showed an improvement from 2.8 to 1.3 cm on a 10-cm (VAS) regarding pain at rest and from 5.7 to 3.0 cm regarding pain during movement. The improvement in pain during movement in the experimental group was both statistically and clinically significant. The control group did not demonstrate such improvement. This improvement may have occurred as a result of its scapular focus.
- As the evaluation of scapular motor control could be of great importance, further study is warranted on the reliability and validity of this test. In addition, in order to evaluate scapular positioning in a clinical setting, there is a need for reliable and valid methods.

Comments:

- This study did not monitor compliance to the home exercise protocols in each group, and thus differences in adherence between groups are unknown. When adherence is not monitored, the direction of the bias is unclear. It is not known if compliance is associated with the effectiveness of the intervention or the acceptability of the intervention. If there is a difference in compliance between groups, the non-adherence group may simply have an intervention that is difficult to comply with or that appears to be ineffective.
- It is unknown whether patients were blinded or aware of the study's hypothesis.
- The authors did not enroll the target number of patients predicted by their initial power analysis and elected to publish their results based on interim analysis and a smaller sample size. Although this study did have sufficient power for the SDQ, the relative small sample may have minimized the potential to detect differences within some of the secondary outcome measures, such as the VAS scores.
- Eligibility criteria included shoulder impingement symptoms lasting at least 30 days, but duration of symptoms was not asked, so it is unknown if differences existed between groups related to duration of shoulder pain.
- The number of patients in each group is a bit ambiguous, since different numbers are reported in two places within the article.

- VAS scores for pain at rest were already fairly low at baseline for both groups and may not have shown significant improvements at post-treatment due to floor effects. The groups as a whole were probably patients with mild pain and shoulder impingement syndrome symptoms, since the exclusion criteria eliminated patients using non-steroidal anti-inflammatory drugs.
- Only one physiotherapist was involved in treatment for both groups which increases standardization. The physiotherapist was not blinded to group assignment, which decreases the internal validity of the results. The interaction and the number of visits with the physiotherapist was however similar in both groups. Lack of blinding could inflate the differences found between the 2 groups away from the null. Although it is impossible to blind the physiotherapist directing the intervention, it is likely that the physiotherapist may have treated the participants in each group differently believing that one therapy was superior to the other. The unblinded physiotherapist could introduce performance bias. The results are susceptible to performance bias if the physiotherapist instructs or motivates one group differently than the other. If true blinding cannot be achieved, then it would be preferable for the physiotherapist to be unaware of the study's hypothesis and not know which intervention is thought to be superior. The non-blinding could influence the direction of the performance bias, and may influence the conclusions of the study. This potential performance bias does not undermine the conclusions of this study, since the effect size observed was quite large.
- There is inadequate information to know what may have influenced the lack of improvement observed in the SDQ scores and VAS pain scores of the control group. These results may be susceptible to performance bias if the physiotherapist treated or instructed the control group differently or increased resistance exercises less rapidly. The control group may not have gotten better because their adherence to the exercise protocol was low. Or perhaps the control exercise protocol was ineffective because the exercises were performed infrequently, only once per day, compared to the intervention group who were instructed to perform their scapular exercises as many times as possible.
- One limitation of this study is the fact that the interventions in the scapular focused group included 3 activities; scapular mobilizations, stretching, and scapular motor control training. Therefore, it is impossible to distinguish which particular component of the intervention led to the observed improvements.
- The exclusion criteria did not specifically identify the exact shoulder structure at fault for causing pain and disability. The study did not use any definitive imaging to include only patients with subacromial impingement syndrome. As a result, they may have really only selected patients with some kind of scapular dyskinesis.
- The study did not include a third intervention group with no exercise treatment, and so it could not evaluate the influence of natural recovery of subacromial impingement syndrome. However, the study is ethically correct to not use a third no-treatment group.

Assessment*:*

- This study is adequate for some evidence that a scapular focused exercise treatment protocol that includes scapular motor control exercises, scapular mobilizations, and stretching is effective for reducing pain and improving shoulder function in patients with subacromial impingement syndrome.