**Maenhout AG, Mahieu NN, De Muynck M, and et al. Does adding heavy load eccentric training to rehabilitation of patients with unilateral subacromial impingement result in better outcome? A randomized, clinical trial. Knee Surgery, Sports Traumatology, Arthroscopy 2013; 21:1158-1167.**

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**Design:** Randomized controlled trial

**Objective:** To determine if adding heavy load eccentric training to conservative rotator cuff rehabilitation treatment, focusing on increasing strength and decreasing pain and dysfunction, is superior to conservative rehabilitation training alone in patients with subacromial impingement.

**Population /sample size/setting:**

- Sixty-one patients with subacromial impingement were recruited by a specialized shoulder surgeon and randomly allocated to the traditional rotator cuff strength training (TT) group (n = 30, mean age = 39.4 ± 13.1 years, 10 males, 20 females) or traditional rotator cuff strength training combined with heavy load eccentric training (TT+ ET) group (n = 31, mean age = 40.2 ± 12.9 years, 15 males, 16 females). Fifty patients completed the trial.
- Eligibility criteria included aged over 18 years, unilateral pain for at least 3 months in the anterolateral region of the shoulder, painful arc, 2 out of 3 impingement tests positive (Hawkins, Jobe, and/or Neer), 2 out of 4 resistance tests painful (full can (thumb up) abduction at $90^o$, resisted abduction at $0^o$, resisted external or internal rotation with the arm adducted, and pain with palpation of the supraspinatus and/or infraspinatus tendon insertion.
- Exclusion criteria included demonstration of partial or full ruptures of the rotator cuff by either ultrasound or MRI, history of shoulder surgery, shoulder fracture or dislocation, traumatic onset of the pain, osteoarthritis, frozen shoulder, traumatic glenohumeral instability or shoulder nerve injuries, cervical pathology or systemic musculoskeletal disease, and physical therapy or corticosteroid injections within 2 months prior to the study.

**Interventions:**

- All participants were randomized to one of two exercise protocols prior to the intervention.
- All patients performed the exercises at home for 12 weeks. Both groups attended 9 physiotherapy sessions over the 12 weeks of the intervention and were not allowed to perform other strengthening exercises outside of their intervention.
- The traditional rotator cuff strength training (TT) group performed two traditional rotator cuff strengthening exercises at home: internal and external rotation resisted with an

elastic band. Each exercise was performed once a day for 3 sets of 10 repetitions.


- The traditional rotator cuff strength training combined with heavy load eccentric training (TT+ ET) group performed the same exercises as the TT group and in addition to that a heavy load eccentric exercise. The heavy load eccentric exercise of full can (thumb up) abduction in the scapular plane was performed with a dumbbell weight. Patients were instructed to perform the eccentric phase at a speed of 5 inches/repetition. Three sets of 15 repetitions were performed twice a day. Whenever the pain was no longer present during the last set of repetitions, dumbbell weight was increased with 0.5 kg.


**Main outcome measures:**

- The primary outcome was the measurements of isometric strength with abduction at $0^{o}$, $45^{o}$, and $90^{o}$ of scapular abduction, isometric strength to internal and external rotation, and shoulder pain and function measured by the SPADI questionnaire, a self-administered, shoulder-specific index consisting of 13 items. Higher scores (100) indicate more pain and disability.
- Outcome measurements were assessed before patients started the exercises and prior to group allocation at baseline, and again at 6 and 12 weeks after the start of the intervention.
- As a secondary outcome, patients rated subjective perception of improvement of their shoulder pain on a 10 point scale after 6 and 12 weeks of treatment as better or worse.
- The main author (investigator) and the treating physiotherapist were not blinded to the treatment groups.
- Intention to treat principle was used and all patients were included in the analysis as randomized.

- There were no significant differences in the background variables and anthropometrics at baseline between the groups, except that gender was unequally distributed among the groups. The TT + ET group contained more men than the TT group (15 vs 10).
- At the 6-week follow-up, 52 patients were assessed and 9 were lost to follow-up. At the 12-week follow-up, 50 patients were assessed and 2 more were lost to follow-up.
- Both groups showed an overall significant increase of isometric strength over time in direction of abduction at $0^o$, $45^{o,}$ and $90^o$ of scapular abduction and in direction of external and internal rotation. All patients demonstrated significant increases of strength from 0 to 6 weeks, but not necessarily from 6 to 12 weeks.
- Isometric strength to abduction at $90^o$ of abduction increased significantly in the TT + ET group after 12 weeks of treatment (mean improvement = 14.7 N (newtons) or 3.28 pounds). In the TT group, this strength was not significantly increased after 12 weeks (mean improvement = 5.1 N or 1.14 pounds).
- An effect size less than 0.2 SD was considered small, around 0.5 SD moderate and greater than 0.8 SD large.
- In both groups, pain and function, measured with the SPADI score, improved significantly over time with decreases after both 6 and 12 weeks that were clinically important. Within group effect sizes were very large, more than 2 SD's for each group; 2.3 SD for the TT + ET group and 2.6 SD for the TT group. When comparing between groups, improvement of the SPADI score was not significantly different.
- Moderate to large within-group effect sizes were demonstrated for all 5 isometric strength variables for both groups.
- Patients' self-rated perception of improvement was not significantly different in the TT + ET and the TT group, both at 6 weeks and at 12 weeks after the start of the intervention.

**Authors' conclusions:**

- A 12-week traditional rotator cuff home training exercise protocol combined with 9 physiotherapy treatments was successful in increasing isometric strength and decreasing shoulder pain and dysfunction in patients with subacromial impingement. Adding heavy load eccentric training resulted in a higher gain of isometric strength at $90^o$ of scapular abduction.
- The TT + ET group showed a 15 % higher gain in abduction strength at $90^o$ abduction than the TT group at 12 weeks with a moderate between-group effect size. A difference in isometric strength of 10% is considered clinically significant.
- Eccentric training did not result in less pain or better shoulder function than traditional rotator cuff training after 12 weeks.
- Both groups showed significantly increased isometric strength, decreased pain and better function after 12 weeks of treatment. Most of the improvement in strength, pain, and function was made during the first 6 weeks of rehabilitation. Natural recovery is unlikely to explain these improvements of pain, function, and strength.
- Eccentric exercise training has been shown to increase collagen production, decrease neovascularization and normalize the pathologic tendon structure.
- Perhaps eccentric training should not be performed to improve clinical symptoms but to strengthen the tendon and restore degeneration.

- This study provided evidence that combining a limited amount of physiotherapy treatment sessions with a home exercise program is highly effective.
- This study supports the integration of an eccentric training program into a multimodal rehabilitation program.

**Comments:**

- The treating physiotherapist and the investigator that collected data were not blinded to the treatment groups, so the influence of their expectations about treatment cannot be excluded. The interaction and the number of visits with the physiotherapist was however similar in both groups. It is unclear who held the dynamometer during patient testing, since an unblinded assessor could potentially introduce a high risk of bias. 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. If true blinding cannot be achieved, then it would be preferable for the physiotherapist or assessor 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 bias, and may influence the conclusions of the study. When the assessment of outcome is not blinded (unblinded assessor holding the dynamometer), it could undermine the isometric strength measurements and conclusions of the study, since the unblinded assessor would be susceptible to the influences of this bias.
- Isometric strength to abduction at $90^{o}$ of abduction showed a "statistically significant", but "clinically dubious" improvement in the TT + ET group after 12 weeks of treatment (mean improvement = 14.7 N). In the TT group, this strength was not significantly increased after 12 weeks (mean improvement = 5.1 N). Both groups improved isometric strength to abduction at $90^{o}$ of abduction equally after 6 weeks of treatment, but the TT group did not improve between 6 and 12 weeks. This was the only isometric strength measurement out of the 30 measurements performed in either group that did not increase over time. The two pound difference between groups that this represents is not clinically significant, does not fairly represent or supersede the other 29 multiple outcomes for isometric strength all of which improved (some reaching significance and some not), and combined with the biased assessment of outcome measurements on the dynamometer held by the unblinded assessor, overemphasizes the importance of this single outcome measure.
- The author has underscored the isometric strength outcomes and in turn overlooked the more important SPADI scores and large effect sizes observed. The isometric strength outcomes are very convenient and can give very precise, objective measurements of strength, but in this study they are nullified by assessor bias. The more relevant outcomes of pain and disability from the SPADI scores which actually document real patient limitations are subjective, but are much less vulnerable to biases affecting the conclusions of the study.
- Both groups showed significantly decreased pain and better function after 12 weeks of treatment. So much in fact that floor effects must be considered, since the SPADI scores were approaching the lower end of the scale (zero) after 12 weeks of treatment.

- The lack of stratification for gender in randomization resulted in unequally distributed gender among the groups. The TT + ET group contained more men and was consequently stronger at baseline. This difference was corrected by adjusting for baseline isometric strength.
- In Table 3, there is a large error (typo or otherwise) in the within-group effect size for the TT + ET group (6.2 SD) with isometric strength at $90^{o}$ abduction. This is an enormous effect size not supported by the data.
- One strength of the study was that the exercise protocols consisted of only a few exercises, which could be completed in a reasonable amount of time. In addition, regular follow-ups by the physiotherapist focused on hands-on guidance to facilitate appropriate performance of the exercises. Both aided in attaining good adherence by the participants.
- Another strength of the study was that definitive imaging was used to exclude patients with rotator cuff tears. As a result, patients with rotator cuff tears were appropriately excluded from the study.
- During the 12 week period of the intervention, 18% of the participants were lost to follow-up.
- This study did not provide information on long-term follow-up of the patients, so it is not clear how long improvements lasted once the exercise training ceased.
- One weakness of the study was that it might have been underpowered for detecting differences between groups in the SPADI score.
- 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 include this third no-treatment group.
- The home exercises are very easy to perform and might decrease the need for hands-on physiotherapy, reducing medical costs.

**Assessment*:***

- This study is adequate for some evidence that conservative rotator cuff rehabilitation treatment for 12 weeks and conservative rotator cuff rehabilitation treatment with the addition of heavy load eccentric training for 12 weeks, focusing on increasing isometric strength and decreasing pain and dysfunction, are both equally effective in increasing isometric strength, reducing pain, and improving shoulder function in patients with subacromial impingement.