# Effectiveness of Adding a Large Dose of Shoulder Strengthening to Current Nonoperative Care for Subacromial Impingement: A Pragmatic, Double-Blind Randomized Controlled Trial (SExSI Trial): Response

DOI: 10.1177/03635465211055449

**Authors' Response:**

We thank *The American Journal of Sports Medicine* for giving us the opportunity to comment on the letter by Mr Koel regarding our study "Effectiveness of Adding a Large Dose of Shoulder Strengthening to Current Nonoperative Care for Subacromial Impingement: A Pragmatic, Double-Blind Randomized Controlled Trial (SExSI Trial)."[6] In the SExSI Trial, we prescribed a large additional dose of strengthening exercises specifically focused on the rotator cuff to half of the patients in usual care (random allocation), finding no additional benefit of the prescribed add-on. In his letter, Mr Koel states that he does not agree with our conclusion that "adding a large dose of shoulder strengthening to current nonoperative care for long-standing subacromial impingement did not result in a superior outcome for shoulder-specific disability after 4 months."[6]

Mr Koel sums up his critique by stating that "in my opinion there is no large dose (2.9 hours in 4 months, 93 seconds per day) and also not strengthening" and that "because the objective strengthening isn't realized, the conclusions are premature."

To reply to Mr Koel's critique, we will (1) explain how the study design (a pragmatic effectiveness trial) affects its conclusion and interpretation, including why our conclusion is based on the intervention as *prescribed* rather than as *adhered to*; (2) elaborate on the rationale behind the content, composition, and intensity of the add-on intervention; and (3) discuss the schism between changes in shoulder strength and patient-reported outcomes, as seen in both the control and intervention groups.

## INTERPRETATION OF A PRAGMATIC EFFECTIVENESS TRIAL

Mr Koel states that (1) "the boring exercises led to a diminished compliance," (2) "the patients in this trial performed the strength exercises during 2.9 hours in 4 months" [as opposed to the 12 hours prescribed], and (3) "the difference [in exercise dose] between the groups is quite small."

The above points of critique relate to intervention adherence and changes in behavior related to intervention prescription, such as reduced time spent on usual care exercise in the intervention group. In this regard, it is important to note that the interpretation of a pragmatic effectiveness trial is quite different from that of the more strictly controlled traditional efficacy/explanatory trial, especially with regard to the above points of critique. The aim of the more common explanatory trial is to investigate whether an intervention can work under ideal (and controlled) circumstances[14] and to understand whether changes in outcome are attributable to the mechanism under investigation. Explanatory trials are often criticized if they entail low adherence to allocated treatment or crossover between groups. This is a fair critique of an explanatory trial, because such circumstances hamper conclusions regarding the mechanism being investigated. In contrast, when adherence is perfect and crossover avoided, the question would still be whether the results are generalizable to the broader population for whom the intervention is intended.

The focus of a pragmatic effectiveness trial is to investigate whether an intervention works under usual clinical conditions and in real (clinical) life.[14] In real life, some patients do not show up for appointments and others do not exercise or take their medication as prescribed. This knowledge can be used to inform real-life policy and decision making when determining which treatments to offer. Because the aim of pragmatic effectiveness trials is different from that of explanatory trials, so are the possible conclusions and potential implications of their findings. As such, low adherence and crossover do not necessarily hamper the conclusion of a pragmatic effectiveness trial, which is based on the *allocation to/prescription of* a real-life intervention similar to the clinical setting. Conversely, the conclusion from a pragmatic effectiveness trial would instead be hampered if it included a highly selected sample of patients or very controlled delivery of interventions and/or control conditions that are not realistic in a real-life setting. In the SExSI trial, we applied broad eligibility criteria, consecutive sampling, and specific precautions so as to not alter the usual care condition, including blinding and minimal information to patients and healthcare professionals, as described elsewhere.[5,6]

The conclusions drawn from the SExSI Trial, a pragmatic effectiveness trial, can be based only on the intervention as delivered (at the prescription level) and not, as suggested by Mr Koel, on the level of adherence or spontaneous changes in behavior (such as reduced time spent on usual care exercise in the intervention group). Thus, basing the conclusion from the SExSI Trial on measurements of add-on adherence and time spent on usual care exercise would be incorrect. We will, however, in forthcoming preplanned secondary analyses,[5] be able to shed light on the relationship between exercise dose and changes in both strength and patient-reported outcomes.

## THE CONTENT, COMPOSITION, AND INTENSITY OF THE ADD-ON EXERCISE INTERVENTION

Mr Koel argues that (1) a "proper exercise program needs to be adjusted to the patients and needs to be functional,"

(2) "the strengthening exercises are nonfunctional and in (too) slow tempo with elastic bands in a (too) limited ROM," and (3) "there is no large dose."

First, we agree with Mr Koel that an exercise program should be adjusted to the individual patient. In the SExSI Trial, the add-on exercise intervention was adjusted to the individual patients using an algorithm based on the repetition maximum principle and symptom response (only pain aggravations lasting >24 hours were considered). Further, it must be stressed that the add-on exercise intervention was designed as a supplement to usual care, which also includes exercise therapy, with the specific intent to increase the dose of strengthening exercises aimed at the rotator cuff muscles in patients with long-lasting subacromial impingement,[5] to improve muscle-tendon health and shoulder-specific disability.

The limited range of motion (ROM) and slow tempo of the add-on exercises were chosen to ensure that the add-on intervention was feasible to complete for the patients for whom it was designed, a population that may differ from that seen by physical therapists in primary care settings, as suggested by Mr Koel. Based on our previous research,[7,8] we expected that patients would present with deconditioned rotator cuff muscles and high pain levels during peak loads as well as limited and painful unloaded ROM (mean abduction ROM of 120° ± 40° with a median pain score of 6 out of 10 [interquartile range: 3, 8]). To achieve a sufficient exercise dose—without excessive peak loads accompanied by severe symptom aggravations—the intervention was designed to have a high volume (time under tension per repetition, number of sets per session, and frequency of sessions). To improve the physiological response, all sets were continued to failure. Further, we chose to load the rotator cuff muscles and tendons in 30° to 45° of scaption, to make sure that patients were able to complete the exercises and hence increase their ability to continue to failure rather than stop due to intolerable pain not related to muscle fatigue. To further support the intensity, we used a time-contingent approach (ie, not stopping exercise because of pain).[18] This was reinforced by our knowledge that 30° to 45° of scaption is the position in which the compressive forces on the supraspinatus muscle and tendon are lowest,[1,4] which in turn allowed us to reassure patients that pain during exercises was not likely due to impinging structures. We used elastic bands to apply external resistance with clear instructions on how and when to increase and decrease resistance. This mode of external resistance is criticized by Mr Koel, but we see no reason why this should not be a relevant choice given that current evidence supports its ability to elicit both strength gains and favorable clinical outcomes.[19,20]

As explained previously, the conclusion of the SExSI Trial is rightly based on the intervention as prescribed rather than as adhered to. In total, the prescribed add-on intervention includes 3 to 6 sets of progressive resistance-based exercise aimed specifically at the rotator cuff muscles, each set continued to failure—each day for the first 5 weeks and every other day for the remaining 11 weeks. The total prescribed add-on dose amounts to approximately 12 hours of time under tension. As explained elsewhere,[6] we have estimated that the total *prescribed* dose of shoulder strengthening in previous trials ranges from 2 to 12 hours. Therefore, we would argue that adding the same amount as the most comprehensive existing program of shoulder exercise for subacromial impingement that we have identified from the scientific literature[11] certainly qualifies as a "large additional dose of shoulder strengthening."

## LACK OF STRENGTH IMPROVEMENTS IN THE INTERVENTION GROUP

Mr Koel argues that (1) "because the objective strengthening isn't realized, the conclusions are premature," (2) "if the strength was increased and the pain scores not, the conclusion of the authors might be correct," and (3) "in my opinion in normal rehabilitation of SAPS patients [ie, patients with subacromial impingement] that correlation [between increase in strength and decrease in pain] is correct."

Because pain and abduction strength actually did increase in both groups from baseline to follow-up, we believe Mr Koel refers to the lack of between-group difference in these outcomes. When designing the study, we shared the opinion (to some degree) that weakness and pain are related, and this was also part of the rationale for adding more strengthening in the SExSI Trial.[6] We had previously shown that a 50% increase in strength would be needed in patients with subacromial impingement to reach the level of the unaffected arm.[8] We believed that these impairments could be an important indicator of poor muscle-tendon health, which was not addressed sufficiently in current care.[7] Hence, we suggested that adding more shoulder strengthening could be a way to improve care, and we were obviously disappointed to see that this was not a viable solution.[6] Interestingly, and despite the statement by Mr Koel that "because the objective strengthening isn't realized, the conclusions are premature," our findings of limited strength gains in both groups are in line with most previous trials that allocated patients to an intervention including rotator cuff strengthening, showing clinically relevant improvements in patient-reported outcomes but most often followed by limited to nonexistent improvements in shoulder strength[2,3,6,9,10,12,13,16,17] (Figure 1). From this, it seems that including strengthening exercise as part of the intervention far from always leads to significant strength improvements, even though clinically relevant improvements in patient-reported outcomes occur.[2,3,6,9,10,12,13,16,17]

Importantly, in the SExSI Trial (and other trials), the amount of completed strengthening might explain the lack of strength improvements, but this does not change our conclusion that adding more strengthening exercises did not improve shoulder disability. Moreover, data from the SExSI Trial on total add-on dose and time spent on usual care exercise reveal an interesting pattern, namely that prescribing the add-on intervention was followed by an average decrease in time spent on other exercises. This has led us to suggest that adding more exercise is not a viable solution to the suboptimal outcomes in this population, as it seems that patients in this population

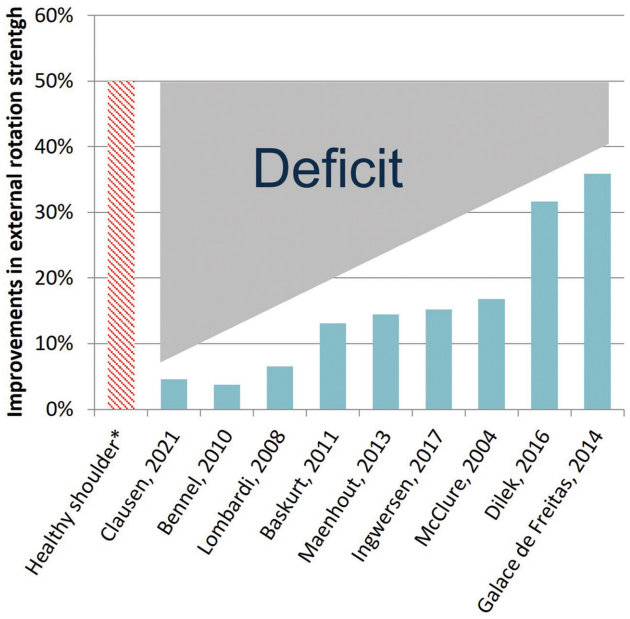


**Figure 1.** Improvements in external rotation strength seen in patients with subacromial impingement allocated to an intervention including rotator cuff strengthening in a range of clinical trials.[2,3,6,9,10,12,13,16,17] Values are calculated as mean changes in the outcomes divided by the mean baseline value for the same outcome, as presented in the published articles. *The improvement needed to reach the same level as healthy shoulder[8] or healthy controls.[15]

are not willing or able to do more exercise than they already do as part of usual care.

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Submitted September 19, 2021; accepted October 7, 2021.

The authors declared that they have no conflicts of interest in the authorship and publication of this contribution. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

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## REFERENCES

1. Andarawis-Puri N, Kuntz AF, Ramsey ML, Soslowsky LJ. Effect of glenohumeral abduction angle on the mechanical interaction between the supraspinatus and infraspinatus tendons for the intact, partial-thickness torn, and repaired supraspinatus tendon conditions. *J Orthop Res*. 2010;28(7):846-851. doi:10.1002/jor.21068
2. Başkurt Z, Başkurt F, Gelecek N, Özkan MH. The effectiveness of scapular stabilization exercise in the patients with subacromial impingement syndrome. *J Back Musculoskelet Rehabil*. 2011;24(3):173-179. doi:10.3233/BMR-2011-0291
3. Bennell K, Wee E, Coburn S, et al. Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial. *BMJ*. 2010;340:c2756.
4. Bey MJ, Song HK, Wehrli FW, Soslowsky LJ. Intratendinous strain fields of the intact supraspinatus tendon: the effect of glenohumeral joint position and tendon region. *J Orthop Res*. 2002;20(4):869-874. doi:10.1016/S0736-0266(01)00177-2
5. Clausen MB, Bandholm T, Rathleff MS, et al. The Strengthening Exercises in Shoulder Impingement trial (The SExSI-trial) investigating the effectiveness of a simple add-on shoulder strengthening exercise programme in patients with long-lasting subacromial impingement syndrome: study protocol for a pragmatic, assessor blinded, parallel-group, randomised, controlled trial. *Trials*. 2018;19(1):154. doi:10.1186/s13063-018-2509-7
6. Clausen MB, Hölmich P, Rathleff M, et al. Effectiveness of adding a large dose of shoulder strengthening to current nonoperative care for subacromial impingement: a pragmatic, double-blind randomized controlled trial (SExSI Trial). *Am J Sports Med*. 2021;49(11):3040-3049. doi:10.1177/03635465211016008
7. Clausen MB, Merrild MB, Witten A, et al. Conservative treatment for patients with subacromial impingement: changes in clinical core outcomes and their relation to specific rehabilitation parameters. *PeerJ*. 2018;6:e4400. doi:10.7717/peerj.4400
8. Clausen MB, Witten A, Holm K, et al. Glenohumeral and scapulothoracic strength impairments exists in patients with subacromial impingement, but these are not reflected in the shoulder pain and disability index. *BMC Musculoskelet Disord*. 2017;18(1):302. doi:10.1186/s12891-017-1667-1
9. Dilek B, Gulbahar S, Gundogdu M, et al. Efficacy of proprioceptive exercises in patients with subacromial impingement syndrome: a single-blinded randomized controlled study. *Am J Phys Med Rehabil*. 2016;95(3):169-182. doi:10.1097/PHM.0000000000000327
10. Galace de Freitas D, Marcondes FB, Monteiro RL, Rosa SG, Maria de Moraes Barros Fucs P, Fukuda TY. Pulsed electromagnetic field and exercises in patients with shoulder impingement syndrome: a randomized, double-blind, placebo-controlled clinical trial. *Arch Phys Med Rehabil*. 2014;95(2):345-352. doi:10.1016/j.apmr.2013.09.022
11. Holmgren T, Björnsson Hallgren H, Öberg B, Adolfsson L, Johansson K. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. *BMJ*. 2012;344:e787.
12. Ingwersen KG, Jensen SL, Sørensen L, et al. Three months of progressive high-load versus traditional low-load strength training among patients with rotator cuff tendinopathy: primary results from the double-blind randomized controlled RoCTEx Trial. *Orthop J Sports Med*. 2017;5(8):2325967117723292. doi:10.1177/2325967117723292
13. Lombardi I, Magri AG, Fleury AM, Da Silva AC, Natour J. Progressive resistance training in patients with shoulder impingement syndrome: a randomized controlled trial. *Arthritis Rheum*. 2008;59(5):615-622. doi:10.1002/art.23576
14. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015;350:h2147.
15. MacDermid JC, Ramos J, Drosdowech D, Faber K, Patterson S. The impact of rotator cuff pathology on isometric and isokinetic strength, function, and quality of life. *J Shoulder Elbow Surg*. 2004;13(6):593-598. doi:10.1016/S1058274604001247

16. Maenhout AG, Mahieu NN, De Muynck M, De Wilde LF, Cools AM. Does adding heavy load eccentric training to rehabilitation of patients with unilateral subacromial impingement result in better outcome? A randomized, clinical trial. *Knee Surg Sports Traumatol Arthrosc*. 2013;21(5):1158-1167. doi:10.1007/s00167-012-2012-8
17. McClure PW, Bialker J, Neff N, Williams G, Karduna A. Shoulder function and 3-dimensional kinematics in people with shoulder impingement syndrome before and after a 6-week exercise program. *Phys Ther*. 2004;84(9):832-848.
18. Nijs J, Malfliet A, Ickmans K, Baert I, Meeus M. Treatment of central sensitization in patients with ''unexplained'' chronic pain: an update. *Expert Opin Pharmacother*. 2014;15(12):1671-1683. doi:10.1517/14656566 .2014.925446
19. Riel H, Matthews M, Vicenzino B, Bandholm T, Thorborg K, Rathleff MS. Feedback leads to better exercise quality in adolescents with patellofemoral pain. *Med Sci Sports Exerc*. 2018;50(1):28-35. doi:10.1249/MSS.0000000000001412
20. Thorborg K, Bandholm T, Zebis M, Andersen LL, Jensen J, Hölmich P. Large strengthening effect of a hip-flexor training programme: a randomized controlled trial. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(7): 2346-2352. doi:10.1007/s00167-015-3583-y