

# Effectiveness of prescribing a large additional dosage of shoulder muscle strengthening in the non-operative care for subacromial impingement (The SExSI-Trial) 1.

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**Background:** In 2019, the British Medical Journal issued a strong recommendation against subacromial decompression surgery, leaving non-operative care as the only treatment option. Evidence-based guidelines recommend shoulder strengthening as key in non-operative care for subacromial impingement (SIS), but recent studies suggest that the dose of strengthening exercise is not sufficient in current care.

**Purpose / Aim of Study:** To assess the effectiveness of adding a large additional dose of home-based shoulder-strengthening exercises to current non-operative care.

**Materials and Methods:** In this double-blinded randomised controlled trial, we randomly allocated 200 consecutive patients with longstanding SIS (>3 months) to intervention (IG) or control (CG). The CG received usual non-operative care according to evidence-based clinical guidelines; the IG received the same plus an add-on intervention with the aim to at least double the total dosage of shoulder strengthening. The Shoulder Pain and Disability Index (SPADI, 0–100), external-rotation and abduction strength, and patient acceptable symptom state (PASS) was evaluated at baseline, 5-weeks, 10-weeks and four-months follow-up (primary end-point).

**Findings / Results:** Intention-to-treat and per protocol analyses showed no significant or clinically relevant between-group difference for the primary or other outcomes. From baseline to four-month follow-up, SPADI improved in both groups (intention-to-treat: CG 22.8 points, IG 22.1 points, mean between-group difference 0.6 points (95%CI -5.5 to 6.6)). Four months after randomization, only 54% (IG) and 48% (CG) had reached patient acceptable symptom state ( $p=0.4127$ ).

**Conclusions:** Prescribing a large additional dosage of shoulder strengthening exercise, in addition to usual non-operative care for SIS, does not result in superior outcome. As the confidence limits for between group differences in shoulder disability did not surpass the margin of clinical relevance, it is unlikely that additional studies will alter this conclusion. Importantly, half of all randomised patients had unacceptable symptoms after four months of non-operative care, leaving a large and substantially disabled group of patients with no further options in the traditional health-care system.