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)

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Background: A strong recommendation against subacromial decompression surgery was issued in 2019. This leaves nonoperative care as the only treatment option, but recent studies suggest that the dose of strengthening exercise is not sufficient in current nonoperative care. At this point, it is unknown if adding more strengthening to current nonoperative care is of clinical value.

Purpose: To assess the effectiveness of adding a large dose of shoulder strengthening to current nonoperative care for subacromial impingement compared with usual care alone.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: In this double-blinded, pragmatic randomized controlled trial, we randomly allocated 200 consecutive patients referred to orthopaedic shoulder specialist care for long-standing shoulder pain (>3 months), aged 18 to 65 years and diagnosed with subacromial impingement using validated criteria, to the intervention group (IG) or control group (CG). Outcome assessors were blinded, and participants were blinded to the study hypothesis as well as to the treatment method in the other group. The CG received usual nonoperative care; the IG underwent the same plus an add-on intervention designed to at least double the total dose of shoulder strengthening. The primary outcome was the Shoulder Pain and Disability Index (SPADI; 0-100) at 4-month follow-up, with 10 points defined as the minimal clinically important difference. Secondary outcomes included shoulder strength, range of motion, health-related quality of life, and the Patient Acceptable Symptom State (PASS).

Results: Intention-to-treat and per-protocol analyses showed no significant or clinically relevant between-group differences for any outcome. From baseline to 4-month follow-up, SPADI scores improved in both groups (intention-to-treat analysis; IG, –22.1 points; CG, –22.7 points; between-group mean difference, 0.6 points [95% CI, –5.5 to 6.6]). At 4 months after randomization, only 54% of the IG and 48% of the CG (P = .4127) reached the PASS. No serious adverse events were reported.

Conclusion: Adding a large dose of shoulder strengthening to current nonoperative care for patients with subacromial impingement did not result in superior shoulder-specific patient-reported outcomes. Moreover, approximately half of all randomized patients did not achieve the PASS after 4 months of nonoperative care, leaving many of these patients with unacceptable symptoms. This study showed that adding more exercise is not a viable solution to this problem.

Registration: NCT02747251 (ClinicalTrials.gov identifier)

Keywords: randomized controlled trial; shoulder pain; rotator cuff; resistance training; physical therapy

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Nonoperative care, including exercise therapy,[19] is considered the first-line treatment for subacromial impingement,[14,17,24,32,38] while subacromial decompression surgery, until recently, was considered in cases in which

nonoperative care had failed.[14,24,32,38] In 2019, a strong recommendation against subacromial decompression surgery as a treatment method for subacromial impingement was issued in *The BMJ*.[41] This recommendation was based on level 1 evidence[1,31] and will undoubtedly have a substantial effect on shoulder care pathways in the near future. Such drastic changes to care pathways may leave patients without further treatment options if nonoperative care fails. Therefore, optimizing nonoperative care for subacromial impingement, that is, making exercise as effective as possible, is currently the highest priority.

Current evidence-based guidelines for the treatment of subacromial impingement recommend shoulder strengthening exercises as a key component in nonoperative care.[14,38] The emphasis on shoulder strengthening in these guidelines seems relevant, as subacromial impingement is often related to histological and molecular indicators of degenerative changes[15] (reduced muscle-tendon health), and shoulder muscle-strengthening exercise (ie, resistance training) has the potential to improve muscle-tendon health through various pathways.[20] The presence of impaired muscle-tendon health is further demonstrated by impaired shoulder muscle strength related to subacromial impingement.[6,13,29] Accordingly, patients with subacromial impingement need to increase shoulder strength by approximately 50% to reach the level of the unaffected arm and asymptomatic controls.[13,29] However, despite recommendations to include shoulder muscle strengthening in nonoperative care for subacromial impingement,[14,38] the currently used approach does not seem to improve shoulder muscle strength adequately,[2,12,27] suggesting that the total strengthening exercise volume over time—that is, the strengthening exercise dose—is not sufficient. This is important, as a higher exercise dose might result in larger improvements in shoulder disability,[30] and hence, an insufficient dose could explain the persistence of shoulder disability in patients with subacromial impingement. This provides a strong rationale for increasing the dose of shoulder muscle-strengthening exercise to improve muscle-tendon health and shoulder-specific disability.

In the current trial, we investigated the effectiveness of prescribing a large additional dose of shoulder muscle strengthening using a home-based elastic band intervention. The intervention was designed to at least double the prescribed dose of shoulder muscle-strengthening exercise in current nonoperative care. We hypothesized that prescribing the home-based shoulder strengthening program in addition to current nonoperative care would be superior to current nonoperative care alone for improving patient-reported shoulder disability in those with long-standing subacromial impingement after 4 months of nonoperative care, which is the time point when an orthopaedic specialist would usually re-evaluate patients who are advised to undergo nonoperative care as a first-line treatment option.

METHODS

This is the primary trial report for the Strengthening Exercises in Shoulder Impingement Trial (SExSI Trial).[10] It was a pragmatic, assessor- and participant-blind, randomized controlled superiority trial with a 2-group parallel design conducted in Denmark from May 1, 2016, to October 29, 2018. The full trial protocol describing its methodology is available via open access.[10] There were no deviations from the protocol after the trial began, except for the addition of a post hoc sensitivity analysis. Ethics approval was obtained from the regional ethics committee of the Capital Region of Denmark (approval No. H-16016763). For patient and public involvement statement, see the Appendix (available in the online version of this article).

We included consecutive patients by conducting an eligibility assessment as part of the clinical examination for all patients referred to our orthopaedic outpatient hospital clinic, which is a high-volume center with more than 1000 shoulder-related consultations per year. Eligibility criteria included the following: age 18-65 years; persistent subacromial impingement (>3 months) diagnosed using predefined and valid criteria; and a medically justified need for general rehabilitation, accompanied by the offer of a rehabilitation plan including free-of-charge physical therapy (in line with the Danish Health Act §140). For further details on eligibility criteria, see the trial protocol[10] and Figure 1.

Participants were randomized 1:1 to the control group (CG) or intervention group (IG) based on a computer-

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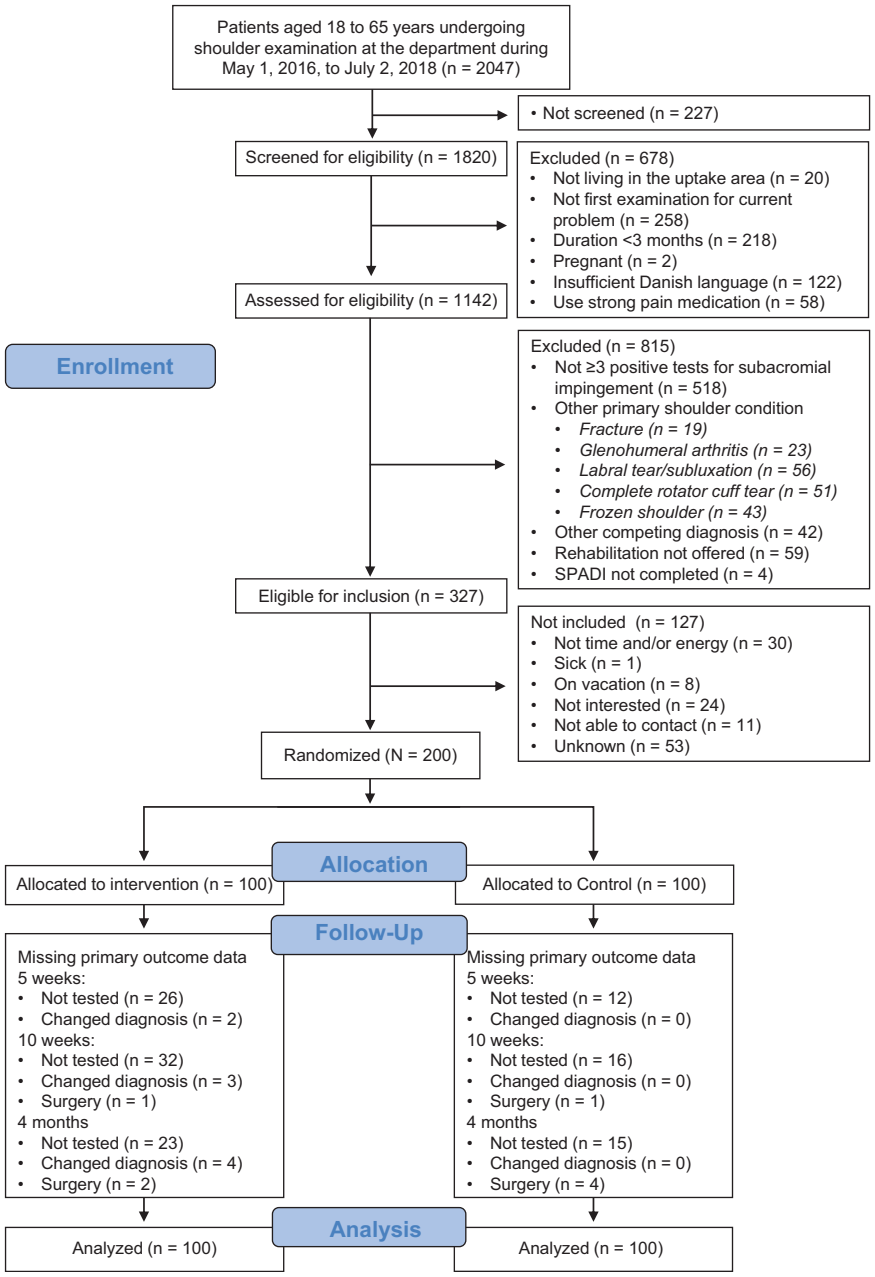

Figure 1. Study flowchart. SPADI, Shoulder Pain and Disability Index.

generated random allocation sequence of permuted blocks of random sizes ranging from 4 to 10, which was concealed using sequentially numbered, opaque, sealed envelopes. The randomization sequence and sealed envelopes were prepared by personnel not otherwise involved in the trial. No personnel involved in the trial had access to the randomization sequence. Sealed envelopes were kept in a locked cabinet and opened solely by intervention providers and only when inclusion was final. During the full trial period, outcome assessors were blinded to group allocation, and intervention providers were blinded to outcome assessments. To blind the participants to group allocation and the study hypothesis, we did not inform participants about the specific treatment method in the 2 groups or the study hypothesis. Before randomization, we informed participants that treatment in both trial arms adhered to the clinical guidelines. After randomization, participants were only informed about the content of their allocated treatment. We instructed all participants not to disclose or discuss treatment allocation with the outcome assessors, medical doctors, or physical therapists providing usual care. We also instructed participants in the IG that their exercises from usual care were the priority and that they should not use the add-on intervention as a substitute for this. We did not inform or discuss with participants whether they had been allocated to the CG or the IG.

Interventions

Both groups received usual nonoperative care. Per clinical guidelines, this included the offer to be referred to general rehabilitation in a municipal clinic under the Danish Health Act §140 but also included any other nonoperative therapy.

Participants in the IG underwent the add-on intervention "Strengthen Your Shoulder," a home-based, progressive, high-volume resistance training program including 1 to 3 exercises performed with an elastic band as external resistance. The program consisted of 3 phases with a duration of 5 to 6 weeks each. For each new phase, 1 exercise was added and the exercise load increased. All exercises targeted the rotator cuff muscles and were continued until contraction failure (muscular exhaustion) to facilitate an optimized physiological response.[4,25] The exercises were (1) external rotation with the elbow supported in approximately 45° of shoulder scaption, (2) abduction with a slight degree of scaption to approximately 45°, and (3) external rotation with the elbow unsupported in approximately 45° of scaption. The exercises were performed with slow dynamic contractions and a 5-second isometric component. This was done to increase the time that the muscle and tendon were under tension during the strengthening exercise (referred to as time under tension), which is related to greater subacute muscle protein synthesis[4] and larger muscle strength gains.[35] Using studies that have investigated exercise interventions for subacromial impingement, we estimated that the total prescribed time under tension for strengthening exercise aimed at the rotator cuff ranged from 2 hours[2] to 12 hours[23] over approximately 3 months. The rotator cuff exercises used in previous studies consisted of loaded external rotation and abduction. In the current study, the add-on intervention had a total prescribed time under tension of approximately 12 hours. As part of the intervention, we included a standard protocol for individualized adaptation of the exercise load based on the pain response and maximum number of repetitions (repetition maximum[16]). Accordingly, participants were instructed to monitor the flare-up of symptoms after exercise and reduce the load if a flare-up lasted more than 24 hours. In case the maximum number of repetitions that a patient could perform was not within the repetition maximum range specified for an intervention phase (ie, 15-20 for phase 1), the patient was advised to adjust the load for the next exercise session. Supervised exercise instructions were provided at baseline and after 2, 5, and 10 weeks, with a final supervised instruction provided after the last follow-up (4 months) to allow participants to continue with the program should they wish to. A full description of the intervention, following the template for intervention description and replication (TIDieR) guidelines,[22] and the rationale to support it are available via open access,[10] and educational videos of the exercises are available at https://video.kp.dk/playlist/dedicated/418727/0_m91947x6/.

Adherence

Adherence to the add-on intervention was quantified as the total time under tension (in hours) for the shoulder strengthening exercise. This was monitored using BandCizer sensor technology (BandCizer), which was specifically developed and validated for capturing time under tension for elastic band exercises.[33,34,40] Self-reported information regarding time spent on exercise in usual care in both groups was collected through a weekly text message using the SMS tracking system and reported as minutes per week. We chose not to report the time spent on exercise in usual care using the same unit of measurement as adherence to the add-on intervention, as utilizing the same unit might suggest that these are measures of the same thing, which is not the case.

Outcomes

Outcome assessments were performed by trained clinical physical therapists immediately before randomization (baseline) and at follow-ups after 5 weeks, 10 weeks, and 4 months. Immediately after each outcome assessment, participants met with the intervention provider to record information on concomitant care. For the IG, instructions for the home-based shoulder strengthening program were provided at these meetings. The primary outcome was the change from baseline to 4-month follow-up in shoulder disability using the valid and reliable patient-reported Shoulder Pain and Disability Index (SPADI),[9,36] which is scored from 0 to 100 (worst). A priori,[10] we defined 10 points to be the minimal clinically important difference.

Secondary outcomes for shoulder function included shoulder strength in abduction and external rotation (in N·m/kg) as well as shoulder abduction range of motion (in degrees). Secondary outcomes for shoulder pain were the mean of average pain and least pain during the previous week, both measured using an 11-point numerical rating scale. Secondary outcomes for health-related quality of life included the EuroQol–5 Dimension–3 Level (EQ-5D-3L) questionnaire and its Danish valuation set[42] for both time trade-off (TTO-index) and the visual analog scale (VAS-index) as well as self-rated health, rated from 0 ("worst imaginable health") to 100 mm ("best imaginable health") using the VAS in the EQ-5D-3L. Dichotomous secondary outcomes for treatment success included the Patient Acceptable Symptom State (PASS; acceptable/unacceptable) and global impression of change (recovered or much improved, yes/no). Additional secondary outcomes will be reported in subsequent publications, as outlined in the trial protocol[10] and registration (ClinicalTrials.gov NCT02747251) (see the Appendix, available online).

Statistical Analysis

For the primary outcome, the sample size of 200 participants allowed for a power of 95% to verify an effect equal to, or higher than, the minimal clinically important difference of 10 points on the SPADI at a 5% significance level. This corresponds to a power of 85.4% in case of a 40% dropout rate, making the study robust to dropouts. We applied constrained linear mixed models to compare the change in the IG with that in the CG, as described in the trial

protocol.[10] Similar analyses were conducted for all continuous secondary outcomes. Dichotomous outcomes were compared between groups using chi-square tests. To create the full data set for intention-to-treat analysis, missing outcome data were imputed using multiple imputations (30 imputation sets). The missingness of data at the different time points is shown in Appendix Table A1 (available online). Prespecified sensitivity analyses included a per-protocol analysis for each intention-to-treat analysis and 2 separate intention-to-treat analyses for the SPADI score, representing the 2 SPADI subscales of pain and function, as 2 Rasch validation studies published after the initiation of this trial have suggested that the SPADI should be reported as 2 separate subscales.[8,26] All analyses were conducted by a statistician (K.B.C.) blinded to group allocation, who followed the prespecified statistical analysis plan.[10] Finally, we conducted a post hoc sensitivity analysis to explore the possible effect of a between-group difference in time spent on usual care exercise by adjusting the primary intention-to-treat analysis for individual time spent on usual care exercise. We imputed missing data on exercise time using the same procedure as for outcome data.

RESULTS

Enrollment and Follow-up

Between May 1, 2016, and July 2, 2018, a total of 2047 patients aged 18 to 65 years underwent a shoulder examination at our institution. Eligibility screening was performed for 1820 of the patients (89%), of whom 678 were not eligible based on the initial screening criteria. Of the remaining 1142 patients, 327 met the predefined inclusion criteria (Figure 1). We attempted to contact all the eligible patients, but 11 did not respond to our telephone calls. As planned, we enrolled and randomized 200 participants with a median symptom duration of 10 months (interquartile range, 6-18 months). Baseline values for demographics, characteristics, and outcomes were balanced between groups (Table 1; Appendix Table A2, available online). All participants were included in the primary intention-to-treat analysis, while 156 were included in the per-protocol analysis. All but 1 of the participants in the IG attended the first intervention appointment. There were no serious adverse events in this trial. We recorded a total of 96 symptom exacerbations lasting at least 1 week (IG: 49 exacerbations; CG: 47 exacerbations).

Primary Outcome

The intention-to-treat analysis revealed no between-group difference for the change in SPADI scores from baseline to 4-month follow-up (mean difference [MD], 0.6 points [95% CI, −5.5 to 6.6]) or any of the intermediate follow-up intervals (Figure 2; Table 3). The SPADI score improved in both the IG (−22.1 points [95% CI, −26.6 to −17.6]) and CG (−22.7 points [95% CI, −26.4 to −19.0]) (Table 2; Appendix Table A2, available online). These results remained essentially unaltered in the prespecified per-protocol analysis (Appendix Table A3, available online) and when using the Rasch-validated SPADI subscales as outcomes of interest (pain: MD, 2.3 points [95% CI, −4.6 to 9.1]; function: MD, −0.7 points [95% CI, −6.7 to 5.3]).

Secondary Outcomes

Tables 2 and 3 and Appendix Table A2 (available online) show results from the intention-to-treat analysis for all continuous outcomes. The intention-to-treat analysis revealed no between-group difference for the change in abduction strength (MD, −0.01 N·m/kg [95% CI, −0.04 to 0.02]), external rotation strength (MD, 0.01 N·m/kg [95% CI, −0.01 to 0.02]), or abduction range of motion (MD, 3.7° [95% CI, −4.6 to 12.1]) from baseline to 4-month follow-up. Moreover, the intention-to-treat analysis revealed no between-group difference in the PASS and global impression of change at 4-month follow-up; the overall chance of reaching the PASS was 51% (54% IG vs 48% CG; P = .4127), while the overall chance of being much improved or fully recovered was 25% (24% IG vs 27% CG; P = .5751). All results for secondary outcomes remained essentially unaltered in the prespecified sensitivity analysis (Appendix Table A2, available online).

Adherence to Add-on Intervention and Concomitant Care

Participants in the IG completed a total of 116,089 repetitions with a mean duration of 8.2 seconds per repetition, as recorded using BandCizer technology. The average total dose (total time under tension during the intervention period) was 10,468 seconds, corresponding to 2.9 hours (1.6 hours from baseline to 5 weeks, 0.8 hours from 5 to 10 weeks, 0.6 hours from 10 wk to 4 mo). In both groups, we monitored the time spent on exercise as part of usual care (eg, strengthening, mobility, and motor control, but not counting the add-on intervention) and found that the IG reported, on average, 16 minutes less per week compared with the CG (35 vs 51 min/wk, respectively). The post hoc analysis adjusting the primary intention-to-treat analysis for individual time spent on usual care exercise showed no between-group difference for the change in SPADI scores from baseline to 4-month follow-up (MD, 0.2 points [95% CI, −6.0 to 6.3]) or any of the intermediate follow-up intervals. Details on the add-on intervention dose, time spent on usual care exercise, and concomitant care are available in Appendix Tables A4 and A5 (available online).

DISCUSSION

In contrast to our hypothesis, we did not find superior effectiveness from prescribing a large additional dose of shoulder muscle-strengthening exercise in patients with long-standing subacromial impingement. This was evident

TABLE 1
Baseline Characteristics[a]

	Control (n = 100)	Intervention (n = 100)
Age, mean ± SD, y	51 ± 10	50 ± 11
Sex		
Female	66 (66)	58 (58)
Male	34 (34)	42 (42)
Symptom duration, median (interquartile range), mo	9 (6-17)	10 (6-18)
Symptom onset		
Sudden	39 (39)	43 (43)
Gradual	60 (60)	57 (57)
Previous surgery in affected shoulder		
No	98 (98)	97 (97)
Yes	2 (2)	3 (3)
Self-rated severity of shoulder condition		
1 (very mild)	4 (4)	1 (1)
2	14 (14)	16 (16)
3	35 (35)	40 (40)
4	34 (34)	28 (28)
5 (very severe)	13 (13)	15 (15)
Expectations for outcome		
Already improving	17 (17)	17 (17)
Will be better soon	41 (41)	41 (41)
Staying the same	14 (14)	13 (13)
Getting worse	8 (8)	10 (10)
Do not know	19 (19)	19 (19)
Over-the-counter medication for shoulder condition		
No	25 (25)	31 (31)
Some days	46 (46)	46 (46)
Most days	19 (19)	13 (13)
Every day	10 (10)	10 (10)
Prescription drugs for shoulder condition		
No	67 (67)	65 (65)
Some days	21 (21)	21 (21)
Most days	8 (8)	4 (4)
Every day	4 (4)	10 (10)
Education		
Elementary school	18 (18)	14 (14)
High school	9 (9)	2 (2)
Vocational education	23 (23)	36 (36)
Short-cycle higher education	14 (14)	18 (18)
Medium-cycle higher education	27 (27)	22 (22)
Long-cycle higher education	9 (9)	7 (7)
Currently working		
Yes	65 (65)	58 (58)
Yes, but part-time because of shoulder	0 (0)	2 (2)
Yes, but part-time for other reason	6 (6)	6 (6)
No, on sick leave or retired because of shoulder	12 (12)	13 (13)
No, on sick leave or retired for other reason	17 (17)	21 (21)
Workers' compensation		
Yes	3 (3)	0 (0)
No	95 (95)	90 (90)
Currently applying	2 (2)	10 (10)
Steroid injection during initial shoulder examination		
Yes	75 (75)	71 (71)
No	25 (25)	29 (29)

[a]Data are shown as n (%) unless otherwise indicated. Values may not add up to 100 due to missing data.

in the primary outcome as well as all secondary outcomes. Moreover, the confidence limits for between-group differences in the primary outcome did not surpass the margin of clinical relevance. An important observation was that approximately half of all randomized patients did not reach the PASS after 4 months of nonoperative care.

Despite the high prevalence of subacromial impingement, no large-scale trials have previously investigated

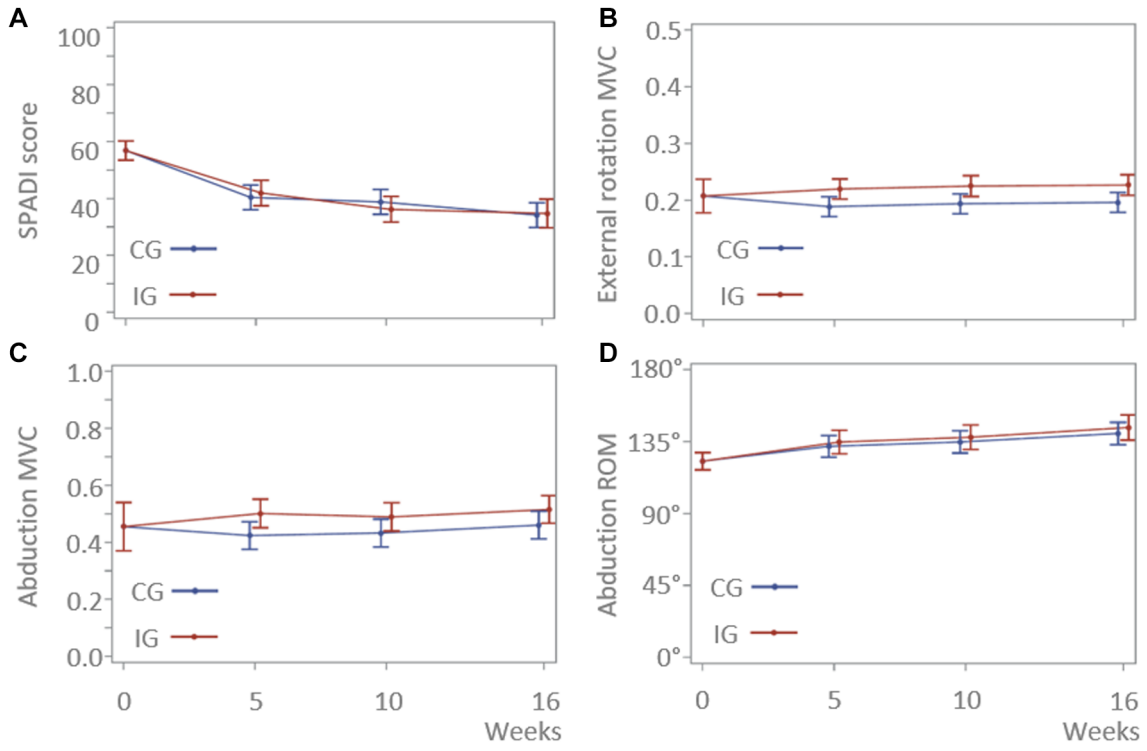

Figure 2. Shoulder function outcomes with 95% CIs in the control group (CG) and intervention group (IG) before randomization and for each follow-up time point for (A) the Shoulder Pain and Disability Index (SPADI) score, (B) external rotation strength (in N·m/kg), (C) abduction strength (in N·m/kg), and (D) abduction range of motion (ROM) (in degrees). MVC, maximum voluntary contraction.

TABLE 2
Within-Group Differences for Changes in Primary and Secondary Outcomes[a]

	Baseline to 5 wk		5 to 10 wk		10 wk to 4 mo		Baseline to 4 mo	
	IG	CG	IG	CG	IG	CG	IG	CG
SPADI score (0 = best, 100 = worst)	−14.9 (−18.8 to −11.1)	−16.5 (−20.2 to −12.8)	−5.8 (−9.9 to −1.6)	−1.6 (−5.3 to 2.2)	−1.4 (−5.9 to 3.1)	−4.6 (−8.3 to −0.9)	−22.1 (−26.6 to −17.6)	−22.7 (−26.4 to −19.0)
Abduction strength, N·m/kg	0.01 (−0.01 to 0.04)	0.00 (−0.02 to 0.02)	−0.01 (−0.04 to 0.02)	0.01 (−0.01 to 0.03)	0.03 (0.00 to 0.05)	0.03 (0.00 to 0.05)	0.03 (0.01 to 0.05)	0.04 (0.01 to 0.06)
External rotation strength, N·m/kg	0.00 (−0.01 to 0.01)	−0.01 (−0.02 to 0.00)	0.01 (−0.01 to 0.02)	0.01 (0.00 to 0.01)	0.00 (−0.01 to 0.01)	0.00 (−0.01 to 0.01)	0.01 (0.00 to 0.02)	0.00 (−0.01 to 0.01)
Abduction range of motion, deg	12.0 (5.6 to 18.4)	9.3 (3.6 to 15.0)	3.0 (−3.3 to 9.4)	2.7 (−3.1 to 8.6)	6.1 (−0.7 to 12.9)	5.3 (−0.7 to 11.4)	21.1 (14.2 to 28.0)	17.4 (11.5 to 23.2)
Pain last week (0 = no pain, 10 = worst pain)	−0.4 (−0.8 to 0.0)	−0.7 (−1.0 to −0.4)	−0.2 (−0.5 to 0.2)	0.1 (−0.3 to 0.4)	−0.2 (−0.6 to 0.2)	−0.1 (−0.5 to 0.2)	−0.8 (−1.2 to −0.3)	−0.7 (−1.1 to −0.4)
EQ-5D-3L TTO (0 = worst, 1 = best)	0.02 (−0.01 to 0.04)	0.04 (0.01 to 0.07)	0.02 (0.00 to 0.05)	0.00 (−0.03 to 0.03)	0.00 (−0.03 to 0.03)	0.01 (−0.03 to 0.05)	0.04 (0.01 to 0.07)	0.05 (0.02 to 0.09)
EQ-5D-3L VAS (0 = worst, 1 = best)	0.02 (−0.01 to 0.04)	0.04 (0.01 to 0.07)	0.02 (0.00 to 0.05)	0.02 (−0.02 to 0.05)	0.01 (−0.01 to 0.04)	0.01 (−0.03 to 0.05)	0.05 (0.03 to 0.08)	0.06 (0.04 to 0.10)
Self-rated health (0 = worst, 100 = best)	1.3 (−2.2 to 4.8)	−0.9 (−4.2 to 2.4)	1.9 (−2.0 to 5.9)	1.8 (−1.8 to 5.3)	1.1 (−3.0 to 5.1)	1.7 (−1.9 to 5.2)	4.3 (0.5 to 8.1)	2.5 (−0.9 to 6.0)

[a]95% CIs are shown in parentheses. CG, control group; EQ-5D-3L, EuroQol–5 Dimension–3 Level questionnaire; IG, intervention group; SPADI, Shoulder Pain and Disability Index; TTO, time trade-off; VAS, visual analog scale.

the effect of additional shoulder muscle-strengthening exercise for this condition. Our finding of no difference supplements the previous results from Holmgren et al,[23] who found a large exercise dose to be superior compared with a very low dose of nonspecific exercise in the only previous trial to investigate the effect of a higher versus lower exercise dose in the treatment of subacromial impingement.[30] It has been argued that this apparent effect of a higher exercise dose identified by Holmgren et al is likely explained by the subtherapeutic doses in the comparison group,[30] making the control exercise dose insufficient to elicit a clinical effect and thus not comparable with current

TABLE 3
Between-Group Differences (Intervention and Control) for Changes in Primary and Secondary Outcomes[a]

	Baseline to 5 wk	5 to 10 wk	10 wk to 4 mo	Baseline to 4 mo
SPADI score (0 = best, 100 = worst)	1.6 (−3.7 to 6.9) *P* = .5622	–4.2 (−9.9 to 1.4) *P* = .1444	3.2 (−2.8 to 9.2) *P* = .2945	0.6 (−5.5 to 6.6) *P* = .8518
Abduction strength, N·m/kg	0.01 (−0.02 to 0.05) *P* = .4177	–0.02 (−0.06 to 0.02) *P* = .2668	0.00 (–0.04 to 0.03) *P* = .9386	−0.01 (−0.04 to 0.02) *P* = .6280
External rotation strength, N·m/kg	0.01 (0.00 to 0.02) *P* = .1457	0.00 (–0.01 to 0.01) *P* = .9992	0.00 (−0.01 to 0.01) *P* = .9463	0.01 (−0.01 to 0.02) *P* = .2062
Abduction range of motion, deg	2.7 (−5.8 to 11.2) *P* = .5367	0.3 (−8.4 to 8.9) *P* = .9485	0.8 (−8.3 to 9.8) *P* = .8676	3.7 (−4.6 to 12.1) *P* = .3819
Pain last week (0 = no pain, 10 = worst pain)	0.3 (–0.2 to 0.8) *P* = .1945	–0.3 (−0.8 to 0.3) *P* = .3243	−0.1 (−0.6 to 0.4) *P* = .6968	0.0 (−0.6 to 0.5) *P* = .8990
EQ-5D-3L TTO (0 = worst, 1 = best)	–0.01 (−0.05 to 0.04) *P* = .3371	0.03 (−0.02 to 0.07) *P* = .1804	–0.02 (−0.07 to 0.03) *P* = .6002	0.00 (−0.05 to 0.05) *P* = .9320
EQ-5D-3L VAS (0 = worst, 1 = best)	–0.02 (−0.06 to 0.02) *P* = .2037	0.01 (−0.04 to 0.06) *P* = .5526	0.00 (−0.05 to 0.06) *P* = .8446	–0.00 (−0.05 to 0.04) *P* = .6875
Self-rated health (0 = worst, 100 = best)	2.2 (−2.3 to 6.8) *P* = .3376	0.2 (−5.1 to 5.4) *P* = .9520	–0.6 (−5.9 to 4.7) *P* = .8218	1.8 (−3.2 to 6.7) *P* = .4807

[a]95% CIs are shown in parentheses. EQ-5D-3L, EuroQol–5 Dimension–3 Level questionnaire; SPADI, Shoulder Pain and Disability Index; TTO, time trade-off; VAS, visual analog scale.

clinical care and the control condition in the present study. Hence, our findings update the evidence regarding the relevance of an increased dose of strengthening exercise, as our predefined analyses have shown that prescribing a large additional dose of shoulder strengthening does not improve the outcome of current nonoperative care. Interestingly, adherence data from the current trial showed that patients in the IG reduced the time spent on exercises that were not part of the intervention, despite our recommendations not to do so. Thus, it could be speculated that the absence of between-group differences arose from the difference in the time spent on usual care exercise in the IG (35 min/wk) compared with the CG (51 min/wk). To avoid further speculation, we performed a post hoc analysis adjusting for the time spent on usual care exercise. This yielded similar results to all other analyses, showing no between-group differences. Thus, the post hoc analysis demonstrated that our results would not be any different even if patients in the IG had spent the same amount of time on usual care exercise as the CG, supporting the finding of the primary analysis, which means that increasing the dose of strengthening exercise is unlikely to improve current nonoperative care. The fact that patients in the IG reduced the time spent on exercises that were not part of the intervention also indicates that many patients suffering from subacromial impingement are not willing or able to spend more time on shoulder exercise than already included in current care. This underpins the view that improving the effectiveness of current nonoperative care is not easily done and, more specifically, that adding more exercise does not seem to be a viable pathway to achieve this, regardless of the exercise type. Instead, patient education could pose a promising different dimension of care if used to address psychological factors related to the outcome of care (eg, pain self-efficacy[7]) as well as central adaptations to long-standing pain[39] without increasing the exercise burden for the patients. At this point, however, this is relatively unexplored in the context of nonoperative care for subacromial impingement. In summary, we suggest that future studies on first-line treatment investigate the relevance and usefulness of supplementary individualized care, such as patient education to support self-management, which can be implemented in current care without increasing the exercise burden for patients.

The overall response to nonoperative care found in both groups in the present study seems slightly better than what was reported in a recent nationwide study including 3306 patients diagnosed with subacromial impingement in a specialist care setting (similar to the current study), as only 43%, compared with 51% in the present study, reached an acceptable symptom state at 4-month follow-up.[11] This is despite the fact that 87% had engaged in exercise therapy as part of their treatment.[11] Such slightly better outcomes in trial settings is to be expected and likely a consequence of well-known trial effects.[3] Hence, it is not surprising that the overall response in our trial is in accordance with another effectiveness trial by Roddy et al[37] on nonoperative care (including rotator cuff strengthening) conducted in a comparable population. Accordingly, Roddy et al found similar within-group differences in the SPADI score, with a large improvement after 6 weeks and only minimal changes after this, using somewhat different strengthening exercises than the add-on intervention utilized in the present study. It therefore seems unlikely that slight differences in shoulder muscle-strengthening exercises alter the effectiveness of this type of exercise intervention to any important degree. Moreover, the fact that such a large group of patients (about half), who all underwent exercise as first-line treatment, did not achieve an acceptable result from current nonoperative care questions the recent strong *BMJ*

recommendation against surgery for subacromial impingement.[41] By rigidly discouraging surgery, we risk leaving a large group of patients, who do not benefit from exercise therapy, with no further treatment options in the orthodox health care system. Along these lines, it is worth noting that recent knowledge indicates a short-term effect of interventions including surgery for subacromial impingement when used as part of a second-line treatment approach.[5] In the study by Cederqvist et al,[5] patients were first prescribed a 3- to 4-month physical therapist−led exercise intervention, and patients who failed this approach were randomized to either continuation of the previously initiated rehabilitation program or a surgical intervention. At 3 months after randomization, between-group differences in improvements were in favor of the surgery group, with differences of 10 to 15 points on the VAS. These findings provide preliminary evidence that surgery might provide some short-term benefit for patients who fail to achieve a successful outcome from initial nonoperative care, but further large-scale studies are needed to inform future decisions on whether surgery still has a place in secondary care for subacromial impingement.

Our methods, which included a high screening rate, consecutive recruitment, and implementation of current nonoperative care as the control condition, increase the generalizability and relevance of our trial. The blinding of outcome assessors and minimal information to participants and providers of usual care reduced the risk of performance and detection bias. We used valid and objective monitoring of the add-on exercise dose, which greatly improved knowledge gained from this pragmatic trial and enabled us to explain our findings based on empirical data rather than theoretical rationales. The add-on intervention was home based and included thorough instructions at each follow-up visit. This is a common approach when it comes to exercise-based interventions, most likely because it is not feasible to provide a fully supervised setup within the current health care system and because such supervision does not provide any additional benefit.[18,21] Moreover, such a setup would mainly appeal to a subset of patients; namely, those who have a very flexible work schedule or no job at all. Collectively, the above factors would greatly reduce the generalizability of our findings, which is a key aspect of pragmatic randomized controlled trials.[28] It can be argued that a limitation of the current study is that the average total dose (time under tension) of 2.9 hours (10,468 seconds) was somewhat lower than the prescribed dose of 12 hours. Despite this, such an addition to the exercise dose seems to be sufficient to expect a clinical response, as a similar dose per week during 6 weeks has previously led to significant clinical improvements.[35] This also makes good sense, as 2.9 hours' time under tension corresponds to more than 3 sets of 10 repetitions every day during the full 16-week intervention period if using a standard exercise tempo of 1-second concentric, 1-second isometric, and 1-second eccentric contractions. Interestingly, the proportion of the prescribed time under tension that was utilized in our study is similar to what was found in a previous study using the same precise and objective technology[35] and hence is likely a good reflection of what can be expected in clinical settings when measuring the actual dose with objective monitoring. At 4-month follow-up, outcome data were missing for 19% who did not attend the follow-up assessments, while an additional 5% were censored because of a revised diagnosis or shoulder surgery. This rate of missing data is comparable with the primary endpoint (1 year) for the C-SAW trial,[1] which is another effectiveness study in a similar population of patients with subacromial impingement. The rate of missing outcome data was higher in the IG, and the majority of the patients who did not participate in the 4-month follow-up assessment also did not participate in the 5- and 10-week intervention meetings, thereby limiting their possible gain from the add-on intervention. We therefore believe that any bias originating from nonretention would most likely skew the results in favor of the IG, which further strengthens our conclusion that the add-on intervention was not effective.

In conclusion, 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. 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. Moreover, with current nonoperative care, approximately half of the patients did not achieve the PASS at 4 months, which is the time point when surgery has traditionally been considered, and future research is needed to understand how treatment can be optimized for this large group of patients. Adherence data from this pragmatic trial showed that adding more exercise to current nonoperative care is not a viable solution to this problem.

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