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Effectiveness of supervised physiotherapy after arthroscopic rotator cuff reconstruction: a randomized controlled trial

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Background: The benefit of supervised physiotherapy after rotator cuff surgery is unclear. The aim of this randomized controlled trial was to assess the effectiveness of supervised physiotherapy after arthroscopic rotator cuff reconstruction.
Methods: Eighty patients with full-thickness supraspinatus tendon tears were randomly assigned to either supervised physiotherapy or home exercises only. The primary outcome measure was the Constant score at 12 months after surgery.
Results: A total of 70 patients were available for analyses at 1-year follow-up. There were no statistically significant differences in the primary outcome between the treatment groups.
Conclusion: Supervised physiotherapy after arthroscopic rotator cuff reconstruction does not provide additional benefit compared with home exercises alone at 1-year follow-up.
Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Shoulder; physiotherapy; arthroscopic rotator cuff reconstruction; effectiveness; supervised exercise; home exercise

Rotator cuff tear is a commonly diagnosed disorder related to shoulder dysfunction, pain, and impaired quality of life.[1,16,29] It may be detected after acute trauma to the shoulder, but it may also be of age-related purely degenerative origin.[10-12] Usually, the tear involves the supraspinatus tendon.[16] Although the optimal treatment for cuff tears remains controversial, surgery, that is, reinsertion of the torn tendon to its bony footprint, is a commonly used treatment for this condition.[7,19] The outcome after rotator cuff reconstruction is reported to be good to excellent, and the incidence of rotator cuff reconstruction is rising worldwide.[8,14,17,21,27]

Operative treatment is usually followed by a period of supervised physiotherapy (SP) to enhance recovery. The rationale for postoperative physiotherapy is to stimulate and protect the tendinous healing process and to train and regain the impaired mobility and strength of the affected shoulder.[5] Physiotherapy usually consists of a specific exercise program first taught by, then repeatedly supervised by, and finally controlled by a specialized physiotherapist. Despite the wide utilization of SP, the evidence on its effectiveness after rotator cuff repair, especially regarding

The ethics committee of the Hospital District of South-West Finland gave approval to this study on February 16, 2010 (study no. 048/2010).

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content, timing, and need for supervision, is lacking.[20] Furthermore, delivery of SP requires health care resources and brings about an additional cost of care.

The objective of this trial was to investigate the effectiveness of SP compared with home exercises alone after arthroscopic rotator cuff reconstruction. The hypothesis was that SP would outperform the self-administered home exercises in terms of functional and subjective outcomes.

Materials and methods

This was a randomized controlled effectiveness trial with 2 parallel treatment arms. The trial was conducted according to the revised Declaration of Helsinki from the World Medical Association and the ICH (International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines for good clinical trial practice. Patients with rotator cuff disorder were referred from local health care providers to the Turku University Hospital. A total of 80 patients with an arthroscopically documented and repaired isolated full-thickness supraspinatus tendon tear between 2010 and 2015 were enrolled in the trial. The inclusion and exclusion criteria are presented in Table I.

The torn supraspinatus tendon was anatomically reinserted to its native footprint area with a titanium suture anchor in all patients in the lateral decubitus position under general anesthesia. Postoperatively, after full recovery from general anesthesia, eligible patients were asked to participate in the trial. After providing written informed consent, the patients were randomly assigned to 1 of 2 studied treatment groups via sealed envelopes. Both treatment groups received the same progressive exercise instructions from a shoulder specialized physiotherapist. The period of immobilization in a sling was 2 weeks in both groups. The instructions included model pictures of training for range of motion and movement and a recommended timetable for training (Supplementary Appendix S1). All patients were advised not to return to strenuous work or activity earlier than 3 months after the operation. All were allowed to call the physiotherapist if they encountered unexpected difficulties with the exercises or if they had extra questions about the recovery process.

Postoperatively, patients in the supervised physiotherapy group (SPG) were asked to return to the hospital for a total of 5 SP sessions between 2 and 10 weeks after the operation; sessions were held roughly every second week. The duration of 1 SP session was between 30 and 60 minutes. The physiotherapist went through the exercises and supervised the patients' practice during sessions. In contrast, postoperatively, patients in the home exercise group (HEG) were given both oral and written detailed instructions alone on how and when to perform the exercises at home for 3 months after the operation.

The range of motion and strength of the affected shoulder and the Constant score were recorded by a separate, independent physiotherapist preoperatively, at 3 months after the operation, and at 1 year after the operation. If a patient had severe pain and/or recovery was delayed at 3 months as judged by the physiotherapist at follow-up, additional SP was scheduled with 2-week intervals at a primary care or occupational health care facility.

Primary outcome: Constant score

The primary outcome measure was the difference in the Constant score between groups at 1-year follow-up. The 100-point scoring scale takes into account both subjective and objective measurements and is divided into 4 domains (pain, 15 points; activities of daily living, 20 points; range of motion, 40 points; and strength, 25 points).[3] The minimal clinically important difference in the Constant score is reported to be between 10.4 and 17 points.[15]

Secondary outcomes

Visual analog scale for pain

The visual analog scale (VAS) for pain is a unidimensional, single-item measure of pain intensity. It is composed of a horizontal line 10 cm in length anchored by endpoints of ''no pain'' and ''pain as bad as it could be.'' The patient is asked to place a line, perpendicular to the VAS line, at the point representing his or her pain intensity in the last 24 hours. With a ruler, the score is determined by measuring the distance (in millimeters) on the

Table I Study inclusion and exclusion criteria

Inclusion criteria
Aged 30-65 yr
Arthroscopically reinserted isolated full-thickness supraspinatus tendon rupture
Written informed consent from participating subject
Exclusion criteria
Aged $<$ 30 yr or $>$ 65 yr
Existing significant malignant, hematologic, endocrine, metabolic, rheumatoid, or gastrointestinal disease
Glenohumeral osteoarthrosis grade III or above (radiographic evaluation with present osteophytes according to Kellgren-Lawrence classification)
Cytostatic or corticosteroid medication
History of alcoholism, drug abuse, or psychological or other emotional problems that are likely to invalidate informed consent
Previous ipsilateral shoulder surgery
Massive tendon tear involving $>$1 tendon and/or combined tear of 2 tendons, ie, supraspinatus with infraspinatus or subscapularis tendon tear
Patient denial

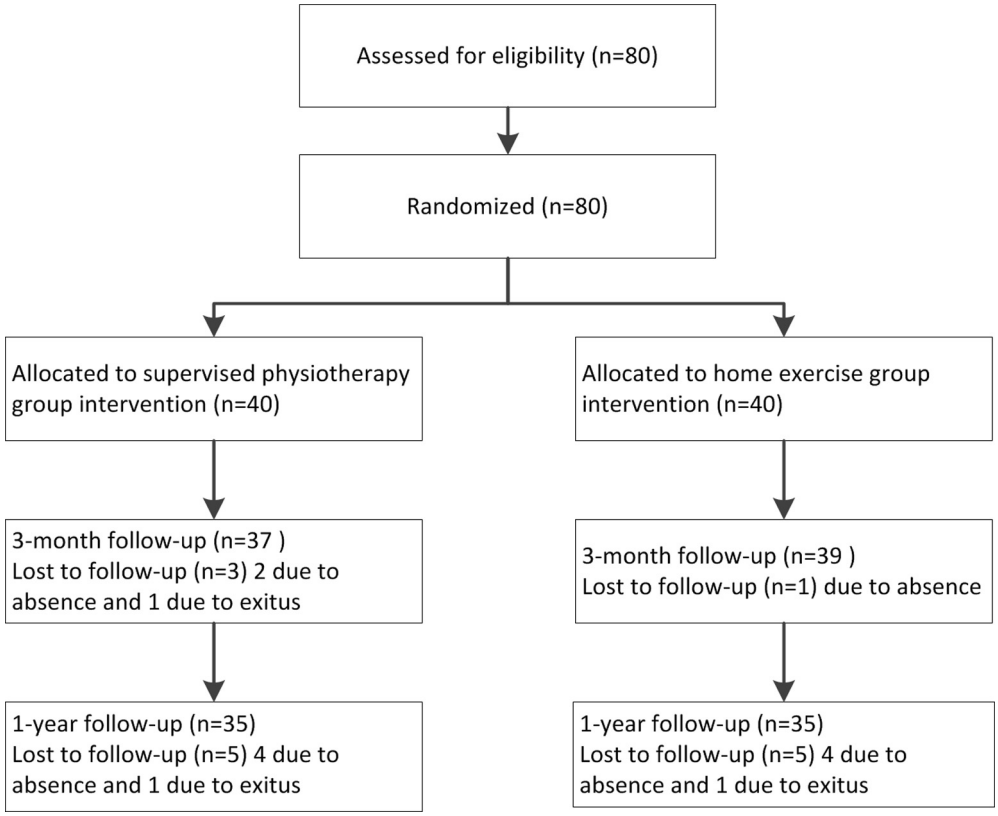

Figure 1 Flowchart of trial.

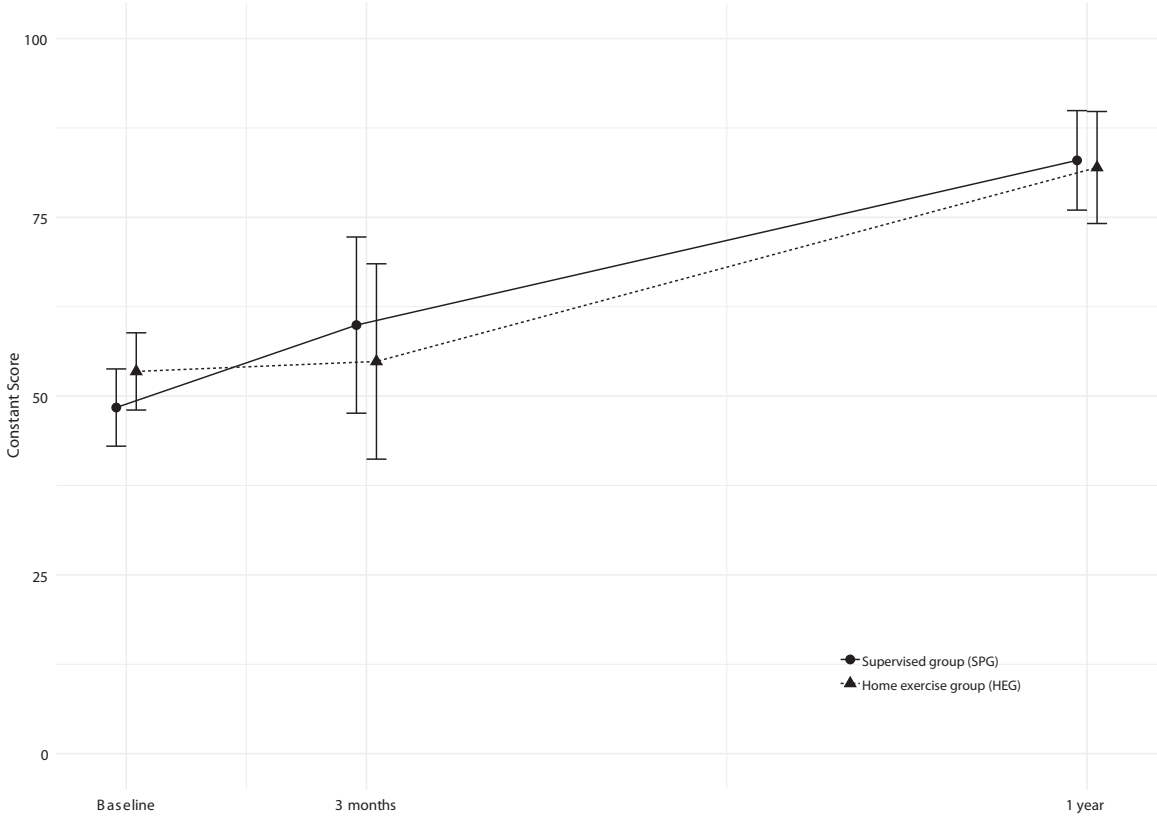

Figure 2 Graph showing total Constant score in both treatment groups. *Whiskers* indicate 95% confidence intervals. *SPG*, supervised physiotherapy group.

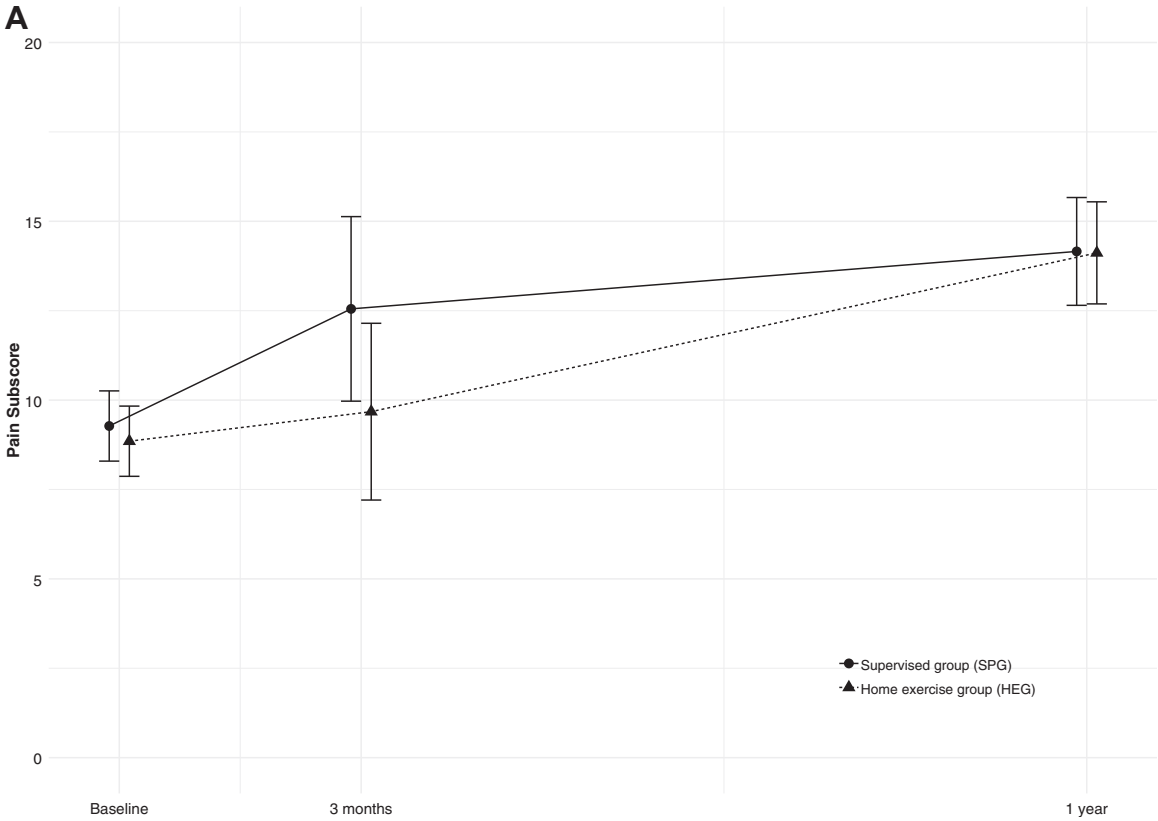

Figure 3 Graphs showing Constant subscores for pain (**A**), activities of daily living (**B**), range of motion (**C**), and strength (**D**) in both treatment groups. *Whiskers* indicate 95% confidence intervals. *SPG*, supervised physiotherapy group.

10-cm line between the ''no pain'' anchor and the patient's mark, providing a range of scores from 0 to 10. The minimal clinically important difference in the VAS pain score is reported to be 2.4 cm.[25]

Subjective Shoulder Value

Patients were asked to rate their shoulder on a 10-cm VAS anchored by ''as bad as it can be'' and ''as good as possible'' endpoints.[9]

Sample size and statistical analysis

The power calculations were based on assumed behavior of the Constant score. The mean score at baseline was assumed to be 50, with a standard deviation (SD) of 15. The score of the best treatment group after follow-up was assumed to be 80 and the score of the worst treatment group, 70, with an SD of 15. The correlation between measurements during follow-up was estimated to be 0.50, and the SD of the change, 15. Using a 2-sided 2-sample t test with $\alpha = .05$ and 80% power, we could expect the findings (difference in change between groups) to be statistically significant if the number of subjects in each group was 37. Because of possible dropouts, the number of subjects per group was decided to be 40.

All data were stored and secured in a specific study subject register. Data were analyzed using methods suitable for clinical trials involving comparison of parallel treatment groups with repeated measurements. Data were summarized in terms of means and SDs or counts and proportions, when appropriate. The primary technique was analysis of variance with repeated measurements. Studentized residuals were checked to confirm model fit to the data. Determination of statistical significance relied on P values; a significance level of .05 was chosen. In addition, figures are presented with 95% confidence intervals. All analyses were conducted using R (version 3.5.2 [2018]; R Core Team, Vienna, Austria).

Results

A total of 80 patients were randomized in this study: 40 to the SPG and 40 to the HEG. There were 25 women and 55 men, and the average age of the patients at baseline was 55 years. The demographic data and clinical characteristics of the patients are presented in Table II. The mean size of the repaired supraspinatus tear was 12 mm in the SPG and 14 mm in the HEG. The intraoperative findings and procedures are presented in Table III. Altogether, 76 patients

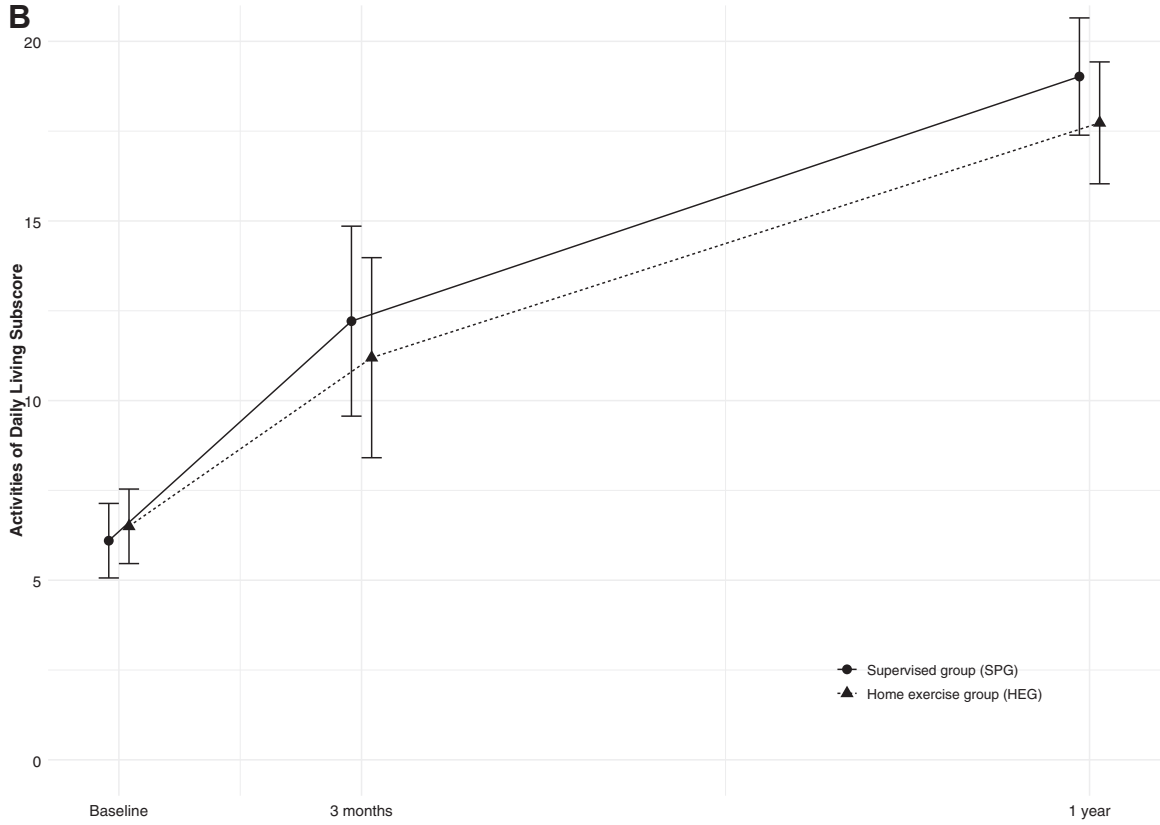

Figure 3 Continued

were available for follow-up at 3 months (dropout rate, 5%), and 70 patients, at 1 year (dropout rate, 12.5%). Follow-up at the 1-year time point was delayed until 15 months for 14 patients (8 in the SPG and 6 in the HEG). The flowchart of this trial is presented in Figure 1. There were no reported treatment-related complications in the trial cohort. In the HEG, 10 patients (25%) contacted the physiotherapist by phone to receive counseling and self-treatment instructions; in the SPG, none of the patients called. Additional physiotherapy after 3 months was administered in 8 patients in the SPG and 3 patients in the HEG.

The mean baseline Constant score was 48 in the SPG and 54 in the HEG ($P = .1990$). At 3 months of follow-up, the mean Constant score was 59 in the SPG and 55 in the HEG ($P = .0647$). At 1 year of follow-up, the mean Constant score was 83 in the SPG and 82 in the HEG ($P = .4185$). The behavior of the Constant score is presented in Figure 2. The behavior of the Constant subscores is presented in Figure 3. No statistically significant difference in the Constant score outcome was found between the groups.

The mean baseline VAS pain score was 3.4 in the SPG and 3.8 in the HEG ($P = .5340$). At 3 months of follow-up, the mean VAS pain score was 1.0 in the SPG and 2.4 in the HEG ($P = .0053$). At 1 year of follow-up, the mean VAS pain score was 0.3 in the SPG and 0.5 in the HEG ($P = .3547$). The behavior of the VAS pain score is presented in Figure 4. A statistically significant difference in the VAS pain score was observed between the groups at 3 months' follow-up but not at baseline or at the 1-year follow-up.

The mean baseline Subjective Shoulder Value (SSV) was 4.6 in the SPG and 4.2 in the HEG ($P = .5810$). At 3 months of follow-up, the mean SSV was 6.8 in the SPG and 6.9 in the HEG ($P = .6870$). At 1 year of follow-up, the mean SSV was 9.0 in the SPG and 8.7 in the HEG ($P = .7070$). The behavior of the SSV is presented in Figure 5. No statistically significant difference in the SSV outcome was found between the groups. Specific values for the Constant score, VAS pain score, and SSV are presented in Table IV.

Discussion

The main finding of this trial was that the SPG was not superior in terms of treatment outcome to the HEG after arthroscopic rotator cuff reconstruction at 1-year follow-up. No statistically significant difference

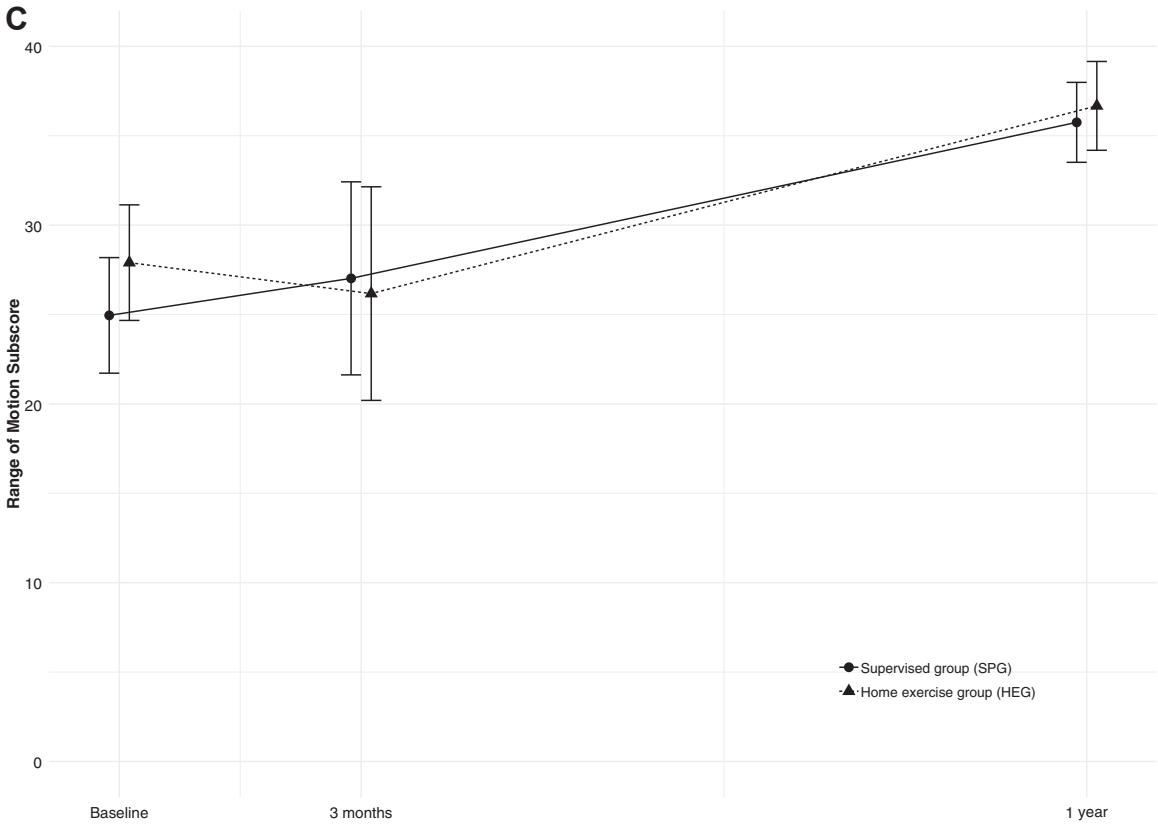

Figure 3 Continued

in the total Constant score was found at any follow-up point.

There is no evidence on the true effectiveness of SP, and it may be that time and the natural healing process itself play substantial roles in recovery. On the other hand, early rehabilitation and range-of-motion exercises are clinically known to be advantageous in reducing pain and stiffness after arthroscopic rotator cuff repair.[2] According to our results, self-administered and monitored home exercises suffice after rotator cuff surgery in most cases and no need for systematic supervision exists. An interesting finding was that at 3 months' follow-up, the mean VAS pain score was statistically higher in the HEG than in the SPG, but the difference was clinically insignificant.[25] It is possible that the supervision, reassurance, and guidance of the physiotherapist may affect the pain sensation of the patient. Nevertheless, it is impossible to determine which part of the SPG constitutes the critical element, and one may argue that this is a placebo effect of the physiotherapy because there were no differences in any of the objective measures.

A recent systematic review has assessed the difference between SP and home exercise after rotator cuff reconstruction.[6] However, the designs of the included studies were not comparable, and hence the evidence was insufficient and inconclusive. The need for postoperative dogmatic SP after rotator cuff reconstruction is indirectly challenged by reports on the nonsignificance of the length of postoperative immobilization or the type of treatment protocol for the treatment outcome.[4,13,18,22,24,26]

The strength of this trial was the prospective randomized controlled setting. According to the power calculation, the results of this trial warrant a conclusion. The primary outcome score, that is, the Constant score, is endorsed by the European Society for Surgery of the Shoulder and the Elbow and is commonly used both in clinical practice and in trial setups.[9,23]

The main limitation of this trial was that because of the trial design, neither the patients nor the outcome assessors were blinded. The beliefs and prejudices of both the patient and the physiotherapist responsible for measurements at follow-up could have been a source of bias.

In addition, the Constant score has some limitations.[28] It lacks persuasive evidence of psychometric properties. There is indeterminate evidence or no information on internal consistency, measurement error, and content, structural, and criterion validity and even negative evidence on hypothesis testing. However, in this trial, the Constant score results were consistent with the secondary outcome measures.

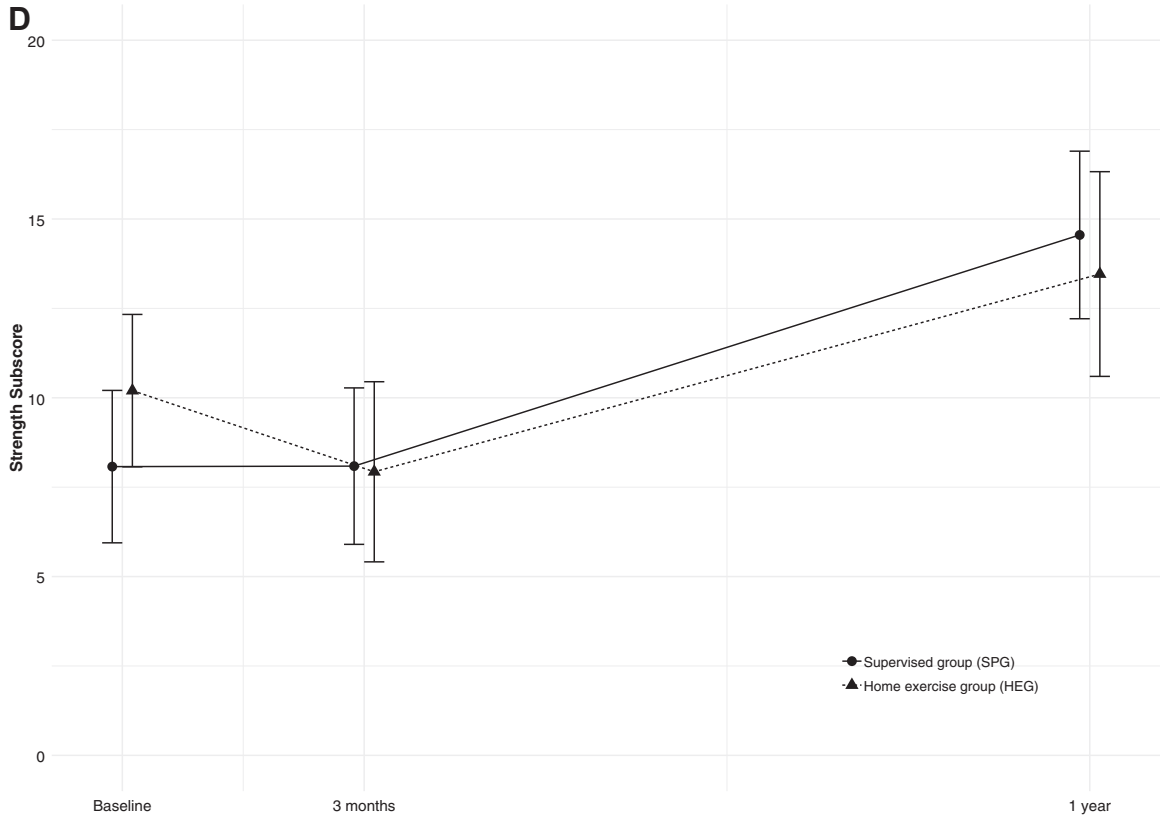

Figure 3 Continued

Furthermore, we did not collect information on the duration of absence from work, use of painkillers, or actual cost of treatment. The potential use of painkillers might have affected the detected slight difference in VAS pain score at 3 months between the groups.

Finally, only 3 patients were administered additional physiotherapy at 3 months after home exercises alone. The documented telephone calls to the physiotherapist indicate that some support and possible counseling are needed for the patients. However, this can be managed primarily without physical attendance. The global economic burden of rotator cuff syndrome is highlighted by the dire lack of evidence on efficacy, effectiveness, and cost-effectiveness of all the administered treatment modalities. Step-wise prioritization is needed to tackle this issue. On the basis of our trial, unnecessary supervision of physiotherapy after rotator cuff surgery can be reduced and these resources allocated to other treatment purposes.

Table II Demographic data and clinical characteristics of participants at baseline

Variable	SPG	HEG	*P* value
Mean age (SD), yr	54 (6.9)	56 (6.2)	.0848
Sex, n (%)			
Male	27 (67)	28 (70)	>.999
Female	13 (33)	12 (30)	>.999
Mean BMI (SD)	26.6 (3.8)	28.7 (4.3)	.0339
Smoking, n (%)	13 (33)	10 (25)	.6213
Working, n (%)	27 (68)	29 (73)	.8073

SPG, supervised physiotherapy group: *HEG*, home exercise group; *SD*, standard deviation; *BMI*, body mass index.

Table III Intraoperative findings and procedures

Variable	SPG	HEG	*P* value
Mean size of SSP tear (SD), mm	12 (7.6)	14 (6.5)	.3870
Biceps tenotomy, n (%)	21 (53)	29 (73)	.4786
Biceps tenodesis, n (%)	5 (13)	2 (5)	.4355
AC resection, n (%)	1 (3)	3 (8)	.6162
Acromioplasty, n (%)	38 (95)	35 (88)	.9267

SPG, supervised physiotherapy group: *HEG*, home exercise group; *SSP*, supraspinatus; *SD*, standard deviation; *AC*, acromioclavicular.

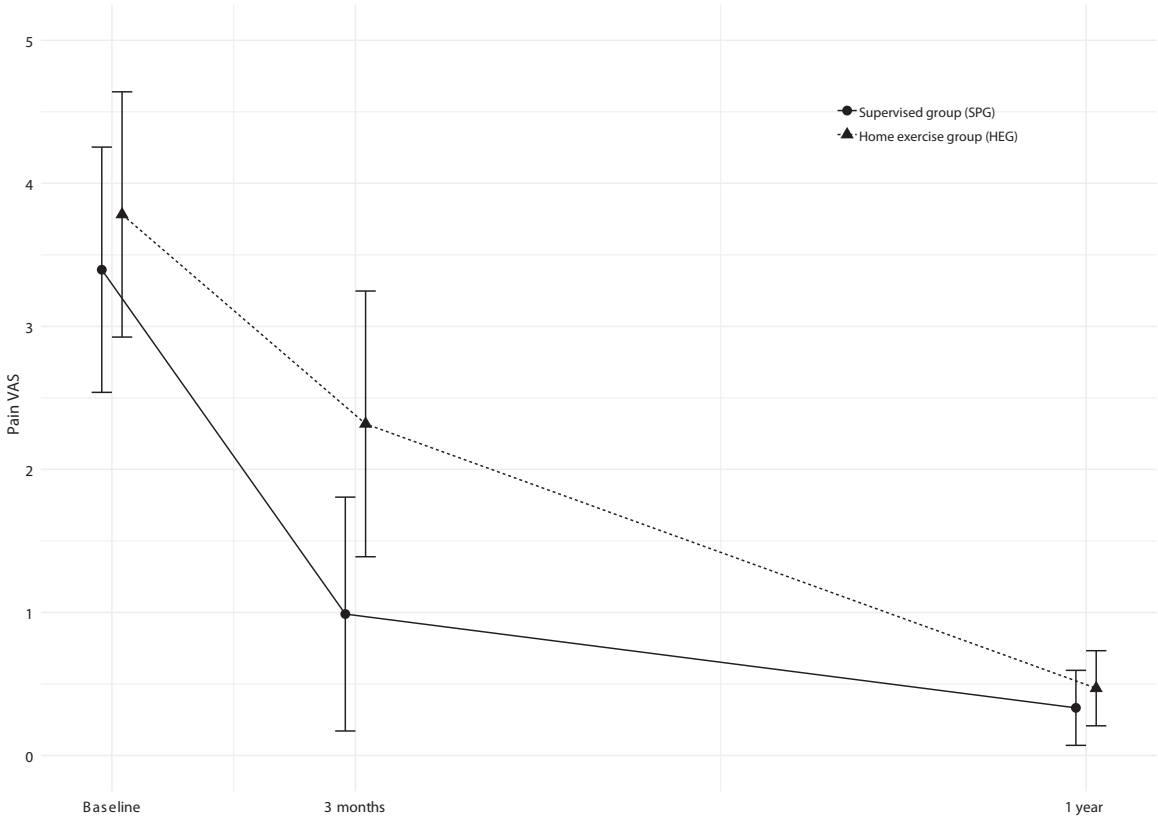

Figure 4 Visual analog scale (*VAS*) pain score during study. *SPG*, supervised physiotherapy group.

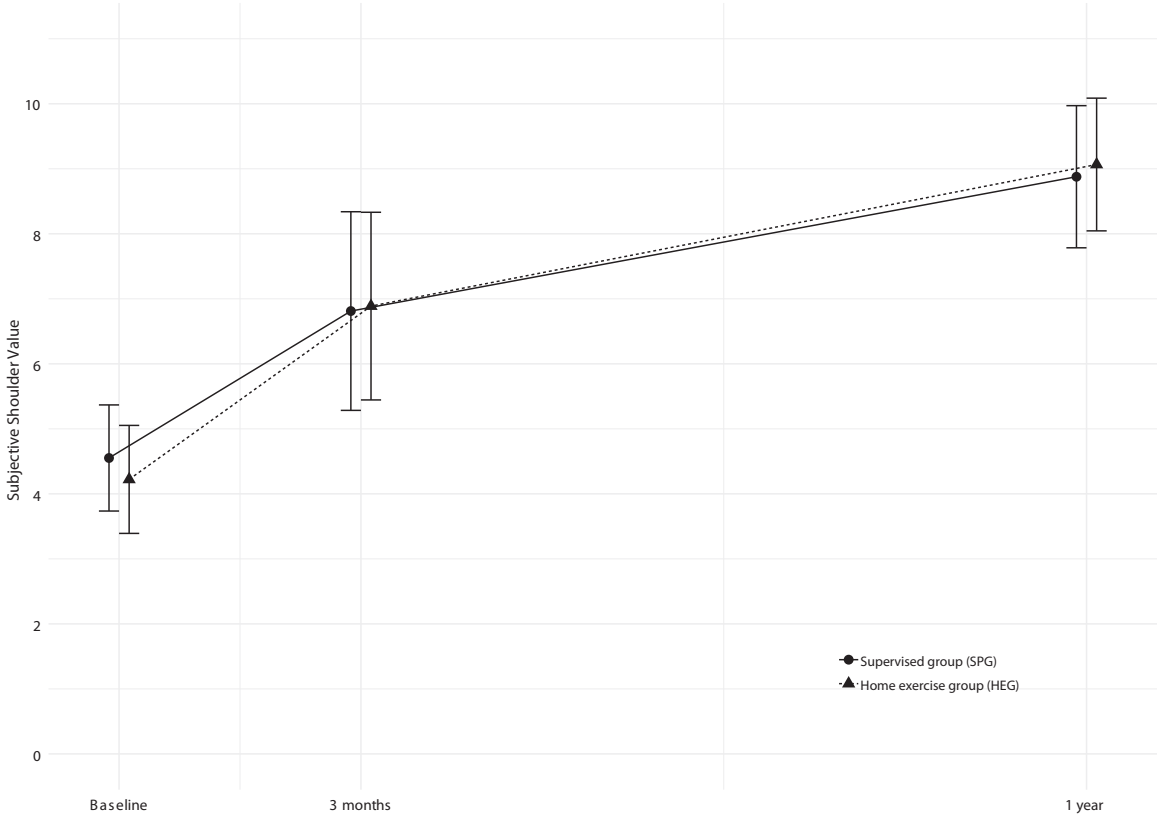

Figure 5 Subjective Shoulder Value during study. *SPG*, supervised physiotherapy group.

Table IV Mean total Constant score, SSV, and VAS pain score results during study

Variable	SPG	HEG	*P* value
Mean total Constant score (SD)			
Baseline	48 (17.5)	54 (17.3)	.1990
3 mo	59 (18.6)	55 (20.3)	.0647
1 yr	83 (9.7)	82(10.5)	.4185
Mean VAS pain score (SD)			
Baseline	3.4 (2.9)	3.8 (2.6)	.5340
3 mo	1.0 (1.3)	2.4 (2.2)	.0053
1 yr	0.3 (0.6)	0.5 (0.5)	.3547
Mean SSV (SD)			
Baseline	4.6 (2.2)	4.2 (1.7)	.5810
3 mo	6.8 (2.3)	6.9 (1.8)	.8670
1 yr	9.0 (1.9)	8.7 (2.0)	.7070

SSV, Subjective Shoulder Value; *VAS*, visual analog scale; *SPG*, supervised physiotherapy group: *HEG*, home exercise group; *SD*, standard deviation.

Conclusion

This study showed that SP after arthroscopic rotator cuff reconstruction did not yield better results than home exercises alone at 1-year follow-up. A statistically significant difference was found only in the VAS pain score at 3 months' follow-up, to the supervised group's advantage.

Disclaimer

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jse.2020.04.034.

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