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Effectiveness of a 12-month home-based exercise program on trunk muscle strength and spine function after lumbar spine fusion surgery. A randomized controlled trial.

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Effectiveness of a 12-month home-based exercise program on trunk muscle strength and spine function after lumbar spine fusion surgery. A randomized controlled trial.

Running head: Effectiveness of 1-year exercise program after LSF

Article category: Research paper

Abstract

The effectiveness of a 12-month home-exercise program on trunk muscle strength after lumbar spine fusion surgery was evaluated.

Three months postoperatively, ninety-eight patients were randomized either to the exercise group (EG), with a progressive 12-month home-based exercise program, or to usual care (UCG), with one guidance session for light home-exercises. Maximal trunk muscle strength was measured by a strain-gauge dynamometer and trunk extensor endurance was measured by Biering-Sørensen's test at baseline and after the intervention.

The mean change in extension strength during the intervention was 75 N in EG and 58 N in UCG. Flexion strength improved 50 N in UCG and 45 N in EG. Trunk extension/flexion strength ratio changed from 0.90 to 1.02 in EG and from 0.98 to 1.00 in UCG. In EG, Biering-Sørensen's test improved by 17 s, and in UCG, it improved by 24 s. No statistically significant between-group differences were found in any variables. Median exercise frequency in EG decreased from 2.5 x/week during the first two intervention months to 1.7 x/week during the last two intervention months.

12-month progressive exercise program was equally effective as usual care in improving trunk muscle strength. Home exercise adherence decreased, which may have influenced the strength changes.

Keywords: lumbar spine fusion; spine surgery; rehabilitation, exercise, muscle strength, physiotherapy; spondylolisthesis

Introduction

Chronic low back pain is a complex problem that causes disability [1] and affects physical activity [2] and many other areas in patients' lives [3], even before lumbar spine fusion (LSF). Therefore, rehabilitation aiming to restore healthy exercise routines, which improve physical functioning, is important after LSF. However, according to a meta-analysis, the evidence of physiotherapy management after LSF is inconclusive and low-quality [4]. Previous literature shows a lack of consensus regarding the type, dose and timing of training after LSF. It is also unclear which activities should be recommended to patients and which activities should be avoided or reduced along the different phases of recovery [5-9].

Since the trunk muscles participate in all bodily movements and in maintaining posture and balance, the trunk muscle strength and endurance performance play an important role in physical functioning. Preoperatively, LSF patients have low trunk muscle strength and stronger trunk flexor muscles than extensor muscles, while in healthy subjects, this strength ratio is the opposite [1, 10-12]. It has also been shown that LSF patients have lower physical functioning one year after surgery than the general population [13]. Most of the previous RCTs regarding rehabilitation have used patient-reported outcomes and compared relatively short supervised exercise programs to exercise programs combined with cognitive intervention [7,9,14,15]. The results of these studies propose that a psychological approach combined with an exercise program is more effective than an exercise program alone [7,9,14]. A real control group, with no treatment or only usual care, is rarely used. Studies evaluating the effectiveness of home-based exercises are also needed, since in practice, they are the most commonly used and most inexpensive rehabilitation method.

The aim of this study was to investigate the effectiveness of a 12-month home-exercise program on trunk muscle strength and spine function after LSF surgery compared to usual care.

Material and Methods

This study is a randomized controlled trial (NCT00834015) reporting secondary outcome measures, trunk muscle strength and spinal range of movement. The primary outcomes were published in 2017 [16]. All adult patients with degenerative or isthmic spondylolisthesis who had undergone lumbar spine fusion in Tampere University Hospital or in Jyväskylä Central Hospital were eligible for this study. Exclusion criteria were severe cardiorespiratory or musculoskeletal disease, severe psychiatric/psychological disorder, extensive lower limb paresis, social reasons (alcohol abuse), and immediate complications after back surgery (infection). The sufficient sample size (80-100 participants) was determined using power calculation for the main outcome measure, pain (visual analogue scale) [17]. Participant recruitment took place from September 2009 to September 2010, it finished when the sufficient sample size was reached.

In total, 104 patients were randomized three months after surgery to the exercise group or to the usual care group at the ratio of 1:1, using the concealed four-block-randomization method compiled by statistician. Patients with isthmic or degenerative spondylolisthesis were randomized using their own separate lists. Six of 104 randomized patients were excluded before the intervention started (1 declined, 2 moved, 2 were scheduled for reoperation, 1 had myocardial infarct). Therefore, the final number of participants was 98, from which 48 were in the exercise group and 50 in the usual care group (figure 1). All patients underwent open approach posterolateral instrumented fusion with or without interbody fusion.

[Figure 1 near here]

Early phase postoperative guidance for all participants

During the first three postoperative months, before the start of the intervention, both groups were treated with an identical protocol. In the first days after LSF, patients were encouraged to perform light walking training and leg muscle stretching, as well as light trunk muscle contraction exercises to relearn a good posture of the upper body. Patients were instructed to avoid continuous sitting for more than 30 minutes at a time during the first 4 weeks. Six weeks after surgery, a physiotherapist updated the home exercise instructions. Patients were instructed to strengthen the abdominal, back and thigh muscles and to stretch their gluteal and hip flexor muscles. In addition, gradual increases in walking time were encouraged. All patients were instructed to avoid extreme flexion and extension of the spine for the first two postoperative months, after which more strenuous physical activities were allowed. Three months postoperatively the fixation and the normal healing process were ensured by radiographs before performing the baseline strength measurements and starting interventions.

Treatment in the usual care group

At the three-month visit to physiotherapy, the usual care group (UCG) received different home exercise instructions than the exercise group (EG) (figure 2). Participants in UCG received one exercise to strengthen the abdominal muscles, two exercises for spine and hip extensor muscles and one strengthening exercise for the lower limbs with no progression. In addition, light stretching, thoracic spine mobility, posture and balance exercises were provided. They were instructed to exercise three times per week at home as well as to increase their daily walking. Pictorial and written information about the exercises was given. UCG had no exercise diary. After this single session guidance, they had no further visits in physiotherapy and no progression for their program.

Intervention in the exercise group

The exercise group (EG) started their progressive 12-month exercise intervention three months postoperatively, when it was considered safe to start intensive home-based training. The timeline and intervention phases are described in figure 2, and the detailed program of the exercise group has been published in the RCT protocol paper [17]. EG had regular individual meetings with a physiotherapist every second month (six meetings in total over 12 months). In those meetings, the experiences of the given exercise program and also possible barriers in performing it were reviewed and discussed using the exercise diaries. The next exercise phase with a suitable progression and possible modifications for the exercises was provided for each participant individually according to the preplanned exercise protocol [17]. In addition, possible barriers for training, such as kinesiophobia, were discussed with the physiotherapist to reduce the irrelevant and harmful beliefs and fears. The physiotherapist encouraged the patients to increase their physical activity level.

The back-specific exercise protocol consisted of exercises in six progressive two-month-phases, aiming to improve the trunk muscle strength and movement control of the lumbar spine. The progression was increased by changing the positions, resistance and functionality of the exercises. For example, at the first phase of the program, the exercises were “low load”-exercises mostly performed in lying position and keeping the lumbar spine in neutral position. In phases four and five to gain higher loading on the trunk muscles during upper limb movements with elastic bands, pelvis was fixed using sitting position. In contrast to that, at the sixth (last) phase of the program, all exercises were performed in standing position, and also spine rotation movements were included to add functionality. It has been confirmed in our earlier studies by EMG that proper trunk muscle activation was gained during strengthening exercises, where the lumbar spine was kept in neutral position while moving upper limbs [18-21]. Exercises were instructed to be performed three times per week at home. The sets and repetitions of the exercises varied from 2 x 10-20 to 4 x 10-20 and the number of exercises was 6-7 in each program phase. Resistance was increased by adding the effect of gravity and increasing the stiffness of the elastic bands. Physiotherapist assessed the suitable resistance individually and the hospital provided the elastic bands for the participants. For the aerobic training, the EG was advised to start regular walks 2-3 times per week from the beginning of the intervention. Four months later, they were instructed to start interval style walking, including four 30 s – 1 minute vigorous bouts with 3 minutes normal speed walking in between each bout. The aim was to progressively increase the total daily step count and the intensity of walking training along the one-year intervention. The use of pedometers as self-monitoring tools and completing the exercise diaries daily also aimed to enhance and to maintain the participants’ motivation and adherence to the exercise program.

[Figure 2 near here]

Blinding

In this study, the assessors were blinded to the treatment. Both study arms had their own physiotherapists to avoid confusion between the two treatment regimens. However, the treating physiotherapists could not be blinded because of the nature of the study.

Outcomes

Measurements were performed at the beginning of the intervention (three months postoperatively) and at the end of the 12-month intervention (figure 2). Maximal isometric trunk extension and flexion strength was measured by a strain-gauge dynamometer and analyzed with a computer program (Isopack, Newtest, Oulu, Finland). The isometric trunk muscle strength tests by strain-gauge dynamometer has been reported to have good reliability [12,22]. The isometric strength test was performed in a standing position, with 20 cm of distance between the feet. The pelvis was fixed against the metal support from below the iliac crest and the harness was placed around the chest right under the armpits. The harness was horizontally attached to the strain-gauge dynamometer with a metal strain. Patients performed two maximal isometric contractions, and if the result improved more than 10%, they were asked to perform the third contraction. The best result was used in the analysis. Absolute strength levels were expressed as Newtons (N). From the extension and flexion strength results, the extension/flexion ratio (E/F-ratio) was calculated, which quantifies the possible imbalance between the extensor and flexor muscle strength. The muscle endurance of the back muscles and muscle fatigability were measured using the Biering-Sörensen's static hold test in the prone position, where the lower body is fixed on the bench and upper body is held in the straight horizontal position as long as possible, max. 240 s [23,24]. The intraclass correlations (ICC) for the reliability of the Biering-Sörensen's test has been reported between 0.83-0.93 in healthy or asymptomatic subjects [24-26], and the critical difference between two measurements has been shown to be 54% in healthy subjects and 57% in low back pain patients [27].

In this study, the term “spine function” comprehends spinal range of movement (ROM) and Timed Up and Go -test (TUG). Active spinal ROM towards flexion was measured by the original 10 cm Schober’s test, first described in 1937 (landmarks in the starting position: lumbosacral junction and 10 cm above it) [28]. The original Schober has acceptable construct validity in inferring the spines’ structural state in the patients with anklylosing spondylitis, which affects the spinal mobility [29]. In addition to the Schober’s test, the fingertip-to-floor distance test was used to measure the functional spine flexion ROM [30]. Lateral bending was assessed by the method described by Frost et al. (1982) [31]. The timed up and go (TUG) test was used to assess strength, agility and dynamic balance during multiple activities including sit-to-stand, walking short distances and changing direction while walking [32]. The TUG-test has high reliability with intra-rater ICC of 0.97 and inter-rater ICC of 0.99, tested in subjects with degenerative disc disease [33], and it is a responsive clinical measurement tool for LSF patients as well [34]. The Visual Analogue Scale was used to measure the intensity of low back pain and leg pain during each strength measurement (0-100 mm) [35]. Pedometers (Omron HJ-113-E, Omron Health Care, UK) were used to measure the daily step counts in EG. Participants in EG kept an exercise diary during the intervention, where they marked down their exercise sessions and the daily step counts extracted from the pedometers. The physiotherapist kept a log (paper form) of possible adverse effects of the exercise intervention. The descriptive information of the participants was collected by questionnaires and from the Spine Database.

Statistics

The data were analyzed using the IBM SPSS Statistics version 24. Results are expressed as the means with standard deviations (SD) or 95 percent confidence intervals (95% CI), median with interquartile range (IQR) or counts with percentages. Comparisons between the groups in sociodemographic and clinical data were made by an independent samples t-test, a bootstrapped-type t-test or the Mann-Whitney U test for continuous variables; McNemar's test or the chi-squared test were used in the case of categorical distributions. The outcomes were analyzed using the intention to treat (ITT) principle. The intervention effectiveness i.e. longitudinal between group difference (group x time interaction) and changes over time within groups in the outcomes were investigated using mixed models with unstructured covariance structure and appropriate contrast. Adjustment for age and sex was used. The mixed model compensates the missing data. Correlation was tested using Pearson's correlation method.

Results

The mean age of the all 98 participants was 59 (range 32-84) years, and 74% were women. The mean (SD) duration of the symptoms before the surgery was 41 (37) months. No differences between the groups were found in sociodemographic or clinical baseline data (Table 1). The mean (SD) low back pain intensity was at baseline 21 (18) mm in EG and 17 (18) in UCG, and the mean (95% CI) changes during the 12-month intervention were -2 (-7 to 4) mm in EG and 4 (1 to 9) mm in UCG (between groups p= 0.16).

[Table 1 near here]

Compliance and feasibility

In the EG (N=48), the median [IQR] frequency of back-specific exercise sessions per week decreased from 2.5 [1.9; 3.4] times per week during the first 2 months to 1.7 [0.6; 1.9] during the last 2 months of the intervention ($p < 0.001$) (figure 3a). The median [IQR] level of the daily steps was 6138 [3759; 8907] during the first 2 months, and 5870 [3587; 8024] steps during the last 2 months of the intervention ($p=0.24$) (figure 3b).

[Figure 3 near here]

Thirty-three participants out of 48 in EG performed the 12-month program without the need to modify the program. In total, 12 EG participants needed individual modifications to the program, which were most often easing the progression or tailoring some specific exercises individually. Overall, seven participants discontinued the exercise program. Four discontinued during or right after the first 2 months, one discontinued after 4 months, one after 6 months and one after 8 months. No one reported discontinuance due to adverse effects caused by exercising. Reasons for discontinuance were: travelling to booster sessions impossible (N=4); deteriorated medical condition (N=1), reoperation and later diagnosed with myopathy leading to progressive muscle weakness (N=1); and death (myocardial infarction) (N=1). All 48 EG participants were included in the analysis of outcomes.

Trunk muscle strength and spine function

There were no significant differences between the groups in the changes in any of the trunk muscle strength measures during the 12-month intervention (Table 2). However, both groups improved their maximal extension and flexion strength significantly. In the extension / flexion strength ratio improvement was found only in EG (figure 4). There was no correlation between the number of completed training sessions and changes in trunk extension or flexion strength (both r=0.07).

[Figure 4 near here]

In active spine ROM measurements, no significant differences between the groups were found. Schober’s test, Fingertip-to-floor distance and lateral flexion tests improved in both groups. The timed up and go test remained unchanged in both groups during the intervention (Table 2).

[Table 2 near here]

Discussion

The present randomized controlled trial showed that the home-based 12-month progressive exercise program after LSF was as effective as usual care in improving trunk muscle strength and spine function. The maximal trunk muscle strength and trunk extensor endurance improved significantly in both groups, but they still remained at low levels after the intervention. The extension/flexion strength ratio improved in the exercise group only, although no between group difference was found.

The back-specific exercise program of this study started three months postoperatively when the most critical postoperative healing process was over and the recovery had proceeded normally according to radiograph check-up. The exercise program was targeted to improve lumbar spine movement control and to increase muscle strength and endurance [17].

It was developed based on our previous studies, using EMG testing in LSF patients, to find the best exercises to activate the trunk musculature through the limb movements, while keeping the lumbar spine in the neutral position [18-21]. The results showed that both the exercise group and usual care group improved their extension strength levels significantly. EG increased their maximal extension strength by 28% and UCG by 19% during the 12-month intervention. In both groups, low back pain intensity was low at the beginning of the intervention. The smallest clinically important change for low back pain has been reported 2.5 in 0-10 the numeral rating scale (NRS) [36], which corresponds roughly 25 mm in the VAS scale. In the present study, the pain did not change during the intervention (back pain VAS -2 mm in EG and 4 mm in UCG). Low back pain and leg pain intensities during the tests were minimal; therefore, the pain did not interfere the performance significantly. In the previous nonrandomized controlled trial by Lee et al. (2017), in which the three-month supervised intervention was also started three months postoperatively [37], the exercise group showed even the 64% increase in extension strength, while the control group improved 22% after three months of training [37]. However, in that study, the patients used rigid lumbosacral orthosis for the first three postoperative months [38]. Therefore, an immobilization-induced strength deficit at the beginning of the exercise intervention may have resulted in larger strength improvements in both groups. In our study, the early postoperative treatment was more activating: patients were encouraged to gradually increase their activity level, and no orthosis was used postoperatively. In the study by Lee et al., the patients were allowed to use full spine range of movement in training [38], while in the present study, special attention was paid to not overload the fused area; therefore, the home-based training program consisted of exercises that allowed the lumbar spine to be kept in a neutral position.

Despite the significant changes in maximal strength, the strength levels remained low still after the 12-month intervention [10-12]. The extension and flexion strengths at the baseline of the present study were only half of the previously reported 629 (SD 233) and 564 (235) N levels, which were measured with the same device in healthy subjects [11]. In a heathy population, the trunk extension strength is approximately 30% greater than flexion strength [10-12]. In the present study, the trunk extensors were approximately ten percent weaker than flexors at baseline, i.e., the E/F ratio was remarkably imbalanced due to the extension strength deficit. During the intervention, the patients in the EG improved their E/F ratio significantly, while UCG did not. Nevertheless, the difference between the groups was not significant. Our results support the previous findings in which trunk extensor muscles were weaker than flexor muscles before the surgery [1]. The most likely reason is that longstanding low back pain has caused decreased activation of paraspinal muscles [39], which together with fusion surgery, result in paraspinal muscle atrophy [40].

In addition to the maximal isometric tests, the Biering-Sörensen's extensor endurance test was used to capture the muscle function more comprehensibly. In line with the results of our maximal strength tests, the results of the Biering-Sörensen's test were quite low at baseline but improved during the intervention to 56 s in EG s and 74 s in UCG. These results are in line with the findings of Keller et al., who reported a mean of 48 s one year after LSF [41]. Both groups reached roughly half of the healthy adults' result of 133 s [42]. However, the reliability of the Biering-Sörensen's test has been controversial in different studies [23-27]. The minimum critical difference between two measurements of 57% has been reported [27]. In the present study, the magnitude of the change in Biering-Sörensen's test was 40 %

in both groups, which is still within the measurement error. Therefore, regardless of the statistically significant improvements, the Biering-Sörensen's test results should be viewed with caution. We used the Timed Up and Go –test (TUG) to measure lower limb strength, agility and dynamic balance, which can be affected because of prolonged low back pain and lumbar fusion surgery. TUG test is commonly used in people with musculoskeletal problems [43]. The previously reported mean (SD) TUG result in healthy adults was 8.1 (1.7) s [44]. The minimum clinically important difference of 1.3 s in TUG after LSF has been reported [34], and the cut-off-point of 12 s for functional impairment [33]. In the present study, the baseline results of both groups were already very close to the values of the healthy subjects (mean 9.1 in EG and 7.2 in UCG), and the observed changes during the intervention were marginal (0.9 in EG and 0.3 in UCG) and clinically insignificant.

The exercise program was safe because no one reported adverse effects due to exercise. One patient in EG was advised to discontinue exercise due to problems with fixation. This patient was later reoperated and diagnosed as having myopathy, inducing progressive muscle weakness. The challenge of committing the participants to a long-lasting 12-month home exercise program was considered as much as possible. In addition to the individually instructed training program, exercise diaries (monitoring) and regular booster sessions with encouragement were used to improve the motivation to commit to the program. Despite the provided support, the adherence to home-based exercise decreased during the intervention and was too low at the end of the intervention to gain larger strength improvements, since twice a week is a minimum for improvements [45]. In this study, the mean age was 59, and the sample included very old adults (age range 32-84 years) meaning in practice that maintaining muscle strength levels, instead of large improvements, may be realistic to expect.

There is some evidence that the supervision of health care professionals improves exercise adherence [46], and therefore, it is possible that closer supervision with more frequent meetings with the patients would have increased adherence. Recent studies in other diseases support this idea, showing that exercise therapy needs to be tailored more individually to the symptoms of the patients and their comorbidities to improve adherence [47,48]. However, in this study, the goal was particularly to offer a low-cost program that is achievable for those who live in sparsely populated areas and cannot travel to training sessions from home because of long distances. In this study, the six physiotherapy meetings for progressive home-based training versus single session guidance for light home exercises with no progression were shown to be equally effective on spine function outcomes. To use health care resources wisely, it is important to direct the intensive support to those patients who have delay or other challenges in the recovery, while some patients recover well with lighter guidance.

The strength of this study was the carefully planned RCT setting, which was conducted according to the Consort Statement guidelines. Randomization was concealed and assessors were blinded to the treatment to reduce the risk of bias. The sample of this study represents the real clinical setting, including the vast age range and patients with comorbidities and different levels of physical functioning. The limitation of this study is that we did not control the physical training of the usual care group. They may have exercised, as well, narrowing the between-group differences. In addition, the present exercise frequencies were low, and this has to be factored in when generalizing the effectiveness of training. The program may have been effective, physically, but keeping up the adherence (motivation) should be invested in even more by conducting the midpoint measurements or other clinical measurement check-ups specifically for motivation with the physiotherapist. In addition, using physical performance measurements in back pain patients is challenging. We cannot exclude completely the possibility that fear of movement or fear of pain may have affected some of the strength test results, although pain intensity remained at low levels during measurements.

In conclusion, one-year home-based back-specific exercise combined with walking seems to be equally effective as usual care in improving trunk muscle strength in lumbar spine fusion patients. Home exercise adherence was low, which may have an influence on the strength changes. More research is needed to find effective and motivating rehabilitation protocols to normalize back function after lumbar fusion surgery.

Declaration of Interest

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Table 1. Sociodemographic and clinical data of the participants.

	EG N=48	**UCG N=50**	**P-value between groups**
Women, n (%)	34 (71)	38 (76)	0.56
Age, years, mean (SD)	59 (12)	58 (12)	0.59
Body mass index, mean (SD)	28.3 (4,8)	28.3 (4.8)	0.99
Smokers, n (%)	9 (19)	6 (12)	0.58
Length of education, years, mean (SD)	12.0 (3.7)	12.6 (3.6)	0.41
Work status, n (%):			0.27
Working	17 (35)	12 (24)	
Temporarily not working	10 (21)	17 (34)	
Retired	21 (44)	21 (42)	
Primary diagnosis n (%):			0.72
Degenerative spondylolisthesis	32 (67)	35 (70)	
Isthmic spondylolisthesis	16 (33)	15 (30)	
Duration of current symptoms before surgery, months, mean (SD)	41 (37)	40 (36)	0.80
Leisure time physical activity, min/week, median (IQR)	300 (180, 450)	360 (2010, 505)	0.14
Self-reported comorbidities, n (%):			
Blood pressure	24 (51)	25 (51)	0.99
Diabetes	3 (6)	6 (12)	0.49
Other musculoskeletal disorders	4 (9)	13 (27)	0.03
Neurological disorders	2 (4)	1 (2)	0.61
Mental health disorders	2 (4)	1 (2)	0.61
Pulmonary disorders	4 (9)	6 (12)	0.74
Cardiovascular disorders	3 (6)	5 (10)	0.71

EG=exercise group, UCG=usual care group, SD=standard deviation, IQR=interquartile range

Table 2. Baseline scores and changes in the strength and performance measurements during the intervention, reported as the means with 95 percent confidence intervals (95% CI) based on mixed model estimates. Between-group p-values are adjusted by age and sex.

	Baseline (3 months after LSF)		At the end of 12 month intervention (15 months after LSF)		Change during the 12-month intervention		P-value between the groups
	EG Mean (95% CI)	UCG Mean (95% CI)	EG Mean (95% CI)	UCG Mean (95% CI)	EG Mean (95% CI)	UCG Mean (95% CI)	
Strength measurements:							
Extension (Newtons)	269 (233 to 304)	301 (265 to 336)	341 (302 to 379)	359 (317 to 400)	75 (53 to 96)*	58 (37 to 79)*	0.29
Flexion (Newtons)	301 (263 to 338)	324 (287 to 360)	348 (306 to 390)	368 (324 to 412)	50 (30 to 71)*	45 (25 to 64)*	0.72
Extension/BW	0.35 (0.31 to 0.40)	0.40 (0.36 to 0.45)	0.45 (0.39 to 0.50)	0.49 (0.43 to 0.54)	0.10 (0.07 to 0.12)*	0.08 (0.06 to 0.11)*	0.50
Flexion/BW	0.39 (0.35 to 0.43)	0.43 (0.39 to 3.47)	0.45 (0.40 to 0.50)	0.50 (0.44 to 0.55)	0.06 (0.04 to 0.09)*	0.07 (0.04 to 0.09)*	0.81
Extension/Flexion ratio	0.90 (0.82 to 0.99)	0.98 (0.90 to 1.07)	1.02 (0.93 to 1.1)	1.00 (0.93 to 1.07)	0.11 (0.05 to 0.17)*	0.02 (-0.04 to 0.08)	0.052
Biering-Sörensen, s	40 (26 to 54)	53 (40 to 67)	56 (40 to 72)	74 (55 to 97)	17 (4 to 29)*	24 (12 to 36)*	0.44
Pain intensity during strength measurement (VAS 0-100 mm):							
LBP during EXT	13 (7 to 18)	12 (7 to 17)	10 (4 to 16)	10 (5 to 14)	-2 (-7 to 2)	-2 (-7 to 2)	0.96
LBP during FLX	9 (4 to 13)	9 (4 to 13)	8 (3 to 13)	6 (2 to 9)	-1 (-8 to 1)	-3 (-8 to 1)	0.52
Leg pain during EXT	6 (3 to 10)	3 (-1 to 6)	8 (3 to 13)	4 (1 to 7)	2 (-3 to 6)	1 (-3 to 6)	0.96
Leg pain during FLX	5 (2 to 9)	3 (-1 to 7)	7 (2 to 12)	2 (1 to 4)	2 (-3 to 6)	-1 (-5 to 4)	0.53
Schober, cm	3.4 (3.1 to 3.7)	3.1 (2.8 to 3.5)	4.2 (3.8 to 4.6)	1.1 (33.7 to 4.4)	0.9 (0.6 to 1.1)*	0.9 (0.7 to 1.2)*	0.70
Finger-tip to floor distance, cm	13.4 (10.1 to 16.9)	13.7 (10.3 to 17.4)	7.2 (4.0 to 10.3)	7.7 (5.1 to 10.4)	-6,5 (-9.1 to -3.9)*	-5.8 (-8.6 to -3.1)*	0.90
Lateral flexion ROM, (mean cm of left and right)	12.9 (11.8 to 14.1)	14.5 (13,4 to 15.7)	14.2 (13.0 to 15.5)	15.4 (14.3 to 16.7)	1.3 (0.5 to 2.1)*	0.9 (0.2 to 1.7)*	0.52
Timed Up and Go -test, s	9.1 (7.6 to 10.6)	7.2 (5.2 to 8.7)	8.2 (5.7 to 10.6)	6.9 (6.1 to 7.8)	-0.9 (-2.0 to 0.1)	-0.3 (-1.3 to 0.8)	0.39

* indicates statistically significant within group change. Abbreviations: EG=Exercise group, UG=Usual care group, 95% CI= 95% Confidence interval, BW= Body weight, s= Second, LBP=Low back pain, EXT= Trunk extension, FLX= Trunk flexion, ROM= Range of motion

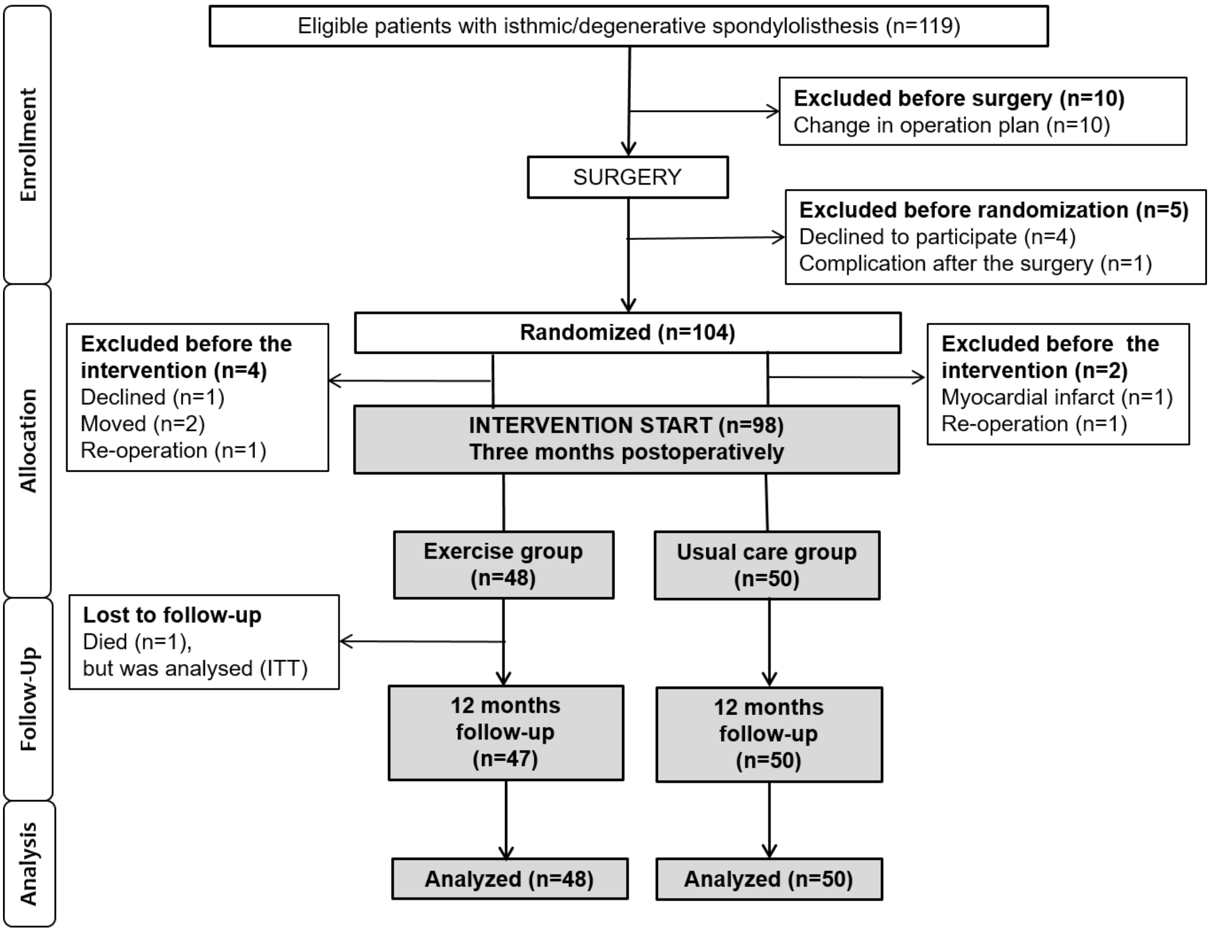

Figure 1. Consort diagram of the participant flow.

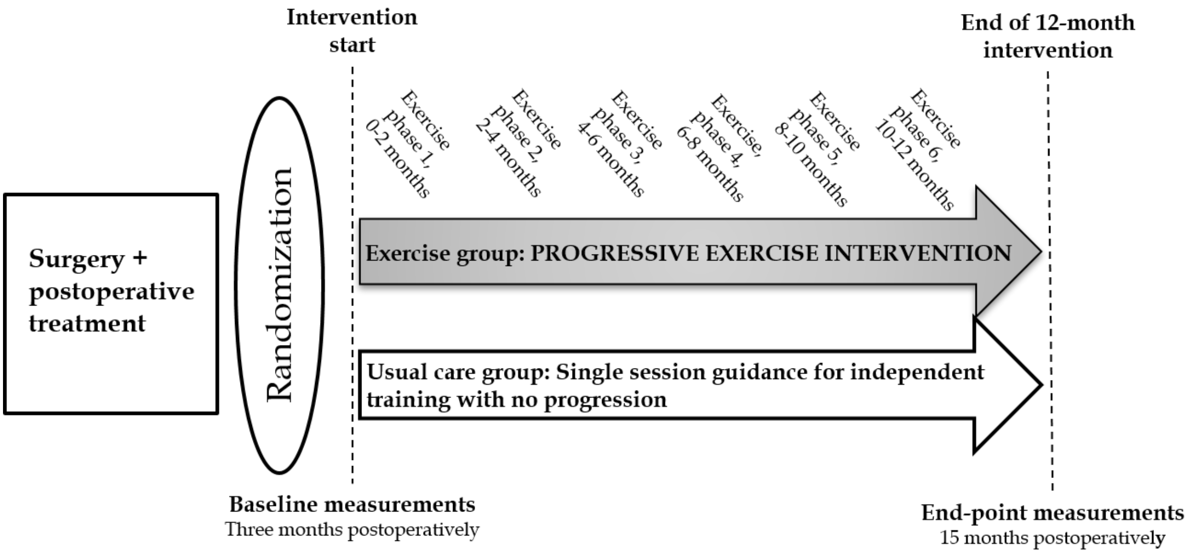

Figure 2. The study timeline.

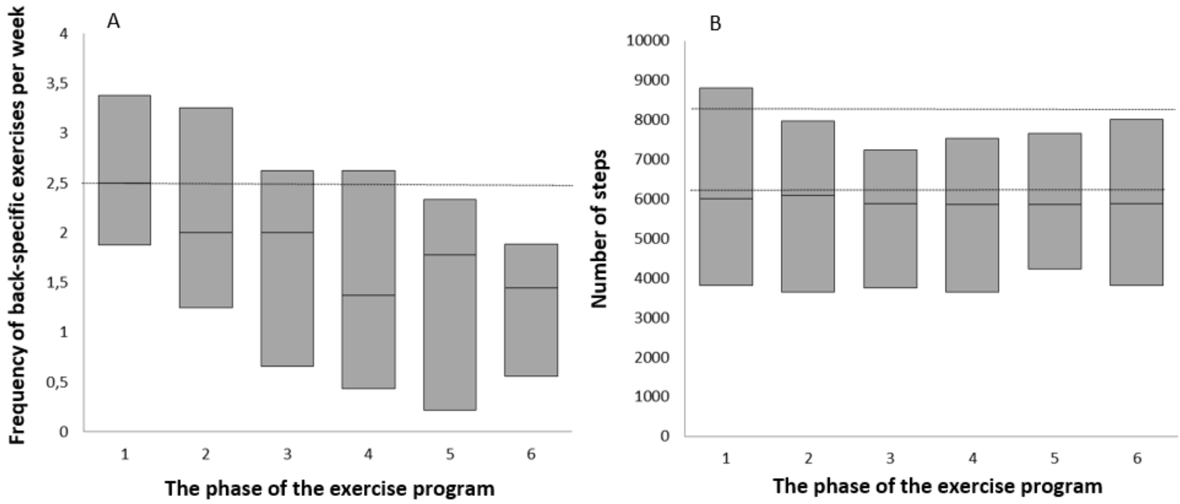

Figure 3. Compliance of the exercise group to 12-month back-specific training during the 2-month phases of the program (3a) and walking training (3b) using nonimputed data.

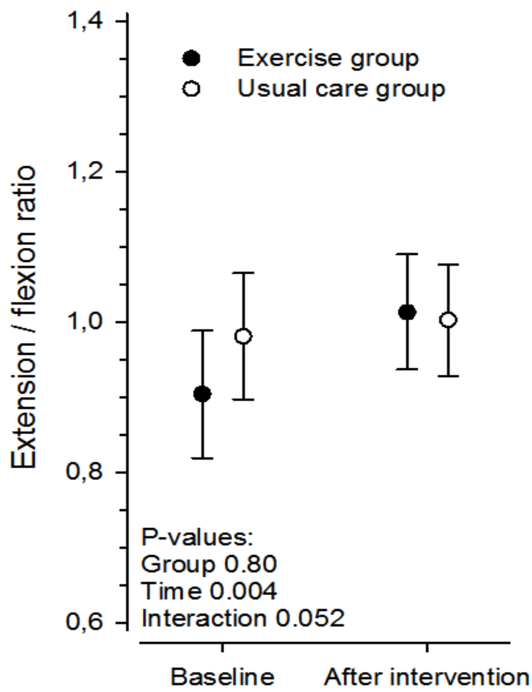

Figure 4. Changes in the trunk extension/flexion strength ratio.