JYU DISSERTATIONS 258

Outi Ilves

Rehabilitation after Lumbar Spine Fusion

The Effectiveness of a 12-Month Home-Exercise Program

UNIVERSITY OF JYVÄSKYLÄ
FACULTY OF SPORT AND HEALTH SCIENCES

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To Lassi and Nelli with love.

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ABSTRACT

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The aim of this thesis was to study the recovery of trunk muscle strength and spine function after lumbar spine fusion surgery (LSF) and standard care, and to evaluate the effectiveness of a 12-month home-exercise program in the postoperative rehabilitation after LSF. Recovery was studied in a one-year prospective cohort study in consecutive patients undergoing non-urgent LSF (N=194, 66% women, mean age 61 years). The effectiveness of rehabilitation was studied in a randomized controlled trial of 98 patients with spondylolisthesis (75% women, mean age 59 years) who were allocated three months after LSF to the exercise group (EG) or to the usual care group (UCG). The EG underwent a 12-month training that consisted of back-specific and aerobic training including six booster sessions with a physiotherapist. The UCG underwent one guided session for light home exercises. The outcomes were isometric maximal strength of abdominal and back muscles, back muscle endurance, the Oswestry Disability Index, the Visual Analogue Scale for low back and leg pain intensities the RAND-36 for health-related quality of life, the Tampa Scale for Kinesiophobia and the International Physical Activity Questionnaire. Although some improvement occurred in the one-year prospective follow-up from preoperative level, the trunk muscle strength remained low and the trunk extension and flexion strength ratio imbalanced. After a one-year rehabilitation, no between-group differences were found in any outcomes. Both groups improved their trunk muscle strength, disability and physical functioning-related dimensions of health-related quality of life and increased their physical activity. The low back and leg pain intensities as well as degree of kinesiophobia were low three months after surgery, and they remained rather unchanged during the intervention. In conclusion, LSF patients had trunk muscle strength deficits and imbalance preoperatively and at one year of follow-up after surgery with standard care. The postoperative 12-month home-exercise after LSF did not bring significant additional benefits compared to usual care. Further, individual variation in all outcomes were large in both groups. Thus, it is important to find those patients with delayed recovery who need more individualized rehabilitation.

Keywords: rehabilitation, lumbar spine fusion, trunk muscle strength, pain, disability, health-related quality of life, physical activity

TIIVISTELMÄ (FINNISH ABSTRACT)

Ilves, Outi
Kuntoutus alaselän jäykistysleikkauksen jälkeen - 12 kuukauden kotiharjoittelun vaikuttavuus
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Tämä väitöskirjatutkimus selvitti vartalon lihasvoimaa alaselän jäykistysleikkauspotilailla sekä leikkauksen jälkeisen vuoden kotiharjoittelun vaikuttavuutta. Vartalon lihasvoimien muutosta tutkittiin prospektiivisessa kohorttitutkimuksessa (N=194, 66% naisia, keskiarvoikä 61 vuotta), jossa mittaukset suoritettiin ennen leikkausta sekä vuosi leikkauksen ja tavanomaisen hoidon jälkeen. Satunnaistetussa kontrolloidussa tutkimuksessa puolestaan verrattiin 12 kk kotiharjoittelua tavanomaiseen hoitoon. Tutkimusjoukko (N=98, 75% naisia, keskiarvoikä 59 vuotta) koostui alaselän jäykistysleikkauspotilaista, joilla oli nikamaliukuma. Kolme kuukautta leikkauksen jälkeen osallistujat satunnaisestettiin harjoittelu- ja kontrolliryhmään. Harjoitteluryhmä toteutti nousujohteista selkäspesifiä vartalon lihasten harjoittelua sekä aerobista kävelyharjoittelua. Heillä oli kuusi ohjauskäyntiä fysioterapiassa. Kontrolliryhmä sai kertaohjauksen omatoimiseen harjoitteluun. Tulosmuuttujina oli vatsa- ja selkälihasten isometrinen maksimivoima, selän lihaskestävyys, Oswestryn oire- ja haittakysely, selkä- ja alaraajakipu, RAND-36-elämänlaatukysely, Tampa Scale for Kinesiophobia -kysely liikkumisen pelosta sekä IPAQ -kysely fyysisestä aktiivisuudesta. Prospektiivisessa kohorttitutkimuksessa havaittiin heikentynyt vartalon lihasvoimataso vielä vuosi leikkauksen jälkeen. Ennen leikkausta havaittu vartalon ojentajalihasten heikkous suhteessa vartalon koukistajiin ei palautunut. Harjoittelututkimuksessa ryhmien välillä ei havaittu merkitseviä eroja missään tulosmuuttujissa. Molemmilla ryhmillä keskimääräiset vartalon lihasvoimat, koetut oireet sekä haitta, fyysiseen toimintakykyyn liittyvät elämänlaadun osa-alueet ja fyysisen aktiivisuuden määrä paranivat. Selän ojentaja- ja koukistajalihasten voimasuhde parani vain harjoitteluryhmällä. Tuloksissa oli suurta vaihtelua yksilöiden välillä. Kipu ja liikkumisen pelko olivat vähäiset jo intervention alkaessa, eivätkä muuttuneet intervention aikana. Johtopäätöksenä, alaselän jäykistysleikkauspotilailla oli heikko vartalon lihasvoima leikkausta edeltävästi ja vuosi leikkauksen jälkeen. Leikkauksen jälkeinen vuoden nousujohteinen kotiharjoittelu säännöllisin fysioterapiaseurannoin oli yhtä vaikuttavaa kuin tavanomainen hoito. Kuntoutus tulisi räätälöidä yksilöllisesti ja kohdistaa niille, joiden toipumisessa on haasteita.

Avainsanat: kuntoutus, alaselän jäykistysleikkaus, vartalon lihasvoima, kipu, toimintakyky, elämänlaatu, fyysinen aktiivisuus

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Muurame, June 2020

Outi Ilves

FIGURES

TABLES

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by their Roman numerals:

I Ilves O, Neva MH, Häkkinen K, Dekker J, Kraemer WJ, Tarnanen S, Kyrölä K, Ylinen J, Piitulainen K, Järvenpää S, Kaistila T, Häkkinen A. 2019. Trunk Muscle Strength after Lumbar Spine Fusion. A 12-Month Follow-Up. Neurospine vol 16, 332-338. DOI:10.14245/ns.1836136.068.

II Ilves O, Neva MH, Häkkinen K, Dekker J, Kyrölä K, Järvenpää S, Häkkinen A. 2020. 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. Disability and Rehabilitation. Online ahead of print. DOI: 10.1080/09638288.2020.1772383.

III Ilves O, Häkkinen A, Dekker J, Pekkanen L, Piitulainen K, Järvenpää S, Marttinen I, Vihtonen K, Neva MH. 2017. Quality of Life and Disability: Can They be Improved by Active Postoperative Rehabilitation after Spinal Fusion Surgery in Patients with Spondylolisthesis? A Randomised Controlled Trial with 12-Month Follow-Up. European Spine Journal vol 26, 777-784. DOI: 10.1007/s00586-016-4789-5.

IV Ilves O, Häkkinen A, Dekker J, Wahlman M, Tarnanen S, Pekkanen L, Kautiainen H, Neva MH. 2017. Effectiveness of Postoperative Home-exercise Compared with Usual Care on Kinesiophobia and Physical Activity in Spondylolisthesis: A Randomized Controlled Trial. Journal of Rehabilitation Medicine vol 49, 751-757. DOI: 10.2340/16501977-2268.

The author was privileged to use preexisting data from the Spine Database in study I. The data from the Spinal Fusion and Rehabilitation Study (NCT00834015), a randomized controlled trial, was used in studies II-IV. The author assisted in data collection and data management in studies III and IV and analyzed all data in co-operation with the biostatistician. The author wrote the first drafts of the original papers and took into account the comments from all the co-authors.

ABBREVIATIONS

BMI	Body mass index
CI	Confidence interval
CBT	Cognitive behavioral therapy
CONSORT	Consolidated Standards of Reporting Trials
CT	Clinical trial
EG	Exercise group
HRQoL	Health-related quality of life
IPAQ	International physical activity questionnaire
IQR	Interquartile range
ITT	Intention-to-treat principle in data analysis
kg	Kilogram
LBP	Low back pain
LSF	Lumbar spine fusion
LTPA	Leisure-time physical activity
Md	Median
METmins/week	A Score of total metabolic equivalent minutes per week
min	Minute
N	Newton
N	Number of participants
n	Number of participants (in subgroups of N)
ODI	Oswestry Disability Index
PA	Physical activity
PROs	Patient-reported outcomes
PT	Physiotherapist
RCT	Randomized controlled trial
ROM	Range of movement
RAND-36	The RAND 36-item health survey
s	Second
SD	Standard deviation
TSK	Tampa Scale for Kinesiophobia
TUG	Timed Up-and-Go –test
UCG	Usual care group
VAS	Visual analogue scale, a measure of pain intensity
wk	Week
y	Year

CONTENTS

1 INTRODUCTION

Low back pain (LBP) has been recognized as the world's leading cause of long-term disability (Vos et al. 2012, Buchbinder et al. 2018). Globally, the mean overall prevalence of LBP is 31%, and the prevalence is highest among 40-80 year-old females (Hoy et al. 2012). In addition, the recurrence rates of LBP are also high, and most patients develop a chronic-episodic disease course, which causes a high burden for society (Hoy et al. 2010). Over the coming decades, the absolute number of people suffering from low back pain is likely to increase in the aging population (Hoy et al. 2010). Therefore, there is a need to develop effective, evidence-based treatment practices.

The vast majority (90-95%) of LBP patients have *non-specific LBP*, which means that they do not have any severe or specific cause of pain (Traeger et al. 2017). Of all LBP cases in primary care, only 5-10% of patients have *specific LBP*, and only 1% have a *serious spine disorder* (Traeger et al. 2017). The classification is important in choosing a suitable treatment.

Conservative treatment for LBP includes pain management and active rehabilitation (Oliveira et al. 2018). Therapeutic exercise is often recommended, and multidisciplinary rehabilitation is also sometimes recommended (Oliveira et al. 2018). Rehabilitation can vary based on patients' needs from including an instructional physiotherapy session mainly targeting physical activities and self-management of LBP to therapeutic exercise or psychologically informed physiotherapy (Hill et al. 2011). However, if conservative treatment including active rehabilitation has not significantly improved the patient's condition, spine surgery may be considered (Oliveira et al. 2018).

Lumbar spine fusion (LSF) surgery is used to stabilize painful spine segments or to prevent instability after decompression surgery (Ekman, Möller & Hedlund 2005, Weinstein et al. 2007). The rates of LSF have been increasing during the last decades (Deyo et al. 2005, Maghout-Juratli et al. 2006). The most common indications for LSF are degenerative spondylolisthesis and isthmic spondylolisthesis, wherein LSF is effective at two to four-year follow-ups (Ekman, Möller & Hedlund 2005, Weinstein et al. 2007, Weinstein et al. 2009, Martin et al. 2019).

Patients undergoing elective LSF have a background of chronic low back pain, and they present preoperatively with a remarkable disability (Pekkanen et al. 2013) and low physical activity levels (Lotzke et al. 2018). They also have decreased trunk muscle strength preoperatively and three months after LSF (Tarnanen et al. 2013). The weakened muscle strength is probably at least partly induced by the diminished physical activity because of the pain. Prolonged LBP itself also inhibits the activation of paraspinal muscles (van Dieën, Selen & Cholewicki 2003) and induces muscle atrophy in the multifidus muscles (Danneels et al. 2000). During open posterior LSF, the paraspinal muscles are detached from the spine and retracted. This iatrogenic muscle trauma complicates the recovery of trunk muscle strength and functioning, together with the background of chronic low back pain. Considering these longstanding challenges of pain, disability, low physical activity and trunk muscle strength, these patients have increased risk for developing new inactivity-induced health problems (Haskell et al. 2007). Therefore, there is a need for evidence-based activating rehabilitation programs for postoperative LSF rehabilitation.

2 REVIEW OF THE LITERATURE

2.1 Low back pain classification and management

Low back pain can be classified based on the time course of the symptoms as acute (<6 weeks), subacute (6-12 week), or chronic (more than 12 weeks). In addition, lumbar spine disorders are divided into three other categories based on symptoms and their severity, in a diagnostic triage process (Traeger et al. 2017). The triage process aims to identify LBP patients with *non-specific LBP*, patients with a *serious spine disorder* who need a rapid approach, and those with a *specific spine disorder* without serious pathology.

Of all LPB cases, non-specific LBP is the most common condition, covering 90-95% of all LBP cases in primary care (Traeger et al. 2017). It has been shown that some psychosocial factors, such as depression, stress, passive coping and fear-avoidance behaviors, may inhibit the recovery of nonspecific low back pain and induce pain chronicity (Leeuw et al. 2007, Ramond et al. 2011).

Serious spine disorders cover less than 1% of all primary care LBP cases. Serious spine disorders include fracture, metastatic disease, spinal infection, axial spondyloarthritis and cauda equina syndrome or signs of lower motor neuron weakness (Traeger et al. 2017).

Of all LBP patients, 5 to 10% end up in the specific LBP group, and patients in this group have radicular pain or neurogenic claudication (Traeger et al. 2017). In specific chronic LBP, the radiological findings are logically associated with the symptoms (O'Sullivan et al. 2014). The background for these symptoms is usually lateral spinal canal stenosis, central stenosis, disc prolapse or spondylolisthesis.

For nonspecific and specific LBP, the primary treatment is conservative, while serious spine disorders need a rapid approach (Alrwaily et al. 2016). The conservative treatment of LBP includes pain management, therapeutic exercise, patient education, cognitive behavioral therapy or other psychosocial therapy interventions (Fersum et al. 2010, Hill et al. 2011, Fersum et al. 2013, Oliveira et al. 2018). It is important to avoid inducing catastrophic thinking and to emphasize

the structural strength of the human spine in a manner that helps the patient understand the pain mechanisms (Delitto et al. 2012). Also informing patients about the favorable prognosis of low back pain and encouraging them to return early to their normal activities even if the pain is still present, is considered important (Delitto et al. 2012).

Exercising prevents recurrence of low back pain episodes (Choi et al. 2010). According to a systematic review and meta-analysis, therapeutic exercise improves physical functioning in chronic LBP (van Middelkoop et al. 2010). However, it is unclear which specific exercise program is the best (van Middelkoop et al. 2010, Oliveira et al. 2018). Delitto et al. (2012) have suggested that patients with chronic nonspecific LBP without generalized pain should perform training at moderate to high intensities. For those with generalized pain, progressive endurance and submaximal-fitness activities should be considered for pain management along with health promotion strategies (Delitto et al. 2012). Using pathoanatomic classification or psychosocial risk profiling, for example Keele STarT Back Screening Tool (Hill et al. 2011), and then providing stratified physiotherapy based on individual needs has shown that the results of the rehabilitation may be better than in standard physiotherapy without classification in nonspecific chronic LBP (Hill et al. 2011, Fersum et al. 2013).

In addition, use of analgesic medication is recommended as part of the conservative management for LBP (Oliveira et al. 2018). Paracetamol has been the first option for acute nonspecific LBP; however, it does not improve the recovery time (Williams et al. 2014). In a recent systematic review, it was noticed that some national guidelines recommend nonsteroidal anti-inflammatory drugs (NSAID) as the first analgesic medication option instead of paracetamol (Oliveira et al. 2018). According to a systematic Cochrane review (2008), which included 65 trials (11 237 patients), NSAIDs were shown to be effective for short-term pain relief in acute and chronic low back pain without sciatica; however, the effect sizes for NSAID efficacy were small (Roelofs et al. 2008). Mild opioids can be used in the short term for neurogenic pain (Lasko et al. 2012, Oliveira et al. 2018).

2.2 Lumbar spine fusion surgery and recovery

For those patients who have chronic LBP caused by, for example, isthmic or degenerative spondylolisthesis or central spinal stenosis, spine surgery becomes an option if the patient is still having severe pain, disability and loss of quality of life after conservative treatment including active rehabilitation. The most common indications for LSF are degenerative or isthmic spondylolisthesis, revision surgery, spinal stenosis and degenerative disc disease (Weinstein et al. 2009, Strömqvist et al. 2013, Irmola et al. 2018, Wu et al. 2018).

Based on the Swedish spine register report in 2014, 62% of patients with isthmic spondylolisthesis were satisfied with the surgery result, 25% were uncertain, and only 14% were dissatisfied one year after surgery. The majority felt im-

provement in pain, but 11% reported deterioration of low back pain and 9% deterioration of leg pain at one year postoperatively (Strömqvist et al. 2013). Gaudin et al. (2017) has presented in their review, that patients with depression, who smokes, and who have ongoing litigation processes seems to recover worse after LSF than people with good health and good impression of their own health. It seems that after careful consideration and strict selection of patients, LSF has a great positive effect on patients' symptoms and lives; however, there are some challenges in the recovery that need to be recognized (Tarnanen et al. 2013, Pekkanen et al. 2014).

The result of LSF varies depending on the surgical indications and clinical domains; however, the spondylolisthesis patients benefit most from LSF (Möller & Hedlund 2000, Weinstein et al. 2007, Yavin et al. 2017). In the RCT study of Weinstein et al. (2007), the surgically treated degenerative spondylolisthesis patients had improved pain and function at the two-year follow-up compared to nonoperated controls. Adult isthmic spondylolisthesis patients benefited modestly more from LSF surgery than from a 1-year exercise program (Ekman, Möller & Hedlund 2005). In addition, LSF surgically treated patients reported a better self-perceived global treatment outcome than conservatively treated patients (Ekman, Möller & Hedlund 2005, Yavin et al. 2017). Some of the gained effect of the fusion surgery was lost over time; however, the spontaneous natural course of symptomatic adult isthmic spondylolisthesis without surgery also showed deterioration and continuing disability (Ekman, Möller & Hedlund 2005). In a prospective study by Pekkanen et al. (2014), clear improvements were found in disability and health-related quality of life at the two-year follow-up in five different diagnosis groups who underwent elective LSF. The diagnosis groups were degenerative spondylolisthesis, isthmic spondylolisthesis, spinal stenosis, disc pathology, and postoperative conditions (Pekkanen et al. 2014). In addition, according to a recent meta-analysis, primary LSF for degenerative spine conditions is shown to particularly improve leg pain and disability (Koenders et al. 2019).

Despite the positive results of LSF, the postoperative recovery is a complex process. During posterior LSF surgery using an open approach, the detachment and retraction of lumbar spine muscles causes iatrogenic trauma to muscles and nerves in the surgical area, which may further lead to impairment in muscle functioning. The posterior open approach with a pedicle screw fixation also causes denervation in paraspinal muscles, and the postoperative reinnervation process in the surgical area is slow (Cha et al. 2016). Moreover, significant reinnervation of the multifidus and erector spinae muscles after L4-5 fusion may take 12 months (Cha et al. 2016). In the study of Ohtori et al. (2016), the most frequent postoperative, degenerative change in the multifidus muscles was fatty infiltration change, found with magnetic resonance imaging. In addition, scarring and inflammatory-like changes were still identified in some cases one year after surgery (Ohtori et al. 2016).

2.2.1 Recovery of trunk muscle strength and spine function after lumbar spine fusion

In addition to surgery-induced iatrogenic muscle damage, low back pain itself is known to decrease the spontaneous activation of paraspinal muscles (van Dieën, Selen & Cholewicki 2003) leading to multifidus atrophy (Danneels et al. 2000). The LBP patients have altered spine movement patterns for example during walking and lifting (Papi et al. 2020), which could also induce muscle strength deficit. Both LBP patients and patients undergoing LSF have deficient trunk muscle strength, and they have abnormal extensor/flexor strength balance, which means that flexor muscles are stronger than extensors (Mayer et al. 1985, Tiusanen et al. 1996). Normally, in a healthy population, the trunk extension strength is approximately 30% higher than flexion strength (Mayer et al. 1985, Häkkinen et al. 2003, Paalanne et al. 2009). The low isometric trunk muscle strength levels in patients undergoing spinal fusion were also shown in the study of Tarnanen et al. (2013). Three months after LSF, the pain was relieved and disability improved. Although the extension strength increased by 24% in females, the muscle strength levels still remained low, and the extension/flexion strength ratio remained abnormal (Tarnanen et al. 2013). The trunk extension strength was found to decrease by 19% from the preoperative situation to the one-year postoperative follow-up in another study of LSF patients (Keller et al. 2004). These findings elucidate that trunk muscle function is not spontaneously recovering well after LSF.

It is unclear how LSF influences the functional spine range of movement (ROM). The fused spine segments become rigid, but on the other hand, when neural irritation is relieved by successful surgery, it can be more comfortable to bend the whole back, thus compensating for the reduced segmental movement of the fused levels with those segments that are still moving. In addition, regarding tasks where forward or downward reaching is needed, it may be less painful to tilt the pelvis from the hip joints to complete a task. A previous study by Tiusanen et al. (1996) showed that LSF patients had a smaller forward bending ROM (measured by goniometer) than healthy control subjects, which still exists 2-10 years after anterior fusion (Tiusanen et al. 1996). It has been shown by imaging that after LSF, the motion is redistributed to adjacent movement segments, usually cranial levels of the spine (Auerbach et al. 2009). The increased mobility in adjacent segments also has unwanted consequences; it can cause increased segmental mechanical loading during spine movements, which has been thought to accelerate the adjacent segment degeneration (ASD) process after LSF (Gillet 2003, Helgeson, Bevevino & Hilibrand 2013, Xia, Chen & Cheng 2013). The ASD process is most importantly associated with long fusion (Zhang et al. 2016). According to a systematic review and meta-analysis, the incidence rate for ASD found in radiographs was 26.6% and for symptomatic ASD was 8.5% after LSF (Xia, Chen & Cheng 2013). At a four-year follow-up of 433 LSF patients, ASD was the most common cause for reoperation, with a cumulative reoperation rate of 8.7% (Irmola et al. 2018). The sample consisted of patients mostly with a background of spondylolisthesis (Irmola et al. 2018). This expected recovery process,

including muscle strength, spine mobility and possible risk for generating the adjacent segment degeneration afterward, needs to be considered before making a surgical decision.

2.2.2 Physical activity and kinesiophobia after lumbar spine fusion

After LSF, walking is usually recommended as a safe and easy option to be physically active during the first postoperative days. It has been reported that lumbar surgery (LSF or decompression) patients use less than one hour per day for walking during the first six postoperative days, which they spend at hospital (range 17-53 minutes/per day) (Gilmore et al. 2019). Mobilizing early is considered important for reducing postoperative complications, improving physical and psychological functioning, and reducing the length of hospital stay (Kalisch, Lee & Dabney 2014). Patients are in a new situation after surgery; therefore, it is important to provide instructions regarding how to increase their long-term physical activity after hospital discharge. A certain amount of physical activity (PA) is essential for preventing noncommunicable chronic diseases (World Health Organization 2009). It has been shown that physical activity lowers the risk of cardiovascular disease mortality, regardless of the metabolic risk factors (i.e., dyslipidemia, type II diabetes, obesity, hypertension, inflammation or insulin resistance) (Reddigan et al. 2011).

Globally, 58% of the population is either inactive or insufficiently physically active, while in Europe's high-income populations, the percentage is as much as 69%, and the rate is 57% in low- and middle-income populations (World Health Organization 2009). The current physical activity guidelines recommends every day physical activity, a minimum of 150 minutes/week of moderate-intensity aerobic training (for example brisk walking) or 75 minutes/week vigorous-intensity training is needed for substantial health benefits (World Health Organization 2009, Physical Activity Guidelines Advisory Committee 2018, Piercy et al. 2018, UKK-institute 2019). In addition, moderate to intensive muscle strengthening activities are needed two times per week (Piercy et al. 2018, UKK-institute 2019). These recommendations also involve LSF patients in terms of diminishing the risk of developing new chronic diseases and maintaining good muscle strength and physical functioning. In addition to training, it is important to avoid excessive sitting in terms of diminishing sedentary time (Physical Activity Guidelines Advisory Committee 2018, Piercy et al. 2018, UKK-institute 2019).

In LSF patients, PA levels have been shown to be low preoperatively (Lotzke et al. 2018). In that study, accelerometer data were available from 116 participants, and only 17% of those met the recommendation of PA for health, while the majority (83%) of LSF patients were insufficiently active or inactive preoperatively. Those patients had severe low back pain due to degenerative disc disease, but they were still quite young and had only moderate disability (mean age 45.7 years, mean Oswestry Disability Index 37.8) (Lotzke et al. 2018), which makes the situation even more concerning. In addition, they found a negative association between the amount of step counts per day and fear of movement

and disability; they suggest that if the disability and fear of movement are relieved, the PA could increase in LSF patients (Lotzke et al. 2018). A report of the same sample with a six-month follow-up showed that those who had a preoperatively low PA level but high exercise-related self-efficacy were likely to increase their PA level (Jakobsson, Brisby, Gutke, Hagg et al. 2019). Preoperative walking capacity did not predict the PA or disability changes postoperatively in that study. They also found that at six months after LSF, the majority of LSF patients had insufficient PA levels and that they needed extra support in increasing those levels (Jakobsson, Brisby, Gutke, Hagg et al. 2019).

Pain-related fear of movement can facilitate low levels of PA. The fear-avoidance model of chronic musculoskeletal pain was first introduced in 2000 (Vlaeyen & Linton 2000) and then updated in 2012 (Vlaeyen & Linton 2012). The principal idea in the fear-avoidance model is that when an injury occurs, the patient experiences normal nociceptive pain. If the patient has no fear toward the pain, he or she can confront the situation and start to recover normally. If the patient has catastrophic thoughts about pain, negative affectivity, or is feeling threatened because of the pain, his or her recovery will continue abnormally. This deteriorates to an unwanted negative cycle, which leads to increased pain-related fear, hypervigilance, disuse, depression and disability and then reverts to an increasingly more complex pain experience (Miller, Kori & Todd 1991, Vlaeyen & Linton 2000). Kinesiophobia means fear of movement or reinjury, and it is a common finding among people with musculoskeletal pain (Lundberg et al. 2006), which not only restricts PA but also narrows involvement in social life and participation in normal activities. In LSF patients, high kinesiophobia levels have been recorded soon after surgery (Monticone et al. 2014). These high levels are associated with high disability and low quality of life in LBP patients (Comachio et al. 2018).

Dekker et al. (1992) have introduced a slightly different pain-related activity-avoidance model. In their model, the pain-related avoidance is assumed to be caused by expectations that renewed activities would cause an increased pain level. These beliefs and avoidance behavior are strengthened by psychological distress, such as anxiety, an ineffective coping style and possibly depression (Dekker et al. 1992, Holla et al. 2014).

2.3 Therapeutic exercise after lumbar spine fusion surgery

Even though LSF patients are mostly satisfied with the surgery results (Strömqvist et al. 2013), the disability is still higher in LSF patients than in the general population one year after surgery (Pekkanen et al. 2013). In line with this, at the two-year follow-up after LSF in the United States, there is still a reported disability of 64% (Maghout-Juratli et al. 2006). However, evidence for the most effective exercise method after LSF has been lacking (Rushton et al. 2012). In a recently published systematic research study including trials of lumbar fusion surgery, where postoperative rehabilitation was described in detail, level A

(good) evidence was found for patient education, and level B (fair) evidence was found for cardiovascular exercise, motor control & exercise, psychosocial considerations and coping (Madera et al. 2017). That review showed a lack of high-quality rehabilitation research, especially after two to three months postoperatively (Madera et al. 2017). Therefore, a systematic review of the literature on rehabilitation after lumbar spine fusion was conducted on June 20, 2019 using three main databases: Ovid Medline, Cinahl and PeDRO. The main aim was to search for all randomized controlled trials or controlled clinical trials evaluating the effectiveness of postoperative exercise therapy and rehabilitation after lumbar spine fusion in adults. The detailed search strategy is presented in Appendix 1.

After conducting the systematic search, 202 references (Medline: 100 studies, Cinahl: 69 studies, PeDRO: 33 studies) were imported to the Covidence review management program for screening. The phases of screening and study selection are shown in Appendix 2. The inclusion and exclusion criteria were formed using the PICO criteria (patients, intervention, comparison, outcomes): lumbar spine fusion patients (P), postoperative rehabilitation as intervention (I) comparing at least two groups (C), any outcomes but not cost-effectiveness (O), and randomized or nonrandomized controlled clinical trials. After removing duplicates, screening the titles and abstracts, and finally screening the full texts of 14 studies, 10 studies were included. After this, one clinical trial was found by manual searching and was included in the review. Descriptions of the studies and main findings of the 11 included studies are presented in Table 1 and Table 2.

From the eleven studies, ten were RCT studies including men and women. The mean age range (minimum-maximum) of the patients in the included studies was 47-61 years. One study was a nonrandomized controlled trial, including only women (Lee et al. 2017). Diagnoses leading to LSF varied in the studies, but most commonly, the diagnoses were degenerative spine conditions, such as degenerative spondylolisthesis and spinal stenosis. Most of the study samples included only LSF patients, but in study of Archer et al. sample included also laminectomy patients without LSF (Archer et al. 2016) and study of Scrimshaw et al. consisted of LSF, discectomy and laminectomy patients (Scrimshaw & Maher 2001). The range of sample sizes was wide, from 27 to 107 participants per study.

The rehabilitation interventions covered different kinds of therapeutic exercise regimens, cognitive behavioral therapy (CBT) elements, orthosis use and neural tissue mobilization techniques. The studies with therapeutic exercises included both supervised exercise sessions and independent home exercising with one-time instruction or regular check-up visits. Comparison of the intervention was often made with "standard exercise" or "standard care", which in many studies meant active treatment as well (Table 1). In most studies, the interventions started during the first three postoperative months, but in four trials (Christensen, Laurberg & Bunger 2003, Kang et al. 2012, Oestergaard, Nielsen et al. 2013, Oestergaard, Christensen et al. 2013, Lee et al. 2017), the start time was three months postoperatively, similar to the present RCT study. Durations of all postoperative interventions were from four to twelve weeks. Two studies did not

have a follow-up, while in others, the follow-up varied from two months to three years (Tables 1 and 2).

TABLE 1. Descriptions of RCT studies and one CT study from the systematic search

Study	Sample size	Participants	Intervention start time (S) & duration (D)	Main contents of the intervention	Training implementation
Abbott et al. 2010 RCT	N=107 G1: n=53 G2: n=54	F=66, M=41 Mean age: 50/51 y LSF for: spinal stenosis, spondylosis, degenerative/isthmic spondylolisthesis or degenerative disc disease	S: Immediately after surgery D: 12 weeks	G1: "Psychomotor therapy" Cognitive behavioral intervention for groups & graded motor re-learning approach to lumbopelvic stabilization training. Program was upgraded during a 90-min PT session at 3, 6 and 9 weeks after surgery. Exercises daily. G2: "Exercise therapy" Home-exercise program for muscle strength and endurance + stretching. One-time instruction of 20 min before the hospital discharge. Exercises daily.	G1: Independent with check-ups G2: Independent
Archer et al. 2016 RCT	N=86 G1: n=43 G2: n=43	F=48, M=38 Mean age: 58 y Laminectomy, with or without fusion, for degenerative condition and screened for high fear of movement	S: 6 weeks postop. D: 6 weeks	G1: "Changing Behavior through Physical Therapy" using brief CBT by educated PT, to increase self-efficacy and reduce fears, to reduce pain and disability. Physiotherapy sessions 1x/wk, with one 60-min meeting and telephone discussions G2: Education program on recovery, biomechanics, importance of daily exercise, etc.	G1: Behavior change (CBT) supported by PT sessions (no training) G2: Independent
Christensen et al. 2003 RCT	N=88 G1: n=28 G2: n=30 G3: n=30	F=58, M=30 Mean age: 47 y LSF for localized segmental instability caused by spondylolisthesis or degeneration	S: 3 months postop. D: 8 weeks	G1: Exercise instruction video + 1 guidance session by PT, independent training G2: Back-Café: Exercise instruction video + 3x90-min sessions including 10 min of small talk with coffee and discussions with the PT and peers about coping schemes G3: Training: 8-week program 2x90 min/wk, supervised by PT.	G1: Independent G2: Independent with check-ups G3: Supervised

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Kang et al. 2012 RCT	N=60 G1: n=20 G2: n=21 G3: n=19	F=29, M=31 Mean age: 61 y Posterior lumbar interbody fusion for chronic low back pain	S: 3 months postop. D: 8 weeks	G1: Traditional McKenzie's extension exercise rehabilitation, 10 s hold, 3 sets, 10 s rest between each exercise. 3x/wk. G2: McKenzie extension rehabilitation and muscle training with MedX-device including 20 repetitions of isotonic exercise with resistance of 50% of the maximal muscle strength. One set with 70% of maximal strength. 3x/wk. G3: Stability exercise 30 mins, by O'Sullivan's method, including transversus abdominis+multifidus activation without gross contractions, hold 10 seconds, rest 10 seconds in between the repetitions. 3x/wk.	G1: Supervised G2: Supervised G3: Supervised
Kernc et al. 2018 RCT	N=27 G1: n=13 G2: n=14	F=13, M=14 Mean age: 61 y LSF for one-level degenerative or isthmic low-grade spondylolisthesis, or degenerative disc disease with or without spinal stenosis	S: 3 weeks postop. D: 9 weeks	G1: Supervised progressive training supporting IAP utilization for stabilization, 2x/wk. G2: Standard protocol, no exercises.	G1: Supervised G2: No exercises
Lee et al. 2017 CT	N=59 G1: n=26 G2: n=33	F=59, M=0 Mean age: 57 y 1-2 level PLIF between L3-S1 levels for women with symptomatic degenerative disc disease, spinal stenosis, or spondylolisthesis (deg. or isthmic), undergoing	S: 3 months postop. D: 12 weeks	G1: Lumbar stability training 3x/week (total of 36 one-hour sessions). Training included 15 min aerobic warm up, supervised stretching and strengthening workout with no range of motion restrictions. G2: No exercise prescription, advise to continue normal activities.	G1: Supervised G2: No exercises

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Monticone et al. 2014 RCT	N=130 G1: n=65 G2: n=65	F=79, M=51 Mean age: 57 y LSF with or without decompression for spondylolisthesis, lumbar spinal stenosis, CLBP with sciatica at least 12 months	S: 1 week postop. D: 4 weeks	G1: CBT by psychologist, as management of catastrophizing and kinesiophobia. 60 min 2x/wk, exercise training, 90-min sessions 5x/wk for 4 weeks G2: Exercise training, 90-min sessions 5x/wk for four weeks	G1: Supervised G2: Supervised
Oestergaard, Christensen et al. 2013 RCT	N=82 G1: n=41 G2: n=41	F=44, M=38 Mean age: 52 y Instrumented LSF for a degenerative disc disease or spondylolisthesis	S: 6 and 12 weeks postop. D: N/A	G1: 6 wk postoperatively started group-based physical rehabilitation. 4x2-h discussions about coping schemes and exercise. Home exercises once a day, 2x10 repetitions for active exercises; stretching was also included. G2: 12 wk postoperatively started group-based physical rehabilitation and discussions about coping schemes. Home exercises once a day, 2x10 repetitions for active exercises, also stretching was included. Different timing but similar contents in G1 and G2.	G1: Supervised and independent G2: Supervised and independent
Oestergaard, Nielsen et al. 2013 RCT	N=82 G1: n=41 G2: n=41	F=44, M=38 Mean age: 52 y Instrumented LSF for a degenerative disc disease or spondylolisthesis	S: 6 and 12 weeks postop. D: N/A	G1: 6 wk postoperatively started group-based physical rehabilitation. 4x2-h discussions about coping schemes and exercise. Home exercises once a day, 2x10 repetitions for active exercises; stretching was also included. G2: 12 wk postoperatively started group-based physical rehabilitation and discussions about coping schemes. Home exercises once a day, 2x10 repetitions for active exercises; stretching was also included. Different timing but similar contents in G1 and G2.	G1: Supervised and independent G2: Supervised and independent

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Scrimshaw et al. 2001 RCT	N=81 G1: n= 35 G2: n=46	F=30, M=51 mean age: 57 y Patients undergoing lumbar discectomy, fusion or laminectomy	S: 1st postop. day D: 6 weeks	G1: Standard therapy: isometric and dynamic exercises for lower limb and trunk. G2: Neural mobilization during hospitalization once every 2 hours; after discharge, 2-3 times/day + standard therapy.	G1: Supervised and independent G2: Supervised and independent
Soliman et al. 2018 RCT	N=43 G1: n=25 G2: n=18	F=23, M=20 mean age: 51 y Patients undergoing posterior spinal fusion for degenerative spondylolisthesis, spinal stenosis or degenerative disc disease	S: 48 h postop. D: 12 weeks	G1: Brace group wore rigid molded lumbosacral orthosis full time for 8 weeks and during daytime for next 4 weeks. Use of orthosis started after drain removal (48 h after surgery) G2: Control group with no orthosis.	N/A

Abbreviations: CBT=cognitive behavioral therapy, CLBP=Chronic low back pain, CT=controlled trial, D= duration of the intervention, F=female, G1=group one, G2=group two, G3=group three, IAP= intra-abdominal pressure, LSF=lumbar spine fusion, M=male, N=sample size, n=number of participants, N/A=not applicable, PLIF=posterior lumbar interbody fusion, RCT= randomized controlled trial, S=start time of the intervention, wk=week, y=year

2.3.1 Trunk muscle strength and physical functioning

The main findings of the included trials are summarized in Table 2. There were only three previous clinical trials of LSF rehabilitation using trunk muscle strength as an outcome (Kang et al. 2012, Lee et al. 2017, Kernc, Strojnik & Vengust 2018). In a nonrandomized controlled study, 59 LSF patients were enrolled in a lumbar stabilization exercise group or a control group (Lee et al. 2017). The exercise group started supervised training three times a week for three months, and the control group did not receive any exercise prescription but was guided to continue with their normal physical activities in that study. The exercise group's program included stretching and strengthening exercises, which were performed without any devices; patients exploited their own body weight (Lee et al. 2017). The use of the full spine range of motion was not restricted either. The results of the Lee et al. (2017) study showed that the exercise group had significant improvements in muscle strength, back pain and health related quality of life (HRQoL) compared to the control group with no exercises. In that study, the spine extensor strength decreased during the first three postoperative months (Lee et al. 2017) when they had used the thoracolumbar orthosis (Cawley 2017). After removing the orthosis and completing the three-month training period, strength increased by 60% in the exercise group (Lee et al. 2017). No adverse effects were reported after commencing an exercise program at three months postoperatively, regardless of the fact that there were no restrictions on the use of spine range of movement during exercising (Lee et al. 2017). In addition, the back pain, physical and mental component scores of SF-36 (health-related quality of life measure) improved more in the exercise group than in the control group at the 6-month follow-up (Lee et al. 2017).

The RCT study of Kang et al. (2012) compared three different postoperative interventions: McKenzie's extension exercises, McKenzie combined with trunk muscle training performed by the MedX-device, and core stability exercises of O'Sullivan's method. McKenzie method is a classification-based mechanistic LBP treatment approach in physiotherapy, which may have positive effects in acute LBP (Kuhnow et al. 2020), but has not been widely studied in LSF patients. In study of Kang et al. 2012, all three interventions were supervised starting three months postoperatively and lasting for eight weeks. In that study, the outcome measurements were performed immediately after the eight-week intervention, and the findings were analogous to the training method of the group. The stability exercise group improved their transversus abdominis activation significantly more than other groups, as measured by pressure biofeedback. The combination group of McKenzie and the MedX-device exercises had improved trunk flexion strength significantly more than other intervention groups. Pain and disability decreased in all groups (Kang et al. 2012).

Kernc et al. (2018) studied early initiation of a nine-week training program progressing from static exercises to exercises with strength training machines. The patients in the intervention group were thought to utilize abdominal bracing during the exercises, which means utilizing the intra-abdominal preactivation

with coactivation of abdominal muscles. This training method was compared to the hospital's standard protocol, which did not include exercises during the first postoperative months. The intervention group improved their result in extension, flexion and lateral flexion strength tests during the intervention, but the gained results could not be maintained to the 18-month follow-up (Kernc, Strojnik & Vengust 2018).

The trunk muscle strength improved by the very different short-term (lasting 2-3 months) interventions used in the three studies with the strength as an outcome. While the gained strength results were maintained at the 6-month follow-up (Lee et al. 2017), they were no longer maintained at the 18-month follow-up (Kernc, Strojnik & Vengust 2018).

2.3.2 Pain, disability and quality of life

Based on the systematic literature search, the disability, pain and quality of life are often used as outcomes. Most common disability measure in this review was Oswestry Disability Index (ODI). For health related quality of life, the Short Form (36) Health Survey (SF-36) and European Quality of Life Questionnaire (EQ-5D) were the most common in the studies of this review (Table 2). The RCT study of Abbott et al. (2010) compared a traditional home-exercise program to the psychomotor therapy, which included cognitive behavioral therapy (CBT) focusing on modifying maladaptive pain cognition and behavior, and motor relearning program which aimed to improve lumbopelvic stabilization. In that study, the psychomotor therapy was superior to traditional exercises at the two-year follow-up in terms of disability and functional self-efficacy. Both interventions started immediately after LSF and lasted for three months (Abbott, Tyni-Lenne & Hedlund 2010).

In a study by Monticone et al. (2014), patients also started their CBT with supervised exercises within one week after LSF and found it more effective than exercising without cognitive therapy in terms of disability measured by ODI and quality of life by SF-36 (Monticone et al. 2014). The timings of the rehabilitation interventions varied, which could have influenced the results. Östergaard et al. (2013) compared the timing of the postoperative supervised exercise interventions, and their findings in two reports support the later commencement time instead of the early start (three months vs. six weeks postoperatively) (Oestergaard, Christensen et al. 2013, Oestergaard, Nielsen et al. 2013). They found significant improvement in disability and lower costs in the later-starting exercise group (Oestergaard, Christensen et al. 2013). The exercise programs were otherwise similar in both groups, and therefore, the effect was conjectured to be influenced by the commencement time of the intervention (Oestergaard, Christensen et al. 2013).

The importance of the psychological intervention approach was found in four studies (Christensen, Laurberg & Bunger 2003, Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014, Archer et al. 2016). In a study by Archer et al. (2016), the traditional education program, including informing patients about re-

covery, biomechanics, and importance of daily exercise, was not effective compared to the three-month CBT program starting six weeks postoperatively (Archer et al. 2016). In that study, a physiotherapist led the CBT program empowering the patients to change their health behavior (Archer et al. 2016). The CBT group showed decreased pain and disability and improved general health, as measured by the 12-Item Short-Form Health Survey, and physical performance was greater than the traditional education group (Archer et al. 2016).

When summarizing the results of the RCTs' utilization of active exercise interventions and measurements of disability and pain changes, the supervised exercising seemed to be beneficial (Kang et al. 2012, Lee et al. 2017). The results were best with long-term follow-up if the psychological components, such as discussions about coping schemes or CBT, were added to the exercise intervention (Christensen, Laurberg & Bunger 2003, Monticone et al. 2014, Archer et al. 2016). However, the relatively short therapeutic exercise program (eight weeks) without the psychological component caused poorer long-term results in pain intensity (Christensen, Laurberg & Bunger 2003).

In addition to therapeutic exercise and psychological approaches, the use of orthosis and neural tissue mobilization was studied in two RCTs, which presented negative results. The effectiveness of the postoperative rigid lumbosacral orthosis use was studied in the RCT of Soliman et al. (2018). They compared the results of the rigid bracing during the first 12 postoperative weeks to a group who did not use a brace (control group) and found that disability and general health improved more in the control group after the 12-week period. The sample size of the study was rather small (N=43), but the results were clear; therefore, bracing is not recommended if solid fixation is received intraoperatively (Soliman et al. 2018). The additional benefit of neural tissue mobilization techniques to standard exercise therapy was studied in a spine surgery patient sample, which included LSF, laminectomy, and lumbar discectomy patients (Scrimshaw & Maher 2001). In that study, the neural tissue mobilization was performed many times per day according to the structured protocol. It did not contribute an additional benefit to pain relief or disability of the global perceived effect compared to standard care, which included isometric and dynamic exercises for the lower limb and trunk (Scrimshaw & Maher 2001).

2.3.3 Kinesiophobia and coping schemes

It seems that psychological approaches are an important part of LSF rehabilitation, and they are usually combined with exercise therapy. Such approaches are beneficial for many outcomes in the long-term follow-up of LSF patients' rehabilitation (Christensen, Laurberg & Bunger 2003, Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014, Archer et al. 2016). Pain catastrophizing, fear of movement and self-efficacy beliefs are the central outcomes that are usually primarily targeted in psychological interventions in this patient group. Only two studies were found reporting the fear of movement after LSF (Table 2).

In a study by Monticone et al. (2014), cognitive behavioral therapy (CBT) was targeted to relieve kinesiophobia and pain, and it was implemented together

with therapeutic exercises soon after surgery. This combination of CBT and exercises was more effective than a four-week supervised intensive exercise program in terms of relieving pain catastrophizing and kinesiophobia. It also improved disability and quality of life, and the results were still retained at the one-year follow-up after the intervention (Monticone et al. 2014). In a 2-3 year follow-up study by Abbott et al. (2010), a 12-week psychomotor therapy including CBT and graded motor relearning stability exercises was significantly better than standard home exercises. Both interventions were implemented soon after surgery (Abbott, Tyni-Lenne & Hedlund 2010). In that study, the motor relearning approach was performed with physiotherapy check-up visits, while standard exercises were instructed once to patients and then performed independently at home. The psychomotor therapy group had significantly larger improvements in self-efficacy, outcome expectancy, kinesiophobia and pain catastrophizing compared to standard home exercises (Abbott, Tyni-Lenne & Hedlund 2010). To summarize, based on two RCTs measuring kinesiophobia and coping schemes, such as pain catastrophizing and self-efficacy, even short-term postoperative interventions that included a combination of a psychological component and supervised therapeutic exercises were shown to improve these outcomes (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014).

2.3.4 Summary of the previous clinical trials of postoperative rehabilitation after lumbar spine fusion

The findings of the present literature review on postoperative rehabilitation after LSF show that some longstanding benefits can be received with a combination of therapeutic supervised exercise and CBT or some other psychological approach with closely similar idea (Christensen, Laurberg & Bunger 2003, Abbott, Tyni-Lenne & Hedlund 2010, Oestergaard, Christensen et al. 2013, Monticone et al. 2014, Archer et al. 2016). The research does not support orthosis use (Soliman et al. 2018) or neural tissue mobilization techniques (Scrimshaw & Maher 2001) as part of standard postoperative care. In addition, previous research recommends postponing the start of an independent home-exercise intervention to 12 weeks postoperatively (Oestergaard, Christensen et al. 2013, Oestergaard, Nielsen et al. 2013). All studied interventions were short term, lasting a maximum of three months.

In summary, the literature review indicates there are still gaps in knowledge about an effective rehabilitation method after LSF. In the published RCT studies, the rehabilitation modalities, exercise dosage, implementation of the exercise method (independent/supervised), timing and duration of interventions, used outcomes, and the gained results vary. Therefore, the most effective rehabilitation method and duration for gaining the best long-term results after LSF is still unclear.

TABLE 2. Outcomes of the trials found in the systematic literature search

Study	Outcomes	Follow-up time after intervention end	Main findings
Abbott et al. 2010	Disability (ODI), back pain (VAS), quality of life (EQ-5D), functional self-efficacy (SES), outcome expectancy (BBQ), kinesiophobia (TSK), catastrophizing (CSQ-CAT), control over pain using coping strategies (CSQ-COP), ability to decrease pain using coping strategies (CSQ-ADP)	2-3 years	Psychomotor therapy group improved results in disability, functional self-efficacy, outcome expectancy, fear of movement/(re)injury and pain catastrophizing significantly more than exercise therapy group at 2-year follow-up. No differences between the groups in the other outcomes.
Archer et al. 2016	Back and leg pain, pain interference (BPI), disability (ODI), general health (SF-12), physical performance (5-Chair stand test, TUG, 10MWT)	3 months	CBT group decreased pain & disability, and increased general health and physical performance more than Education group at 3-month follow-up (6 mo postop.)
Christensen et al. 2003	Back and leg pain (LBPR), daily level of function and psychological capacity (structured questionnaire)	2 years	Back-Café group had significantly lowest back pain scores at 2 y follow-up compared to other groups. Supervised training group (G3) scored significantly higher leg pain intensity than G1 or G2 at 2 y follow-up (unwanted effect).
Kang et al. 2012	Pain (VAS), disability (ODI), isotonic lumbar muscle strength (MedX)	At the end of the interventions (5 months postoperatively)	Pain and ODI decreased in all groups similarly. Pressure-biofeedback (IAP), increased more in G3 (O'Sullivan's stability). G2 (McKenzie + isotonic MedX) had higher trunk flexion strength gain.

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Kernc et al. 2018	Physical performance (6MWT, CST, SRH), isometric trunk muscle strength (strain-gauge dynamometer), disability (ODI), IAP pre-activation pattern (force plate). X-ray check-up for possible hardware loosening	18 months	No between-group differences at the 18-month follow-up. G1 improved all functional outcomes, while G2 did not.
Lee et al. 2017	Isometric back muscle strength (MedX- lumbar extension machine), back pain (VAS), HRQoL (SF-36), body mass index, trabecular bone growth connecting the vertebral bodies (CT scan)	6 months	Lumbar stability training group (G1) demonstrated significantly better results in muscle strength change, back pain and in mental and physical component scores of SF-36. No adverse effects in lumbar stability training using full lumbar range of motion.
Monticone et al. 2014	Disability (ODI), catastrophizing (PCS), kinesiophobia (TSK), pain (11-point NRS) and HRQoL (SF-36)	1 year	Cognitive behavioral therapy (CBT) with supervised exercising was superior to only exercising in improving disability, catastrophizing, kinesiophobia and quality of life. Few minor adverse effects (pain worsening, mood alterations) occurred in both groups. However, they were manageable.
Oestergaard, Christensen et al. 2013	Disability (ODI), HRQoL (EQ-5D), costs, quality-adjusted life years (QALY), pain (Dallas Pain Questionnaire and LBPR)	1 year	12 wk postoperatively commenced group-based physical rehabilitation resulted in better result in disability and costs, than 6 wk postoperatively commenced did. Earlier start (6 weeks postop.) is associated with higher costs and poorer outcomes.

(jatkuu)

Taulukko 2 jatkuu

Oestergaard, Nielsen et al. 2013	6-minute walk test (6MWT), Åstrand Fitness test (sub-maximal cycle ergometer test)	1 year	G1 and G2 had similar effects on walking distance in the 6MWT and aerobic fitness (Åstrand). Overall outcome of this RCT (studies VIII and IX) favors postponing the initiation of home-based rehabilitation to 12 weeks after a LSF.
Scrimshaw et al. 2001	Global perceived effect (GPE), pain (VAS, McGill Pain Questionnaire), disability (QDS)	1 year	No benefits from neural mobilization compared to standard isometric and dynamic exercises for trunk and lower limb. Neural tissue mobilization may be harmful in LSF patients.
Soliman et al. 2018	Disability (ODI), general health survey (SF-12v2), back pain (VAS)	At the end of the interventions (3 months postoperatively)	Mental and physical component scores of SF-12v2 and ODI improved in control group but not in brace group. Postoperative rigid bracing of 12 weeks is not recommendable, if the solid fixation is received intraoperatively.

Abbreviations: BBQ=Back Beliefs Questionnaire, BPI=The Brief Pain Inventory, CLBP=chronic low back pain, CSQ=Coping Strategy Questionnaire, CST=Chair Stand Test, CT = computed tomography, EQ-5D=European Quality of Life Questionnaire, HRQoL=health-related quality of life, IAP=intra-abdominal pressure LBPR=Low Back Pain Rating Scale NRS=Numeral Rating Scale, ODI=Oswestry Disability Index, PCS=Pain Catastrophizing Scale, Postop.=postoperatively, SF-12=Short-form Health Survey of 12 items, SF-36=Short-Form Health Survey, SES=Self-efficacy Scale, SRH=Standing Reach Height Test, TSK=Tampa Scale for Kinesiophobia, TUG-Timed Up-and-Go -test, QALY=quality-adjusted life years, QDS=Quebec Disability Scale VAS=Visual Analogue Scale, 10MWT=10-Meter Walk Test, 6MWT=6-Minute Walk Test

3 PURPOSE OF THE STUDY

The purpose of this thesis was two-fold. The first aim was to study the effect of LSF on muscle strength and spine function in a one-year prospective cohort study. The second aim was to study the effectiveness of postoperative 12-month progressive home-based exercise therapy in an RCT setting in LSF patients with a background of degenerative or isthmic spondylolisthesis.

The specific aims of the present thesis were as follows:

1. To study the changes in trunk muscle strength, disability, and spine function in patients undergoing lumbar spine fusion and standard care with a one-year prospective follow-up

2. To compare the effectiveness of a 12-month postoperative progressive exercise intervention with usual care on trunk muscle strength and spine function

3. To examine the effectiveness of exercise interventions on pain, disability and health-related quality of life

4. To investigate the early postoperative changes as well as the effectiveness of a 12-month exercise intervention on kinesiophobia and physical activity after lumbar fusion

4 MATERIALS AND METHODS

4.1 Study design and patient samples

This thesis is based on two separate datasets: a prospective cohort study evaluating recovery after lumbar spine fusion (study I) and a randomized controlled trial investigating rehabilitation after LSF (studies II-IV). Both studies were conducted in collaboration with Tampere University Hospital and Central Finland Central Hospital in Jyväskylä (Figure 1). Both the prospective cohort study and the RCT study were approved by the ethic committees of Central Finland Central Hospital and Tampere University Hospital. A written consent form was obtained from all study participants.

The prospective cohort study (study I) is based on data from a larger Spine Database of Tampere University Hospital and Central Finland Central Hospital. All patients scheduled for nonurgent spinal fusion, regardless of the indication or diagnosis leading to surgery, were invited to participate in the study. The exclusion criteria were as follows: spinal fracture, malignant cause of low back pain, severe psychiatric disorders or other limitations in terms of the cognitive or mental condition, for example, dementia, or reoperation during the follow-up-period. In a total of 253 LSF surgically treated patients, 10 were excluded due to the exclusion criteria: 21 patients had missing preoperative data, and 28 had missing postoperative strength measurement data. Therefore, the final sample size of the prospective cohort study was 194 (77%). Between January 2008 and December 2009, patients underwent physical measurements (strength, spine mobility and physical functioning) before the surgery and 12 months after the surgery.

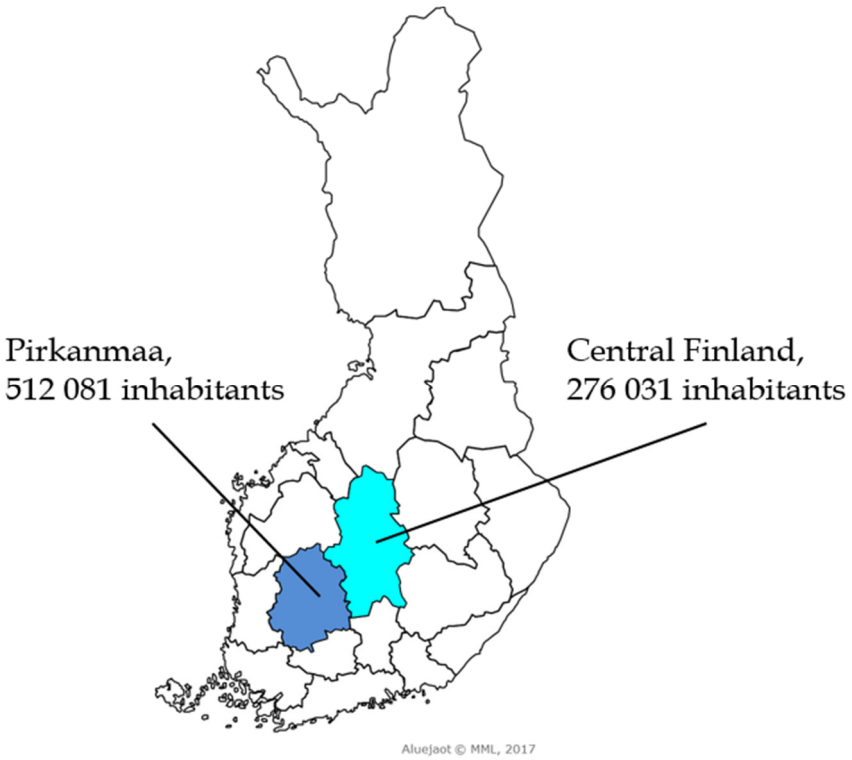

FIGURE 1. The health care districts of Tampere University Hospital and Central Finland Central Hospital. All lumbar spine fusion operations in these areas were centralized in these two hospitals.

In the RCT study (studies II-IV), the sample consisted of lumbar spine fusion patients with either isthmic or degenerative spondylolisthesis. All patients over 18 years of age and those scheduled for nonurgent LSF surgery for isthmic or degenerative spondylolisthesis were eligible for the study. The exclusion criteria were severe cardiorespiratory or musculoskeletal disease, fracture, tumor, severe psychiatric disorder, extensive lower limb paresis, alcohol abuse and immediate complications after surgery that could prevent the patient's ability to participate in the postoperative rehabilitation. The sample size determination was based on a power calculation for the main outcome, pain (VAS) (Christensen, Laurberg & Bunger 2003). We assumed a dropout rate of 15-20% at the one-year follow-up; therefore, the sufficient sample size was evaluated to be between 80 and 100 (Tarnanen, Neva et al. 2012).

Participants of the RCT were recruited between September 2009 and September 2010. The last participant ended the 12-month intervention in January 2012. The RCT study has been registered in advance in the Clinical Trials Database (clinicaltrials.gov, registration no: NCT00834015), and the study protocol has been published in advance (Tarnanen, Neva et al. 2012).

4.2 Randomization and blinding

In the RCT study (studies II-IV), the allocation of LSF patients was performed randomly, and patients were divided into an exercise group (EG) or to a usual care group (UCG) using computer-generated four-block randomization lists compiled by a biostatistician. An allocation ratio of 1:1 was used. Two randomization lists were created, one for (i) isthmic and one for (ii) degenerative spondylolisthesis, to ensure that both diagnoses were evenly represented in both groups. Concealed randomization was used, and nurses who were not otherwise involved in the study conducted it. In total, 104 consecutive patients undergoing spinal fusion were randomized. Six patients dropped out before the start of the intervention: four in the EG (reasons: 1 declined, 2 moved, and 1 had a reoperation) and 2 in the UCG (1 had a myocardial infarct; 1 had reoperation). Thus, the final number (N) of participants was 98 (48 in EG and 50 in UCG) (Figure 2).

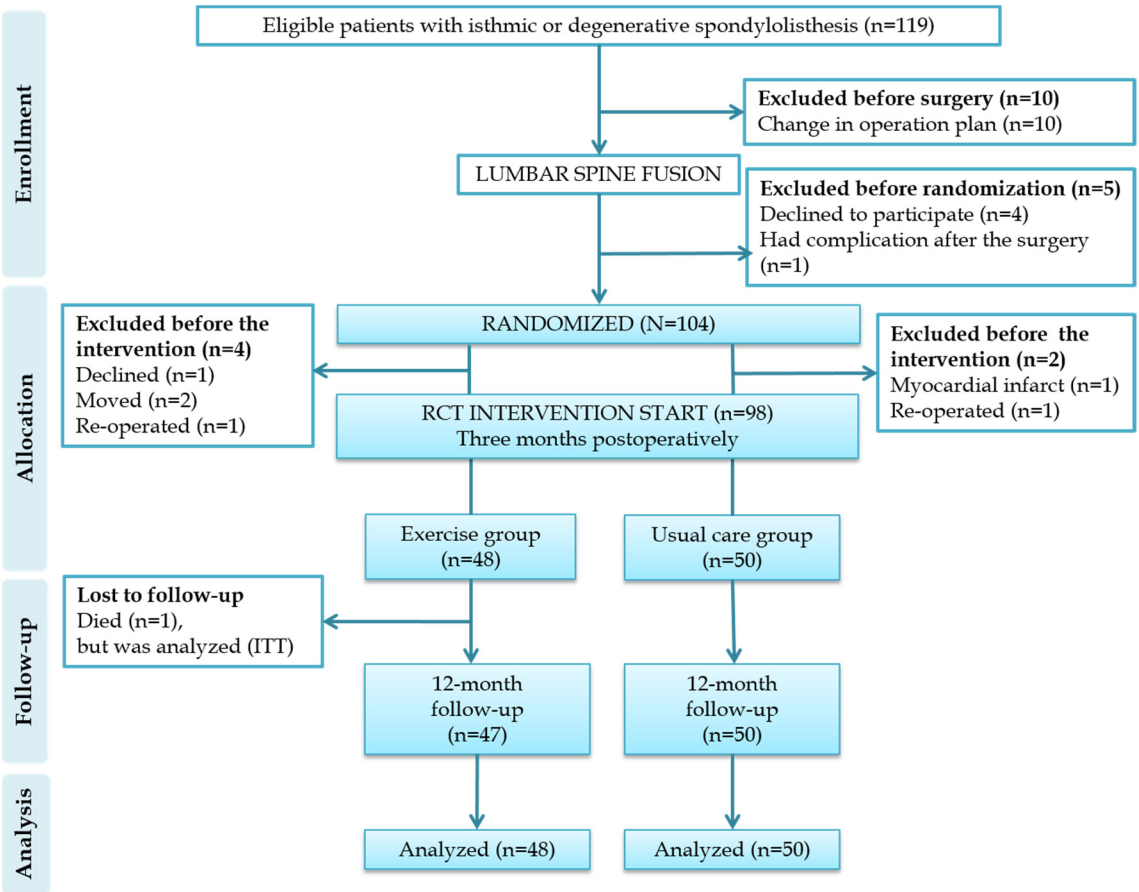

FIGURE 2. CONSORT patient flow diagram of the RCT study.

The research assistants who collected the data were blinded to the treatment the participant received. Because of the nature of the study, the intervention physiotherapists and the patients could not be blinded. To avoid confusion between the

EG and UCG treatments, both study arms in the two hospitals had their own physiotherapist.

4.3 Surgical methods and early postoperative instructions

The surgical indications and techniques and the pre- and postoperative rehabilitation protocols were updated and matched between the two hospitals before the study started. The surgical procedure used was instrumented posterolateral fusion (PLF) with or without posterior lumbar interbody fusion (Figure 3). The PLF procedure was performed using the midline approach; muscles were detached from the spine and retracted during the operation. Transpedicular fixation was placed between the fused segments. Decompression was performed to relieve compression of nerve roots, and interbody fusion was added if needed. The transverse processes were decorticated, and either an autograft from the iliac crest, removed lamina and allograft bone, or bone substitute was placed bilaterally. The surgeons from the hospitals performed some of the operations together to ensure that the surgical techniques used were similar.

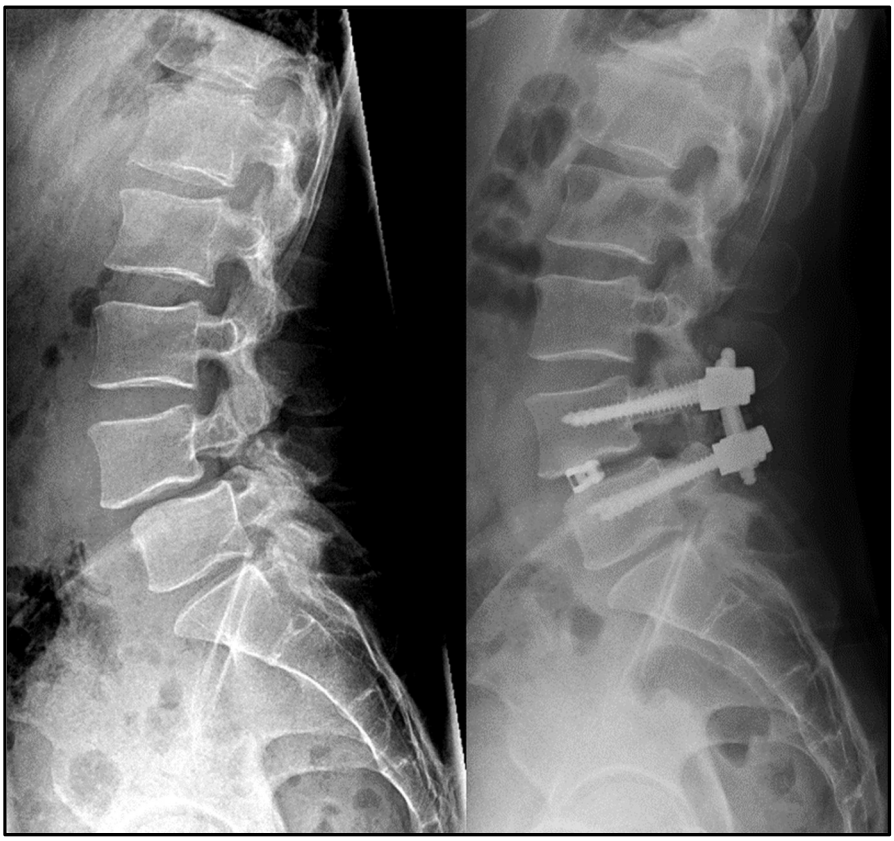

FIGURE 3. Radiographs of a patient with isthmic spondylolisthesis before the surgery and after instrumented posterolateral fusion with transforaminal lumbar interbody fusion.

The physiotherapist provided standard early postoperative instructions for up to the first three postoperative months. Right after the surgery, patients were advised to avoid continuous sitting longer than 30 minutes at a time during the first four weeks after surgery and to avoid extreme trunk flexion and extension for two months.

Six weeks postoperatively, participants were instructed to begin daily walking and to perform home exercises, such as transversus abdominis activation exercises, pelvic lifts in a crook lying position and squatting exercises every other day. In addition, patients were given instructions for calf, thigh, and hip stretching. Participants were taught to keep the lumbar spine stable in a neutral position during all the exercises.

Three months after surgery, a physiotherapy meeting for home exercises was provided. The standard home exercises consisted of light muscle endurance exercises (abdominal muscles, back muscles and hip muscles), stretching and balance training (one-leg standing). The patients were advised to perform the home exercises three times per week. Pictorial and written instructions for the exercises were issued; the exercises are displayed in Table 3.

TABLE 3. Contents of the standard exercise guidance three months postoperatively

Usual care exercises	Aim of the exercise
1. Abdominal crunch (SUP)	Muscle endurance
2. Bird dog exercise (FPKP)	CNSP/muscle endurance
3. Forward lunge (SP)	Muscle endurance & strength
4. Posterior pelvic tilt (CLP)	CNSP/muscle endurance
5. Hamstring stretch	Mobility
6. Lateral flexion of the thoracic spine	Mobility
7. One-leg standing	Balance

Abbreviations: SUP=supine position, FKPK=four-point-kneeling position, CNSP=control of the neutral spine position, SP=standing position, CLP=crook lying position

4.4 Interventions in the randomized controlled trial

At the baseline of the 12-month intervention, both groups had a meeting with the physiotherapist, but the contents of that meeting were different. The patients who were randomized to the exercise group (EG) started the 12-month progressive exercise intervention with regular booster meetings with the PT. The usual care group (UCG) received the standard exercise instructions (Table 3, Figure 4).

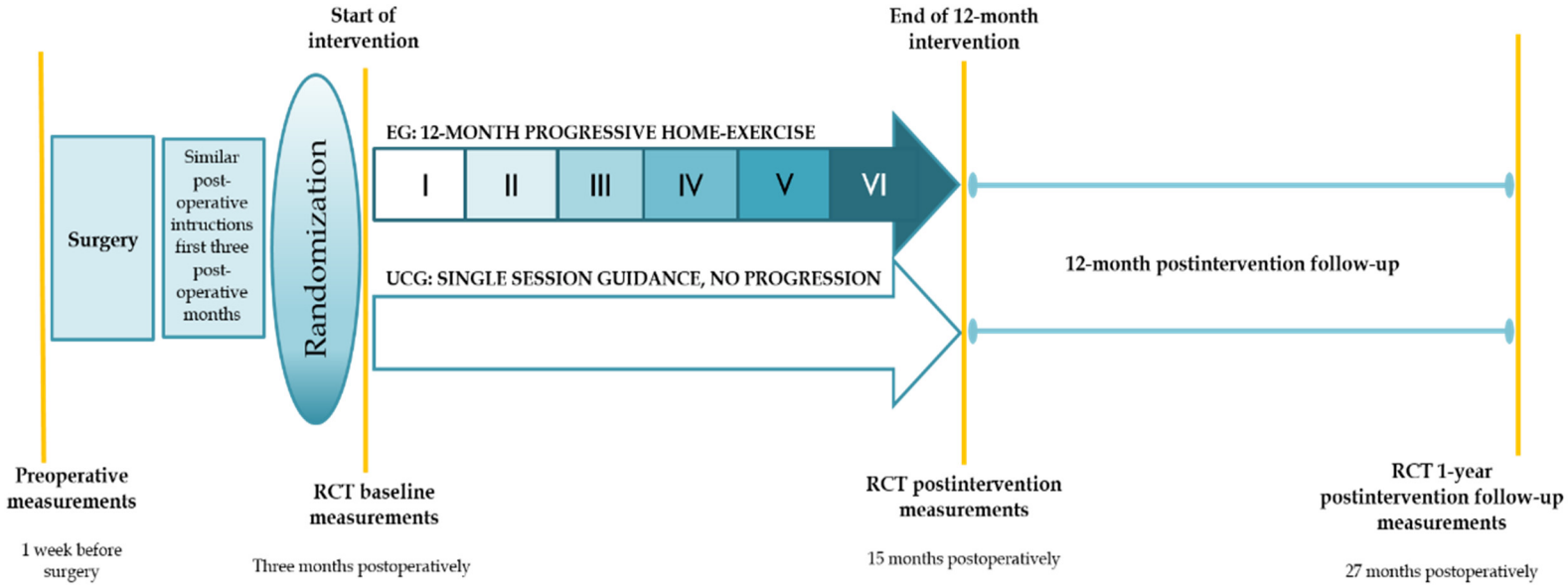

FIGURE 4. Study design and measurements of the exercise group (EG) and usual care group (UCG).

4.4.1 Progressive 12-month exercise intervention

The exercise program consisted of a 12-month progressive back-specific and aerobic training program together with fear-avoidance counseling. A physiotherapist gave each patient individual instructions in terms of the exercises according to the exercise protocol (Tarnanen, Neva et al. 2012). The patients exercised at home and had booster sessions with the physiotherapist every second month (in total, six meetings), where the next phase of the program was instructed (Table 4). Patients in EG determined their own goals for the 12-month exercise intervention. This action was taken to improve the patients' motivation and commitment to the long-lasting exercise intervention.

Back-specific exercise

The main aims of the 12-month back-specific exercise program were to improve lumbar spine movement control and to increase trunk and hip muscle coordination, strength and endurance. The selection of the exercises was partly based on electromyographic studies in healthy subjects and LSF patients (Akuthota & Nadler 2004, McGill 2007, Reiman 2009, Reiman, Weisbach & Glynn 2009, Tarnanen, Siekkinen et al. 2012). The main muscle groups to train were the abdominal, gluteal, thigh, and low back muscles. The hospital supplied the patients with elastic bands of differing stiffnesses (Thera-Band®) for use in some of the exercises.

The program was progressive, starting with exercises performed in the unloading position (supine, prone or four-point kneeling), where the lumbar spine was kept in a neutral position. As the program proceeded, the strengthening exercises became more challenging for coordination and for muscle strength. The degree of difficulty was increased by changing the functionality of the exercises, for example, by changing the performance positions and increasing the resistance of the elastic bands. The stiffness of the elastic bands were set to provide proper resistance for planned sets and repetitions, which varied from 2 x 10-20 to 4 x 10-20, depending on the exercise and the fitness level of the participant. The suitable progression of training was evaluated in meetings with the physiotherapist. The participants were instructed to perform the exercises three times a week. The patients were provided with pictorial and written instructions for the exercises. The back-specific exercise protocol has been published in the RCT protocol article (Table 4) (Tarnanen, Neva et al. 2012).

TABLE 4. The 12-month back-specific exercise program (Tarnanen, Neva et al. 2012)

Phase	Back-specific exercises	Aim of the exercise
I	1. Squat (SP, EB)	Muscle strength
	2. Abdominal crunch (SUP)	Muscle endurance
	3. Hip abduction (CLP)	CNSP
	4. Hip abduction and external rotation (SLP, EB)	CNSP/muscle endurance
	5. Hip extension (PRO)	CNSP
	6. Hip extension (FPKP, EB)	CNSP/muscle endurance
	Sets x Repetitions: 2 x 10-15-20	
II	1. Squat (SP, EB)	Muscle strength
	2. & 3. Bilateral shoulder extension and flexion (SP, EB)	Muscle endurance & strength
	4. Heel slide or leg lift and knee extension with one leg (SUP)	CNSP
	5. Hip extension or hip extension and knee extension (CLP)	CNSP/muscle endurance
	6. Hip abduction (SLP, EB)	CNSP/muscle endurance
	7. Hip extension (EB) or bird dog exercise (FPKP)	CNSP/muscle endurance
	Sets x Repetitions: 2 x 10-15-20	
III	1. Squat (SP, EB)	Muscle strength
	2. & 3. Bilateral shoulder extension and flexion (SP, EB)	Muscle endurance & strength
	4. Leg lift and knee extension with one leg (SUP)	CNSP
	5. Hip extension and knee extension (CLP)	CNSP/muscle endurance
	6. Bird dog exercise (FPKP)	CNSP/muscle endurance
	7. Hip abduction (SP)	CNSP/muscle endurance
	Sets x Repetitions: 2–3 x 10-15-20	
IV	1. Squat (EB) or forward lunge (SP)	Muscle strength
	2. Waiters bow exercise with elastic band (SP, EB)	Muscle strength
	3. & 4. Bilateral shoulder extension and flexion (SP, EB)	Muscle strength & endurance
	5. & 6. Unilateral shoulder horizontal adduction and abduction (SIP, EB)	CNSP/muscle endurance
	7. Hip abduction (SP, EB)	CNSP/muscle endurance
	Sets x Repetitions: 2–3 x 10-15-20	
V	1. Forward lunge (SP)	Muscle endurance & strength
	2. Waiters bow exercise (SP, EB)	Muscle strength
	3. & 4. Unilateral shoulder horizontal adduction and abduction (SP, EB)	CNSP/muscle endurance
	5.& 6. Downward chop and upward chop (SIP, EB)	CNSP/muscle endurance
	7. Hip abduction (SP, EB)	CNSP/muscle endurance
	Sets x Repetitions: 2-3-4 x 10-15-20	
VI	1. Forward lunge (SP)	Muscle endurance & strength
	2. Waiters bow exercise (SP, EB)	Muscle strength
	3. & 4. Unilateral shoulder horizontal adduction and abduction (SP, EB)	CNSP/muscle endurance
	5. & 6. Downward chop and upward chop (SP, EB)	CNSP/muscle endurance
	Sets x Repetitions: 2-3-4 x 10-15-20	

Abbreviations: SP=standing position, SUP=supine position, CLP=crook lying position, SLP=side lying position, FPKP=four-point-kneeling position, SIP=sitting position, EB=elastic band resistance, CNSP=control of the neutral spine position.

Aerobic training

The participants in the EG were instructed to walk regularly 2-3 times per week in terms of aerobic training and increasing their physical activity levels. Walking training was progressive. The number of daily steps was monitored by pedometers (Omron HJ-113-E, Omron Health Care, UK) to quantify the activity and to motivate the patients. The aim was to increase the total number of daily steps during the intervention up to 10 000-12 500 steps per day if the patient was under 65 years old and had no health-related restrictions in terms of aerobic training (Tudor-Locke et al. 2008). A target level of 7 500 steps per day was used if the patient was over 65 years old or had health-related restrictions for walking. However, the most important idea was to increase the step count by 5-15% in every other month depending on the individual's own baseline level (Tudor-Locke et al. 2008) (Table 5).

To ensure that the walking was vigorous enough to obtain health benefits, four months after the beginning of the intervention (7 months postoperatively), the patients started interval-type walking training. After warming up, patients were instructed to perform walking sessions consisting of 30 seconds – 1 minute of brisk walking alternating with 3 minutes of walking at a normal speed. At the beginning of the intervention, the duration of one walking session was approximately 25-30 minutes.

Progression was added based on intensity and time. The number of steps per day and frequency of exercise sessions per week were noted in exercise diaries, which were returned to the physiotherapist in the booster sessions. The experiences regarding the aerobic training in the past phase of the program were discussed. A new target level for daily steps was defined in each booster session based on the fitness and activity level of the patient (Table 5). If needed, adjustments were made to the next phase of the program.

TABLE 5. Progression of walking training during the 12-month intervention (Tarnanen, Neva et al. 2012)

Aim	Progression model
10 000 steps/day, if: age under 65 years, healthy and no restrictions to increase physical activity	1. If baseline level <5 000 (sedentary), number of steps is increased 15% every other month until the target level is reached
	2. If baseline level 5 000–7 499 (”low active”), number of steps is increased 10% every other month until the target level is reached
	3. If baseline level 7 500–9 999 (”somewhat active”), number of steps is increased 5% every other month until the target level is reached
	4. If baseline level >10 000 (active), this level is maintained or number of steps is increased 5% every other month until 12 500/day (”highly active”) is reached (Categorized according to Tudor-Locke et al. 2008)
7 500 steps/day, if: age >65 years and/or chronic diseases and/or some restriction to increase physical activity (Tudor-Locke & Bassett 2004, Tudor-Locke, Hart & Washington 2009)	1. If baseline level <4 250, number of steps is increased 15% every other months until the target level is reached. In the later phase, this level is maintained or a new goal is set.
	2. If baseline level >4 250, number of steps is increased 10% every other month until the target level is reached. In the later phase, this level is maintained or a new goal is set.

Patient education and motivation

During the booster sessions, barriers to physical activity, such as kinesiophobia or pain, were also identified by reviewing the Tampa Scale for Kinesiophobia (TSK) –questionnaire. The patient was carefully interviewed, and the irrational beliefs about activity and pain and its consequences were discussed with the physiotherapist. The physiotherapist gave valid information about pain mechanisms and aimed to correct the harmful, irrational beliefs and fears regarding activity. With those who had a high TSK score (37 or more) or who otherwise felt themselves unsure about exercising, additional support was provided by phone one week after the PT meeting.

Each participant in the EG was given exercise diary forms for each two-month exercise period. They marked down every training session they had completed, as well as the daily step count from the pedometer, which they wore every day from the early morning until bed time. The physiotherapist reviewed the exercise adherence from the exercise diaries and discussed the patient’s experiences about the past phase of the exercise program before instructing the next phase of the program. Adjustments to the progression of the program were made if needed.

4.4.2 Usual care group instructions

The patients in the UCG received standard postoperative instructions three months postoperatively, but no further instructions for progression or regular follow-up in physiotherapy were given. The standard instructions are described in detail in section 4.3 and in Table 3. In contrast to the EG, the UCG had no exercise diaries or pedometers because it could have stimulated them to exercise more than they usually would.

4.5 Outcomes

In the prospective cohort study (I), measurements were carried out before the surgery and one year after the surgery. In the RCT study (II-IV), the protocol included measurements at the beginning of the intervention, which was three months after surgery, and at the end of the 12-month intervention, i.e., 15 months after surgery. As an exception from those timeframes, study III regarding the primary outcome measures (disability, health-related quality of life and pain intensity) also included a one-year post-intervention follow-up, which occurred 27 months after the surgery. In study IV, additional preoperative questionnaires for kinesiophobia and physical activity were included (Table 6, Figure 4).

TABLE 6. Designs, samples and main outcomes of the thesis

Study	Design	Follow--up	N	Participants	Outcomes
I	Prospective cohort study	Preoperative – 12 months postoperative	194	Elective LSF patients: Spondylolisthesis, spinal stenosis, disc herniation or degeneration, postoperative conditions, scoliosis	Trunk muscle strength
II	RCT	12-month intervention	98	Elective LSF patients with spondylolisthesis (EG 48/UCG 50)	Trunk muscle strength, spine range of movement Timed Up-and-Go–test
III	RCT	12-month intervention + 12-month post-intervention follow-up	98	Elective LSF patients with spondylolisthesis (EG 48/UCG 50)	Pain, disability, health-related quality of life (RCT primary outcomes)
IV	RCT	Preoperative – three-month postoperative + 12-month intervention	98	Elective LSF patients with spondylolisthesis (EG 48/UCG 50)	Kinesiophobia, physical activity

Abbreviations: N=number of participants, RCT= randomized controlled trial, EG= exercise group, UCG = usual care group

4.5.1 Objective outcome measurements

Strength and spine function were objectively measured. The maximal isometric strength of the trunk flexors and extensors was measured using a strain-gauge dynamometer (DS Europe Milano, Italy) (Rantanen, Airaksinen & Penttinen 1994) and analyzed with a computer program (Isopack, Newtest, Oulu, Finland). The isometric strength test was performed in a standing position (Paalanne et al. 2009) with a distance of 20 cm between the feet. The pelvis was fixed against the metal support from below the iliac crest, and the harness was placed around the chest just under the armpits. The harness was attached with a metal strain to the strain-gauge dynamometer horizontally. Patients performed two maximal isometric contractions, and if the result improved more than 10%, they performed a third contraction. The best result was used in the analysis. Absolute strength levels are expressed as Newtons (N) (one kilogram force equals 9.81 N). The extension/flexion strength ratio (E/F ratio) was calculated to quantify the possible imbalance between these two antagonist muscle groups. Participants were weighed, and the height was measured by the physiotherapist. This information was used in body mass index (BMI) calculations and in strength / body weight calculations,

where kilogram force is used instead of Newtons. Back extensor endurance and muscle fatigability was measured using the Biering-Sörensen's static hold test in the prone position, where the lower body was fixed on the bench, and the upper body was held in a straight horizontal position as long as possible, with a max. of 240 seconds (Biering-Sørensen 1984, Latimer et al. 1999).

The spinal flexion range of movement (ROM) was measured by the original 10 cm Schober's test, first described in 1937 (Tousignant et al. 2005). In that test, landmarks are marked to the lumbosacral junction and 10 cm above the junction in the standing position, and the change in distance is measured during flexion (Tousignant et al. 2005). The combined thoracic and lumbar spine flexion was measured with Stibor's test with similar principles to those of Schober's test, but the landmarks were the lumbosacral junction and C7 spinous process (Macrae & Wright 1969). The fingertip-to-floor distance test was used to measure the functional downward reach (Perret et al. 2001). Lateral bending was assessed by the method described by Frost et al. (1982), where the patient is performing lateral flexion in a standing position with straight arms at the sides, and the fingertip movement (distance) during the bending is measured from the thigh (Frost et al. 1982).

The Timed Up-and-Go (TUG) test (Gautschi et al. 2016) was used as an objective measure of functioning and mobility. It consists of chair rises, a three-meter walk, turning around, walking back to the chair and sitting down as fast as possible. The mean result in healthy adults has been reported as 8.1 s (Bohannon 2006).

4.5.2 Patient-reported outcomes

Patient-reported outcome measures (PROs) were also used. Physical functioning was assessed by the Finnish version of the Oswestry Disability Index (ODI) 2.0 questionnaire (Fairbank et al. 1980, Pekkanen et al. 2011). The ODI consists of 10 questions, each comprising six statements. Patients evaluate themselves regarding how they feel today and how much difficulty they have with the mentioned activities because of back pain or leg pain. Each question is scored from zero (lowest disability) to five (greatest disability). The total ODI score is a percentage of the maximum sum score of the answered items. A score of 0-20 indicates minimal disability, 20-40 moderate disability, 40-60 severe disability, 60-80 a crippled patient, and 80-100 either a bed-bound or symptom-exaggerating patient (Fairbank et al. 1980).

Health-related quality of life (HRQoL) was assessed using The RAND 36-Item Health Survey 1.0 (Aalto, Aro & Teperi 1999). Eight dimensions were formulated from the RAND-36. The scaling of each dimension ranged from 0 to 100. The higher value means a better HRQoL (Hays, Sherbourne & Mazel 1993, Aalto, Aro & Teperi 1999). Age- and sex-adjusted RAND-36 reference values for the normal Finnish population were used as a reference (Aalto, Aro & Teperi 1999).

Average low back and leg pain intensities for the previous 7 days were assessed using a 100-mm visual analogue scale (VAS) (Price et al. 1983). The VAS

was also used to measure the intensity of low back pain and leg pain during each strength measurement.

Fear of movement or reinjury was assessed by the Tampa Scale for Kinesiophobia -questionnaire (TSK). It comprises 17 items rated on a 4-point Likert response scale (1 totally disagree – 4 totally agree), with total scores ranging from 17 (minimum – no fear) to 68 (maximum – intense fear) points (Miller, Kori & Todd 1991, Woby et al. 2005, Koho et al. 2014, Koho et al. 2015). In the TSK, every fourth item is reversed.

Overall physical activity was measured by the short form of the International Physical Activity Questionnaire (IPAQ) (IPAQ Research Committee 2005). Physical activity is expressed as a continuous score of total metabolic equivalent minutes per week (METmins/week). According to the IPAQ Scoring Protocol, less than 600 METmins/week is considered inactive, 601-2999 is considered moderate activity, and 3000 or more is considered highly active and meeting the criteria for health-enhancing physical activity (IPAQ Research Committee 2005, Bauman et al. 2009). During the intervention, the EG marked down their back-specific exercises in the exercise diary, recorded the number of steps per day by a pedometer (Omron HJ-113-E, Omron Health Care, UK) and then marked that sum of the daily steps in the diary as well. UCG did not have pedometers or exercise diaries, but after the intervention they reported the regularity of back-specific exercises by a single question: "How often you have performed trunk strengthening exercises during the last month?" The three options were: "Not at all", "Irregularly" and "Regularly". In the prospective cohort study, the amount of leisure-time physical activity (LTPA) (minutes/week) was gathered by a question, which covered the time/week spent in leisure-time activities that lasted at least 10 minutes at a time.

In addition, sociodemographic data, such as sex, age, employment status, pain duration before surgery, and smoking status, were collected by questionnaires. Clinical data, such as diagnosis and fusion length, were collected from the spine database. Patient-reported adverse effects or harms caused by the intervention were marked down on the paper form by the physiotherapist.

4.6 Statistical methods

The descriptive data are presented as the mean with standard deviation (SD) or with 95% confidence intervals (95% CI), counts (N) with percentages (%), or medians with interquartile ranges (IQRs). Analyses were performed with normal t-tests for normally distributed continuous variables, bootstrap-type t-tests for skewed continuous variables, Chi-square tests for dichotomous variables, or Mann-Whitney U-tests for categorical variables or when using the median instead of the mean. Univariate and multivariate linear regression analyses with a forward stepwise method were performed to investigate which factors were associated with the extension and flexion muscle strength levels at the one-year

follow-up. Correlative analyses were performed using the Pearson correlation coefficient (r).

The data from the RCT study were analyzed using the intention-to-treat (ITT) principle. In studies II and III, the difference between the groups was analyzed using a mixed model method with no need for imputation of missing data. In study IV, the intervention outcomes (difference between the groups) were analyzed using the nonparametric independent samples Mann-Whitney U-test because of the skewed distributions of the data. Significance of change over time in the early postoperative phase (one group only) was analyzed using the nonparametric Wilcoxon's signed rank test for related samples. The exercise diary data of the EG was imputed with the last carried forward method in this summary. In the original articles, no imputation was performed. Effect sizes were calculated regarding the Cohen's d method, and outcome change scores were converted to the same direction, where a positive ES change indicated an improvement in each outcome. An effect size of <0.20 was negligible, 0.20-0.49 small, 0.50-0.79 medium and ≥0.80 large (Cohen 1988).

Statistical analyses were carried out using IBM SPSS Statistics (IBM Corporation Armonk, NY); Stata statistical software (StataCorp LP, College Station, TX, USA) (release 13.0) was used for RAND-36 HRQoL analysis, and the statistical program "R" (version 3.5.1) was used for effect-size calculations.

5 RESULTS

5.1 Patient characteristics

In the prospective cohort study (I), the most common diagnosis leading to the surgery was degenerative spondylolisthesis (in 71% of participants), and in the RCT study, 68% of the cases of spondylolisthesis were degenerative. In both patient samples, the participants had remarkable and longstanding low back pain and leg pain before surgery. The mean (SD) age was 61 (12) years in the prospective cohort study and 59 (12) years in the RCT study. In both study samples, women represented the majority of patients (Table 7). In the RCT study, there were no between-group differences in the sociodemographic or clinical data.

TABLE 7. Sociodemographic and clinical background data

	Prospective cohort study (study I)	Randomized controlled trial (studies II-IV)	
	N=194	Exercise group n=48	Usual care group n=50
Age, years, mean (SD)	61 (12)	59 (12)	58 (12)
Women, n (%)	129 (66)	34 (71)	38 (76)
Body mass index, mean (SD)	28.4 (4.4)	28.3 (4.8)	28.3 (4.8)
Smokers, n (%)	27 (14)	9 (19)	6 (12)
Length of education, years, mean (SD)	12 (4)	12.0 (3.7)	12.6 (3.6)
Employed, n (%)	48 (25)	27 (56)	29 (58)
Primary diagnosis, n (%)			
Degenerative spondylolisthesis	103 (53)	32 (67)	35 (70)
Isthmic spondylolisthesis	35 (18)	16 (33)	15 (30)
Spinal stenosis	14 (7)		
Disc herniation or degeneration	10 (5)		
Postoperative conditions	20 (11)		
Scoliosis	12 (6)		
Length of fusion, n (%)			
1-2 levels	138 (71)		
3 levels or more	56 (29)		
Duration of current symptoms before surgery, months, median (IQR)	31 (18, 66)	29 (15, 48)	24 (15, 60)
Preoperative low back pain, VAS mean (SD)	63 (27)	58 (23)	60 (23)
Preoperative leg pain, VAS mean (SD)	64 (26)	58 (24)	65 (23)

5.2 Recovery after lumbar spine fusion in the prospective cohort study

5.2.1 Trunk muscle strength changes

In the prospective cohort study (I), before the LSF surgery, the mean (SD) maximal isometric trunk extension strength was 205 (144) N and the mean flexion strength was 295 (172) N. One year postoperatively, the mean (95% CI) trunk extension strength had increased by 53 (37 to 70) N ($p<0.001$), and the mean flexion had increased by 69 (53 to 85) N ($p<0.001$). In females, the mean (SD) extension strength increased from 158 (88) to 213 (101) N ($p<0.001$), and the mean flexion increased from 222 (106) to 292 (105) N ($p<0.001$) at the one-year follow-up. In males, the mean (SD) extension strength increased from 297 (184) to 349 (168) N ($p=0.013$) and the mean flexion increased from 437 (190) to 506 (167) N ($p=0.001$). The differences between the sexes in terms of strength changes were not statistically significant (Figure 5 a). A similar trend was also seen in the strength per bodyweight ratios (Figure 5b).

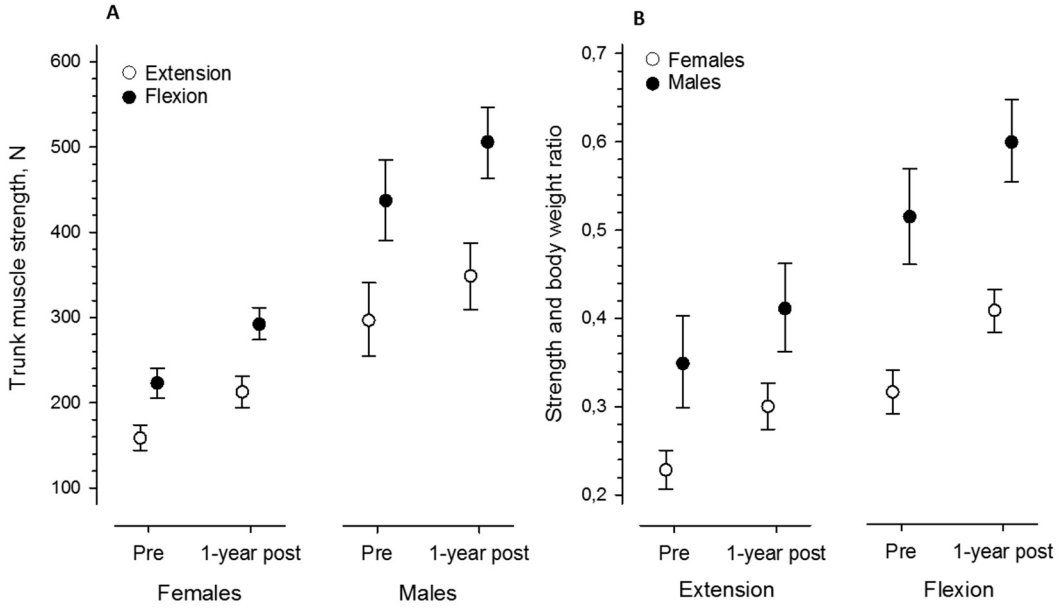

FIGURE 5. Maximal isometric trunk muscle strength levels in females and males preoperatively and one year after lumbar fusion. Absolute values (Newtons) in figure A and strength per bodyweight ratios in figure B.

The preoperative mean (SD) extension/flexion strength ratio in all patients was 0.75 (0.38), and it did not significantly change during the follow-up (Figure 6). Women's extension/flexion ratios were 0.77 (0.40) preoperatively and 0.75 (0.27) at the one-year follow-up (p=0.44), and men's ratios were 0.71 (0.32) and 0.69 (0.23) (p= 0.72), respectively.

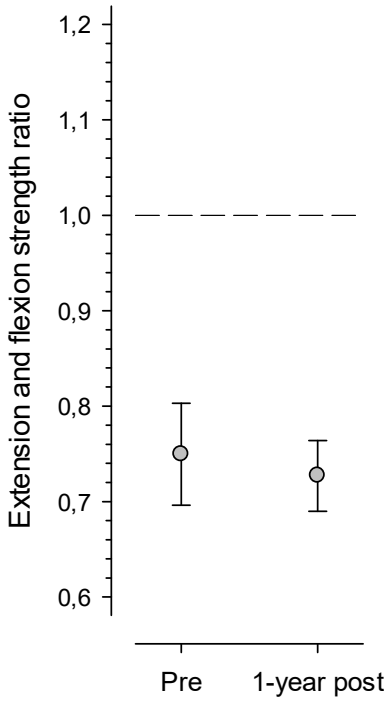

FIGURE 6. Trunk muscle extension/flexion strength ratio preoperatively and one year after lumbar fusion.

The mean (SD) pain intensity (VAS) during the maximal isometric trunk extension strength test was 55 (29) mm preoperatively and 14 (25) mm ($p<0.001$) one-year postoperatively. During the flexion test, preoperative pain values were 41 (29) and 11 (21) mm at the one-year follow-up ($p<0.001$). There were no differences between the sexes in terms of the decrease of pain during the flexion and extension strength tests. The mean (SD) leisure-time physical activity before surgery was 254 (294) minutes/week and was 291 (373) minutes/week ($p=0.013$) at the one-year follow-up.

Both univariate and multivariate regression analyses showed that male sex, lower age, milder preoperative back pain, and a greater preoperative starting level of trunk muscle strength were associated with better one-year extension and flexion strength levels (Tables 8 and 9). In addition, lower back pain during the measurement was associated with a higher trunk extension strength level one year postoperatively (Table 8).

TABLE 8. Linear regression analyses of the variables, which explains the maximal isometric trunk extension strength levels one year after the lumbar fusion

	Extension strength at the one-year follow-up			
	Univariate		Multivariate	
Variable	**Beta (95% CI)**	**P-value**	**Beta (95% CI)**	**P-value**
Sex, male	136.43 (98.24 to 174.62)	<0.001	63.18 (31.30 to 95.07)	<0.001
Age, years	-6.23 (-7.71 to -4.75)	<0.001	-3.97 (-5.16 to -2.78)	<0.001
Smoking	59.36 (1.55 to 117.17)	0.04		
BMI	1.56 (-3.04 to 6.16)	0.51		
Preoperative back pain (VAS)	-0.90 (-1.68 to -0.11)	0.03	-0.69 (-1.32 to -0.06)	0.03
Preoperative leg pain (VAS)	-0.95 (-1.65 to -0.25)	0.01		
LTPA, min/week	0.03 (-0.02 to 0.09)	0.21		
Back pain during measurement (VAS)	-0.81 (-1.61 to -0.00)	0.05	-0.65 (-1.29 to -0.01)	0.04
Preoperative extension strength	0.65 (0.55 to 0.76)	<0.001	0.45 (0.34 to 0.55)	<0.001

Abbreviations: BMI= body mass index, VAS= visual analog scale, LTPA= leisure-time physical activity, Beta= regression coefficient

TABLE 9. Linear regression analyses of the variables, which explains the maximal isometric trunk flexion strength levels one year after the lumbar fusion

	Flexion strength at the one-year follow-up			
	Univariate		**Multivariate**	
Variable	**Beta (95% CI)**	**P-value**	**Beta (95% CI)**	**P-value**
Sex, male	214.18 (175.48 to 252.87)	<0.001	93.29 (57.29 to 129.30)	<0.001
Age, years	-5.18 (-7.02 to -3.34)	<0.001	-2.44 (-3.61 to -1.26)	<0.001
Smoking	40.79 (-26.14 to 107.71)	0.23		
BMI	5.82 (0.59 to 11.05)	0.03		
Preoperative back pain (VAS)	-0.47 (-1.38 to 0.44)	0.31	-0.86 (-1.39 to -0.32)	0.002
Preoperative leg pain (VAS)	-0.99 (-1.79 to -0.28)	0.02		
LTPA, min/week	-0.003 (-0.067 to 0.060)	0.92		
Back pain during measurement (VAS)	-0.50 (-1.61 to 0.61)	0.38		
Preoperative flexion strength	0.73 (0.64 to 0.81)	<0.001	0.54 (0.44 to 0.64)	<0.001

Abbreviations: BMI= body mass index, VAS= visual analog scale, LTPA= leisure-time physical activity, Beta= regression coefficient

5.2.2 Changes in mobility, disability and spine range of movement

The mean (SD) time spent in the Timed Up-and-Go-test (TUG) was 10.0 (4.8) s preoperatively, and the mean (95 CI %) postoperative change at the one-year follow-up was -2.2 (-2.9 to -1.4) s (p<0.001). The mean (SD) Oswestry Disability Index (ODI) score decreased from 44.5 (14.4) preoperatively to 21.2 (16.5) at the one-year postoperative follow-up (p<0.001).

Significant improvements were observed in all spine range of movement (ROM) measures at the one-year follow-up (Table 10). Decreases in low back pain intensity correlated with improvements in the fingertip-to-floor distance r=0.33 (0.19 to 0.45) and with lateral flexion r=-0.25 (-0.38 to -0.11) (both p<0.001). The length of fusion correlated with the one-year ROM measurements: Schober r=-0.30 (0.16 to 0.42), Stibor r=-0.27 (0.14 to 0.40), fingertip-to-floor distance r=0.23 (0.09 to 0.36), and lateral flexion r=-0.32 (-0.44 to -0.18) tests, respectively.

TABLE 10. Changes in clinical spine range of movement measurements at the one-year follow-up

	Preoperative Mean (SD)	One year after LSF Mean (SD)	Mean Change (95% CI)	p-value for change
Lateral flexion, right & left mean, cm	12.8 (4.4)	14.0 (4.0)	1.03 (0.4 to 1.7)	0.0013
Schober, cm	3.6 (1.6)	3.9 (1.5)	0.3 (0.0 to 0.5)	0.043
Stibor, cm	6.7 (2.4)	7.2 (2.0)	0.6 (0.2 to 0.9)	0.0033
Fingertip-to-floor distance, cm	13 (16)	9 (11)	-4.3 (-5.6 to -3.2)	<0.001

5.3 Effectiveness of the 12-month home-exercise program (RCT)

In the randomized controlled trial (studies II-IV), the exercise group (EG, n=48) started their 12-month exercise intervention, and the usual care group (UCG, n=50) had single-session guidance for lighter home exercises. Until then, the treatment had been the same in both groups. In terms of the intervention baseline, the sociodemographic factors were similar in both groups (Table 7).

5.3.1 Exercise adherence and feasibility of the program

According to the exercise diary data of the EG, the median [IQR] frequency of the back-specific exercise sessions in the EG decreased from 2.5 [1.9; 3.4] times per week during the first two months of the intervention to a median of 1.7 [0.6; 1.9] during the last two months of the intervention (p < 0.001). The frequencies of the back-specific exercises per week are presented in Figure 7 for each month. The median daily step count [IQR] was 6138 [3759; 8907] during the first two months and 5870 [3587; 8024] steps during the last two months of the intervention (p=0.24)

in the EG. According to the questionnaire after 12 months, 23 (40%) participants of the UCG reported that they had performed back-specific exercises regularly, 28 (50%) irregularly and 2 (4%) not at all during the last month of the 12-month intervention.

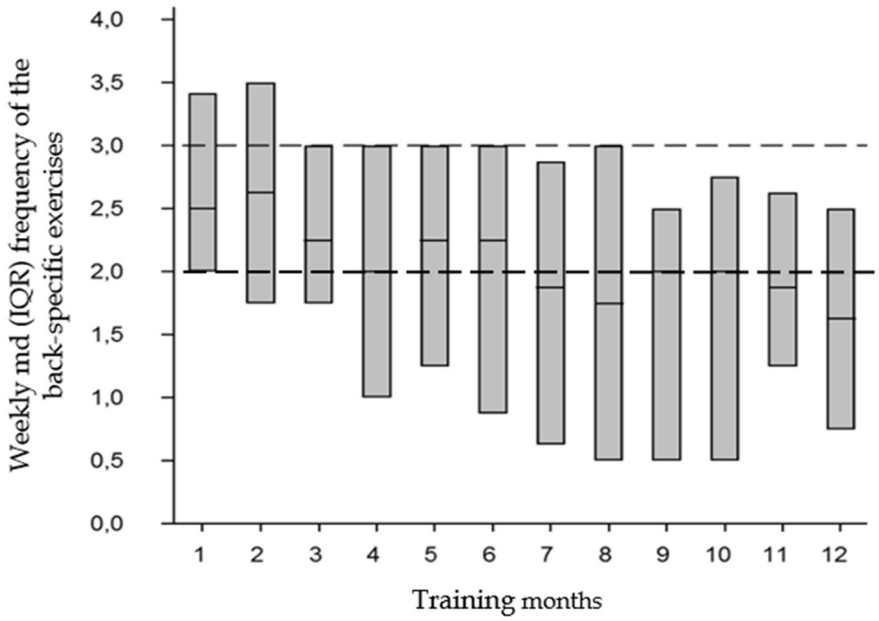

FIGURE 7. Frequency (times/week) of back-specific exercise during the 12-month intervention in the exercise group.

No discontinuance due to harms caused by the exercise program was reported. There was one dropout during the intervention due to death. The reason for death was not related to the exercise protocol. Six patients in the EG discontinued the exercise intervention for other reasons: difficulties in commuting to physiotherapy meetings (n=4), sudden decline in general condition and hemoglobin (n=1), physician's advice to discontinue (n=1) because of a problem with fixation (patient was later reoperated on and diagnosed with myopathy leading to muscle weakness).

The back-specific exercise program was modified for 12 participants in the EG who had difficulties performing some of the exercises. The modifications most often needed were slowing down the progression of the program or tailoring the specific exercise individually if the participant had problems with their knees, hips, or shoulders or if they had very weak leg strength preventing safe squatting, for example. Those 12 EG participants whose program was modified, did not differ from the rest of the EG participants in terms of sex, age, or back and leg pain levels at any time points.

5.3.2 Trunk muscle strength and spine function during the exercise intervention

At baseline, the mean (SD) maximal isometric trunk extension strength in the EG was 269 (125) N, and the mean (95% CI) increase was 75 (53 to 96) N. In the UCG, the baseline extension strength was 301 (125) N, and it improved by 58 (37 to 79) N (between groups p=0.29). The maximal isometric trunk muscle flexion was 301 (119) N at baseline in the EG, and it improved by 50 (30 to 71) N, while in the UCG, the baseline was 324 (140), and the improvement was 45 (25 to 64) N (between groups p=0.72). The mean changes in the maximal isometric trunk muscle strength are shown in Figure 8.

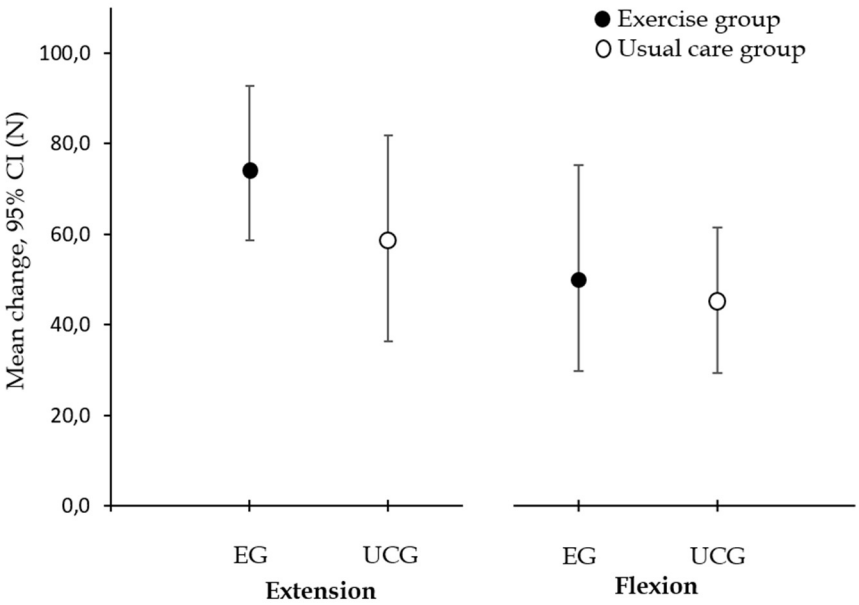

FIGURE 8. The changes in maximal isometric trunk muscle strength during the 12-month intervention.

The mean (SD) trunk extension/flexion strength ratio was 0.90 (0.31) at baseline, and it increased by 0.11 (0.05 to 0.17) during the intervention in the EG. In the UCG, the ratio was 0.98 (0.28), and it remained unchanged 0.02 (-0.04 to 0.08) during the intervention (between groups p= 0.052) (Figure 9). Biering-Sörensen's static hold test results improved in both groups, in the EG from 40 (41) s by 17 (4 to 29) s and in the UCG from 53 (53) s by 24 (12 to 36) s (between groups p=0.44). At baseline, the low back pain intensity during the maximal isometric extension strength test was 13 (18) mm in the EG and 12 (17) mm in the UCG, and it remained unchanged during the intervention in both groups (between groups p=0.96).

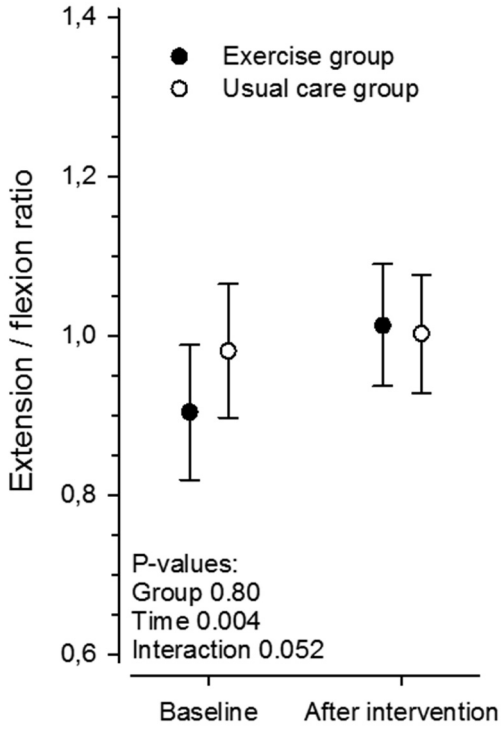

FIGURE 9. Changes in the trunk extension/flexion strength ratio during the 12-month intervention.

To observe the effects of individual exercise adherence on strength changes in the EG, the mean weekly exercise frequency was first calculated. This calculation was based on each individual's one-year total count of back-specific training sessions, reported in the exercise diaries. Thereafter, EG was split into the two groups based on this training frequency: those who exercised less than two times per week (less than 104 completed training sessions over a one-year intervention, n=27) and those whose training frequency was two or more sessions per week (104 sessions or more, n=20). The results showed no statistically significant difference between the groups in terms of the magnitude of change in Biering-Sörensen's test (p=0.14) (Figure 10).

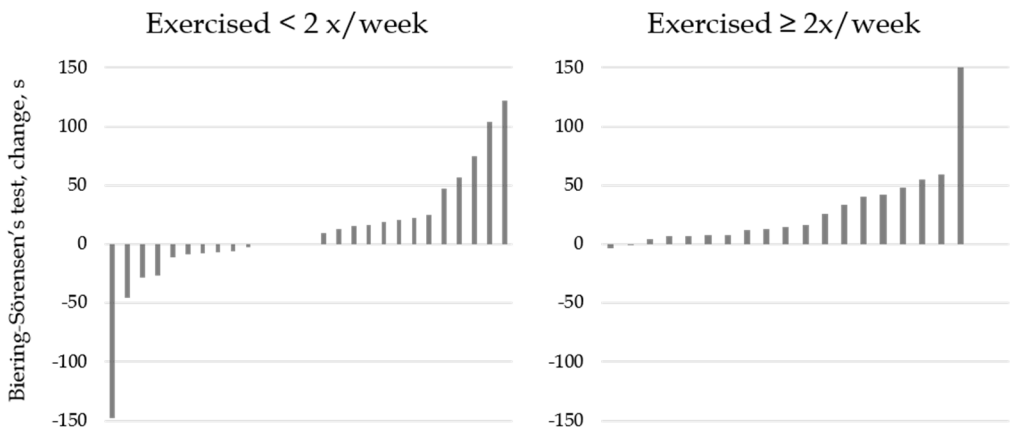

FIGURE 10. Individual changes in Biering-Sörensen's test in the exercise group classified by the adherence of back-specific exercise. The bars represents individuals.

In terms of the back extension/flexion strength ratio, the changes were very similar in those who exercised less than two times per week and in those who exercised more than two times per week (Figure 11). There was no statistically significant difference between the two adherence groups in terms of the magnitude of the extension/flexion strength ratio change (p=0.51).

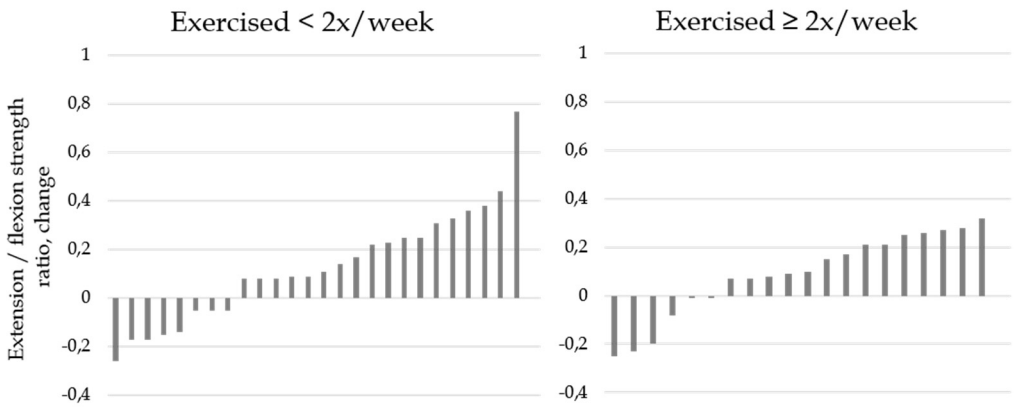

FIGURE 11. Individual changes in extension/flexion strength ratio in the exercise group classified by the adherence of back-specific exercise. The bars represents individuals.

In terms of the changes in active spine range of movement (ROM) measurements, there were no statistically significant differences between the groups. At the intervention baseline, the mean (SD) Schober's test was 3.4 (1.2) cm in the EG and 3.1 (1.0) cm in the UCG. It improved by 0.9 cm in both groups during the intervention. The fingertip-to-floor-distance test improved from 13.4 (12.0) cm by 1.3 (95% CI 0.5 to 21) cm in the EG and from 13.7 (12.6) cm by 0.9 (0.2 to 1.7) cm in the UCG. The baseline mean (SD) Stibor's test in the EG was 7.6 (2.2) cm, changing by -0.03 (-0.4 to 0.4) cm, and in the UCG was 7.0 (1.7) cm, changing by 0.3 (-

0.1 to 0.7) cm. In the lateral flexion ROM, the mean of the left and right side bending was 12.9 (4.4) in the EG and 14.5 (3.8) in the UCG. The EG increased their lateral flexion ROM by 1.3 (0.7 to 2.0) cm, and the UCG increased by 0.9 (0.04 to 1.8) cm.

5.3.3 Pain, disability and health-related quality of life

At baseline, there were no between-group differences in the mean (SD) low back pain or leg pain intensities (VAS during the past seven days), and these values did not significantly change during the 12-month intervention in either group. The baseline level of low back pain intensity in the EG was 21 (18) mm, changing by -2 (95% CI: -7 to 4) during the intervention. In the UCG, the baseline low back pain intensity was 17 (18), changing by 4 (-1 to 9) (between the groups p=0.16). The leg pain intensity decreased from 19 (22) by 4 (-4 to 12) in the EG and from 14 (20) by 0.4 (-7 to 6) in the UCG (between groups p=0.38).

At baseline, the mean (SD) TUG test results were 9.1 (7.4) s in the EG and 7.2 (2.0) s in the UCG, and no changes occurred during the intervention. The ODI decreased from 24 (12) by -5.6 (-9.2 to -1.9) in the EG and from 18 (12) by -4.6 (-8.2 to -1.0) in the UCG during the intervention (between groups p=0.69). At the one-year postintervention follow-up, the ODI scores did not change further in either group. At baseline, 54% of the EG had an ODI score of 20 or higher; after the 12-month intervention and at the one-year postintervention follow-up, 29% and 25%, respectively, of the EG had an ODI score <20, while the proportions in the UCG were 36%, 25% and 28%, respectively.

In terms of the health-related quality of life, measured by the RAND-36, there were no between-group differences in the changes in any of the eight dimensions during the intervention or at the one-year postintervention follow-up. However, both groups improved their results significantly in the Physical Functioning and Role Physical dimensions during the intervention (Table 11). Compared to the Finnish reference values of the Physical Functioning, Role Physical and Bodily Pain dimensions; the patients' scores were lower in both groups, and the EG also had lower values in the Social Functioning dimension at baseline. Both groups achieved the Finnish reference values in all dimensions by the one-year postintervention follow-up (Figure 12).

TABLE 11. Baseline scores and changes in the RAND-36 dimensions during the intervention and at follow-up, reported as the means with standard deviations (SDs) or 95% confidence intervals (95% CIs). The changes are based on mixed-model estimates. Between-group p-values were adjusted by age and sex

	Baseline		Change during the intervention		p-value between the groups	Change during the one-year postintervention follow-up		p-value between the groups
	EG Mean (SD)	UCG Mean (SD)	EG Mean (95% CI)	UCG Mean (95% CI)		EG Mean (95% CI)	UCG Mean (95% CI)	
Physical functioning	59.6 (20.4)	67.1 (17.4)	10.0 (4.6 to 15.3)	7.8 (2.5 to 13.0)	0.53	-0.5 (-4.8 to 3.7)	-1.4 (-5.5 to 2.6)	0.75
Role physical	22.3 (31.7)	38.5 (36.8)	20.0 (7.7 to 32.3)	16.4 (4.4 to 28.4)	0.67	9.9 (-3.6 to 23.3)	5.7 (-7,2 to 18.5)	0.65
Bodily pain	55.1 (20.7)	60.8 (19.3)	5.3 (-1.7 to 12.4)	6.3 (-0.6 to 13.1)	0.88	1.5 (-5.4 to 8.3)	1.5 (-5.0 to 8.0)	0.99
General health	62.4 (20.4)	59.4 (19.0)	-2.6 (-7.1 to 2.0)	1.3 (-3.2 to 5.7)	0.23	2.7 (-2.2 to 7.6)	-0.8 (-5.4 to 3.8)	0.30
Vitality	61.1 (24.0)	65.8 (18.5)	1.3 (-4.7 to 7.4)	-1.9 (-7.8 to 4.1)	0.44	-1.1 (-6.9 to 4.6)	0.1 (-5.4 to 5.7)	0.74
Social functioning	71.5 (25.0)	79.7 (20.2)	3.0 (-4.9 to 10.9)	5.4 (-2.3 to 13.1)	0.68	7.9 (1.0 to 14.8)	-1.2 (-7.7 to 5.4)	0.06
Role emotional	60.1 (44.2)	68.1 (40.1)	2.1 (-16.6 to 20.8)	4.9 (-8.5 to 18.3)	0.86	1.2 (-11.1 to 13.5)	-5.6 (-17.2 to 6.0)	0.43
Mental health	74.0 (19.5)	77.1 (16.6)	-0.4 (-5.4 to 4.7)	-1.2 (-6.2 to 3.7)	0.81	2.1 (-2.7 to 6.9)	-1.0 (-5.6 to 3.6)	0.36

Abbreviations: EG=exercise group, UCG=usual care group

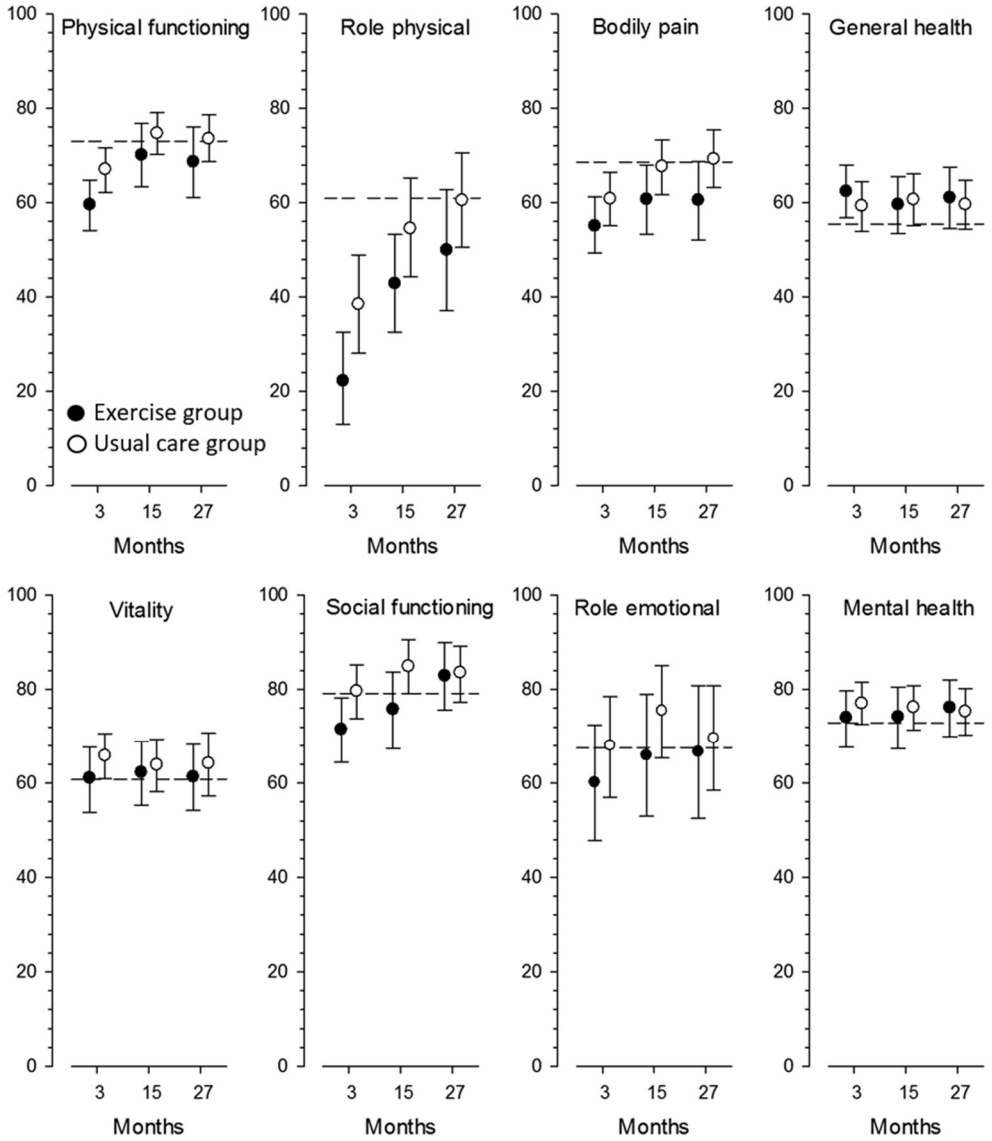

FIGURE 12. Health-related quality of life dimensions (RAND-36) during the intervention (three to 15 months postoperatively) and at the 1-year follow-up after the intervention (27 months). The dotted line shows the Finnish normal population reference values, which are weighted to match the age and sex distribution of the study population.

5.3.4 Kinesiophobia and physical activity

The preoperative median [IQR] total Tampa Scale for Kinesiophobia (TSK) score was 39 [33; 44] points. Three months after surgery, the score had decreased to 31 [26; 36] points ($p<0.001$) across the whole sample (N=98). The largest item-specific improvements were in the TSK items 3 "My body is telling me I have something dangerously wrong" and 11 "I wouldn't have this much pain if there weren't something potentially dangerous going on in my body". The item-specific changes with effect sizes within each group are shown in Figure 13, and the items are described in detail in Appendix 3. During the exercise intervention, the

mean change in the total TSK score in the EG was -1.6 points (95% CI -3.23 to 0.12) and was 0.2 in the UCG group (95% CI -1.47 to 1.94). The difference between the groups was not significant (p=0.17). When the TSK item-specific changes were analyzed in the intervention phase, item 9 "I'm afraid that I might injure myself accidentally" showed significant between-group differences in favor of the EG (p=0.01).

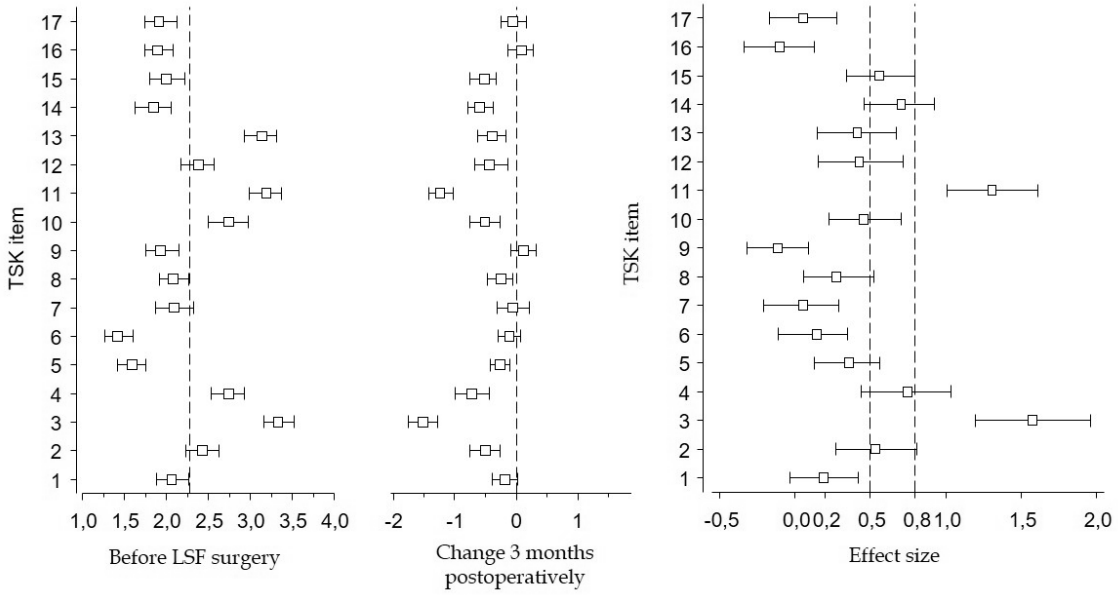

FIGURE 13. The preoperative mean scores with 95% CIs for each Tampa Scale for Kinesiophobia item, and the mean changes (95% CI) at three months postoperatively. Cohen d effect sizes (95% CI) for each item. (N=98).

The overall PA was assessed by the IPAQ. The preoperative median [IQR] IPAQ was 1709 [396; 3982] METmins/week, and at three months postoperatively, it was 2079 [1386; 3792] METmins/week across the whole RCT sample (N=98) (p=0.15). In the EG, the median [IQR] IPAQ was 1863 [1040; 3042] METmins/week at the beginning of the intervention and 3190 [1150; 6384] METmins/week at the end of the intervention (p=0.01). The corresponding values in the UCG group were 2569 [1501; 4075] and 3590 [1634; 6485] METmins/week (p=0.01). The difference between the groups in terms of the PA change was not significant (Figure 14).

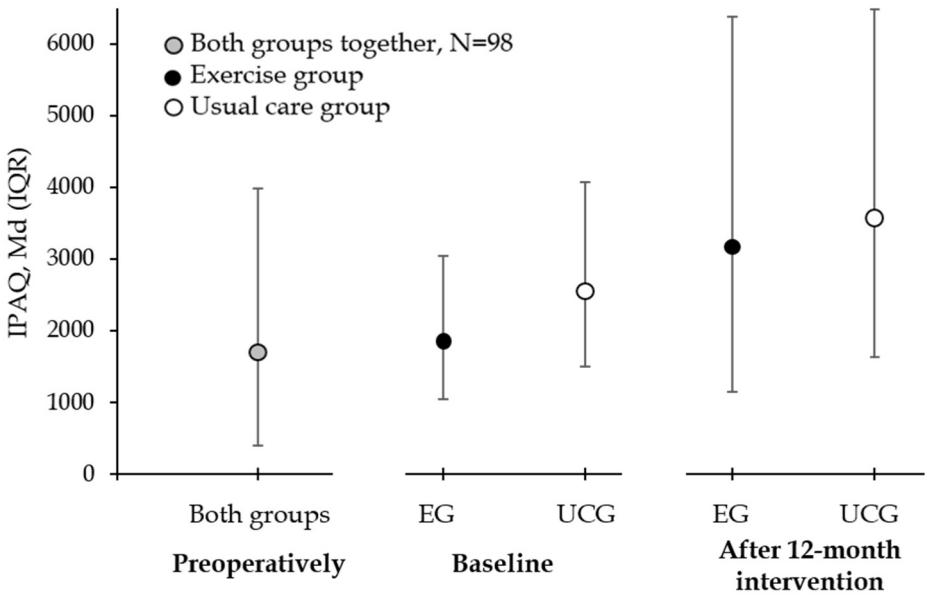

FIGURE 14. Physical activity levels (METmins/week) preoperatively in all RCT patients, at the intervention baseline (three months after surgery) and after the 12-month intervention.

5.3.5 Effectiveness of a one-year postoperative home-exercise program

Within-group effect size (ES, Cohen's d) shows the treatment effect for different outcomes in the RCT study during the 12-month exercise program. Large or at least moderate effect sizes were observed in the isometric maximal trunk muscle strength outcomes in both groups, except in the extension/flexion strength ratio, which remained small in the UCG, and in the Biering-Sörensen's static hold test, which remained small in the EG. In terms of the health-related quality of life, both groups had the greatest effect sizes in the Physical Functioning and Role Physical dimensions. In terms of the ODI, a significant positive effect was seen in both groups, but the effect sizes were small (Figure 15).

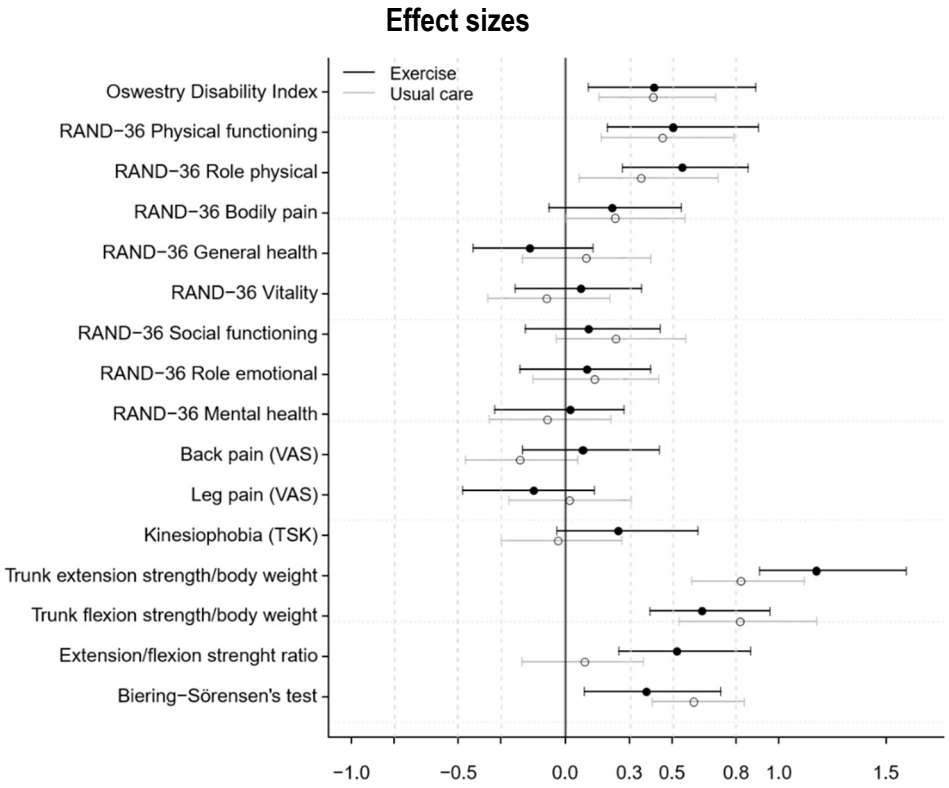

FIGURE 15. Effect sizes with 95% confidence intervals of outcomes of the RCT study.

6 DISCUSSION

This thesis investigated the changes in trunk muscle strength and spine function after LSF and standard clinical postoperative practice, and the effectiveness of progressive 12-month rehabilitation after LSF surgery. The prospective cohort study showed a deficit in trunk muscle strength preoperatively and showed that regardless of improvements, the trunk muscle strength levels still remained low one year after LSF. A preoperatively found remarkable imbalance between trunk flexion and extension strength did not improve postoperatively. Therefore, the effectiveness of the postoperative 12-month home-exercise program was studied by randomizing LSF patients three months after the surgery either to the EG or UCG. The EG received progressive exercise intervention that included neutral spine control exercises and aerobic training, which were performed at home. It also included individual discussions for motivation and aimed to hinder fear of movement or reinjury. The UCG had only one guidance session for light home exercises with no progression.

The main results of the RCT showed that the postoperative 12-month home-exercise program was not superior to usual care. Despite the statistically significant within-group changes in maximal isometric trunk muscle strength in both groups, the strength levels still remained low after the 12-month intervention, when compared to normal population values (Mayer et al. 1985, Häkkinen et al. 2003, Paalanne et al. 2009). Interestingly, the trunk muscle endurance and extension/flexion strength ratio improved after the 12-month exercise intervention only in the EG. Disability, physical performance-related dimensions of the HRQoL, physical activity, spine function and maximal trunk muscle strength improved in both groups, while the kinesiophobia level remained unchanged.

6.1 Trunk muscle strength deficits and disability in the prospective follow-up after LSF

Trunk muscle strength is required in all bodily movements and in posture control; therefore, it is an important part of overall physical functioning. In this prospective cohort study, the preoperative trunk muscle strength was low. After LSF surgery, maximal isometric trunk muscle strength levels increased at the one-year follow-up, with increases of 26% in extension and 23% in flexion strength that were significant; however, the strength levels still remained low compared to the reference values of healthy subjects (Mayer et al. 1985, Häkkinen et al. 2003, Paalanne et al. 2009). The trunk muscle strength reached only half of the corresponding values of the healthy subjects because the mean (SD) maximal trunk extension strength has been reported to be 629 (233) N and flexion strength 564 (235) N, measured by using the same isometric device as used in this study (Häkkinen et al. 2003). Mayer et al. (1985) reported a maximal isometric flexion strength/body weight ratio of ~0.65 in men and ~0.45 in women (aged <45 years, healthy participants). The respective strength/bodyweight ratios for extension strength were ~1.15 in men and ~1.00 in women (Mayer et al. 1985). In the present study, the one-year extension strength/body weight ratio was only one-third of earlier reported values (Mayer et al. 1985).

The trunk muscle extension/flexion strength ratio (E/F ratio) has been reported to be approximately 1.3 in healthy men and 1.4 in healthy women, meaning that the extensor muscles should be approximately 30% stronger than flexors (Mayer et al. 1985, Häkkinen et al. 2003, Paalanne et al. 2009). In the present prospective study, the extensor strength was remarkably low preoperatively, resulting in the imbalance in the trunk muscle E/F strength ratio. The trunk flexors were stronger than the extensors, and this imbalance remained unchanged in the one-year postoperative follow-up. Previously, also in conservatively treated chronic LBP patients with disc degeneration, the E/F ratio has also been reported to stay imbalanced during 7 to 11 years of follow-up (Froholdt et al. 2012).

In this cohort, patients followed a standard protocol including physiotherapy during the hospital stay and meetings with the physiotherapist six weeks and three months postoperatively for light home exercises. However, these light trunk muscle exercises did not facilitate sufficient trunk muscle strength recovery. In this cohort, the regression analysis showed that male sex, younger age, better preoperative trunk muscle strength levels and lower intensity of low back pain predicted better extension and flexion strength levels one year postoperatively. Interestingly, the amount of leisure-time physical activity was not associated with the strength levels one year postoperatively, which emphasizes the need for a more specific exercise protocol if larger strength changes are needed.

To the best of our knowledge, there is only one previous study with a long (5.2 years) follow-up (Tiusanen et al. 1996) and one with a three-month follow-up (Tarnanen et al. 2013) that measure the trunk muscle strength levels after lumbar fusion. In contrast to the present study, the sample of Tiusanen et al. (1996)

also included children (age range 9-61 years), and they all had anterior lumbar interbody fusion, while the present study focused on posterior fusion in adults. A previous study by Tiusanen et al. (1996) also presented findings of lower trunk muscle strength levels after LSF compared to normal population values (Tiusanen et al. 1996, Tarnanen et al. 2013).

In addition, in the RCT study by Keller et al (2004), trunk muscle strength in patients undergoing intensive exercise intervention or LSF was compared in chronic low back pain patients (Keller et al. 2004). After intensive rehabilitation (without surgery), the isokinetic trunk extension strength increased by 27% during the one-year postoperative follow-up (Keller et al. 2004). In contrast to the findings of the present prospective study in LSF patients, the trunk extension strength level of the surgery group decreased by 19% (Keller et al. 2004). The strength increase in the rehabilitation group was large in Keller's study, showing that in chronic low back pain patients, intensive three-week rehabilitation comprising 25 hours per week of supervised training, patient education and discussions with professionals is effective for recovering trunk muscle strength in chronic low back pain (Keller et al. 2004); however, this finding cannot be generalized to LSF surgically treated patients. In a study by Froholdt et al. (2011), trunk muscle strength levels were the same in the LSF group and in a group receiving cognitive intervention instead of surgery. In that study, the sample included chronic low back pain patients or disc degeneration patients (Froholdt et al. 2011). These divergent findings regarding the recovery of trunk muscle strength after LSF underline the need for clinical research in terms of recovery after surgery.

The Timed Up-and-Go-test (TUG) was used to objectively measure LSF patients' mobility and functioning. This test is commonly used in people with musculoskeletal problems (Dobson 2015), and it has been shown to be a responsive measure in low back pain patients undergoing LSF (Jakobsson, Brisby, Gutke, Lundberg et al. 2019). In the present cohort, the preoperative TUG was 10.0 s, and it improved to 7.8 s. The observed improvement in TUG exceeded the LSF patients' minimum clinically important change of 1.3 s (Jakobsson, Brisby, Gutke, Lundberg et al. 2019), and the LSF patients reached the healthy subjects mean level of 8.1 s (Bohannon 2006). The Oswestry Disability Index (ODI) was used to evaluate the level of disability. In the present cohort study, the patients had a preoperative mean ODI score of 44.5, which indicates a severe disability level (Fairbank et al. 1980). One year after LSF, the mean ODI had decreased to the moderate disability level of 21.5, which is already quite near the cut-off point of minimal disability (<20). However, large variation still existed between individuals in terms of the ODI score. There were patients who had minimal disability and those who were still suffering from severe disability one year after LSF.

6.2 The trunk muscle strength changes during the intervention

In the present RCT investigating the effectiveness of a 12-month progressive home-training program compared to usual care after LSF, no between-group differences were found. The isometric extension strength increased by 28% in the EG and by 19% in the UCG during the intervention. The extension strength increase seen in the UCG conflicts with the previous finding of a postoperative strength decrease of 19% presented by a study from Keller et al. (2004). In the study by Keller et al. (2004), the patients undergoing LSF also received the usual postoperative physiotherapy instructions regarding activity during the first three postoperative months. In the present RCT, despite the significant increases in the strength levels, the maximal extension strength levels reached only 55% in the EG and 57% in the UCG of the corresponding levels of healthy subjects reported by Häkkinen et al. (2003). Maximal flexion strength reached 65% in the EG and 62% in the UCG of the reported flexion strength levels of healthy subjects (Häkkinen et al. 2003). Despite the strength improvements, the strength levels remained low after long-term postoperative exercise intervention.

Kang et al. (2012) compared three different postoperative exercise interventions lasting eight weeks: McKenzie's extension exercises, McKenzie method combined with trunk muscle training using the MedX-device, and core stability exercises from O'Sullivan's method. The combination group from the McKenzie method and the isokinetic MedX-device exercises improved their trunk flexion strength significantly more than other intervention groups, while the stability exercise group improved their transversus abdominis activation significantly more than other groups (Kang et al. 2012). That study showed that each trained quality improved; however, the pain and disability decreased in all groups similarly.

Lee et al. (2007) reported a remarkable increase of 64% in the exercise group and 22% in the control group in terms of isometric trunk extension strength after a three-month intervention. In their study, the participants used a rigid lumbosacral orthosis for the first three postoperative months before the intervention started (Cawley 2017, Lee et al. 2017). Therefore, a partly immobilization-induced strength deficit before the beginning of the exercise intervention may have resulted in larger strength improvements in both groups, especially in the exercise group (Cawley 2017). In addition, the patients from that study were allowed to use a full spine range of movement in the supervised training. In contrast, in the present study, special attention was paid to not overload the fused area or the adjacent segments. Therefore, the home-based training program mostly consisted of exercises where the lumbar spine was kept in a neutral position, especially at the beginning of the intervention. However, neither the present RCT nor the CT of Lee et al. (2017) showed fixation failure or other severe harm due to the exercise. Thus, more research is needed to determine the necessity of emphasizing neutral position control during exercises or whether a wider spine range of movement should be used during exercises. Effectiveness and safety of exercises

with natural motor patterns allowing lumbar spine movements and larger synergistic muscle activation could be studied in the future.

In this RCT, the trunk extensors were approximately ten percent weaker than flexors at baseline, indicating trunk muscle strength imbalance. The E/F strength ratio improved in the EG only. However, no between-group differences in terms of the change in the E/F ratio were observed. The Biering-Sörensen's static hold test was used to capture the endurance of the back extensor muscles. Similar to the findings of the maximal strength tests, there were no between-group differences in terms of the changes in the test results. The baseline results of the Biering-Sörensen's test were quite poor (40 s in the EG and 53 s in the UCG). The results improved significantly in both groups, reaching 57 s in the EG and 77 s in the UCG. To the best of our knowledge, there is only one previous study reporting Biering-Sörensen's test in LSF patients. In that study, the result decreased from 69 s preoperatively to 48 s one year after LSF (Keller et al. 2004). When compared to the previously reported healthy adults' Biering-Sörensen test result of 133 s (Adedoyin et al. 2011), both groups reached roughly half of that level in this study. Pain did not interfere with these muscle endurance results since it was reported to be minimal during the measurements. In the present RCT study, the baseline TUG test results were already very close to the values of the healthy subjects (8.1 s) (Bohannon 2006) in both groups (mean 9.1 in the EG and 7.2 in the UCG), and possibly, the observed changes during the intervention were therefore small and clinically nonsignificant (0.9 in the EG and 0.3 in the UCG) (Jakobsson, Brisby, Gutke, Lundberg et al. 2019).

6.3 Pain, disability and health-related quality of life after the intervention

The mean low back pain and leg pain intensities were already low at baseline and showed no changes during 12-month training or at the one-year postintervention follow-up (27 months after LSF). There were no between-group differences either in the ODI or in HRQoL. However, both groups had significant within-group improvements in ODI and in the HRQoL Role Physical and Physical Functioning dimensions during the intervention. Furthermore, at the one-year postintervention follow-up, the achieved improvements were maintained in both groups.

The mean ODI scores were 24 in the EG and 18 in the UCG at the intervention baseline, indicating moderate disability in the EG and minimal disability in the UCG. Compared to the results of previous studies, the baseline ODI was remarkably lower in this study. In the previously published RCT studies in LSF patients, the mean ODI scores showed a severe disability level at baseline, which might be because of the earlier commencement times of the rehabilitation programs (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014, Archer et al. 2016). In the study by Abbott et al. (2010), the baseline measurement was per-

formed preoperatively, and the ODI score had the most significant decrease during the first three postoperative months in both groups (in the psychomotor therapy group from preoperative 45 to 25 and in the exercise therapy group from preoperative 45 to 34). In the study by Monticone et al. (2014), the baseline ODI was measured during the first week after surgery (score 49 in both groups). In their study, the four-week cognitive behavioral therapy (CBT) regimen together with exercise was a more effective treatment than exercise alone in terms of disability in the early stage of recovery after LSF. The postintervention ODI score was 22 in the CBT with exercise group and 33 in the exercise group, and they further improved at the one-year follow-up, reaching scores of 16 and 27 in favor of CBT with exercise (Monticone et al. 2014). In addition, in a study by Archer et al. (2016), CBT consisting of a once a week meeting with a PT, aiming to improve patients' self-efficacy and to reduce their fears, showed significant effects in terms of the ODI at the three-month follow-up compared to usual patient education. The intervention started six weeks postoperatively and lasted for six weeks (Archer et al. 2016).

In addition to CBT being implemented soon after surgery, supervised therapeutic exercise has been shown to reduce postoperative disability. Kang et al. (2012) compared three exercise protocols: McKenzie, McKenzie with isotonic trunk muscle resistance training and the MedX-device, and core stability exercises; all supervised interventions commenced three months postoperatively, and they lasted eight weeks (Kang et al. 2012). They also found that the ODI score was at the severe disability level at intervention baseline in all exercise groups (higher than 50) and that it improved to the moderate disability level during the eight-week intervention in all groups (Kang et al. 2012). The largest improvement in disability was seen in the group having McKenzie with isotonic trunk muscle resistance training and the MedX-device (Kang et al. 2012). Based on our results and previous studies, it seems that LSF surgery itself is effective at reducing disability. Exercise programs that start soon after surgery and psychological interventions effectively expedite recovery compared to usual care; however, after one year, the disability seems to level off to minimal-moderate disability regardless of the intervention.

In the present study, the Role Physical and Physical Functioning dimensions of the HRQoL improved significantly in both groups during the intervention, and the gained levels were maintained by the 1-year postintervention follow-up. The Role Physical dimension was very low at baseline in both groups, and it had the highest increase throughout follow-up. The Vitality, Social Functioning, Role Emotional and Mental Health dimensions did not change during the intervention or at the postintervention follow-up.

In a study by Montione et al. (2014), the eight dimensions of the SF-36 HRQoL measure were reported separately. The Mental Health component score was reported based on five dimensions of the SF-36 in the study by Abbott et al. (2010). Lee et al. (2017) reported both the Physical and Mental component scores, which are based on the eight dimensions of the SF-36. It was found that early implemented psychomotor therapy was equally as effective as 12-week home-

based exercise in terms of the Mental Health component of HRQoL (Abbott, Tyni-Lenne & Hedlund 2010). In a nonrandomized clinical trial by Lee et al. (2017), the supervised exercise intervention improved both the Mental and Physical component scores. Moreover, in a study by Monticone et al. (2014), there were significant differences between the two treatment groups in terms of the changes in all eight HRQoL dimensions of the SF-36, meaning that four weeks of CBT with exercise was more effective than the exercise intervention without the psychological approach. In the present study and in the study by Monticone et al. (2014), the HRQoL of LSF patients was the lowest in the Role Physical and the highest in the Social Functioning dimensions at intervention baseline. Apart from the Role Physical dimension, generally, the HRQoL was lower at baseline in their study than in the present study (Monticone et al. 2014). When the HRQoL was rather good in most dimensions at baseline, it was unlikely to gain further improvements. Monticone et al. (2014) had an early postoperative start in their interventions, and CBT therapy aimed to decrease kinesiophobia and catastrophic thinking. Because the fear of pain can constrain life (Crombez et al. 1999), relief in that area may have effectively improved the HRQoL in the study by Monticone et al. 2014.

The HRQoL findings of the present study and the previous rehabilitation studies varied as a result of different timing and content of the interventions; therefore, more research is needed. However, most importantly, the participants of the present study in both groups reached the age- and sex-matched reference levels of the normal Finnish population two years postoperatively regarding the Physical Functioning, Role Physical, Bodily Pain and Social Functioning dimensions of the HRQoL (Aalto, Aro & Teperi 1999).

6.4 Kinesiophobia and physical activity during the intervention

Kinesiophobia is a multidimensional phenomenon, and it has not been studied much in LSF patients. In the present RCT, the kinesiophobia levels measured by the Tampa Scale for Kinesiophobia (TSK) were high before surgery, and the most significant decrease occurred before the intervention started. The cut-off point for the kinesiophobia score measured by the TSK has been shown to be 37 (Vlaeyen et al. 1995), and later on, Finnish population reference values of 34.2 for men and 32.9 for women were published (Koho et al. 2015). Therefore, in this study, the mean kinesiophobia score of 31 reached the Finnish population reference value by the intervention baseline, at three months postoperatively. Perhaps because of that, the changes in kinesiophobia during the intervention were small in both groups.

No previous studies have examined TSK items separately in LSF patients. In the present study, all RCT participants had remarkable improvements in TSK item 3: "My body is telling me I have something dangerously wrong" and item 11: "I wouldn't have this much pain if there weren't something potentially dangerous going on in my body" from the preoperative level to the three-month

postoperative time point. During the 12-month intervention, the EG showed a decrease, especially in TSK item 9: "I am afraid that I might injure myself accidentally". It seems that initially, after the surgery, the patients started to rely more on their back again, and then the exercise intervention with regular PT meetings specifically boosted the decrease in their accidental injury-related fear.

Two previous RCT studies have evaluated kinesiophobia during postoperative rehabilitation in LSF patients (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014). Abbott et al. compared psychomotor therapy to exercise therapy during the first three postoperative months in LSF patients. Psychomotor therapy was shown to be superior to exercise therapy in terms of decreasing kinesiophobia, measured by the TSK, at the 2-3-year follow-up (Abbott, Tyni-Lenne & Hedlund 2010). Monticone et al. started hospital-based, intensive 1-month therapy also soon after surgery. They found that kinesiophobia improved significantly more in the combined CBT and exercise group than in the exercise-only group (Monticone et al. 2014). However, the timing and content of the therapy in these two studies differed from those in our study. The present study also focused on patients with spondylolisthesis only, while in previous studies, the selection of patients was wider, including also patients with spinal stenosis (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014) and degenerative disc disease (Abbott, Tyni-Lenne & Hedlund 2010). In addition, the present intervention emphasized more physical rehabilitation than the CBT or psychomotor therapy approaches, which were used in the other studies (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014, Archer et al. 2016). In the present study, the given guidance by the physiotherapist in terms of the booster sessions was partly structured based on the cognitive behavioral model of the fear of movement/(re)injury (Vlaeyen et al. 1995), but it had a smaller role during the physiotherapy sessions, and the sessions were conducted less frequently than they would have been in CBT therapy.

Thus, soon after surgery, part of the kinesiophobia may be explained by postoperative pain and caution. However, it seems that early postoperative psychomotor therapy or CBT with exercises can accelerate the reduction of irrational fear of movement or reinjury (Abbott, Tyni-Lenne & Hedlund 2010, Monticone et al. 2014). However, the kinesiophobia level reached by previous studies was approximately the same as the baseline kinesiophobia levels in the present study.

Low levels of physical activity (PA) have also been reported among both LBP and LSF (Lotzke et al. 2018). A sufficient amount of physical activity (PA) is essential for maintaining good health (Garber et al. 2011). According to PA guidelines for adults, aerobic training, resistance training, neuromotor training (balance, agility) and flexibility should be performed regularly (Physical Activity Guidelines Advisory Committee 2018). In the present RCT study, all LSF patients, regardless of the treatment group allocation, had a low level of PA before surgery, as measured by the IPAQ questionnaire. Recently, the same observation was implemented in a cross-sectional study measuring PA objectively by accelerometers (Lotzke et al. 2018). However, in the present RCT, at three months postoperatively, the self-reported PA levels had increased to a moderate level. At the end

of the intervention, the median MET-mins/week in both groups reached the high activity level measured by the IPAQ, suggesting that the activity level meets the criteria of the amount of health-enhancing physical activity (IPAQ Research Committee 2005, Haskell et al. 2007, Bauman et al. 2009). This observation may partly be a result of the nature of the support provided, such as encouragement. In addition, in both groups, the PA increase could be partly due to relief from pain and reduced kinesiophobia. Kinesiophobia and low back pain changes were moderately correlated (r= 0.37) during the early postoperative phase (study IV). Based on our findings, we suggest the presence of a cycle, in which the reduction in pain achieved by surgery provides a safe feeling and a foundation for an intensive back-training intervention. Subsequently, as pain and kinesiophobia decreased soon after LSF, physical activity started to increase during the process of recovery.

6.5 Exercise adherence and intervention feasibility

In the RCT, no between-group differences were found in the outcomes selected in this study, which means that the 12-month exercise intervention and the usual care were equally effective in terms of used outcomes. One possible explanation for the null result is that the contrast between the realization of independent home exercising and usual care may have been too subtle. The usual care group also received one instruction session for light home exercises because it would have been unethical to not provide them the standard care. The UCG participants knew that the EG was going on with the training intervention and that they would have a one-year check-up visit with measurements, which may have partly influenced their exercise motivation in a positive manner as well. However, the UCG had no exercise diaries or pedometers because such devices could have influenced their behavior. Therefore, it is difficult to analyze their precise adherence to their exercise instructions which were given at three months postoperatively.

The rehabilitation intervention was planned to be progressive and long enough to gain strength changes and aerobic fitness as well as to adopt health behavior changes in terms of increasing physical activity and learning good self-treatment methods (Tarnanen, Neva et al. 2012). The back-specific exercise program of the EG was based on the EMG studies and literature to find the most effective exercises for this patient group (Tarnanen et al. 2008, Tarnanen, Siekkinen et al. 2012, Tarnanen et al. 2014). Each of the six program phases included from six to seven back-specific exercises, and the challenge of committing the participants to a long-lasting 12-month home-exercise program was considered in multiple ways. In addition to the individually instructed exercises, exercise diaries (monitoring adherence) and regular booster sessions with encouragement were used.

It has been reported that a frequency of 1.5 times per week of strength training maintains strength levels, 2 times per week is reasonable for small improvements, and 3 times per week is considered sufficient frequency for strength gain, where the loading intensity and volume of the sessions are sufficient (Schoenfeld, Ogborn & Krieger 2016). For the EG, the median frequency for back-specific exercises was 2.5 during the first six months of the intervention. After that, the adherence started to decrease, ending up at a median of 1.7 times per week, which should be acceptable to maintain the gained strength levels (Schoenfeld, Ogborn & Krieger 2016). Even though the exercises in the EG had been pre-confirmed by EMG testing by Tarnanen et al. (2014) to activate the trunk muscles effectively, and the physiotherapist evaluated the proper resistance of elastic bands for each participant, it is possible that these kinds of home-based, repetitive dynamic exercises were not loading enough to increase the maximal trunk muscle strength. For example, in a gym-based supervised weight training, it is easier to standardize the intensity, evaluate the training process and modify the loading and exercises individually, compared to the present home-based training. However, Biereing-Sörensen's static hold test showed improvements in trunk muscle endurance, possibly also improving the stability of the lumbar spine, which itself is difficult to measure.

It has been shown that muscle strength starts to decrease at the age of 35, and it decreases by 2.5-4% per year at the age of 75 (Mitchell et al. 2012). In the present study, the mean age of the participants was 59. Therefore, small increases or the maintenance of muscle strength levels and the prevention of decline may have also been more realistic to expect rather than a continuum of large strength improvements, especially in older participants (Aartolahti et al. 2020).

The aerobic training of the EG was instructed to be performed three times per week by walking in interval style to gain effective, brisk walking intensity. The step counts were planned to progressively increase during the 12-month intervention. The new target step counts per day were calculated for everyone individually based on their activity level (progression scheme presented in the methods, Table 5) (Tudor-Locke, Hart & Washington 2009). However, the pedometer data showed no increase in the step counts during the intervention. The median step count per day was 6138 during the first two months of the intervention and 5870 during the last two months of the intervention in the EG. The daily step count of 5000-7499 is equal to a low activity level (Tudor-Locke et al. 2008). The "somewhat active" PA level is represented by 7500-9999 steps, "active" by 10 000-12 499 steps, and "highly active" by ≥ 12 500 steps per day (Tudor-Locke et al. 2008). Even though the pedometers did not show any activity changes in the EG during the intervention, the IPAQ showed a total PA increase in both groups. It is possible that the patients had increased PA levels, but they chose sports such as cycling, skiing or swimming, which pedometers could not measure. Moreover, pedometers also do not count most of the back-specific exercises.

The interpretation of step counts per day has also changed according to new research. The recommendation of 10 000 steps per day as a target level for health-

enhancing PA has been questioned; it may be too demanding for elderly individuals or people with chronic diseases (Cao et al. 2014). Cao et al. (2014) found that 7700-8000 steps per day may be enough to gain the generally recommended 150 minutes of moderate- to vigorous-intensity PA per week. Although the participants in the EG were instructed to increase their step counts and their intensity of walking, the basic pedometers did not capture the intensity, which is a limitation of the measurement tool used. Capturing both the increase and the intensity of PA is important. The IPAQ covers PA at different intensities. However, the IPAQ is a self-reported assessment tool, which has shown to overestimate PA compared to modern objective accelerometer data (Dyrstad et al. 2014). The discrepancy that step counts remained unchanged while IPAQ showed a significant increase in PA in the EG during the intervention may partly be explained by these factors.

There is some evidence that the supervision of health care professionals improves exercise adherence (Beinart et al. 2013), and therefore, it is possible that closer supervision and more frequent meetings with some patients would have improved adherence at the end of the intervention. It would be important to recognize those who need more support in terms of their motivation and those who will recover well with independent home exercises with less frequent meetings. The same rehabilitation protocol may not be suitable for every patient. Other recent studies in other diseases, such as coronary disease, diabetes or osteoarthritis, show that exercise therapy needs to be very much individually tailored to the symptoms of the patients and their comorbidities to improve adherence (Dekker, de Rooij & van der Leeden 2016, van der Leeden et al. 2018). In the present RCT study, the physiotherapists performed individual tailoring by making small adjustments to the preplanned exercises and progression. However, the main elements of the intervention and the scheme were standardized in this RCT study. This also ensured the safety of the exercise program. No one reported severe adverse effects due to exercise; therefore, this kind of exercise program can be considered safe for LSF patients.

6.6 Methodological considerations

The strengths of this study are the prospective setting in the cohort study consisting of a comprehensive sample of consecutive patients undergoing LSF, which well represents the nonurgent LSF patient population in Finland. The sample size in the prospective cohort study using strength measurements was large. The sample represents all principal types of spinal disorders leading to LSF over a wide age range (29-85 years). The measurements were performed at precise time points one week before and one year after the LSF surgery.

The RCT was carefully planned, and it was conducted in accordance with CONSORT Guidelines as much as possible. Randomization was concealed, and assessors were blinded to the treatment to reduce the risk of bias. In the RCT

study, the sample size was based on power calculations for pain outcome (Christensen, Laurberg & Bunger 2003, Tarnanen, Neva et al. 2012), and the sample size clearly exceeded the minimum, which was set to 80 patients. However, in some outcomes, the study may have remained unpowered, partly because the UCG improved their results as well narrowing the between group differences. The RCT sample consisted of spondylolisthesis patients, which is the most important patient group in LSF operations. The data collection was well organized between the two hospitals, and special attention was paid to ensure that the measurement and treatment protocols were similar in both hospitals when the interventions were performed and data were collected. Both hospitals had similar measurement equipment, and the sensors of the strain-gauge dynamometers were calibrated.

This study combines objective physical measurements and subjective patient-reported outcomes (PROs), which shows the treatment effect from the patient's perspective. In addition, the used PROs were shown to be reliable and valid in Finnish populations (Aalto, Aro & Teperi 1999, Pekkanen et al. 2011, Koho et al. 2014, Koho et al. 2015). The maximal strength tests with the strain-gauge dynamometer and the endurance strength test by Biering-Sörensen were isometric, meaning that the spine was kept in a neutral position during the tests. Isometric testing is a safe and reliable way to measure the trunk muscle strength (Moreau et al. 2001). The tests showed changes in both groups. However, the back-specific exercises of the EG were dynamic and functional. It is possible that these measurements cannot capture the discreet improvements in strength of the stabilizing muscles of the lumbar spine. The HRQoL was measured using the RAND-36, which has an identical questionnaire to the SF-36. By using the RAND-36, it was possible to use age- and sex-matched reference values of the normal Finnish population (Aalto, Aro & Teperi 1999).

The novelty of this RCT is the exceptionally long-term home-exercise program combining back-specific and aerobic training with regular patient education meetings with a PT. This approach combines multiple intervention elements, and these elements have a grade A (good) or B (fair) level of evidence (Madera et al. 2017). In addition, to the best of our knowledge, this is the first study that measured physical activity changes after rehabilitation in this LSF patient group. If shown to be effective, the home-based exercise protocol is a resource-friendly and realistic option for long-term individual rehabilitation. In this study, the RCT intervention was implemented by two PTs (one at each hospital) who were skilled and experienced in both science and clinical practice. The exercise protocol and patient education materials were carefully preplanned by a multidisciplinary team and based on previous scientific research (Tarnanen, Neva et al. 2012). The dropout rate was very small: in the prospective cohort study, 77% attended the follow-up, and in the RCT, there was only one dropout, which was unrelated to the intervention or its contents. In the RCT study, the intention-to-treat principle was used in the analysis.

The limitation of the present study is that the results can be generalized to recovery after LSF, not to other spine surgery methods. The nature of the RCT

study meant that it was not possible to blind caregivers or the patients. One limitation of the RCT study is that we did not control the adherence to instructions given to the UCG during the 12-month intervention; they had no exercise diary or pedometers. In addition, regardless of the regular booster sessions and individual guidance given for the EG, the adherence to the exercise program somewhat decreased during the intervention, and this may have influenced the results. For example, conducting the midpoint measurements or other clinical measurements during the check-ups could have improved the exercise adherence. In addition, 12 participants of EG needed modifications to their back-specific exercise program during the intervention. Modifications were changing the starting positions of the exercises or slowing down the progression. These aspects may have contributed to the mean strength gains in the EG. In some outcomes, the results were already at a good level at baseline and at three months postoperatively, and due to this "floor effect", small magnitude improvements are understandable.

6.7 Future directions

The results of this study show that there is a need for rehabilitation after LSF; however, there is still a gap of knowledge regarding which kind of exercise or rehabilitation is the most effective. Future studies on LSF patients' rehabilitation should focus on recognizing individual rehabilitation needs in LSF patients and finding effective methods to respond to those varying needs in a precise and timely manner. New technological solutions and devices could be one option in the future for monitoring and quantifying physical activity, suitable exercise intensity and adherence. The use of technology could also work as a motivational support in some cases, especially if it enables interactions with health care professionals and peers. In addition, with larger patient samples, it would be beneficial to analyze the determinants influencing on the rehabilitation outcome. By recognizing the determinants, it could be possible to develop algorithms to stratify patients to different subgroups and thereby respond to their specific rehabilitation needs individually and cost-effectively.

However, the key element of rehabilitation is health behavior change. The most important goals of LSF rehabilitation are to educate patients with concrete methods regarding how to master their recovery and to empower the patients' own agency in mastering their overall physical and mental health by themselves using methods based on scientific evidence. It means that each patients' rehabilitation needs and capabilities to assimilate new information should be considered before planning the interventions. The therapeutic interaction should be studied in addition to the therapeutic training in this patient group. Using the mixed method combining qualitative and quantitative research methodology would enrich future knowledge.

7 MAIN FINDINGS AND CONCLUSIONS

The main findings of this study can be summarized as follows:

1. By the one year after LSF, the trunk muscle strength, spine function and disability improved compared to the preoperative levels. Despite the observed improvements, the strength levels remained low, and the imbalance between trunk flexors and extensors remained at the one-year follow-up after LSF.
2. The trunk muscle strength and spine function improved equally in both groups with either 12-month progressive back-specific exercise combined with walking or usual care. However, the trunk extension/flexion strength balance improved significantly in the exercise group only.
3. Low back pain and leg pain intensities were already at a good level at the intervention baseline, and they did not change in either group during the 12-month exercise intervention. The disability and physical dimensions of the HRQoL improved in both groups similarly during the intervention. In HRQoL both groups achieved the Finnish reference values in all dimensions by the one-year postintervention follow-up. One-fourth of participants had at least moderate disability at the 1-year post-intervention follow-up.
4. LSF patients had preoperatively remarkable kinesiophobia, and their self-reported physical activity levels were low. Kinesiophobia decreased most significantly early after LSF, before the 12-month exercise intervention. During the intervention, kinesiophobia levels did not change, but physical activity improved in both groups.

In conclusion, in the prospective cohort study, trunk muscle strength levels remained low even at the one-year follow-up after fusion surgery with standard care. The proposed 12-month progressive rehabilitation intervention starting

three months postoperatively was equally as effective as usual care for improving both subjective and objective outcomes in LSF patients. Regardless of the increases in trunk muscle strength and physical activity in both groups, trunk muscle strength deficits and imbalance were still observed after the 12-month intervention in the exercise group and usual care group. In addition, there were marked individual differences in the recovery and in the adherence to home-based exercise program. Therefore, in the future, the effectiveness of more individualized rehabilitation needs to be studied.

YHTEENVETO (FINNISH SUMMARY)

Kuntoutus alaselän jäykistysleikkauksen jälkeen - 12 kuukauden kotiharjoittelun vaikuttavuus

Alaselkäkipu on merkittävin toimintakykyä haittaava tuki- ja liikuntaelinsairaus. Maailman terveysjärjestö WHO:n arvion mukaan teollistuneissa maissa alaselkäkivusta kärsii noin 60-70% väestöstä elämänsä aikana. Tälläkin hetkellä kolmannes väestöstä kärsii alaselkäkivusta. Kivun kroonistumisen riskiä nostaa tietyt psyko-sosiaaliset tekijät, kuten liikkumisen pelko. Suurin osa alaselkäkipuongelmista on hoidettavissa lääkehoidolla ja kuntouksella. Pieni osa tarvitsee leikkaushoitoa, mikäli konservatiivinen hoito ei ole tuonut riittävää helpotusta oireisiin. Leikkauksen jälkeisessä kuntoutuksessa on tärkeää huolehtia toimintakyvyn parantamisesta sekä rohkaista potilasta pitämään yllä fyysistä kuntoaan tilanteeseen soveltuvalla tavalla. Tämän väitöskirjatutkimuksen tarkoituksena oli selvittää vartalon lihasvoimaa vuoden seurannassa alaselän jäykistysleikkaukseen jälkeen sekä tutkia leikkauksen jälkeisen 12 kuukauden nousujohteisen kotiharjoittelun vaikuttavuutta.

Yhteensä 194 potilasta, joille tehtiin selän jäykistysleikkaus, osallistui vartalon lihasvoimaa ja selän toimintaa selvittävään prospektiiviseen kohorttitutkimukseen. Potilaiden keski-ikä oli 61 vuotta ja heistä 66% oli naisia. Leikkauksen jälkeiseen kuntoutustutkimukseen osallistui 98 potilasta, joille tehtiin nikamaliukuman takia alaselän jäykistysleikkaus. Heidän keski-ikänsä oli 59 vuotta ja 75% oli naisia. Kolme kuukautta leikkauksen jälkeen harjoitteluryhmään satunnaistettujen ohjelma sisälsi kotona tehtäviä selkäspesifejä vartalon hallintaa ja lihasvoimaa parantavia harjoitteita sekä aerobista kävelyharjoittelua 12 kuukauden ajan. Ohjelman haastavuutta ja intensiteettiä lisättiin fysioterapian ohjauskäynneillä joka toinen kuukausi. Liikkeitä muutettiin toiminnallisemmiksi ja kuormitusta lisättiin vaihtamalla liikkeiden suoritusasentoja sekä kuminauhavastusta. Lisäksi ohjauskäynneillä potilaita motivoitiin itsehoitoon ja käsiteltiin psyko-sosiaalisia tekijöitä, kuten heidän kokemaansa liikkumisen pelkoa. Kontrolliryhmä sai tavanomaisen hoito-ohjelman mukaisen kertaohjauksen kevyisiin, kotona tehtäviin selkäharjoitteisiin, venyttelyyn ja liikuntaan.

Prospektiivisessa kohorttitutkimuksessa mittaukset tehtiin ennen leikkausta sekä vuosi leikkauksen jälkeen. Satunnaistetussa kontrolloidussa tutkimuksessa mittaukset tehtiin ennen intervention alkua (3 kk leikkauksen jälkeen) ja vuoden kestävän intervention loputtua. Lisäksi seurantakysely toteutettiin vuosi intervention päättymisestä. Vartalon lihasten maksimivoimaa mitattiin isometrisella voimadynamometrilla ja kestovoimaa Biering-Sörensenin testillä. Lisäksi tutkittiin potilaiden kokemia oireita ja haittaa, elämänlaatua, selkä- ja ala-

raajakipua, liikkumisen pelkoa ja fyysistä aktiivisuutta. Harjoitteluryhmän kotiharjoittelun toteutumista seurattiin askelmittarilla ja harjoituspäiväkirjojen avulla.

Alaselän jäykistysleikkaukseen tulevilla potilailla vartalon lihasvoima oli heikko ja ojennus-/koukistusvoimasuhde epätasapainossa ennen leikkausta. Vartalon maksimaalinen ojennus- ja koukistusvoima lisääntyivät neljänneksen. Etenkin vartalon ojentajalihasten voimataso jäi heikoksi, aiheuttaen vartalolihasten voimaepäsuhdan säilymisen vielä vuoden seurannassa. Satunnaistetussa kontrolloidussa tutkimuksessa molemmilla ryhmillä vartalon lihasvoima, toimintakyky, fyysiseen toimintakykyyn liittyvät elämänlaadun osa-alueet, sekä fyysisen aktiivisuuden määrä parantuivat tilastollisesti merkitsevästi, eikä ryhmien välillä ollut eroa intervention päättyessä. Kuitenkin selän ojennus-/koukistusvoimasuhde parani vain harjoitteluryhmällä. Kivun voimakkuus ja liikkumisen pelko olivat vähäiset jo harjoitusintervention alussa, eivätkä ne muuttuneet merkittävästi intervention aikana. Tuloksissa oli suurta yksilöllistä vaihtelua. Intervention jälkeisessä vuoden seurannassa elämänlaadun osalta molemmat ryhmät saavuttivat suomalaisten keskiarvotason. Kaikkiaan neljännes interventiotutkimukseen osallistuneista koki vähintään kohtalaisia oireita ja toimintakyvyn haittaa kyselyn perusteella vuosi intervention päättymisen jälkeen.

Johtopäätöksenä voidaan todeta, että lannerangan jäykistysleikkaukseen tulevien potilaiden vartalon lihasvoimatasot olivat heikot ja epätasapainossa. Vaikka lihasvoimat parantuivatkin hieman vuoden seurannassa, jäivät ne edelleen matalalle tasolle vuoden kuluttua leikkauksesta, kun tuloksia verrataan terveillä raportoituihin tuloksiin. Vuoden kestävä kotiharjoittelu, jossa yhdistettiin keskivartaloharjoitteita ja kestävyysharjoittelua, oli yhtä vaikuttavaa kuin tavanomainen kertaohjaus. Jatkossa olisi tärkeää kohdistaa yksilöllistä kuntoutusta heille, joiden kuntoutumisessa on haasteita, kun taas osalle riittää vähemmän terveydenhuollon resursseja kuormittava ohjaus.

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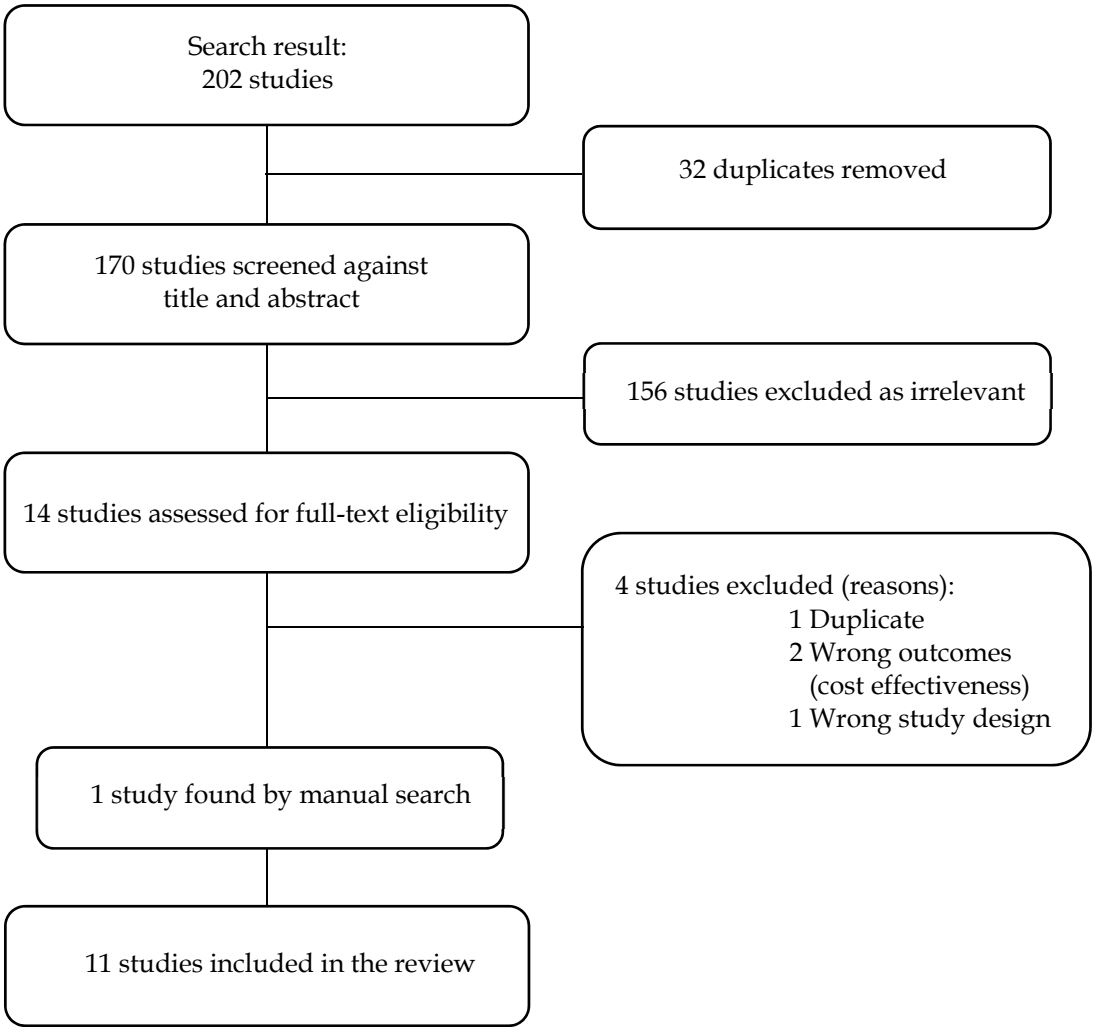
APPENDIX 1 OVID Medline search strategy

#▲	Searches	Results
1	Spinal Fusion/	23716
2	lumbar spine surgery.mp.	981
3	lumbar spin* fusion.mp.	921
4	lumbar fusion.mp.	2030
5	1 or 2 or 3 or 4	25133
6	REHABILITATION/	17864
7	Physical Therapy Modalities/	35156
8	physiotherapy.mp.	17999
9	physical therapy.mp.	48184
10	therapeutic exercise.mp.	938
11	Exercise Therapy/	37528
12	therapeutic training.mp.	53
13	training.mp.	404646
14	EXERCISE/ or exercise.mp.	327408
15	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	736006
16	Randomized Controlled Trials as Topic/	124552
17	randomized controlled trial/	484039
18	Random Allocation/	99371
19	Double Blind Method/	151805
20	Single Blind Method/	26911
21	clinical trial/	516607
22	clinical trial, phase i.pt.	19036
23	clinical trial, phase ii.pt.	30716
24	clinical trial, phase iii.pt.	15164
25	clinical trial, phase iv.pt.	1716
26	controlled clinical trial.pt.	93116
27	randomized controlled trial/	484039
28	multicenter study.pt.	251986
29	clinical trial.pt.	516607
30	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1171825
31	(clinical adj trial$).tw.	335567
32	((singl$ or doubl$ or tripl$) adj (blind$3 or mask$3)).tw.	164419
33	PLACEBOS/	34377
34	placebo$.tw.	205164
35	randomly allocated.tw.	26434
36	(allocated adj2 random$).tw.	29598
37	31 or 32 or 33 or 34 or 35 or 36	592937
38	30 or 37	1463033
39	case report.tw.	289933
40	letter/	1032047
41	historical article/	352295
42	39 or 40 or 41	1659303
43	38 not 42	1434269
44	5 and 15 and 43	100

APPENDIX 2 PRISMA Flow of the study selection



APPENDIX 3 Description of the items of the Tampa Scale for Kinesiophobia

1. I'm afraid that I might injure myself if I exercise
2. If I were to try to overcome it, my pain would increase
3. My body is telling me I have something dangerously wrong
4. My pain would probably be relieved if I were to exercise
5. People aren't taking my medical condition seriously enough
6. My accident has put my body at risk for the rest of my life
7. Pain always means I have injured my body
8. Just because something aggravates my pain does not mean it is dangerous
9. I am afraid that I might injure myself accidentally
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body
12. Although my condition is painful, I would be better off if I were physically active
13. Pain lets me know when to stop exercising so that I don't injure myself
14. It is really not safe for a person with condition like mine to be physically active
15. I can't do all the things normal people do because it's too easy for me to get injured
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous
17. No one should have to exercise when he/she is in pain

(Woby et al. 2005)

ORIGINAL PAPERS

I

TRUNK MUSCLE STRENGTH AFTER LUMBAR SPINE FUSION: A 12-MONTH FOLLOW-UP

by

Outi Ilves, Marko H. Neva, Keijo Häkkinen, Joost Dekker, William Kraemer, Sami Tarnanen, Kati Kyrölä, Jari Ylinen, Kirsi Piitulainen, Salme Järvenpää, Tiina Kaistila & Arja Häkkinen, 2019

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Original Article

Trunk Muscle Strength After Lumbar Spine Fusion: A 12-Month Follow-up

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Objective: The aim of this study was to investigate changes in trunk muscle strength 12 months after lumbar spine fusion (LSF) compared to preoperative strength.
Methods: A total of 194 patients (mean ± standard deviation [SD] age, 61 ± 21 years) who underwent LSF participated in this prospective longitudinal study. Physical measurements of the participants were made before surgery and 12 months postoperatively. Isometric trunk extension and flexion strength was measured using a strain-gauge dynamometer in the standing position. Strength changes were calculated. Regression analysis was performed to explore which factors predicted strength levels at 12 months postoperatively.
Results: The preoperative mean ± SD extension strength was 205 ± 144 N, which increased to 258 ± 142 N ($p < 0.001$) at the 12-month follow-up. Flexion strength increased from 295 ± 172 N to 364 ± 164 N ($p < 0.001$). The preoperative extension/flexion strength ratio was 0.75 ± 0.38 and remained similar (0.73 ± 0.26) at 12 months postoperatively ($p = 0.39$).
Conclusion: Although trunk muscle strength increased by 26% for extension and 23% for flexion at the 12-month postoperative follow-up, both values remained objectively low. In addition, flexion strength remained higher than extension strength, which indicates an imbalance between those muscle groups. Age, severe back pain, and low trunk muscle strength before surgery predicted low trunk muscle strength at 1 year after spinal fusion.

Keywords: Spine, Muscle strength, Isometric strength, Spinal fusion, Spine surgery

INTRODUCTION

Lumbar spine surgery may be considered in some spinal disorders if conservative treatment has not satisfactorily relieved symptoms.[1-3] Most patients undergoing lumbar spine fusion (LSF) have a background of long-standing and disruptive back pain, which may decrease the activation of the paraspinal muscles[4] and lead to multifidus atrophy.[5] During posterior LSF surgery, the detachment and retraction of the lumbar spine may lead to further impairment in the functioning of other paraspinal muscles.[6-8]

According to previous studies, low levels of trunk muscle strength per body weight and abnormal extensor/flexor strength balance, in which the flexor muscles are stronger than the extensors, have been identified in patients with chronic low back pain[9] as well as in those who have undergone LSF.[10] Keller et al.[11] reported a decrease of 19% in isokinetic trunk extension strength after LSF at the 1-year follow-up compared to the preoperative value. Tarnanen et al.[12] also found low isometric trunk flexion and extension strength levels in both genders before

surgery and three months after LSF.

However, the understanding of muscle function after LSF remains limited. Therefore, this study evaluated the changes in maximal trunk muscle strength after LSF in the 12-month postoperative follow-up compared to preoperative strength. In addition, factors associated with strength levels at 12 months were examined.

MATERIALS AND METHODS

This was a prospective longitudinal follow-up study with physical assessments before surgery and 12 months after. The study was conducted in Tampere University Hospital and Central Finland Central Hospital (Finland). Between January 2008 and December 2009, 253 consecutive patients with different types of spinal disorders undergoing elective LSF surgery were enrolled. Exclusion criteria were spinal fracture, malignant causes of low back pain, and severe psychiatric disorders or other limitations in mental condition, such as dementia. Of all of the patients, 10 were excluded from the study due to the exclusion criteria, 21 had missing preoperative data, and 28 had missing postoperative data. The final sample size was 194 (77%). The present study obtained ethical approval from the Ethics Committees of Tampere University Hospital and Central Finland Central Hospital, Finland. Informed consent from all the study participants was received.

The surgical procedure was instrumented posterolateral fusion (PLF) with or without posterior lumbar interbody fusion. PLF was performed using a midline incision; the muscles were detached from the spine and retracted during the operation. Transpedicular fixation was placed between the fused segments. Decompression was performed to relieve compression of the nerve roots and interbody fusion was added if needed. Transverse processes were decorticated and either an autograft from the iliac crest, removed lamina and allograft bone, or bone substitute, was placed bilaterally. Surgeons from both study centers performed part of the LSF surgeries together.

Postoperatively, the patients were advised to avoid continuous sitting longer than 30 minutes at a time and avoid extreme trunk flexion and extension during the first 4 weeks after surgery. Six weeks postoperatively the participants were advised to begin daily walking and to perform light home exercises for their trunk muscles and lower limb stretches. Three months postoperatively, in addition to daily walking, light trunk muscle, stretching, and balance exercises were advised to be performed 3 times a week at home.

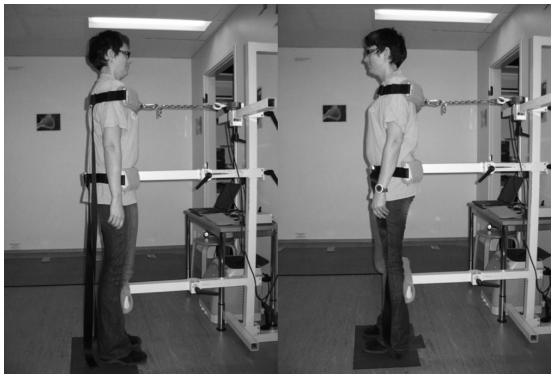

Fig. 1. Isometric maximal trunk flexion and extension strength tests using the strain gauge-dynamometer.

1. Outcome Measures

Strength assessments were conducted before the surgery and 12 months postoperatively. The maximal isometric strength of the trunk flexors and extensors was measured using a strain-gauge dynamometer and analyzed with a computer program (Isopack, Newtest, Oulu, Finland) (Fig. 1). The isometric strength test was performed in a standing position, with 20 cm between the feet. The pelvis was fixed against a metal support from below the iliac crest and a harness was placed around the chest just under the armpits. The harness was attached with a metal strain to the strain-gauge dynamometer horizontally. The patients performed 2 maximal isometric contractions, and if the result improved more than 10%, they performed a third contraction. The best result was used in the analysis. The absolute strength levels are expressed in Newtons (N) (10 N = 1.02 kg). The extension/flexion (E/F) strength ratio was calculated to quantify the possible imbalance between these 2 antagonist muscle groups.

In addition, socio-demographic data, the amount of leisure time engaged in physical activity (minutes/wk), low back pain, and leg pain intensities during the prior week were obtained using questionnaires. Background data, such as sex and age, and clinical data, such as diagnosis, fusion length, and pain duration before the surgery, were collected from the spine database.

2. Statistical Analysis

Descriptive data are presented as means with standard deviation (SD) or with 95% confidence intervals (95% CI), counts (n) with percentages (%), or medians with interquartile ranges (IQR). Analyses were performed using the normal t-test for normally distributed continuous variables, the bootstrap-type t-test for

skewed continuous variables, the chi-square test with dichotomous variables, or the Mann-Whitney U-test for categorical variables. Univariate and multivariate linear regression analyses with the forward stepwise method were performed to investigate the factors associated with the extension and flexion muscle strength levels at the 12-month follow-up.

Table 1. Demographic and clinical data of the participants

Variable	All (n = 194)	Women (n = 129)	Men (n = 65)	p-value
Age (yr)	61 ± 12	63 ± 11	57 ± 13	0.004
Marriage or common-law marriage	125 (64)	75 (58)	50 (77)	0.01
Education (yr)	12 ± 4	12 ± 4	12 ± 3	0.93
Employed	48 (25)	25 (19)	23 (35)	0.04
Smoking	27 (14)	15 (12)	12 (18)	0.27
Body weight (kg)	77.9 ± 15.3	73.0 ± 14.2	87.7 ± 12.6	< 0.001
Height (cm)	165.4 ± 9.8	160.3 ± 6.4	175.6 ± 7.1	< 0.001
Body mass index (kg/m^2)	28.4 ± 4.4	28.3 ± 4.7	28.4 ± 3.7	0.90
Diagnosis group				0.03
Degenerative spondylolisthesis	138 (71)	98 (76)	40 (61)	
Spinal stenosis	14 (7)	5 (4)	9 (14)	
Disc herniation or degeneration	10 (5)	5 (4)	5 (8)	
Postoperative conditions	20 (11)	13 (10)	7 (11)	
Scoliosis	12 (6)	8 (6)	4 (6)	
Length of fusion				0.35
1–2 Levels	138 (71)	89 (69)	49 (75)	
3 Levels or more	56 (29)	40 (31)	16 (25)	
Duration of back pain (mo), median (IQR)	31 (18–66)	31 (16–66)	30 (20–60)	0.84
VAS preoperative back pain	63 ± 27	65 ± 26	59 ± 27	0.12
VAS preoperative leg pain	64 ± 26	67 ± 25	57 ± 26	0.015

Values are presented as mean ± standard deviation, number (%), or median (IQR).
IQR, interquartile range; VAS, visual analogue scale.

Table 2. Trunk muscle strength before and 12 months after lumbar spine fusion surgery

Variable	Preoperative	12 Months	Change from preoperative to 12 months	p-value for change
Muscle strength measures				
Maximal extension (N)	205 ± 144	258 ± 142	53 (37–70)*	< 0.001
Maximal flexion (N)	295 ± 172	364 ± 164	69 (53–85)*	< 0.001
Extension/BW ratio	0.27 ± 0.18	0.34 ± 0.18	0.07 (0.05–0.09)*	< 0.001
Flexion/BW ratio	0.38 ± 2.0	0.47 ± 0.18	0.09 (0.07–0.11)*	< 0.001
Extension/flexion strength ratio	0.75 ± 0.38	0.73 ± 0.26	-0.02 (-0.07 to 0.03)	0.39
Pain intensity during measurement, VAS (mm)				
Extension strength test	55 ± 29	14 ± 25	-41 (-45 to -36)*	< 0.001
Flexion strength test	41 ± 29	11 ± 21	-29 (-34 to -25)*	< 0.001

Values are presented as mean ± standard deviation or mean (95% confidence interval).
N, Newtons; BW, body weight; VAS, visual analogue scale.
*Improvement.

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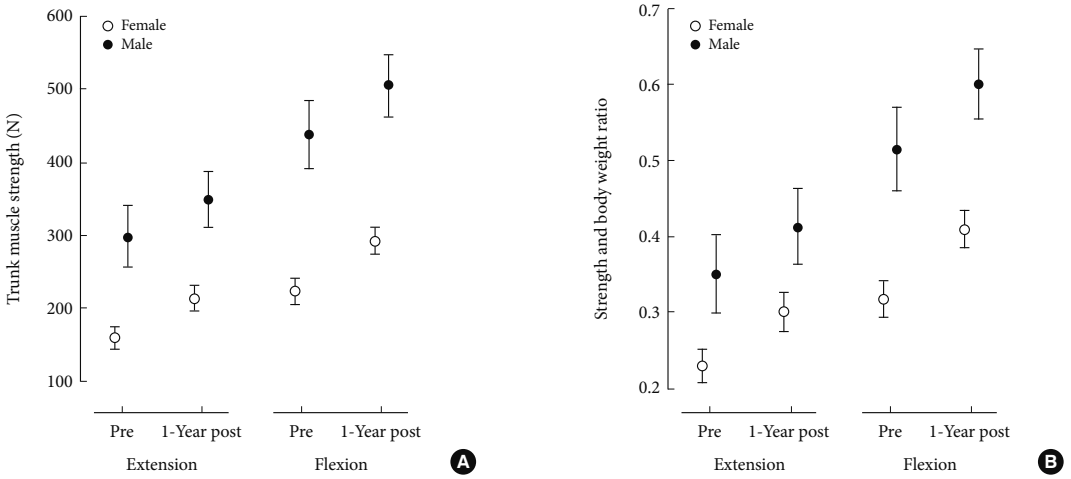

Fig. 2. Maximal trunk muscle strength before surgery and 12 months postoperatively in men and women. (A) Absolute strength levels (in Newtons). (B) Strength per body weight ratios.

RESULTS

The mean ± SD age of all participants was 61 ± 12 years, body weight 78 ± 15 kg, and the median (IQR) duration of low back pain before the LSF was 31 months (18–66 months) (Table 1). The majority of the participants (66.5%) were women. Degenerative spondylolisthesis (71%) was the major diagnostic group; the other groups are listed in Table 1. The women were older and had higher preoperative leg pain intensity than the men (Table 1). The mean low back pain intensity during the previous week decreased from preoperative 63 ± 27 to 25 ± 26 mm in the 12-month follow-up ($p < 0.001$) and the leg pain from 63 ± 26 to 27 ± 27 mm, respectively (both $p < 0.001$). The average leisure time physical activity before surgery was 254 ± 294 minutes/wk and at the 12-month follow-up was 291 ± 373) minutes/wk ($p = 0.013$).

The preoperatively measured trunk muscle strength levels were considerably low (Table 2). The mean ± SD increase in trunk extension strength was 53 ± 118 N and in flexion 69 ± 116 N (both $p < 0.001$) from before surgery to the 12-month postoperative follow-up. The mean increase per body weight was 0.07 ($p < 0.001$) for extension and 0.09 for flexion ($p < 0.001$). The strength levels of sex are presented in Fig. 2A and B. The pain intensity, during both trunk extension and flexion tests, decreased significantly and the E/F remained almost unchanged during the follow-up. Fig. 3 shows the E/F strength ratio in the men and women. In both univariate and multivariate regression analyses, male gender, lower age, milder preoperative back pain, and greater preoperative strength were significantly associated with better 12-month extension and flexion strength levels (Table 3). In addition, less back pain during the measurement was associated with a higher 12-month extension strength level.

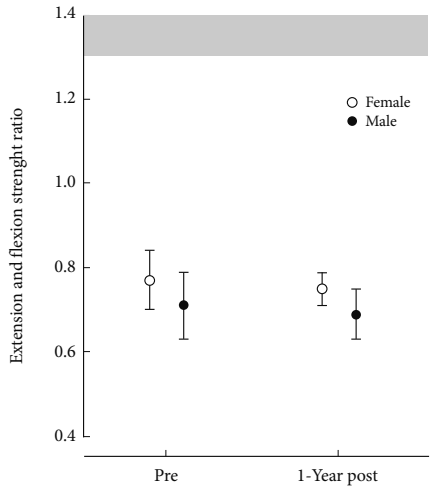

Fig. 3. Mean (standard deviation) trunk extension/flexion strength ratios before surgery and at the 12-month follow-up. The gray area shows the level of the extension/flexion ratio in healthy subjects.[9]

Table 3. Linear univariate and multivariate regression analysis of variables, which explains the endpoint strength levels

Variable	Extension strength 12 months				Flexion strength 12 months			
	Univariate		Multivariate		Univariate		Multivariate	
	Beta (95 % CI)	p-value	Beta (95 % CI)	p-value	Beta (95 % CI)	p-value	Beta (95 % CI)	p-value
Male sex	136.43 (98.24 to 174.62)	<0.001	63.18 (31.30–95.07)	<0.001	214.18 (175.48–252.87)	<0.001	93.29 (57.29–129.30)	<0.001
Age	-6.23 (-7.71 to -4.75)	<0.001	-3.97 (-5.16 to -2.78)	<0.001	-5.18 (-7.02 to -3.34)	<0.001	-2.44 (-3.61 to -1.26)	<0.001
Being a smoker	59.36 (1.55 to 117.17)	0.044			40.79 (-26.14 to 107.71)	0.23		
Body mass index	1.56 (-3.04 to 6.16)	0.51			5.82 (0.59–11.05)	0.029		
Preoperative back pain (VAS)	-0.90 (-1.68 to -0.11)	0.025	-0.69 (-1.32 to -0.06)	0.032	-0.47 (-1.38 to 0.44)	0.31	-0.86 (-1.39 to -0.32)	0.002
Preoperative leg pain (VAS)	-0.95 (-1.65 to -0.25)	0.0079			-0.99 (-1.79 to -0.28)	0.016		
LTPA	0.03 (-0.02 to 0.09)	0.21			-0.003 (-0.067 to 0.060)	0.92		
Back pain (VAS) during measurement	-0.81 (-1.61 to -0.00)	0.049	-0.65 (-1.29 to -0.01)	0.045	-0.50 (-1.61 to 0.61)	0.38		
Preoperative strength	0.65 (0.55 to 0.76)	<0.001	0.45 (0.34–0.55)	<0.001	0.73 (0.64–0.81)	<0.001	0.54 (0.44–0.64)	<0.001

Beta, regression coefficient; CI, confidence interval; VAS, visual analog scale; LTPA, leisure time physical activity.

DISCUSSION

Trunk muscle strength is required for all body movements and posture control, and therefore is an important part of overall daily physical functioning. In the present study, the maximal trunk muscle strength has increased during the 1-year postoperative follow-up. However, the strength gain was small and may not be clinically significant. The imbalance already found before surgery between the trunk extensors and flexors remained 12 months postoperatively.

In the present study, we found increases in the maximal trunk muscle strength levels at the 12-month postoperative follow-up. There are no previous 1-year follow-up studies without additional postoperative interventions and measuring trunk muscle strength as an outcome in LSF patients. The improvements in the strength of this study (26% in extension and 23% in flexion) were similar to those of the conservative treatment arm in a 1-year follow-up in the previous randomized controlled trial study by Keller et al.[11]. In that study, the isokinetic trunk extension strength increased by 27% after intensive rehabilitation. The rehabilitation protocol was a 3-week program, including supervised training, patient education, and discussions 25 hours/wk. In contrast, in their surgery group, the strength levels decreased by 19% during the 1-year postoperative follow-up.[11] However, despite the improvements observed in the present study, strength remained low: previously, in healthy subjects, the mean ± SD maximal trunk extension strength was reported to be 629 ± 233 N and the flexion strength was reported at 564 ± 235 N, measured with the same isometric device used in this study.[13] In the present study, the trunk muscle strength reached only half of the corresponding values of the healthy subjects. Mayer et al.[9] reported a maximal isometric flexion strength/body weight ratio of ~0.65 in men and ~0.45 in women (aged < 45 years, healthy participants). The respective ratios for extension strength were ~1.15 in men and ~1.00 in women.[9] In the present study, the 1-year extension strength/body weight ratio was only one-third of the earlier reported values.[9]

The low extensor strength observed in this study resulted in the imbalance in the trunk muscle strength, that is, the trunk flexors were stronger than the extensors before surgery and after the 12-month postoperative follow-up. Previously, in healthy subjects, the extensor muscles have been shown to be remarkably stronger than the flexors.[9,13] The isokinetic E/F strength ratio has been reported to be approximately 1.3 in healthy men and 1.4 in healthy women.[9] In contrast, in patients with chronic back pain and disc degeneration, the E/F strength ratio has been

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reported to remain imbalanced in follow-ups of 7 to 11 years.[14] In patients with chronic low back pain, the possible explanations for low extensor strength are muscle atrophy associated with disc degeneration and spondyloarthrosis, as well as pain inhibition.[15] Also avoiding the use of the back, that is, disuse, affects the spinal musculature.[16] Therefore, paraspinal muscle wasting has already begun before surgery due to long-standing pain.[17] Furthermore, during surgery, the retraction of the paraspinal muscles may lead to additional injury of the extensor muscles and maintain poor extension strength. In this study, the low back and leg pain intensities decreased significantly after LSF, which enabled better use of the spinal musculature and back. The patients received postoperative advice to self-administer physical activities in the early recovery phase. However, these physical activities and light trunk muscle exercises did not facilitate sufficient trunk muscle strength recovery.

The results of the present study also showed that milder preoperative low back pain and preoperative strength (in addition to male gender and lower age) were associated with better trunk flexion and extension strength levels at 12 months. Previous research found a wide spectrum of potential factors that contribute to muscle strength and function in patients with low back pain, such as changes in muscle structure,[17] the patients' motivation and pain tolerance,[18] changes in fear-avoidance beliefs, in pain, or in self-efficacy.[19]

The strengths of this study are the prospective setting and the representative sample of patients with LSF, including all principal types of spinal disorders leading to LSF over a wide age range (29–85 years). In addition, we used physical measurements, which provide objective information about back function. The drop-out rate was considerably lower; of all of the recruited patients, 77% attended the 12-month follow-up. The limitation of the study is that the results cannot be generalized to the recovery of spinal surgery other than LSF.

In conclusion, trunk muscle strength improved during the 12-month follow-up after LSF. Despite the observed improvements, the strength levels remained low, and the imbalance between the extensors and the flexors persisted during the follow-up period. Sex and age as well as preoperative trunk muscle strength levels and the intensity of low back pain predicted the extension and flexion strength levels.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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II

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

by

Outi Ilves, Marko H. Neva, Keijo Häkkinen, Joost Dekker, Kati Kyrölä, Salme Järvenpää & Arja Häkkinen, 2020

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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.

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.

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.

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).

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).

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).

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).

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

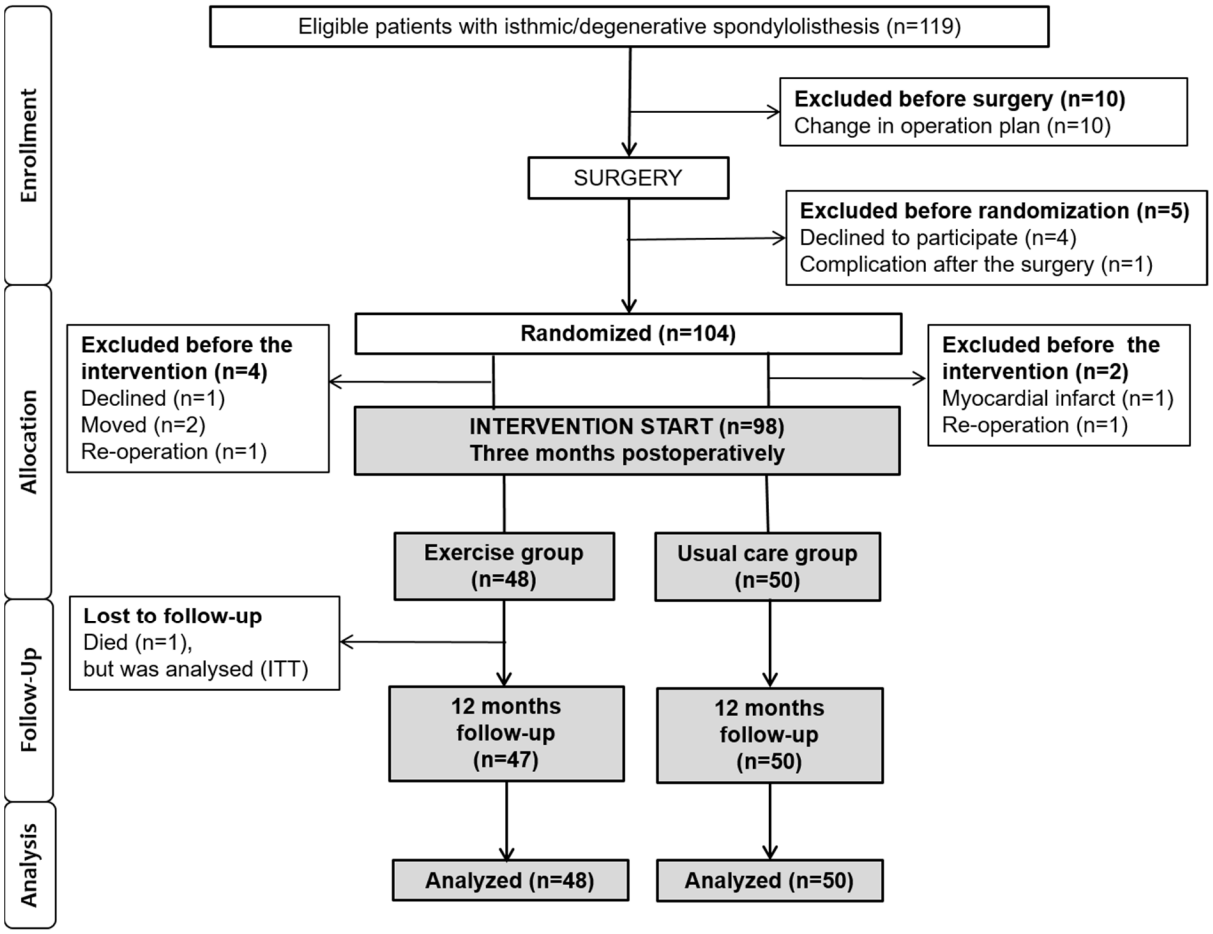

Figure 1. Consort diagram of the participant flow.

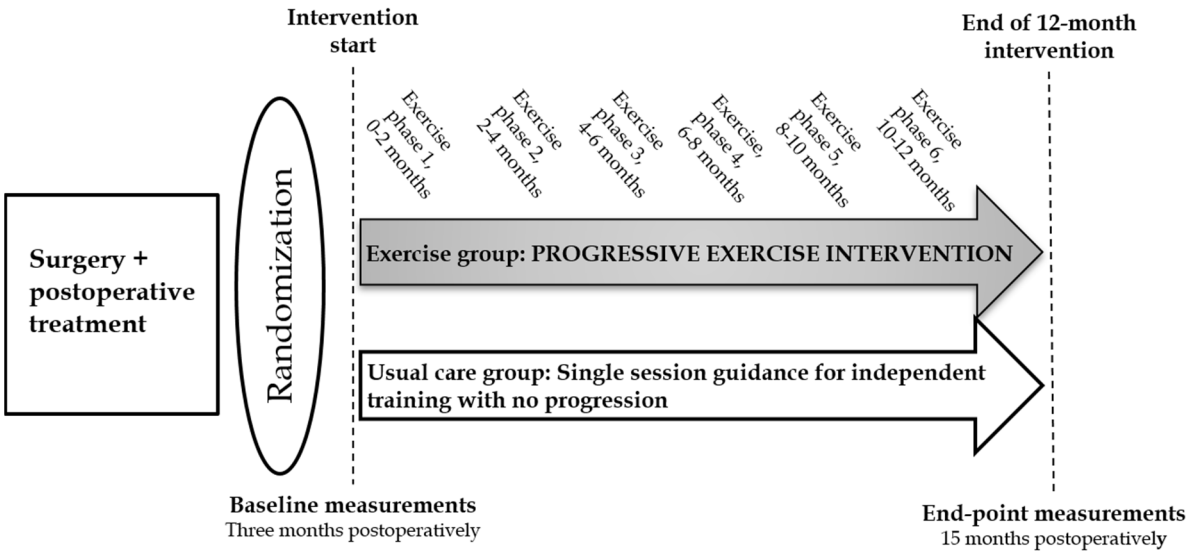

Figure 2. The study timeline.

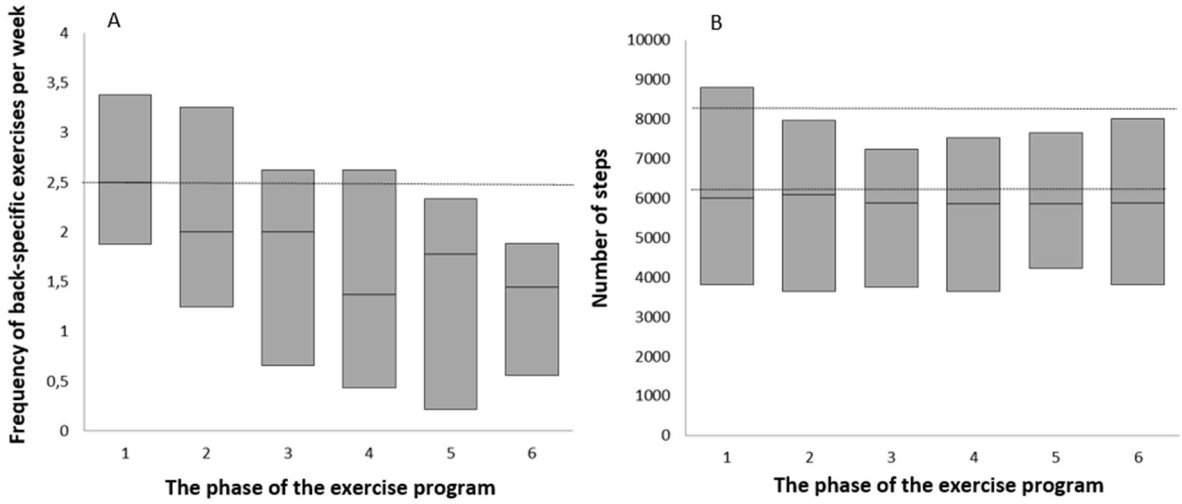

Figure 3. Compliance of the exercise group to 12-month back-specific training during the 2-month phases of the program (3a) and walking training (3b) using nonimputed data.

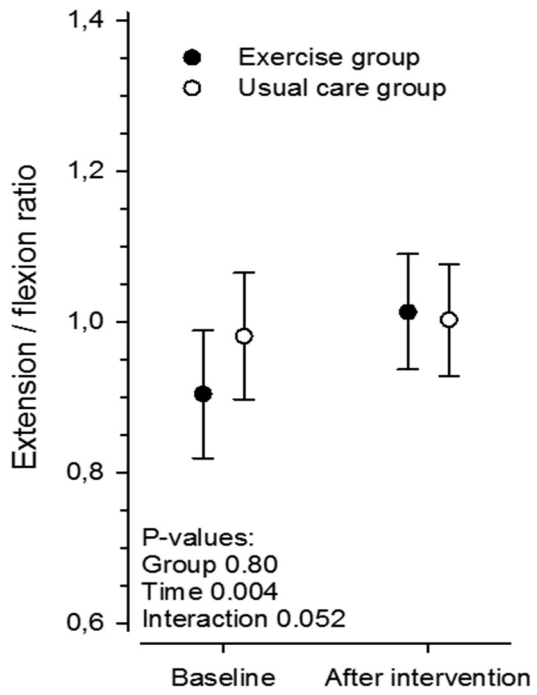

Figure 4. Changes in the trunk extension/flexion strength ratio.

III

QUALITY OF LIFE AND DISABILITY: CAN THEY BE IMPROVED BY ACTIVE POSTOPERATIVE REHABILITATION AFTER SPINAL FUSION SURGERY IN PATIENTS WITH SPONDYLOLISTHESIS? A RANDOMISED CONTROLLED TRIAL WITH 12-MONTH FOLLOW-UP

by

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Quality of life and disability – can they be improved by active postoperative rehabilitation after spinal fusion surgery in patients with spondylolisthesis? A randomised controlled trial with 12-month follow-up.

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Purpose: The aim of the study was to investigate the effectiveness of the postoperative 12-month exercise program compared to usual care on disability and health-related quality of life (HRQoL) in patients after lumbar spine fusion surgery (LSF).

Methods: Altogether, 98 patients with isthmic (31) or degenerative (67) spondylolisthesis were randomised to exercise therapy group (EG) (n = 48) or usual care group (UCG) (n = 50) 3 months after LSF. EG patients had home-based progressive strength and aerobic training program for 12 months. UCG patients received only oral and written instructions of exercises. Oswestry Disability Index (ODI) and HRQoL (RAND-36) were evaluated at the time of randomization, at the end of the intervention and 1 year after intervention.

Results: The mean ODI score decreased from 24 (12) to 18 (14) in the EG and from 18 (12) to 13 (11) in the UCG during intervention (between-groups p = 0.69). At 1-year follow-up, 25 % of the EG and 28 % of the UCG had an ODI score ≥20. No between-group differences in HRQoL change were found at any time point. The mean (95 % CI) physical functioning dimension of the HRQoL improved by 10.0 (4.6-15.3) in the EG and by 7.8 (2.5-13.0) in the UCG. In addition, the role physical score improved by 20.0 (7.7-32.3) in the EG and by 16.4 (4.4-28.4) in the UCG during the intervention.

Conclusions: The exercise intervention did not have an impact on disability or HRQoL beyond the improvement achieved by usual care. However, disability remained at least moderate in considerable proportion of patients.

Keywords: Disability; Health-related quality of life; Lumbar spine fusion; Physiotherapy; Spine surgery.

Introduction

Isthmic and degenerative spondylolistheses are common spinal disorders leading to chronic back and leg pain. Lumbar spine fusion has been shown to be effective treatment in both of these disorders when compared to conservative treatment [1, 2]. Although lumbar spine fusion surgery (LSF) reduce disability and improve health-related quality of life (HRQoL) in patients with several spinal disorders, they do not reach the level of normal population in disability of physical component score of HRQoL at the 1-year follow-up [3]. In these patients, the chronic low back pain may have affected the muscle functioning [4] and cardiorespiratory fitness [5]. In addition, fusion surgery itself leads to changes in spinal function [6–9].

Thus far, a limited number of randomised controlled trials (RCTs) have been published and the evidence of exercise therapy in restoring the spinal functioning and improving disability or HRQoL after fusion surgery is weak [10–16]. The commencement time and structure of the rehabilitation programs in previous RCT's varies [10–14, 17]. Most trials were implemented close to time of surgery, starting preoperatively [13, 14], during hospital stay or soon after discharge [10, 12]. The two trials, which have been measuring disability and health-related quality of life, indicate that combination of exercises and cognitive-behavioural therapy is more effective than exercises alone, when implemented within first postoperative months [10, 12]. Because the existing evidence concerning exercise rehabilitation after LSF is limited and controversial, there is no consensus on the contents of effective rehabilitation program after LSF.

The purpose of the present randomised controlled trial was to study the effectiveness of the 12-month progressive exercise intervention compared to usual care on quality of life and disability during the intervention and at the 1-year follow-up in LSF patients with spondylolisthesis.

Materials and methods

This randomised controlled trial (RCT) was carried out in Tampere University Hospital and Central Finland Central Hospital, Finland. All patients aged over 18 years scheduled to have elective LSF surgery for isthmic or degenerative spondylolisthesis were eligible for the study. The exclusion criteria were severe cardiorespiratory or musculoskeletal disease, fracture, tumour, severe psychiatric disorder, extensive lower limb paresis, alcohol abuse, and immediate complications after surgery (infection) that may prevent participation in postoperative rehabilitation. The sample size calculation was performed for the main outcome measure, pain (visual analogue scale), and it is explained in the study protocol [18]. Participant recruitment started in September 2009 and ended in September 2010 when a sufficient sample size had been achieved. This study was approved by the Ethics Committee of Tampere University Hospital and by the Ethics Committee of Central Finland Central Hospital.

Altogether, 104 consecutive adults were randomised into either the exercise group (EG) receiving active postoperative rehabilitation or to the usual care group (UCG) 3 months after the operation. Six participants dropped out before the start of the intervention (Fig. 1); thus, the number of participants was 98. Allocation to the EG or to the UCG was done randomly using computer-generated four-block randomisation lists, compiled by

biostatistician. There were separate randomisation lists for isthmic and degenerative spondylolisthesis patients to ensure that both diagnoses were evenly represented between both intervention groups. Randomisation was concealed and was carried out in both hospitals by a study nurse who was not otherwise involved with the study. The data were collected by research assistants who were blinded to the treatment. The physiotherapists could not be blinded because of the nature of the study. To avoid confusion between the EG and UCG treatments, both study arms had their own physiotherapists in each hospital.

Surgical indications and techniques, and pre- and postoperative rehabilitation protocols, were standardized between both hospitals before the study. Six experienced consultant surgeons were involved to the trial, and they performed part of the operations together, so the operation techniques were similar. All participants had posterolateral instrumented fusion which was performed using midline approach, and 21 % also had posterior or transforaminal interbody fusion. All participants received similar pre- and postoperative instructions for up to three postoperative months during which they were encouraged to walk and perform light muscle exercises and stretching [18].

The 12-month progressive home-based exercise program of EG started three months postoperatively. The program consisted of back-specific and aerobic exercises, and fear avoidance-counselling given by physiotherapist. The exercises were taught to each participant individually according to the exercise protocol targeting for improving coordination, muscle strength and also for increasing physical activity (PA) by walking [18]. Participants performed all of the exercises independently at home and had booster sessions with the physiotherapist every second month (6 meetings in total). During booster sessions, possible barriers to physical activity were identified and discussed with the patient. Harmful, irrational beliefs and fears towards activity were corrected, and more support was given over the phone as needed. The patients' experiences from the previous phase of exercise program were reviewed, and the next phase of the back-specific program was determined, as well as new aerobic training (step amount) target levels. Patients were also given pictorial and written instructions for the exercises.

Patients in the UCG received one guidance session in physiotherapy 3 months after the surgery, consisting of instructions for home exercises. The instructed home exercise program included light muscle endurance exercises (abdominal muscles, back muscles, and hip muscles) and stretching and balance training (one leg standing), with no progression. The participants were instructed to perform the home exercises three times a week. Participants were also given pictorial and written instructions for the exercises.

Outcome measures

The socio-demographic and clinical data included age, weight, height, smoking status, length of education, employment status and duration of symptoms, and self-reported comorbidities were evaluated preoperatively. Exercise compliance in the EG was assessed by exercise diaries. Exercise data were not collected from the UCG during the intervention period to avoid confusion between the two treatments. The outcomes were assessed at the baseline (3 months after surgery), at the end of the intervention (15 months after surgery) and 1 year after intervention (27 months after surgery).

Disability was measured by the Oswestry Disability Index (ODI), Finnish version 2.0 [19, 20]. The ODI contains 10 questions, and the score ranges from 0 to 100, with higher scores indicating more severe disability [20]. Health-related quality of life was assessed using the RAND-36 questionnaire. Eight dimensions were formulated from the RAND-36 questionnaire. The scaling of each dimension is from 0 to 100. The higher the value is, the better the HRQoL [21, 22]. Age- and sex-adjusted RAND-36 reference values for the normal Finnish population were used as Ref. [21]. Average low back and leg pain intensity for the previous 7 days were assessed using a 100-mm visual analogue scale (VAS) [23].

Statistics

Statistical analysis was carried out using IBM SPSS Statistics (version 20) and STATA 13 softwares. The results are expressed as mean with standard deviation (SD), median with interquartile range (IQR) or counts with percentages. The main outcomes are given with 95 percent confidence intervals (95 % CI). Comparisons between the groups in socio-demographic and clinical data were made by independent samples t test, bootstrapped type t test or Mann–Whitney U test for continuous variables; McNemar's test or Chi-square test was used in case of categorical distributions. The differences between the groups and changes over time in outcomes were investigated using mixed models with unstructured covariance structure and appropriate contrast. Data were analyzed with "intention to treat" (ITT) strategy. The Finnish reference values in RAND-36 dimensions were weighted to match the gender and age distribution of study population. The 95 % CI for the RAND-36 dimensions were obtained by bias-corrected bootstrapping.

Results

No between-group differences in socio-demographic or clinical data occurred at the baseline, except control group had more musculoskeletal comorbidities (Table 1). Most (74 %) of the participants were women, and the mean age was 59 years (range 32–84 years). According to the exercise diaries of the EG, the median (IQR) frequency of back-specific exercises was 2.5 (1.9; 3.4) times per week during the first 2 months of the intervention, and 1.4 (0.6; 1.9) times per week during the last 2 months ($p < 0.001$).

There were no between-group differences in changes in any RAND-36 dimensions during the intervention or at the 1-year follow-up (Table 2). However, both groups improved significantly in the physical functioning and role physical dimensions during the intervention. Compared to the Finnish reference values for the physical functioning, role physical, and bodily pain dimensions, the patients' scores were lower in both groups at baseline, and the EG also had lower values in the social functioning dimension. Both groups achieved the Finnish reference values in all dimensions by the 1-year follow-up (Fig. 2).

The ODI score decreased from 24 (12) to 18 (14) in the EG ($p = 0.003$) and from 18 (12) to 13 (11) in the UCG ($p = 0.012$) during the intervention (between groups $p = 0.69$) (Table 2). At baseline, 54 % of the EG had an ODI score of 20 or higher. After the intervention 29 %, and at 1-year follow-up, 25 % of the EG had an ODI score ≥20. The respective proportions in the UCG were 36, 25, and 28 %.

Discussion

The aim of this study was to investigate the effectiveness of the home-based progressive 12-month exercise program compared to usual care after lumbar spine fusion surgery in patients with spondylolisthesis. This study showed that disability and physical performance-related dimensions of the HRQoL improved in both groups. However, we did not detect any difference between the groups during the intervention or at the 1-year follow-up visit. At the 1-year follow-up visit, one-fourth of all participants still had at least moderate disability.

The exercise program of EG comprised of progressive neutral spine control exercises and aerobic training, but it also included individual discussions and counselling aiming to prevent irrational fears of movement or reinjury. This program was expected to reduce disability and to improve HRQoL in long-term follow-up. In this study, the EG followed a progressive exercise program with individual adjustments to determine the optimal level of intensity or to enable persons with different functional abilities to perform the program at home [18]. According to the HRQoL findings of this study, the role physical and physical functioning dimensions improved significantly in both groups during the intervention, but the increase levelled out by the 1-year follow-up. The role physical dimension was very low at baseline in both groups, and it also had the highest increase during the intervention and throughout follow-up. In other words, usual care also efficiently enhanced these outcomes. The vitality, social functioning, role emotional, and mental health dimensions did not change during the intervention or at the postintervention follow-up. The most importantly participants in both groups reached the age- and sex-matched levels of the reference normal Finnish population 2 years postoperatively in the physical functioning, role physical, bodily pain, and social functioning dimensions of the HRQoL.

In this study, all dimensions of the HRQoL, except the role physical dimension, were higher at baseline compared to the baseline in the study by Monticone et al. in 2014 [12]. In that study, there were significant differences between the two treatment groups in the changes in all HRQoL dimensions of the SF-36, meaning that the 4-week cognitive-behavioural therapy (CBT) with exercise training was more effective than the 4-week exercise training alone, when implemented within the first five postoperative weeks [12]. The later timing of the intervention in the present study may explain the smaller changes, as the surgery and early postoperative care already improved outcomes before the 12-month intervention started. Despite the shift in clinical practice towards earlier rehabilitation using fast-track strategies, Oestergaard et al. 2013 found that later timing (start 12 weeks postoperatively) of exercise rehabilitation has shown better results and cost-effectiveness than fast-track rehabilitation (start 6 weeks postoperatively) [24].

In this study, the disability of UCG was lower than EG at the baseline, but the changes in disability were analogous between the groups during the intervention. Furthermore, at the 1-year follow-up, the achieved ODI levels were maintained, meaning that one-fourth of participants reported at least moderate disability. The future challenge will be to identify these patients in an earlier postoperative phase to offer them more individual rehabilitation interventions, while most of the LSF patients could possibly recover with subtler interventions. In previously published RCTs, the mean ODI scores showed severe disability (over 40) at baseline [10, 12], while in this study, the mean disability levels were moderate in the EG and minimal in the UCG at baseline. In the

study by Abbott et al. [10], the baseline measurement was actually performed preoperatively when the patient's clinical status was worse than three months postoperatively, which was the time point used as a baseline of present study. In the study by Abbott et al., the ODI score had the most significant decrease during the first three postoperative months in both groups (psychomotor therapy and exercise therapy), but the difference between the groups remained unchanged after 2 to 3 years of follow-up, in favour of psychomotor therapy (mean difference of 9.8 points, $p = 0.011$) [10]. A similar trend is also seen in the study by Monticone et al. [12], suggesting that CBT together with exercise is a more effective treatment than exercise alone when investigating disability. In addition, qualitative study about patient's postoperative experiences after interdisciplinary CBT as part of surgery rehabilitation suggests that CBT as part of therapy may alter patient's pain perceptions and improve pain coping behaviour [25].

Only in the study of Christensen et al., the commencement time of intervention was the same 3 months as in our study [11, 16]. However, the length of intervention in that study was only eight weeks, and exercise protocol of training group was more intensive than the protocol used in this study. The intensity and length of the intervention are probably the explanation why the significant pain problem found in study of Christensen was not found in present study. Therefore, the long-term postoperative rehabilitation is not problematic according our study because of inferior results; instead, it is controversial because of cost-effectiveness, since the results were not superior when compared to the usual care group.

In this study, we used patient-reported outcome measures (PROMs), which show the effect of the treatment for the patients. The novelty of this study is the long-term combined back-specific and health-enhancing home-exercise program, which is resource-friendly option. These can be considered as the strengths of this study, as well as the authentic clinical setting, which could be easily implemented in clinical practice. This study has some limitations as well. In both groups, the results of surgery were good and the patients had already started light exercises in the early recovery phase, before the actual exercise intervention started; thus, the outcomes had already improved by the starting time of the intervention. To avoid confusion between the treatments of the two groups, we did not monitor the activities of the UCG with exercise diaries during the intervention.

Conclusion

In conclusion, the disability and physical dimensions of the HRQoL improved in both groups during the intervention. The progressive 12-month home-exercise intervention, which commenced 3 months postoperatively, was not superior to usual care. However, one-fourth of participants had at least moderate disability at the 12-month follow-up, and therefore, postoperative rehabilitation may need to be composed of more individually supported and tailored interventions.

Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1. Baseline characteristics 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
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=inter-quartile range

Table 2. Baseline scores and changes in the RAND-36 dimensions during the intervention and at follow-up, reported as the means with standard deviation (SD) or 95 percent confidence intervals (95% CI). The changes are based on mixed model estimates. Between group p-values are adjusted by age and sex.

	Baseline		Change during intervention		p-value between the groups	Change during 1-year follow-up		p-value between the groups
	EG	UCG	EG	UCG		EG	UCG	
	Mean (SD)	Mean (SD)	Mean (95% CI)	Mean (95% CI)		Mean (95% CI)	Mean (95% CI)	
RAND-36:								
Physical functioning	59.6 (20.4)	67.1 (17.4)	10.0 (4.6 to 15.3)	7.8 (2.5 to 13.0)	0.53	-0.5 (-4.8 to 3.7)	-1.4 (-5.5 to 2.6)	0.75
Role physical	22.3 (31.7)	38.5 (36.8)	20.0 (7.7 to 32.3)	16.4 (4.4 to 28.4)	0.67	9.9 (-3.6 to 23.3)	5.7 (-7,2 to 18.5)	0.65
Bodily pain	55.1 (20.7)	60.8 (19.3)	5.3 (-1.7 to 12.4)	6.3 (-0.6 to 13.1)	0.88	1.5 (-5.4 to 8.3)	1.5 (-5.0 to 8.0)	0.99
General health	62.4 (20.4)	59.4 (19.0)	-2.6 (-7.1 to 2.0)	1.3 (-3.2 to 5.7)	0.23	2.7 (-2.2 to 7.6)	-0.8 (-5.4 to 3.8)	0.30
Vitality	61.1 (24.0)	65.8 (18.5)	1.3 (-4.7 to 7.4)	-1.9 (-7.8 to 4.1)	0.44	-1.1 (-6.9 to 4.6)	0.1 (-5.4 to 5.7)	0.74
Social functioning	71.5 (25.0)	79.7 (20.2)	3.0 (-4.9 to 10.9)	5.4 (-2.3 to 13.1)	0.68	7.9 (1.0 to 14.8)	-1.2 (-7.7 to 5.4)	0.062
Role emotional	60.1 (44.2)	68.1 (40.1)	2.1 (-16.6 to 20.8)	4.9 (-8.5 to 18.3)	0.86	1.2 (-11.1 to 13.5)	-5.6 (-17.2 to 6.0)	0.43
Mental health	74.0 (19.5)	77.1 (16.6)	-0.4 (-5.4 to 4.7)	-1.2 (-6.2 to 3.7)	0.81	2.1 (-2.7 to 6.9)	-1.0 (-5.6 to 3.6)	0.36
ODI	24.0 (12.0)	17.8 (11.7)	-5.6 (-9.2 to -1.9)	-4.6 (-8.2 to -1.0)	0.69	-1.2 (-3.9 to 1.3)	2.1 (-0.4 to 4.5)	0.065
Back pain (VAS)	21.1 (17.9)	17.3 (18.0)	-1.6 (-6.6 to 3.7)	3.8 (-0.9 to 8.8)	0.16	2.0 (-3.2 to 7.5)	4.4 (-2.5 to 10.7)	0.64
Leg pain (VAS)	18.8 (22.2)	14.3 (20.0)	4.1 (-4.4 to 11.7)	0.4 (-6.4 to 5.8)	0.38	3.3 (-1.1 to 8.4)	5.1 (-3.2 to 13.2)	0.71

EG=exercise group, UCG=usual care group, 95% CI= 95% confidence interval, ODI=Oswestry Disability Index, VAS=Visual analogue scale

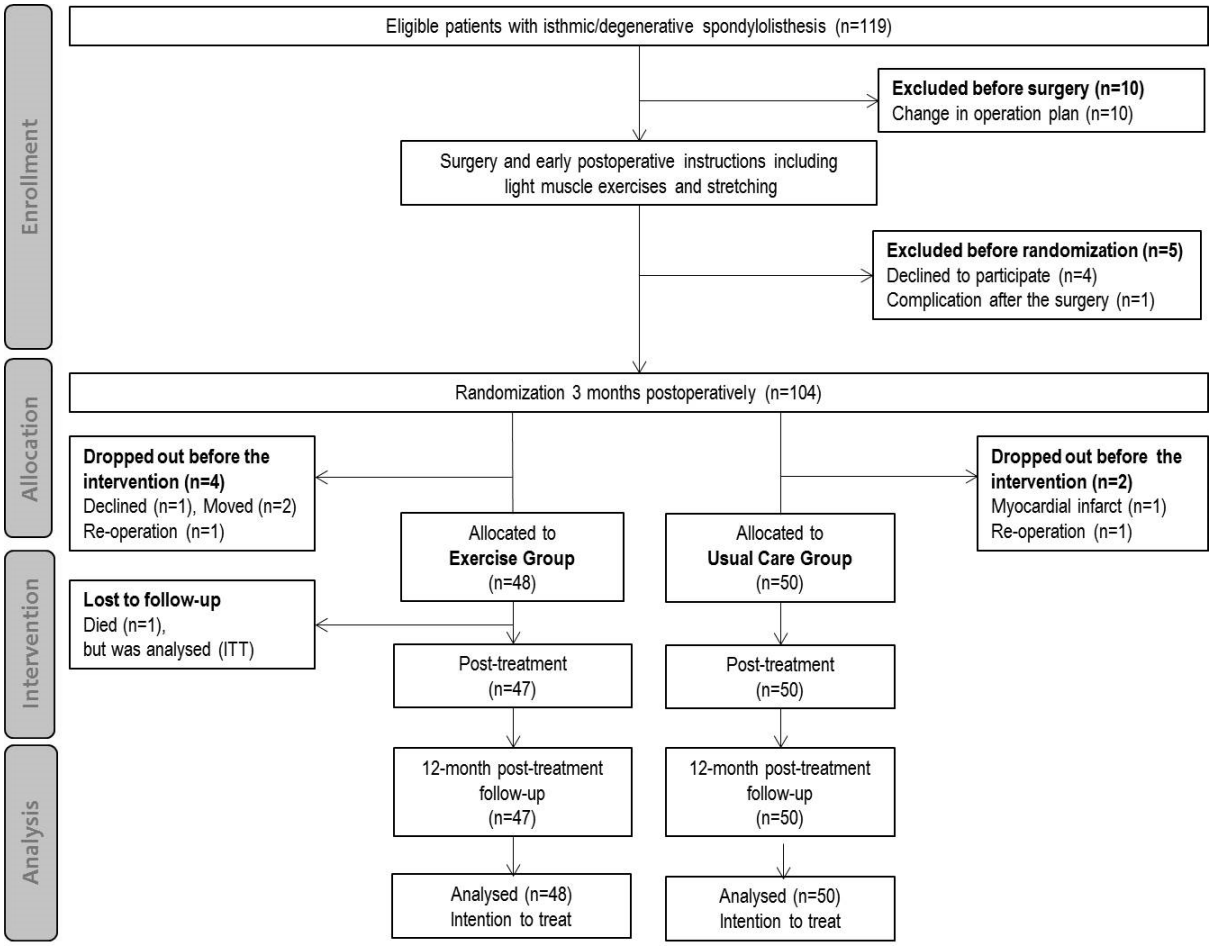

Figure 1. Participant flow diagram

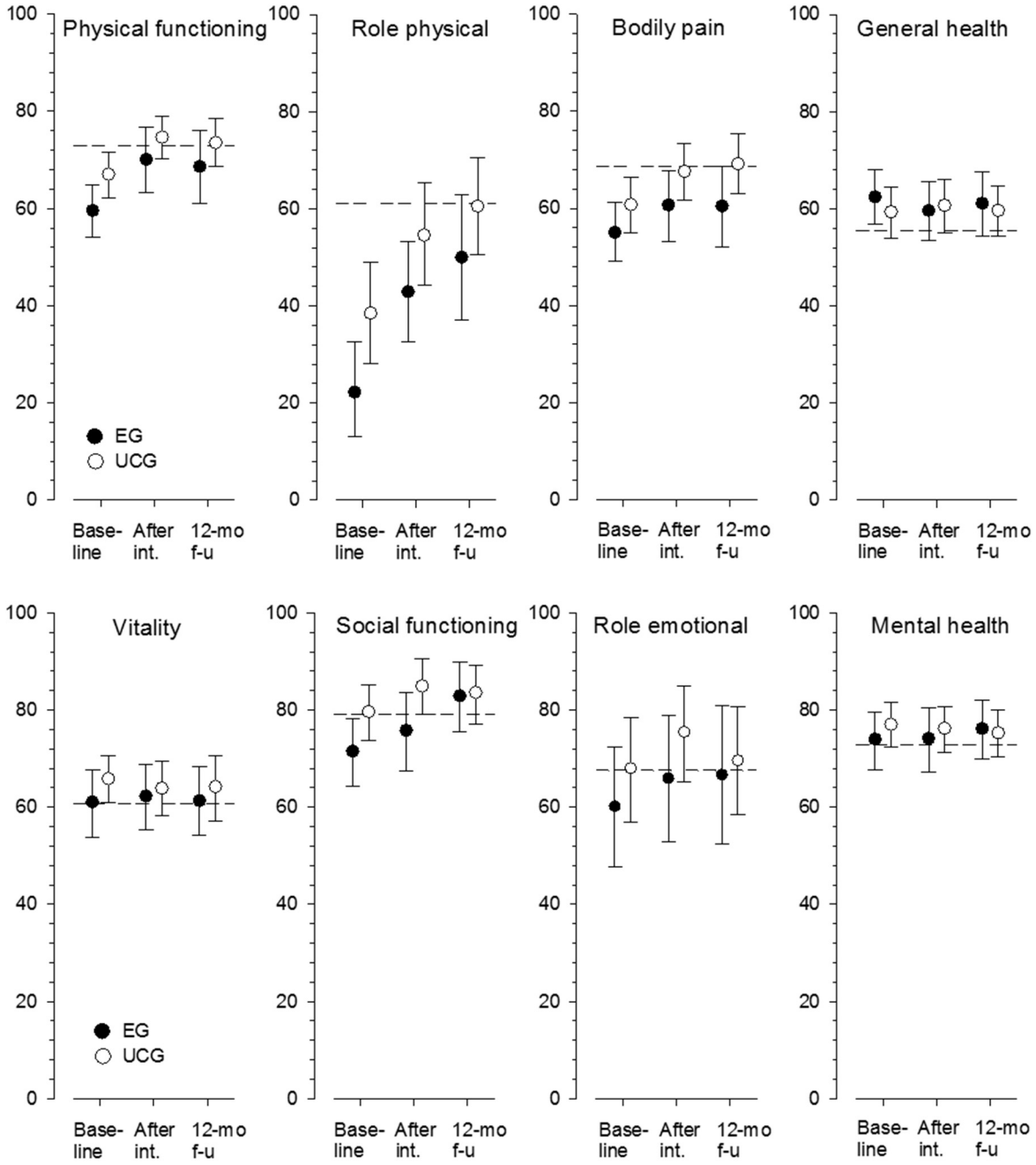

Figure 2. The-RAND-36 dimensions (mean with 95%CI) by group at each measurement point. The dashed lines show the Finnish population reference values. EG=exercise group, UCG=usual care group, After int.=after intervention, 12-mo f-u=12-month follow-up

IV

EFFECTIVENESS OF POSTOPERATIVE HOME-EXERCISE COMPARED WITH USUAL CARE ON KINESIOPHOBIA AND PHYSICAL ACTIVITY IN SPONDYLOLISTHESIS: A RANDOMIZED CONTROLLED TRIAL

by

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ORIGINAL REPORT

EFFECTIVENESS OF POSTOPERATIVE HOME-EXERCISE COMPARED WITH USUAL CARE ON KINESIOPHOBIA AND PHYSICAL ACTIVITY IN SPONDYLOLISTHESIS: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To study the effectiveness of a 12-month exercise therapy on kinesiophobia and physical activity in patients with spondylolisthesis after lumbar spine fusion.**
Design: **Randomized controlled trial.**
Subjects: **Patients (*n* = 98) with spondylolisthesis who had undergone lumbar spine fusion.**
Methods: **All patients (mean age 59 years) had received lumbar spine fusion surgery and identical postoperative instructions. Three months postoperatively, they were randomized into an exercise group (*n* = 48) or usual care group (*n* = 50). The exercise group received 12-month progressive home-based training with regular booster sessions, and the usual care group a single session of physiotherapy instruction. Kinesiophobia was assessed with the Tampa Scale for Kinesiophobia (TSK) and physical activity by the International Physical Activity Questionnaire (IPAQ) preoperatively, 3 months after lumbar spine fusion, and at the end of the 12-month intervention.**
Results: **Before the intervention, the median (first quartile; third quartile) of TSK was 32.5 (29.0; 37.0) in the exercise group and 30.0 (25.8; 36.0) in the usual care group, changing to 30.0 (25; 36) in the exercise group and to 30.5 (24; 36.3) in the usual care group (between-group *p* = 0.17). IPAQ metabolic equivalent minutes per week increased from 1,863 (1,040; 3,042) to 3,190 (1,634; 6,485) in the exercise group and from 2,569 (1,501; 4,075) to 3,590 (1,634; 6,484) in the usual care group (between-group *p* = 0.92).**
Conclusion: **Progressive 12-month home-exercise starting 3 months postoperatively was not superior to usual care in decreasing kinesiophobia or increasing physical activity in spondylolisthesis.**

Key words: spondylolisthesis; spinal fusion; physical therapy modalities; exercise therapy; low back pain.

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Fear of movement or re-injury, also known as kinesiophobia, is a common problem among patients with musculoskeletal pain (1). It may result in avoidance behaviour and inactivity, leading eventually to disability (2–5). Kinesiophobia also has a central role in the development of chronicity in low back pain (3, 5). Lumbar spine fusion (LSF) surgery may be a treatment option for chronic low back pain caused by spondylolisthesis if conservative treatment fails (6, 7). Physical activity and early return to normal daily activities after LSF surgery is considered important for several reasons. Patients concern over whether the fusion has healed may lead to inactivity and fear-avoidance behaviour. Physical activity enhances recovery from a prolonged period of back pain (8) as well as from surgery. Physical activity may also lower the risks of other health problems caused by inactivity (9, 10). Kinesiophobia can be considered a barrier to physical activity, as well as a condition that restricts social life following LSF surgery.

To the best of our knowledge, only 2 RCT studies have evaluated kinesiophobia in postoperative rehabilitation after LSF surgery (11, 12). In the study by Abbott et al. (11), psychomotor therapy with exercises was more effective than exercises alone in decreasing fear of movement. Monticone et al. (12) reported that combined exercise and cognitive-behavioural therapy was superior to an exercise programme alone in reducing disability, kinesiophobia-related dysfunctional thoughts and pain, and enhancing quality of life. Both short-term interventions were implemented during the first 3 postoperative months. Archer et al. (13) suggest that, in laminectomy patients (with or without arthrodesis) with high kinesiophobia, targeted cognitive-behavioural-based physical therapy 6 months postoperatively may improve pain, disability and general health more than an educational programme. No studies have evaluated the effects of lumbar spine fusion on kinesiophobia and physical activity, or the effectiveness of later postoperative exercise therapy compared with usual care on kinesiophobia and physical activity.

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This study evaluated the effects of a 12-month postoperative back-specific exercise programme combined with aerobic training on fear of movement and physical activity compared with usual care in patients with isthmic or degenerative spondylolisthesis. The effect of surgery before the intervention is also reported.

MATERIAL AND METHODS

This parallel group randomized controlled trial (RCT) (registration no: NCT00834015) was conducted at 2 Finnish hospitals: Tampere University Hospital and Central Finland Central Hospital. A sample size calculation was performed for the main outcome measure of the trial (pain, visual analogue scale) (14) and is explained in the RCT study protocol article by Tarnanen et al. (15). All patients scheduled for non-urgent LSF surgery for isthmic or degenerative spondylolisthesis, who were over 18 years of age were eligible for the study. Exclusion criteria were: severe cardiorespiratory or musculoskeletal disease, fracture, tumour, severe psychiatric disorder, extensive lower limb paresis, alcohol abuse and immediate complications after surgery that could prevent the patient from participating in the postoperative rehabilitation programme.

In total, 104 consecutive patients underwent LSF. Six patients were excluded before the start of the intervention, and thus the final number of participants was 98, of whom 48 were allocated to the exercise group (LSF-EX) and 50 to the usual care group (LSF-UC) (Fig. 1). The study was approved by the ethics committees of both study centres (recorded as decision 4E/2008 at Central Finland Central Hospital, and subsequently also confirmed by Tampere University Hospital).

Allocation to LSF-EX or LSF-UC was performed randomly using computer-generated 4-block randomization lists compiled by a biostatistician. Two lists were created: (*i*) isthmic and (*ii*) degenerative spondylolisthesis. Concealed randomization was used, and was conducted by nurses who were not otherwise involved in the study. The study questionnaires were collected and saved by research assistants who were blinded to treatment. However, owing to the nature of the study, the physiotherapists could not be blinded. To avoid confusion between the LSF-EX and LSF-UC treatments, each study arm in each hospital had its own physiotherapist. Participant preoperative recruitment started in September 2009 and ended in September 2010, when a sufficient sample size had been achieved. The last recruited participants completed the 12-month intervention in January 2012.

Surgical indications and techniques and the pre-and post-operative rehabilitation protocols were matched in the 2 hospitals before the study. Some of the operations were collaboratively performed by surgeons from both hospitals to ensure that the surgical techniques used were similar. All patients had posterolateral instrumented fusion and 21% also had posterior interbody fusion. The frequencies of the techniques used were similar in both study groups: 20% in LSF-EX and 22% in LSF-UC had posterior interbody fusion, (χ^2 test between groups $p = 0.89$). All patients were provided with similar postoperative instructions for up to the first 3 postoperative months. During the first few days after LSF, patients were encouraged to start light walking training and leg muscle stretching, as well as light trunk muscle contraction exercises to re-learn good posture of the upper body. They were also instructed to avoid continuous sitting for more than 30 min at a time during the first 4 weeks, after which the use of a cycling ergometer was encouraged. Six weeks after surgery, a physiotherapist at the outpatient clinic instructed all patients to gradually increase the amount of walking training time, to perform light abdominal, back and thigh muscle exercises, and to stretch their hip muscles. All patients were instructed to avoid extreme flexion and extension of the spine for the first 2 postoperative months, after which more strenuous physical activities were allowed.

The LSF-EX programme consisted of 12 months of progressive home-based back-specific and aerobic training together with fear avoidance counselling by a physiotherapist, starting 3 months postoperatively, i.e. at a time when the LSF healing process had advanced and it was safe to start progressive training. A physiotherapist gave each patient individual instructions on the exercises in accordance with the exercise protocol (15). The patients exercised independently at home, and had booster sessions with the physiotherapist every second month (6 meetings in total).

The main aims of the 12-month back-specific exercise programme were to improve lumbar spine control and to increase trunk and hip muscle coordination, strength and endurance. Exercises were selected partially on the basis of electromyographic studies in healthy subjects and LSF patients (16–22). The muscle groups trained were the abdominal, gluteal, thigh, and low back muscles. The hospital supplied the patients with 2–3 elastic bands of differing stiffness (Thera-Band®, The Hygienic Corporation, Akron, Ohio, USA) for use in some of the exercises. The programme was progressive, starting with exercises performed in the unloading position (supine, prone or 4-point kneeling). As the programme advanced, the strengthening exercises became more challenging in both the coordination and muscle strength required. The degree of difficulty was increased by increasing the functionality of the exercises and the resistance of the elastic band. Progression was also implemented by increasing the number of repetitions and sets from 2 × 10–20 to 2–4 × 10–20, depending on the exercise and the participant's fitness level. The precise training resistance was re-evaluated at check-up visits by repetition maximum tests, and the stiffness of the elastic bands set to provide a training resistance of 50–70% of estimated maximum strength using the 10-repetition maximum method. The par-

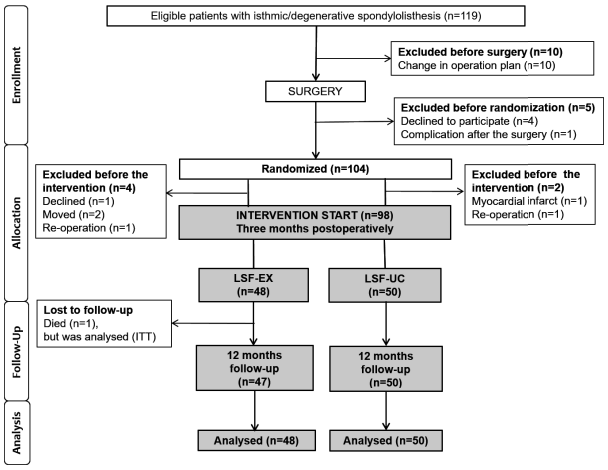

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) patient flow diagram. LSF: lumber spine fusion; EX: exercise group; UC: usual care group.

ticipants were instructed to perform the exercises at least 2–3 times a week.

The participants in the LSF-EX group were also instructed to increase the total number of daily steps during the intervention by walking training, performance of which was encouraged at least 3 times per week. To ensure that the walking was vigorous enough to obtain health benefits, the patients, after warming up, were instructed to perform walking sessions consisting of 30 s to 1 min of brisk walking, alternating with 3 min of walking at normal speed. At the beginning of the intervention, the duration of 1 walking session was approximately 25–30 min. Progression was increased based on a dose-response relationship (intensity/time). The number of steps per day and frequency of exercise sessions per week were noted in exercise diaries.

During the booster sessions in physiotherapy, barriers to physical activity, such as kinesiophobia or pain, were identified and discussed with the patient. The physiotherapist sought to allay harmful, irrational beliefs and fears regarding activity, and provided additional telephone support when needed. The physiotherapist also reviewed the patient's experiences regarding the previous phase of the exercise programme, instructed the patient in the next phase of the programme, and defined the new target number of daily steps (walking training). The patients received pictorial and written instructions for the exercises.

The patients in the LSF-UC group received just one guidance session with a physiotherapist 3 months after surgery. The session consisted of instructions for the standard home exercises. The home exercise programme included light muscle endurance exercises (abdominal muscles, back muscles and hip muscles), stretching and balance training (1-leg standing). The patients were advised to perform the home exercises 3 times per week. Pictorial and written instructions for the exercises were issued.

Outcome measures

Kinesiophobia was assessed with the Tampa Scale for Kinesiophobia questionnaire (TSK) (23–25). The TSK comprises 17 items rated on a 4-point Likert response scale (1 totally disagree to 4 totally agree), with total scores ranging from 17 (minimum – no fear) to 68 (maximum – intense fear) points. The TSK items are shown in Appendix I. Physical activity was measured with the short form of the International Physical Activity Questionnaire (IPAQ) (26). Physical activity is expressed as a continuous score of total metabolic equivalent minutes per week (METmins/week). According to the IPAQ Scoring Protocol, less than 600 METmins/week is considered inactive, 600–2,999 is considered moderate activity and 3,000 or more is considered highly active, and meeting the criteria for health enhancing physical activity (26, 27).

In addition, age, weight, height, smoking status, education, employment, and duration of symptoms were gathered by questionnaire. The intensity of low back and leg pain during the previous week was measured using a 100-mm visual analogue scale (VAS) (28). During the intervention, the LSF-EX group recorded their back-specific exercises and number of steps per day measured by a pedometer (Omron HJ-113-E, Omron Health Care, UK) in their exercise diary.

Statistics

Data were analysed according to the intention-to-treat principle. The results are expressed as mean (standard deviation: SD), with 95% confidence intervals (95% CI) or median (lower and upper quartiles: Q1; Q3), counts with percentages, or frequency distributions. The normality of the variables was tested by the Shapiro-Wilk W-test. Comparisons between the groups in preoperative descriptive data were made by independent samples *t*-test or bootstrapped type *t*-test for continuous variables and χ^2 test were used for categorical variables. The intervention outcomes were analysed using the non-parametric independent samples Mann-Whitney *U* test for between-groups differences. The significance of change over time was assessed using the non-parametric-related samples Wilcoxon signed-rank test. Effect size (ES) was calculated by Cohen's d (mean baseline scores minus mean follow-up scores, divided by the pooled standard deviation). An effect size ≥ 0.20 was considered small, ≥ 0.50 medium, and ≥ 0.80 large (29). The 95% confidence intervals (95% CI) of ES for the effect sizes were obtained by bias-corrected bootstrapping (5,000 replications). Pearson's rho was used as a correlation coefficient. Statistical analysis was performed using IBM SPSS Statistics 20 software (IBM Corporation Armonk, NY, USA) and STATA 11.1 (StataCorp LP, College Station, TX, USA) software.

RESULTS

Mean patient age was 59 (range 32–84) years, and 74% were women. Almost half of the participants were retired, and one-third were employed. The diagnosis for surgery was degenerative spondylolisthesis in 69% and isthmic spondylolisthesis in 31% of cases. Mean (standard deviation; SD) preoperative duration of low back symptoms was 3.5 (3.4) years. Mean intensity was 60 (22) mm for low back pain and 61 (25) mm for radicular leg pain across the whole sample. No preoperative differences between the groups were found in socio-demographic or clinical data (Table I).

Table I. Preoperative clinical and socio-demographic data

	All *n* = 98	LSF-EX *n* = 48	LSF-UC *n* = 50
Socio-demographic data			
Women, *n* (%)	72 (74)	34 (71)	38 (76)
Age, years, mean (SD)	59 (12)	59 (12)	58 (12)
BMI, mean (SD)	28.3 (4.8)	28.3 (4.8)	28.3 (4.8)
Smokers, *n* (%)	15 (15)	9 (19)	6 (12)
Length of education, years, mean (SD)	12.3 (3.7)	12.0 (3.7)	12.6 (3.6)
Work status, *n* (%)			
Working at least part-time	30 (31)	17 (35)	13 (26)
Retired or unemployed	45 (46)	23 (48)	22 (44)
Sick leave	23 (23)	8 (17)	15 (30)
Clinical data			
Primary diagnosis, *n* (%)			
Degenerative spondylolisthesis	67 (68)	32 (67)	35 (70)
Isthmic spondylolisthesis	31 (32)	16 (33)	15 (30)
Duration of current symptoms before surgery, months, mean (SD)	41 (36)	41 (37)	40 (36)
Low back pain, VAS mm, mean (SD)	60 (23)	58 (23)	60 (23)
Lower limb pain, VAS mm, mean (SD)	61 (24)	58 (24)	65 (23)
Disability score (Oswestry Disability Index) mean (SD)	40.3 (11.8)	40.2 (11.1)	40.4 (12.6)

VAS: visual analogue scale; LSF: lumbar spine fusion; EX: exercise group; UC: usual care group; SD: standard deviation.
Tests used: *t*-test, bootstrap-type *t*-test and X^2 test.

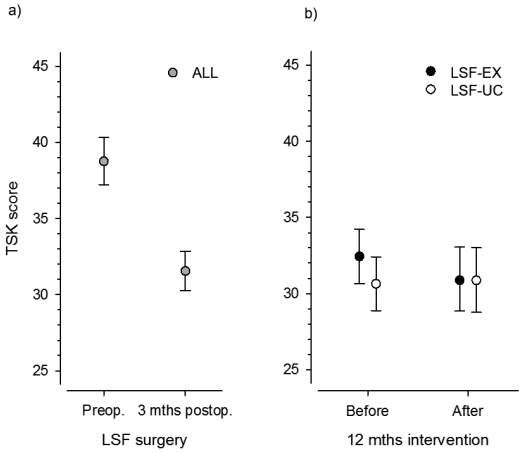

Fig. 2. Mean scores with 95% confidence intervals on the Tampa Scale for Kinesiophobia (TSK) before surgery and 3 months after surgery in (a) all patients and (b) by groups before and after the 12-month intervention. LSF: lumbar spine fusion; EX: exercise group; UC: usual care group.

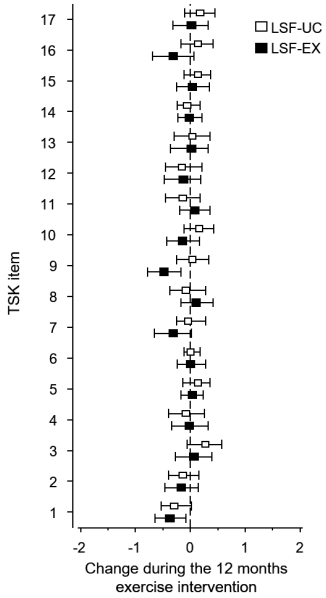

Fig. 3. Item-specific mean changes with 95% confidence intervals in the Tampa Scale for Kinesiophobia (TSK) during the 12-month postoperative intervention by groups. LSF: lumbar spine fusion; EX: exercise group; UC: usual care group.

Intervention phase

Table II shows the main results of TSK, IPAQ and pain intensity in medians with first and third quartiles (Q1; Q3). During the exercise intervention, the mean change in the total TSK score in the LSF-EX group was –1.6 points (ES 0.23, 95% CI –0.05 to 0.51) and in the LSF-UC group 0.2 (ES –0.03 95% CI –0.28 to 0.21). The difference between the groups was not significant ($p=0.17$) (Fig. 2b). When the items were analysed separately, a significant difference between the groups was found for TSK item 9 ("I am afraid that I might injure myself accidentally") ($p=0.01$). The mean within-group change was significant in the LSF-EX group for items 1 ("I'm afraid that that I might injure myself if I exercise") ($p=0.01$) and 9 ($p=0.006$) (Fig. 3). In the LSF-EX group, a high TSK score at the beginning of the intervention was associated with a larger decrease during the intervention (r=–0.29, $p=0.05$). In the LSF-EX group, the median (Q1; Q3) IPAQ score was 1863 (1040; 3042) METmins/week before the intervention and 3190 (1,150; 6,384) METmins/week ($p=0.01$) at intervention end. The corresponding scores in the LSF-UC group were 2,569 (1,501; 4,075) and 3,590 (1,634; 6,485) METmins/week ($p=0.01$). The difference between the groups was not significant (Table II). No changes in low back or leg pain were observed within the groups during the 12-month intervention.

Compliance was assessed by exercise diaries. The median (Q1; Q3) frequency of the back-specific exercise was 2.5 (1.9; 3.4) times per week during the first 2 months of the postoperative intervention in the LSF-EX group. During the last 2 months of the intervention, the frequency was 1.4 (0.6; 1.9) times per week (within-group change $p<0.001$). The median (Q1; Q3) numbers of daily steps at the same time points were 6,138 (3,759; 8,907) and 5,870 (3,587; 8,024) (within-group change

Table II. Changes in kinesiophobia, physical activity and pain intensity during the 12-month exercise intervention

	Before intervention		Change during the intervention		
	LSF-EX Median (Q1; Q3)	LSF-UC Median (Q1; Q3)	LSF-EX Median (Q1; Q3)	LSF-UC Median (Q1; Q3)	*p*-value between groups
TSK	32.5 (29.0; 37.0)	30.0 (25.8; 36.0)	–1.0 (–6.0; 2.0)*	–0.5 (–5.0; 5.0)	0.17
IPAQ	1,863 (1,040; 3,042)	2,569 (1,501; 4,075)	333 (–396; 4,173)*	449 (–553; 3,227)*	0.92
VAS, low back	15 (3; 30)	13 (3; 31)	–1 (–14; 7)	–2 (–11; 12)	0.76
VAS, leg	10 (2; 29)	7 (1; 26)	0 (–9; 23)	–1 (–18; 6)	0.40

*Significant within-group change. Used test: Mann–Whitney *U* test for between-group differences and Wilcoxon related-samples signed-rank test for within-group differences.
LSF-EX: exercise group; LSF-UC: usual care group; TSK: Tampa Scale for Kinesiophobia; IPAQ: International Physical Activity Questionnaire; VAS: visual analogue scale.

$p=0.24$). No participant reported discontinuance due to harms caused by the exercise programme. Seven patients in LSF-EX discontinued the exercise intervention. Four patients discontinued due to difficulties in commuting to booster meetings. One patient presented with a sudden decline in haemoglobin and general condition and was referred for further examination. A physician advised 1 patient to discontinue exercising, owing to a problem with fixation (patient subsequently had a re-operation and was diagnosed with myopathy, leading to muscle weakness) and one died (myocardial infarction). The intention-to-treat method was used and all patients ($n=98$) were thus included in the analysis in their original assigned groups.

Before surgery to 3 months after surgery

The preoperative median (Q1; Q3) total TSK score was 39 (33; 44) points. At 3 months after surgery, it had decreased to 31 (26; 36) points ($p<0.001$) across the whole sample (Fig. 2a). The effect size of the change in the TSK total score was 1.02 (95% CI 0.82–1.26). Three months after surgery, a significant improvement was observed in 11 of the 17 items. The largest changes were observed in items 3 ("My body is telling me I have something dangerously wrong") and 11 ("I wouldn't have this much pain if there weren't something potentially dangerous going on in my body"). A higher pre-operative TSK score was associated with a larger decrease in the same score 3 months postoperatively ($r=-0.62$, $p<0.001$). The preoperative median (Q1; Q3) IPAQ was 1,709 (1,396; 3,982) METmins/week, and at 3 months postoperatively it was 2079 (1,386; 3,792) METmins/week across the whole sample ($p=0.15$). Three months after surgery, median (Q1; Q3) low back pain intensity had decreased from 61 (47; 76) to 14 (3; 30) mm, and leg pain intensity from 64 (43; 80) to 9 (2; 29) mm across the whole sample ($p<0.001$). The association between the change in low back pain and the change in TSK score was $r=0.37$ ($p<0.01$).

DISCUSSION

The results of the study showed a slight tendency towards a decrease in fear of movement during the 12-month intervention in the LSF-EX group compared with LSF-UC group, especially in accidental injury-related fear. The preoperative measurements showed that kinesiophobia was at a high level before the LSF surgery, but had decreased by the 3-month follow-up after surgery. However, participants' physical activity levels remained unchanged during the first 3 postoperative months.

The TSK total score decreased significantly soon after surgery. This was understandable, as pain relief was experienced after surgery. It is also possible that patients' fear of movement is lessened by the belief that surgery has remedied their lower back problem. The reference values reported for the Finnish TSK are 32.9 in women and 34.2 in men (21); these levels had already been reached when the exercise intervention began, i.e. at 3 months postoperatively. Therefore, the mean decrease in the TSK total score during the intervention was rather small. In previous RCT studies evaluating kinesiophobia during the postoperative rehabilitation of LSF patients, the interventions were carried out soon after surgery (11, 12). Abbott et al. compared psychomotor therapy with exercise therapy during the first 3 postoperative months in LSF patients. The psychomotor therapy consisted of behavioural therapy and exercises based on lumbo-pelvic stabilization training and motor re-learning approaches and was shown to be superior to the exercise therapy in decreasing kinesiophobia at the 3-month follow-up. The improvement remained unchanged up to the follow-up 2–3 years later (11). Monticone et al. (12) started their hospital-based intensive 1-month therapy protocol soon after surgery. They compared cognitive-behavioural therapy combined with supervised exercises with supervised exercises alone. They found that fear of movement and re-injury improved significantly more in the combined than exercise-only group (12). However, the timing and contents of the therapy in these 2 studies differ from those in our study. The present study also focuses on patients with spondylolisthesis only, while in previous studies the selection of primary diagnoses has been wider, including spinal stenosis (11, 12) and degenerative disc disease (11). In addition to differences in timing and patient samples, the present intervention was implemented by a physiotherapist and the training protocol was more physical than the protocols used in the previous studies (11–13). Although the booster sessions in the present study were conducted by a physiotherapist, the guidance given was also partly structured based on the cognitive behavioural model of the fear of movement/(re)injury (2).

During the intervention, the confidence of the LSF-EX group in the use of the back and trunk improved. LSF-EX improved significantly more in item 9 ("I am afraid that I might injure myself accidentally") than LSF-UC, whereas the other items showed no significant between-group difference. In LSF-EX, change over time was significant for item 1 ("I'm afraid that I might injure myself if I exercise"). No previous studies have examined the TSK items separately after treatment.

In this study, in terms of meeting the criteria set for the minimum amount of physical activity considered

to be health-enhancing, the level of physical activity reached during the 12-month intervention was acceptable in both groups (26, 27). This observation may partly be a result of the nature of the support provided, such as encouragement, and, in both groups, also partly due to relief from pain and reduced kinesiophobia. Based on this study, we can only speculate on the underlying associations; interestingly, however, Koho et al. (24) found a significant inverse association between kinesiophobia and physical activity in patients with musculoskeletal disease, but not in the cardiovascular or mental disorder subgroups. We propose a cycle, in which the reduction in pain achieved by surgery provided a safe foundation for an intensive back-training intervention. As pain and kinesiophobia decreased, physical activity started gradually to increase. The time-frame might also explain the increase in physical activity during the intervention in both groups: the first 3 months are the most critical phase in the postoperative healing processes, after which the majority of mobility limitations are removed. Because no severe adverse events or discontinuance due to intervention harms were observed, a programme like the present one seems to be feasible, also for elderly persons undergoing LSF. However, long distances (up to 150 km) from the hospital were challenging for some elderly patients, especially for attendance at booster sessions, and thus patient guidance should be organized closer to their homes.

The strengths of this study include the well-planned RCT setting. The data collection was well organized between the 2 hospitals, and special attention ensured that the treatment protocols were similar in both settings. The intervention was performed by physiotherapists skilled and experienced in scientific research and clinical practice. The exercise protocol and patient education materials were pre-planned by a multidisciplinary team, and based on previous scientific research (15). The drop-out rate and number of discontinued participants was very low, which adds to the credibility of the study. However, the study has some limitations. The nature of the study meant that it was not possible to blind caregivers and patients. Also, we did not collect data on the number of steps or exercise data from the LSF-UC participants, as the use of pedometers and exercise diaries could have affected their behaviour. Regardless of the regular booster sessions and individual guidance, compliance decreased during the intervention, and this may have influenced the results. When the TSK items were analysed separately, we did not use multiple testing, which may have affected the findings on the between-group differences for specific TSK items.

In conclusion, the progressive 12-month home-exercise programme, starting 3 months postoperatively, and including patient education and regular follow-up meetings, was not more effective than usual care after LSF in relieving kinesiophobia or increasing physical activity.

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The authors declare no conflicts of interest.

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Appendix 1. Description of the Items of the Tampa Scale for Kinesiophobia (23)

1.	I'm afraid that that I might injure myself if I exercise
2.	If I were to try to overcome it, my pain would increase
3.	My body is telling me I have something dangerously wrong
4.	My pain would probably be relieved if I were to exercise
5.	People aren't taking my medical condition seriously enough
6.	My accident has put my body at risk for the rest of my life
7.	Pain always means I have injured my body
8.	Just because something aggravates my pain does not mean it is dangerous
9.	I am afraid that I might injure myself accidentally
10.	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening
11.	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body
12.	Although my condition is painful, I would be better off if I were physically active
13.	Pain lets me know when to stop exercising so that I don't injure myself
14.	It is really not safe for a person with condition like mine to be physically active
15.	I can't do all the things normal people do because it's too easy for me to get injured
16.	Even though something is causing me a lot of pain, I don't think it's actually dangerous
17.	No one should have to exercise when he/she is in pain