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Clinical Study

Supervised physical therapy vs. home exercise for patients with lumbar spinal stenosis: a randomized controlled trial

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Abstract

BACKGROUND CONTEXT: Exercise has been reported to improve short-term outcomes for patients with LSS in terms of disability and back and leg pain. However, no studies have compared supervised exercise with unsupervised exercise or quantified physical activity using a pedometer to confirm compliance with a home exercise program.

PURPOSE: To compare the effectiveness of supervised physical therapy (PT) with unsupervised exercise for patients with lumbar spinal stenosis (LSS).

STUDY DESIGN/SETTING: A single-center, open-label, randomized controlled trial.

PATIENT SAMPLE: Patients presenting with symptoms of neurogenic claudication caused by LSS, which was confirmed by magnetic resonance imaging.

OUTCOME MEASURES: The primary outcome was improvement in symptom severity scores on the Zurich Claudication Questionnaire (ZCQ) at 6 weeks. Secondary outcomes included physical function on the ZCQ, self-paced walking test (SPWT) performance, pain indicated using a numerical rating scale (NRS), and the number of daily steps measured by pedometer.

METHODS: Patients with LSS were randomized to a PT group, who performed supervised PT twice a week for 6 weeks, or a home exercise (HE) group. PT sessions included manual therapy, individually tailored stretching and strengthening exercises, cycling, and body weight-supported treadmill walking.

RESULTS: Forty-three patients were randomly allocated to the PT group and 43 patients to the HE group. Compared with the HE group, the PT group had greater percentage of responders achieving minimum clinically important difference in ZCQ symptom severity (difference for percentage between groups [95%confidence interval], 30.2% [9.1–48.6], p=.01), ZCQ physical function (32.6% [11.6–50.6], p<.01), walking distance on the SPWT (39.5% [18.8–56.7], p<.01), leg pain on the NRS (34.9% [13.9–52.7], p<.01), and number of daily steps (25.6% [4.9–43.9], p=.01).

CONCLUSIONS: Supervised PT for patients with LSS resulted in significant short-term improvements in symptom severity, physical function, walking distance, pain, and physical activity compared with unsupervised exercise.

FDA device/drug status: Not applicable.

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Introduction

Lumbar spinal stenosis (LSS) is a common and often debilitating condition in older people. It is characterized by neurogenic claudication, consisting of lower limb pain and neurologic symptoms exacerbated by walking [1]. Patients with LSS often avoid walking because of neurogenic claudication, and have reduced walking distance and physical activity [2,3]. Inadequate physical activity is linked to the development of many chronic diseases such as cardiovascular diseases, type 2 diabetes, neurodegenerative diseases, and certain cancers [4]. Therefore, LSS affects not only quality of life but also increases the risk for developing chronic diseases.

Because it is unlikely that LSS symptoms will worsen or that neurologic function will deteriorate rapidly, nonoperative treatments are almost always recommended initially [5]. The many options for nonoperative management of LSS include medication, spinal injections, physical therapy (PT), and patient education [5]. PT includes flexion exercises, strengthening exercises, aerobic conditioning such as body weight-supported treadmill walking and cycling, and PT regimens such as ultrasound, hot packs, and transcutaneous electrical nerve stimulation [6–11]. A previous systematic review of PT for patients with LSS reported that exercise therapy leads to better short-term outcomes for disability and back and leg pain than no exercise [12]. Cycling and body weight-supported treadmill walking have similar effects. Modalities such as ultrasound, transcutaneous electrical nerve stimulation and heat packs, and manual therapy have no additional benefit over an exercise program alone [12]. However, previous studies have not compared supervised exercise with unsupervised exercise or quantified physical activity using a pedometer to confirm compliance with a home exercise (HE) program. It is unknown which types of exercise are effective and whether patients with LSS can benefit from physical therapist interventions. The purpose of this study was to compare the effectiveness of supervised PT with unsupervised exercise for patients with LSS.

Materials and methods

This study was a single-center, randomized, open-label, controlled trial comparing supervised PT with HE. Screening for eligibility was performed by one of three orthopedic spine surgeons in our Spine Care Center. The inclusion criteria were (1) presence of neurogenic intermittent claudication and pain and/or numbness in the lower extremities with or without low back pain; (2) LSS confirmed by magnetic resonance imaging (MRI); (3) a history of ineffective responses to pharmacotherapy for more than 3 months; (4) over 50 years of age; and (5) consent to be randomly assigned to PT or HE program. The exclusion criteria were previous spine surgery, treatment with epidural steroid injection or selective nerve root injection, loss of bowel or bladder control, degenerative scoliosis, compression fractures at the level being considered for decompression, osteoarthrosis of the knee and/or hip, peripheral artery disorders, diabetes mellitus, cognitive impairment, or a history of psychiatric illness.

Randomization was performed using an online statistical computer program (Graph Pad Software, https://www.graphpad.com/quickcalcs/index.cfm), employing permuted blocks of random block sizes and stratification by sex. A medical doctor who was not a contributor to the study conducted the randomization process and assigned patients to either a PT or an HE group after screening for eligibility. Treating physical therapists were unaware of the block size, and allocation concealment was preserved until the first treatment appointment. Two authors who were blinded to group allocation and not involved in the treatments collected the self-report questionnaires and results of walking tests at baseline and at completion of the treatment period. All patients read an information leaflet and signed an informed consent statement before starting the study. The study, conducted at the Spine Care Center, Wakayama Medical University Kihoku Hospital, was reviewed and approved by the Institutional Review Board at Wakayama Medical University (No. 1426). The trial was registered at UMIN-CTR, UMIN000018981.

Interventions

Patients were randomized to a PT group, which performed supervised PT twice a week for 6 weeks, or a HE group. All patients in both groups were asked to take a daily walk that did not exacerbate their lower extremity symptoms using a pedometer and walking diary and to perform a HE program consisting of lumbar flexion exercises including three 30-second bouts of both single and double knee-to-chest exercises, ten 6-second bouts of trunk raises and bridging in the supine position, and a four-point kneeling exercise at least twice daily [13]. Supervised PT sessions included manual therapy, individually tailored stretching and strengthening exercises, cycling, and body weight-supported treadmill walking. The manual therapy included manipulation, stretching, and massaging of the thoracic and lumbar spine, pelvis, and lower extremities [14]. The individually tailored muscle exercises included those for the trunk (eg, abdominal planks, side bridge, and/or back extension) and lower extremities (eg, unloading hip and/or knee exercise with ankle weight and/or standing squats). The typical dosage for strengthening exercises was a total of

2 to 3 sets with 10 repetitions, each of 6-second contraction. The typical duration of stretching was three repetitions of 30 seconds. The selection of the manual therapy and individually tailored exercise was based on the underlying impairments identified by the treating physical therapist. The duration of the cycling session was 20 minutes. The exercise intensity of the cycling was set at a load of 50% to 60% of the patient's heart rate reserve. Heart rate reserve was calculated using this equation: (maximal heart rate −resting heart rate)+resting heart rate and was monitored during each of the supervised sessions [15]. The duration of the treadmill session was limited by participant tolerance or to a maximum of 20 minutes. The amount of support used for each treadmill session was the minimum amount of unloading required to minimize the patient's symptoms and to allow the patient to walk as comfortably as possible. Because body weight-supported treadmill walking decreases the ground reaction forces associated with gait [16], it should theoretically decrease axial compression forces, increase cross-sectional area of the neuroforamen and central spinal canal, and improve walking tolerance. Previous study demonstrated that body weight-supported treadmill walking increases walking distance in patients with LSS [17]. We included body weight-supported treadmill walking to increase walking tolerance. Patients in the HE group visited a physical therapist once a week for 6 weeks to monitor whether they performed HE. At the first visit, patients in the HE group performed HE under the supervision of the physical therapist. After second visit, patients in the HE group were encouraged to perform HE and walking based on their diary. All patients were allowed to continue with previously prescribed medications but were not allowed to change the type and dosage of these medications during the 6-week treatment period.

Outcome measures

The primary outcome was the change in the symptom severity scores on the Zurich Claudication Questionnaire (ZCQ) [18,19] at 6 weeks. Secondary outcomes included physical function and satisfaction on the ZCQ; self-paced walking test (SPWT) [20] performance; a numerical rating scale (NRS) [21,22] for back pain, leg pain, and leg numbness; and scores on the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ) [23], 36-Item Short-Form Survey (SF-36) [24–26], Hospital Anxiety and Depression Scale (HADS) [27,28], Pain Catastrophizing Scale (PCS) [29,30], Pain Anxiety Symptoms Scale (PASS-20) [31,32], and Tampa Scale for Kinesiophobia (TSK-11) [33,34]. Scores on the ZCQ symptom severity subscale range from 1 to 5 and scores on the physical function subscale range from 1 to 4, with higher scores indicating more severe symptoms. Scores on the satisfaction subscale range from 1 to 4, with lower scores indicating more satisfaction with treatments. The ZCQ satisfaction subscale was modified from the original scale by replacing the word "surgery" with the word "rehabilitation" in each question [6]. The SPWT is measured as the distance a person is able to walk continuously on a flat surface at a self-selected pace until being forced to stop because of symptoms of LSS, including neurogenic claudication and/or low back pain, up to a limit of 30 minutes. The JOABPEQ comprises five domains: pain-related disorders, lumbar spine dysfunction, gait disturbance, social life dysfunction, and psychological disorders. The scores for the JOABPEQ range from 0 to 100, with a higher score indicating better health status. Compliance with the HE program was measured using a diary and a pedometer. Patients were asked to fill in number of HE program sessions and their daily steps on diary. In the first week, patients were asked to carry on their normal life while wearing the pedometer (Active Style Pro HJA-350IT, Omron Heath Care, Kyoto, Japan) [35]. From the second week, patients were prompted to increase their daily steps by using a walking diary. MRI findings were examined using a seven-grade classification based on the morphology of the dural sac on T2-weighted images of the lumbar axial spine [36]. Two orthopedic spine surgeons who were certified as specialists by the Japanese Orthopaedic Association and Japanese Society for Spine Surgery and Related Research determined the grade of the dura mater compression and reached consensus for all patients. Cost data excluding medication costs were collected from medical records.

Sample size determination and statistical analysis

Sample size was calculated based on the previously determined minimum clinically important difference (MCID) of 0.36 points for the ZCQ symptom severity scale [37], and assuming a standard deviation of 0.54 [38,39] and allowing for a drop-out rate of 20%. Power was set at 0.8, alpha 0.05; a minimum of 43 patients per treatment group was required to achieve significance using a two-tailed Student *t* test.

Responder analyses showing the percentage of patients achieving MCID values were performed using the Pearson chi-square test with 95% confidence interval (CI). The MCID for the ZCQ, 0.36 points for symptom severity and 0.10 points for physical function subscales, for the NRS, 1.25 points for back pain and 1.5 points for leg pain [37], and for the each domains of JOABPEQ of 20 points [40] were used based on the previously published values. The MCID for other outcomes were defined at least a 30% improvement between their baseline and follow-up scores. Patients dropped out with missing follow-up data were counted as nonresponders for all outcomes. The Fragility Index was also used to determine the robustness of statistically significant result on primary outcome. The Fragility Index is calculated by converting one patient in the group (control or experimental group) from a "non-event" to an "event" outcome and recalculating a two-sided Fisher exact test

until the p value meets or exceeds .05 [41,42]. Scores and mean changes after 6 weeks were also compared between the groups. Between-group comparisons were made using Student *t* test for parametric variables and the Mann-Whitney *U* test for nonparametric variables. All statistical tests were two-tailed, and the significance level was fixed at 0.05 for all analyses. The statistical analysis was performed based on intention to treat using SPSS (v. 20, IBM Statistics, Armonk, NY).

Results

One hundred and twenty-one patients were screened between September 2014 and May 2018. Twenty patients did not meet the inclusion criteria and 15 patients declined to participate. Eighty-six patients were enrolled in this study (39 men and 47 women, average age 72.7 years). Forty-three patients (20 men and 23 women, average age 72.3 years) were randomly allocated to the PT group and 43 patients (19 men and 24 women, average age 73.2 years) to the HE group. One patient in the PT group did not attend therapy sessions after 3 weeks because of personal reasons, and one patient in the HE group dropped out because of health problems not related to LSS. Data for the 6-week follow-up were available for 84 patients (98%) (Figure).

At baseline, there were no significant differences in age, sex, body mass index, duration of symptoms, MRI findings, and the outcome measures between groups (p≥0.05;Tables 1 and 2).

At 6 weeks, the PT group had greater percentage of ZCQ symptom severity responders (62.8%; difference for percentage between groups [95%CI], 30.2% [9.1–48.6], p=.01), ZCQ physical function responders (72.1%; difference for percentage between groups [95%CI], 32.6% [11.6–50.6], p<.01), ZCQ satisfaction responders (88.4%; difference for percentage between groups [95%CI], 27.9% [9.2–44.1], p<.01), walking distance on the SPWT responders (76.7%; difference for percentage between groups [95%CI], 39.5% [18.8–56.7], p<.01), leg pain on the NRS responders (62.8%; difference for percentage between groups [95%CI], 34.9% [13.9–52.7], p<.01), JOABPEQ pain-related disorders responders (52.8%; difference for percentage between groups [95%CI], 24.2% [1.2–44.6], p=.04), JOABPEQ lumbar dysfunction responders (42.1%; difference for percentage between groups [95%CI], 33.5% [13.4–50.0], p<.01), JOABPEQ gait disturbance responders (57.5%; difference for percentage between groups [95%CI], 30.0% [8.3–48.8], p=.01), SF-36 physical functioning responders (32.6%; difference for percentage between groups [95%CI], 18.6% [0.4–35.2], p=.04), SF-36 general health responders (27.9%; difference for percentage between groups [95%CI], 18.6% [1.7–33.9], p=.03), and number of daily steps responders (51.2%; difference for percentage between groups [95%CI], 25.6% [4.9–43.9], p=.01) compared with the HE group (Table 3). The Fragility Index value of ZCQ symptom severity was 3 which indicates that if three patients in PT group did not reach a threshold of MCID, the difference between groups lose statistical significance (p≥.05).

For the mean changes after 6 weeks, compared with the HE group, the PT group showed significant improvements in ZCQ symptom severity (mean difference −0.4; 95% CI: −0.6 to −0.2, p<.01), ZCQ physical function (mean difference −0.4; 95%CI: −0.6 to −0.2, p<.01), walking distance on the SPWT (mean difference 455.9 m; 95% CI: 308.5–603.2, p<.01), leg pain (mean difference −1.4;

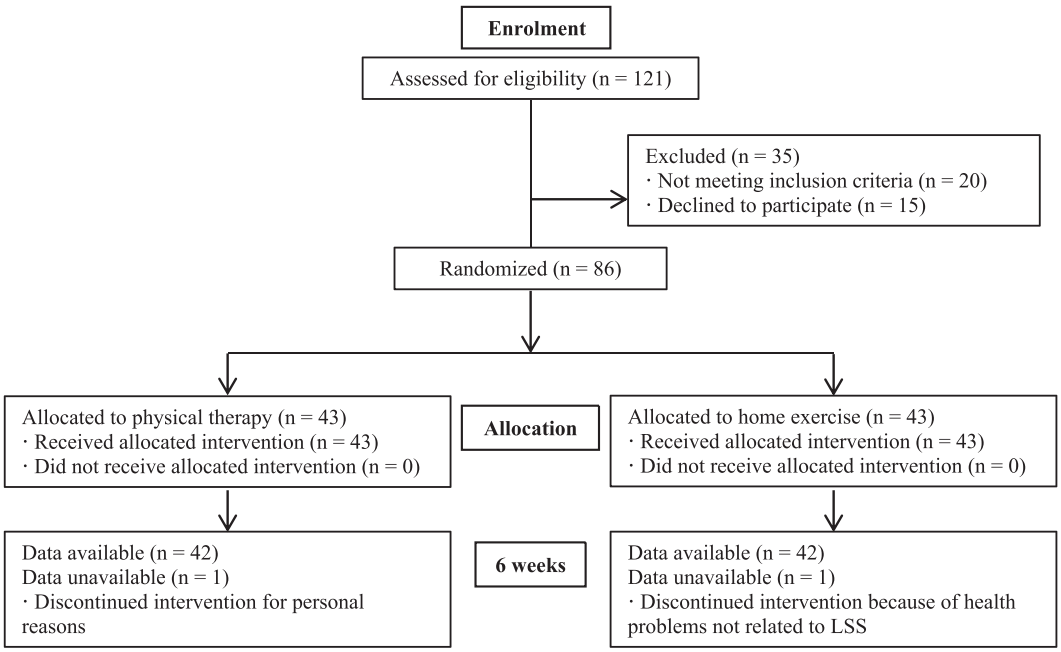

Figure. Flow chart of the study.

Table 1
Comparison of clinical characteristics between PT and HE groups at baseline

	PT (n = 43)	HE (n = 43)	p
Age (y)	72.3 ± 6.9	73.2 ± 8.2	.59*
Sex	Female: 23	Female: 24	.83†
	Male: 20	Male: 19	
Body mass index (kg/m^2)	23.4 ± 2.6	23.7 ± 3.5	.57*
Duration of symptoms (mo)	19.7 ± 15.0	20.5 ± 20.5	.53‡
Moderate or severe stenosis			
0	9	8	.79†
1	13	7	.13†
2	9	11	.61†
≥3	12	17	.25†
Spondylolisthesis	28	28	1.00†
Mean slippage (mm)	3.3 ± 2.9	3.4 ± 3.0	.91‡
ZCQ			
Symptom severity	3.2 ± 0.6	3.2 ± 0.7	.62‡
Physical function	2.4 ± 0.6	2.3 ± 0.6	.60*
SPWT (m)	572.4 ± 461.1	549.1 ± 608.0	.27‡
NRS			
Back pain	5.3 ± 2.4	4.9 ± 2.6	.45*
Leg pain	6.3 ± 2.2	6.2 ± 1.9	.67*
Leg numbness	5.7 ± 2.6	5.9 ± 2.6	.68*
JOABPEQ			
Pain-related disorders	57.5 ± 30.6	61.8 ± 34.1	.41‡
Lumbar dysfunction	64.8 ± 26.7	71.5 ± 23.4	.30‡
Gait disturbance	42.2 ± 26.5	44.3 ± 29.6	.90‡
Social life dysfunction	44.5 ± 17.1	45.8 ± 22.6	.93‡
Psychological disorders	49.7 ± 15.2	46.4 ± 16.8	.27‡
SF-36			
Physical functioning	62.0 ± 19.6	56.2 ± 22.0	.12‡
Bodily pain	38.2 ± 13.8	40.6 ± 18.6	.50*
Role physical	55.0 ± 24.6	52.6 ± 30.4	.66‡
Role emotional	62.4 ± 27.9	64.7 ± 31.2	.65‡
Mental health	62.6 ± 22.9	61.7 ± 19.5	.86*
Social functioning	70.9 ± 26.0	72.1 ± 23.3	.61‡
Vitality	51.8 ± 19.8	52.9 ± 21.5	.98‡
General health	48.4 ± 14.8	50.6 ± 16.1	.51*
HADS			
Depression	5.5 ± 3.6	5.3 ± 3.3	.82‡
Anxiety	4.4 ± 3.5	4.3 ± 3.5	.68‡
PCS	27.9 ± 10.7	27.0 ± 12.1	.74*
PASS-20	37.2 ± 17.6	32.9 ± 18.5	.28*
TSK-11	26.0 ± 4.8	23.9 ± 5.3	.06*
Daily steps	3,582.5 ± 2,255.4	3,621.3 ± 2,827.9	.95*

ZCQ, Zurich Claudication Questionnaire; SPWT, self-paced walking test; NRS, numerical rating scale; JOABPEQ, Japanese Orthopaedic Association Back Pain Evaluation Questionnaire; SF-36, Medical Outcomes Study 36-Item Short-Form General Health Survey; HADS, Hospital Anxiety and Depression Scale; PCS, Pain Catastrophizing Scale; PASS-20, Pain Anxiety Symptoms Scale; TSK-11, Tampa Scale for Kinesiophobia.

Values are mean ± SD.

*Student *t* test.

† chi-square test.

‡Mann-Whitney *U* test.

95%CI: −2.5 to −0.3, p=.013) on the NRS, gait disturbance (mean difference 16.0; 95%CI: 5.4−26.7, p<.01) on the JOABPEQ, physical functioning (mean difference 9.2; 95%CI: 2.1−16.3, p=.01) and bodily pain (mean difference 10.4; 95%CI: 3.3−17.5, p<.01) on the SF-36, the TSK-11 (mean difference −2.1; 95% CI: −3.9 to −0.2, p=.037), and number of daily steps (mean difference 723.4 steps/day; 95%CI: 199.1−1,283.5, p<.01) (Table 4).

The self-reported HE compliance did not differ significantly between the two groups during the 6-week treatment period (PT group 39.1/42 days, HE group 39.1/42 days, p=.99, PT group 1.9 sessions/day, HE group 1.7 sessions/-day, p=.38). Total costs for the PT group were $331 and for the HE group were $100 (mean difference $231; 95%CI: $223−$239, p<.01). Patient's own expenses were $63 in the PT group and $20 in the HE group (mean difference $44; 95%CI: $35−$53, p<.01).

Discussion

To our knowledge, this is the first randomized controlled trial (RCT) comparing supervised exercise with unsupervised exercise for patients with LSS. The results of this study indicate that supervised PT for patients with LSS resulted in significant short-term improvements in symptom severity, physical function, walking distance, pain, disability, and physical activity compared with HE alone. With regard to the primary outcome, the mean changes in symptom severity score on the ZCQ at 6-week follow-up were 0.60 points for the PT group and 0.20 points for the HE group. The mean changes in symptom severity score on the ZCQ in the PT group exceeded the MCID of 0.36 points [37]. It has been reported that a HE program is no more effective than advice and education [11]. In that study, the mean changes in symptom severity score on the ZCQ at 8 weeks were 0.10 points for HE combined with advice and education and 0.18 points for the advice and education group, and did not exceed the MCID of 0.36 points. Therefore, HE alone might be of little benefit in patients with LSS. Surgery remains an effective option for patients with persistent and severe LSS symptoms that include both back and leg pain, but it is known that the advantage of surgery was noticeable at 3 to 6 months and remained for up to 2 to 4 years, although at the end of that period differences tended to be smaller and that surgery has higher complication rates than conservative treatments [43,44]. In a RCT comparing surgical decompression with PT in patients with LSS who were surgical candidates, surgical decompression yielded similar effects to a PT regimen, although 57% of the patients assigned to physiotherapy crossed over to surgery [45]. Secondary analysis of the nonrandomized Spine Patient Outcomes Research Trial found that use of physiotherapy was associated with no improvement in pain but some improvement in self-reported physical function and a reduced likelihood of patients receiving surgery within 1 year [46]. Therefore, it is possible that adequate PT enables patients with LSS to avoid surgery.

In this study, those in the PT group increased their daily steps by 36% in contrast to a 16% increase in the HE group. Previous systematic reviews of pedometer use reported that using a pedometer increased daily steps by 26.9% over baseline [47]. A pilot study for the spinal stenosis

Table 2
Number of patients with spinal stenosis at each spinal level

	PT (n=43)			HE (n=43)			
	Minor stenosis	Moderate stenosis	Severe stenosis	Minor stenosis	Moderate stenosis	Severe stenosis	p
L1–L2	37	6	0	36	7	0	.33
L2–L3	30	11	2	25	17	1	.16
L3–L4	19	14	10	13	17	13	.27
L4–L5	18	12	13	17	8	18	.35
L5–S1	39	3	1	38	4	1	.24

Data were analyzed using the Mann-Whitney *U* test.

pedometer and nutrition lifestyle intervention study for overweight or obese individuals with LSS reported that interventions consisting of pedometer-based physical activity promotion, nutrition education by a dietitian, and advice from an exercise physiologist showed a 15% increase in daily steps over a 12-week intervention [48]. Therefore, our supervised PT, which included manual therapy, individually tailored exercise, and aerobic exercises, significantly improved the physical activity in patients with LSS. Several researchers have proposed that taking <5,000 steps/day is an indicator of being inactive and having a sedentary lifestyle [49,50]. Indicators of cardiometabolic risk, and

Table 3
Responder analysis (patients achieving MCID)

	Patients achieving MCID (%)		Difference between groups	
	PT (n=43)	HE (n=43)	PT minus HE (95% CI)	p
ZCQ				
Symptom severity	62.8	32.6	30.2 (9.1–48.6)	.01
Physical function	72.1	39.5	32.6 (11.6–50.6)	.00
Satisfaction	88.4	60.5	27.9 (9.2–44.1)	.00
SPWT (m)	76.7	37.2	39.5 (18.8–56.7)	.00
NRS				
Back pain	41.8	25.6	16.2 (−3.8 to 34.9)	.11
Leg pain	62.8	27.9	34.9 (13.9–52.7)	.00
Leg numbness	32.6	27.9	4.6 (−14.7 to 23.5)	.64
JOABPEQ-acquired points				
Pain-related disorders	52.8	28.6	24.2 (1.2–44.6)	.04
Lumbar dysfunction	42.1	8.6	33.5 (13.4–50.0)	.00
Gait disturbance	57.5	27.5	30.0 (8.3–48.8)	.01
Social life dysfunction	34.9	16.7	18.2 (−0.7 to 35.4)	.05
Psychological disorders	14.0	7.0	7.0 (−6.8 to 20.1)	.29
SF-36				
Physical functioning	32.6	14.0	18.6 (0.4–35.2)	.04
Bodily pain	51.2	32.6	18.6 (−2.3 to 37.9)	.08
Role physical	41.9	30.2	11.6 (−8.7 to 30.9)	.26
Role emotional	41.9	25.6	16.3 (−3.8 to 34.9)	.11
Mental health	27.9	14.0	14.0 (−3.6 to 30.3)	.11
Social functioning	20.9	20.9	0 (−17.2 to 17.2)	1.00
Vitality	37.2	23.3	14.0 (−5.6 to 32.3)	.16
General health	27.9	9.3	18.6 (1.7–33.9)	.03
HADS				
Depression	34.9	20.9	14.0 (−5.2 to 31.9)	.15
Anxiety	37.2	23.3	14.0 (−5.6 to 32.3)	.16
PCS	9.3	18.6	−9.3 (−23.8 to 6.0)	.21
PASS-20	16.3	18.6	−2.3 (−18.4 to 13.9)	.78
TSK-11	9.3	4.7	4.7 (−7.3 to 16.2)	.40
Daily steps	51.2	25.6	25.6 (4.9–43.9)	.01

Data were analyzed using the Pearson chi-square test.

MCID, minimal clinically important difference; ZCQ, Zurich Claudication Questionnaire; SPWT, self-paced walking test; NRS, numerical rating scale; JOABPEQ, Japanese Orthopaedic Association Back Pain Evaluation Questionnaire; SF-36, Medical Outcomes Study 36-Item Short-Form General Health Survey; HADS, Hospital Anxiety and Depression Scale; PCS, Pain Catastrophizing Scale; PASS-20, Pain Anxiety Symptoms Scale; TSK-11, Tampa Scale for Kinesiophobia.

Table 4
Comparison of clinical outcomes between PT and HE groups at 6 weeks

	At 6 weeks			Mean change at 6 weeks		Difference between groups
	PT (n=42)	HE (n=42)	p	PT (n=42) (95% CI)	HE (n=42) (95% CI)	PT minus HE (95% CI)
ZCQ						
Symptom severity	2.6 ± 0.4	3.0 ± 0.7	.00*	−0.6 (−0.7 to −0.4)	−0.2 (−0.3 to 0)	−0.4 (−0.6 to −0.2)
Physical function	1.9 ± 0.5	2.2 ± 0.6	.01*	−0.5 (−0.7 to −0.3)	−0.1 (−0.3 to 0)	−0.4 (−0.6 to −0.2)
Satisfaction	2.0 ± 0.4	2.4 ± 0.7	.00†			
SPWT (m)	1,116.4 ± 618.0	629.2 ± 624.4	.00†	525.8 (384.8–666.8)	69.9 (24.4–115.5)	455.9 (308.5–603.2)
NRS						
Back pain	4.0 ± 2.3	4.7 ± 2.3	.17*	−1.3 (−2.3 to −0.4)	−0.2 (−0.9 to 0.5)	−1.1 (−2.3 to 0.1)
Leg pain	4.4 ± 2.3	5.6 ± 2.9	.03†	−2.0 (−2.8 to −1.3)	−0.6 (−1.5 to 0.2)	−1.4 (−2.5 to −0.3)
Leg numbness	4.5 ± 2.4	5.5 ± 2.8	.07†	−1.2 (−1.9 to −0.4)	−0.4 (−1.2 to 0.3)	−0.8 (−1.8 to 0.3)
JOABPEQ-acquired points						
Pain-related disorders				18.1 (9.0–27.2)	5.4 (−3.1 to 13.9)	12.6 (0.4–24.9)
Lumbar dysfunction				11.4 (4.7–18.1)	−0.2 (−3.9 to 3.5)	11.6 (4.0–19.1)
Gait disturbance				21.1 (13.1–29.2)	5.1 (−2.1 to 12.4)	16.0 (5.4–26.7)
Social life dysfunction				15.7 (9.7–21.6)	2.6 (−2.7 to 7.9)	13.1 (5.3–20.9)
Psychological disorders				7.0 (2.7–11.2)	4.9 (2.0–7.9)	2.0 (−3.1 to 7.1)
SF-36						
Physical functioning	73.1 ± 12.2	58.0 ± 22.4	.00*	11.2 (6.5–15.9)	2.0 (−3.4 to 7.5)	9.2 (2.1–16.3)
Bodily pain	53.7 ± 14.8	45.7 ± 20.5	.04*	15.8 (11.1–20.5)	5.4 (−0.1 to 10.9)	10.4 (3.3–17.5)
Role physical	71.9 ± 20.7	57.3 ± 29.6	.02†	17.4 (10.2–24.6)	5.2 (−3.2 to 13.6)	12.2 (1.3–23.1)
Role emotional	74.2 ± 20.2	63.9 ± 33.5	.31†	11.9 (4.7–19.1)	−0.8 (−9.9 to 8.3)	12.7 (1.3–24.1)
Mental health	72.6 ± 17.9	63.5 ± 23.0	.07†	10.0 (4.7–15.3)	1.7 (−3.8 to 7.2)	8.3 (0.8–15.8)
Social functioning	78.3 ± 20.3	70.2 ± 28.8	.29†	7.4 (1.7–13.2)	−1.8 (−8.6 to 5.0)	9.2 (0.5–18.0)
Vitality	61.6 ± 17.2	52.7 ± 23.4	.05†	9.8 (4.6–15.0)	−0.3 (−6.5 to 5.9)	10.1 (2.1–18.1)
General health	57.2 ± 16.3	51.5 ± 15.4	.10*	8.9 (5.5–12.3)	1.0 (−2.6 to 4.5)	7.9 (3.1–12.8)
HADS						
Depression	4.5 ± 3.5	5.2 ± 3.7	.42†	−1.0 (−1.7 to −0.2)	−0.1 (−0.9 to 0.7)	−0.9 (−1.9 to 0.2)
Anxiety	3.7 ± 3.8	4.4 ± 3.7	.33†	−0.7 (−1.4 to 0.1)	0.1 (−0.7 to 0.9)	−0.8 (−1.9 to 0.3)
PCS	25.7 ± 10.5	26.6 ± 12.5	.71*	−2.5 (−4.4 to −0.7)	−0.8 (−3.1 to 1.6)	−1.8 (−4.7 to 1.1)
PASS-20	35.3 ± 17.0	32.8 ± 19.4	.53*	−2.3 (−5.1 to 0.5)	−0.5 (−3.8 to 2.9)	−1.9 (−6.2 to 2.4)
TSK-11	24.1 ± 4.5	24.0 ± 5.5	.93*	−1.9 (−3.2 to −0.5)	0.2 (−1.1 to 1.5)	−2.1 (−3.9 to −0.2)
Daily steps	4,881.5 ± 1,962.1	4,196.9 ± 2,766.5	.23*	1,299.0 (926.9–1,671.1)	575.6 (176.2–975.0)	723.4 (199.1–1,283.5)

ZCQ, Zurich Claudication Questionnaire; SPWT, self-paced walking test; NRS, numerical rating scale; JOABPEQ, Japanese Orthopaedic Association Back Pain Evaluation Questionnaire; SF-36, Medical Outcomes Study 36-Item Short-Form General Health Survey; HADS, Hospital Anxiety and Depression Scale; PCS, Pain Catastrophizing Scale; PASS-20, Pain Anxiety Symptoms Scale; TSK-11, Tampa Scale for Kinesiophobia.

Values are mean ± SD.

*Student *t* test.

† Mann-Whitney *U* test.

specifically metabolic syndrome, have also been associated with taking <5,000 steps/day [51]. Although the daily steps in the PT group did not reach 5,000, meaning that the participants were defined as having low activity, an increase of 36% from 3,582 steps/day to 4,881 steps/day represents a notable improvement in physical activity.

In the present study, responder rates of anxiety and depression, which can be evaluated by HADS, pain catastrophizing, pain anxiety symptoms of PASS-20, and kinesiophobia measured by TSK-11 did not differ between the PT and HE groups. Therefore, the supervised PT appeared no more effective for the treatment of psychological factors than HE. Monticone et al. [52] reported that a rehabilitation program including the management of catastrophizing and kinesiophobia was superior to an exercise program alone in reducing disability, dysfunctional thoughts, and pain, and in enhancing the quality of life of patients after lumbar fusion for degenerative spondylolisthesis and/or LSS. They found that PCS and TSK scores in the experimental group decreased to nearly half at 1 year after the intervention ended. PT including the management of psychological factors might help to improve catastrophizing, pain anxiety symptoms, kinesiophobia, pain, and disability in patients with LSS.

This study has some limitations. We have no long-term follow-up data for the participants. Many of RCTs evaluating PT are short-term follow-up studies [7,8,10,53]. However, it is unknown which types of exercise are effective and whether patients with LSS can benefit from physical therapist interventions. On the other hand, long-term follow-up RCTs evaluating PT showed that clinical outcomes remain stable up to 1 to 2 years after 6 to 8-week PT interventions [6,11,45]. Our previous retrospective study of prospectively collected data showed that the patient-reported

outcomes of these LSS patients under follow-up observation after PT for 6 weeks were maintained or improved and did not differ significantly from those in patients who underwent surgery after less successful PT at the 2-year follow-up [39]. Therefore, short-term outcomes are important for decision-making process after PT. Further trials with longer follow-up periods are required to establish whether our supervised PT yields greater improvement of symptoms and lower surgery rates than HE alone. Two different volumes of exercises might have influenced the results of this study rather than level of supervision. Although number of sessions which patients performed HE program did not differ between the PT and HE groups, number of daily steps as home-based walking exercise was significantly higher in the PT group compared with the HE group and the PT group performed 1 hour of supervised program twice a week for 6 weeks in addition to 6-week HE. It should have been performed a similar volume of exercises to identify different effects between supervised and unsupervised exercise. Patients who indicated before enrolment that they wanted to undergo surgery were excluded. Patients in our study had slightly less severe symptoms for physical function and bodily pain on SF-36 than those in other RCTs that compared surgery with nonsurgical treatment [45,54]. The results of this study may not be generalizable to other RCTs comparing surgical vs. nonsurgical treatment for LSS since the present study did not evaluate surgery vs. nonsurgical treatment. The additional effect of manual therapy is not clear because of the lack of an appropriate control group. Future trials are needed to compare supervised exercise and manual therapy with supervised exercise alone.

Conclusion

Supervised PT that included manual therapy, individually tailored exercise, body weight-supported treadmill walking, and cycling resulted in significant short-term improvements in symptom severity, physical function, walking distance, pain, disability, and physical activity compared with unsupervised exercise. Therefore, patients with LSS can benefit from physical therapist interventions. Future studies should focus on long-term outcomes and surgery rates after exercise programs.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2019.04.009.

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