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ORIGINAL RESEARCH

Comprehensive Nonsurgical Treatment Versus Self-directed Care to Improve Walking Ability in Lumbar Spinal Stenosis: A Randomized Trial

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Abstract

Objectives: To compare the effectiveness of a comprehensive nonsurgical training program to a self-directed approach in improving walking ability in lumbar spinal stenosis (LSS).

Design: Randomized controlled trial.

Setting: Academic hospital outpatient clinic.

Participants: Participants (N = 104) with neurogenic claudication and imaging confirmed LSS were randomized. The mean age was 70.6 years, 57% were women, 84% had leg symptoms for >12 months, and the mean maximum walking capacity was 328.7 m.

Interventions: A 6-week structured comprehensive training program or a 6-week self-directed program.

Main Outcome Measures: Continuous walking distance in meters measured by the Self-Paced Walk Test (SPWT) and proportion of participants achieving at least 30% improvement (minimally clinically important difference [MCID]) in the SPWT at 6 months. Secondary outcomes included the Zurich Claudication Questionnaire (ZCQ), Oswestry Disability Index (ODI), ODI walk score, and the Short-Form General Health Survey subscales.

Results: A total of 48 versus 51 participants who were randomized to comprehensive (n = 51) or self-directed (n = 53) treatment, respectively, received the intervention and 89% of the total study sample completed the study. At 6 months, the adjusted mean difference in walking distance from baseline was 421.0 m (95% confidence interval [95% CI], 181.4-660.6), favoring the comprehensive program and 82% of participants in the comprehensive group and 63% in the self-directed group achieved the MCID (adjusted relative risk, 1.3; 95% CI, 1.0-1.7; $P = .03$). Both primary treatment effects persisted at 12 months favoring the comprehensive program. At 6 months, the ODI walk score and at 12 months the ZCQ, Medical Outcomes Study 36-Item Short-Form Health Survey-physical function and -bodily pain scores showed greater improvements favoring the comprehensive program.

Conclusions: A comprehensive conservative program demonstrated superior, large, and sustained improvements in walking ability and can be a safe nonsurgical treatment option for patients with neurogenic claudication due to LSS.

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Lumbar spinal stenosis (LSS) is a leading cause of pain, disability, and loss of independence in older adults.[1] It is caused by age-related degenerative changes leading to spinal canal narrowing and compression and diminished blood flow to the nerve roots.[2] Neurogenic claudication is the clinical syndrome caused by LSS and is characterized by bilateral or unilateral lower extremity pain, heaviness, numbness, tingling or weakness brought on by standing and walking and relieved by sitting and bending forward.[2] Limited walking ability is the dominant functional impairment caused by LSS that can lead to a sedentary lifestyle and a progressive decline in health status.[3,4] Impaired walking is the most common reason for seeking care in LSS[5] and is associated with increased levels of depression, anxiety, and hopelessness that can further perpetuate disability.[4,6]

The prevalence and economic burden of LSS are growing rapidly due to the aging population.[1] Although LSS is the most common reason for spine surgery in older adults, the vast majority of individuals with LSS receive nonsurgical care.[7] Systematic reviews evaluating nonsurgical interventions for LSS concluded that they were of unproven benefit including the ability to improve walking outcomes.[8,9] In addition to unknown effective treatments, the natural history of LSS suggests no significant improvement in walking ability over time.[10]

We designed a structured comprehensive conservative training program for LSS[11] with a focus on self-management and improved walking ability. We conducted a randomized controlled trial to compare the effectiveness of this comprehensive conservative training program to a self-directed program in improving walking ability in patients with neurogenic claudication due to LSS.

Methods

Study design

This assessor-blinded, pragmatic randomized controlled trial was conducted in an outpatient hospital clinic. Trial design and methods were published previously.[12] The hospital institutional review board approved the study (certificate #14-0020-E). This report is focused on the primary patient outcomes at 6 and 12 months after randomization.

Participants

Using an eligibility checklist, interested and potentially eligible participants were referred to the study by medical specialist, family physicians, and chiropractors from participating local hospitals and community clinics. Local newspaper advertisements were also used to recruit potential participants. Eligible participants were 50 years or older, had symptoms of neurogenic claudication for at least 3 months, had imaging-confirmed spinal canal narrowing, were able to walk without assistance for at least 20 m and <30 minutes, were able to perform mild-to-moderate exercise, and were not likely surgical candidates in next 12 months. Patients with previous back surgery, cardiovascular disease, or osteoarthritis of lower extremities impacting walking ability or psychiatric disorders were excluded (supplemental table S1 for detailed eligibility criteria, available online only at http://www.archives-pmr.org/). All participants provided written informed consent.

List of abbreviations:

95% CI	**95% confidence interval**
LSS	**lumbar spinal stenosis**
MCID	**minimally clinically important difference**
ODI	**Oswestry Disability Index**
SF-36	**Medical Outcomes Study 36-Item Short-Form Health Survey**
SPWT	**Self-Paced Walk Test**
ZCQ	**Zurich Claudication Questionnaire**

Randomization

A trained study coordinator assessed eligibility (initially screening by phone and then by in-person assessment). Eligible and consenting participants were randomized to 1 of 2 intervention groups. A biostatistician prepared the randomization sequence using a computerized random number table (using SAS version 9.3[a]). Sequentially numbered and sealed opaque envelopes containing the sequence were stored in a locked drawer. For each enrolled participant, the study coordinator (not involved in the preparation of the allocation sequence) retrieved and opened the next sequentially numbered envelope and assigned the participant according to the random allocation scheme.

Procedures

Structured comprehensive conservative training program

Details of the structured comprehensive training program have been published elsewhere.[11,12] Participants assigned to the comprehensive group were scheduled to receive two 15- to 20-minute treatment sessions per week over a 6-week period followed by a single (booster) session, 4 weeks later. Participants were scheduled as regular patients at an outpatient hospital clinic with treatments provided by licensed chiropractors. The intent was to provide participants with treatment that simulated real practice in terms of scheduling, time spent, and content of treatment. Using a structured graded protocol, the treating chiropractor provided the following interventions over a 6-week period:

Education

Participants received one-on-one instruction on self-management strategies using a cognitive behavioral approach,[13] including how to manage symptoms using problem solving, pacing, and relaxation. Reassurance, positive reenforcement, goal setting, and graded activity were used to reduce pain-related fear and improve self-efficacy.[13] Participants were trained on body repositioning (the pelvic tilt) to reduce the lumbar lordosis and maximize spinal canal diameter when standing and walking.[14]

Exercises

A standardized set of 18 exercises was provided and demonstrated gradually over 6 weeks and was part of a structured home exercise program.[11,12] Participants received instruction on muscle stretching, strengthening, and conditioning exercises directed at improving overall back and lower extremity fitness and facilitating lumbar flexion. At each session, previously instructed exercises were reviewed (until participants were proficient) and new ones provided. Stationary cycling (forward leaning) was strongly recommended as part of the daily home exercise routine. A written schedule was provided outlining the type, frequency, and intensity of the exercises to be performed. Typically, the recommended cycling duration was 5 minutes at week 1 increasing by 5 minutes

each week to a maximum of 30 minutes. The intensity of each exercise increased by 1 second per week from 5 second holds and 5 sets at week 1 to 10 seconds holds and 5 sets at week 6. The cycling and exercises were to be performed twice daily at home. The frequency of exercise was reduced to once daily after the 6-week program with the recommendation that the daily exercise routine (30min cycling plus 30min of structured exercises) and self-management strategies be maintained for life.

Manual therapy

The main aim of the manual therapy was to reduce pain and improve the flexibility of the lumbar spine and to facilitate lumbar intersegmental flexion. A standardized combination of side posture low amplitude high-velocity spinal manipulation; joint, soft tissue, and neural mobilization; lumbar flexion-distraction (Leander 9000 Table[b]); and manual muscle stretching were applied and replicated at each visit.[11,12]

Each participant received an instructional video and workbook that provided educational information and instruction on how to perform all the required exercises and self-management strategies. The workbook was also used to record the required exercise and self-management activities during the 6-week program. Participants received a pedometer (Pedusa PE-771) with instructions to record once weekly the maximum number of continuous walking steps they could perform before stopping due to neurogenic symptoms. The recorded steps counts were to be used for self-monitoring and personal feedback only.

Self-directed training program

Participants randomized to the self-directed group received the same instructional video, workbook, and pedometer, plus a single 15- to 30-minute training session with an experienced independent licensed chiropractor (not involved in the treatment of the comprehensive group). The aims of the single session were to describe the structure of the 6-week program, review the material in the workbook, and explain how to use the pedometer and record weekly walking steps. The video and workbook contained educational information and the same exercise instruction and self-management strategies received by the comprehensive group. There was no personalized education or instruction, no cognitive behavioral interventions, and no manual therapy or other interventions provided to participants in the self-directed group during the single session or thereafter.

Outcomes

The primary measure was walking distance measured at 6 months using the Self-Paced Walk Test (SPWT),[15] which measures distance walked without stopping for a maximum of 30 minutes. The primary outcome was the proportion of participants who achieved at least 30% improvement (estimated minimally clinically important difference [MCID]) in the SPWT from baseline.

Secondary measures included the following self-report questionnaires: (1) the Zurich Claudication Questionnaire (ZCQ),[16] which includes subscales for symptoms (ZCQ Symptom Scale) (scores 1-5, with higher scores indicating worse symptoms), physical function (ZCQ Functional Scale) (scores 1-4, with higher scores indicating worse function), and a composite ZCQ Symptom Scale + ZCQ Functional Scale (scores 2-9, with higher scores indicating worse symptoms and function); (2) the Oswestry Disability Index (ODI)[17] (scores 0-1, which represent a mean summary score of 10 individual scores divided by 50 the maximum score, with higher scores indicating higher disability) and the walking section of the ODI[17] (scores 0-5, with higher scores indicating worse walking ability). Other secondary outcomes included the Numeric Pain Scale,[18] Fall Efficacy Scale,[19] the Short Physical Performance Battery,[20] Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36),[21] and the Center for Epidemiological Studies-Depression Scale.[22] The proportion of participants who achieved at least 50% improvement in the SPWT from baseline was also assessed.

At baseline, participants provided demographic and clinical information. All outcomes were assessed at baseline, 8 weeks, and 3, 6, and 12 months after randomization by a blinded assessor. The assessor conducted all the SPWTs at the study hospital at each follow-up period using a distance-measuring instrument (Lufkin Pro-Series Model PSMW38) and stopwatch. The self-report questionnaires were administered at the hospital or by telephone.

A standardized questionnaire was used at each follow-up to assess adverse events, cointerventions, and compliance to the exercise program. Adverse events associated with each intervention such as worsening of symptoms, the need for hospitalization, or visits to the emergency department were recorded.

Statistical analysis

A full description of the statistical analysis plan is in the published protocol.[12]

Using a sample size calculation based on a 2-tailed t test for 2 independent samples, a power of 0.8, an alpha of 0.05, and a dropout of 20%, we needed 52 participants per group to detect a between-group difference of 30% in the proportion of participants who achieved at least 30% improvement (MCID) in the SPWT at 6 months. This sample size also provided adequate power to detect at least a 30% between-group difference in walking distance based on the same assumptions used to calculate adequate sample size for the primary outcome.

Our analyses were conducted according to the *intention to treat* principle. We assessed between-group differences in baseline characteristics using 2-tailed independent sample t tests and chi-square tests. For the primary measure difference in distance walked in 30 minutes (SPWT), we first computed the group-specific mean, SD, and median at each follow-up interval.

Then we built linear regression models using a generalized estimating equation while adjusting for potential confounders (age, sex, baseline SPWT, marital status, perceived health status, dominant leg or back pain, other secondary outcomes) and accounting for the autocorrelation present in the outcomes. We included all potential confounders with P values$<.2$ in the individual regression model to build a multivariate regression model. Stepwise, forward, and backward model selection approaches were used to determine the final regression model. The group effects were reported as mean differences and 95% confidence intervals (95% CIs) for each follow-up period. The same analysis was used for continuous secondary outcomes.

For the primary outcome differences in proportions meeting the MCID in the SPWT, we used the Pearson Chi-square test with 95% CI. A marginal standardization approach was used to calculate the adjusted difference in group proportions and the relative risk of treatment effects. Dichotomous secondary outcomes were analyzed similarly. We used the chi-square test to compare the between-group rates per person of adverse events, cointerventions, and program compliance. Statistical analyses were performed using SAS version 9.3. This trial was registered at ClinicalTrials.gov, number NCT02592642.

Results

From August 2014 to January 2016, a total of 640 potential participants were screened for eligibility; 106 were eligible and of the 104 that were randomly allocated, 48 received the comprehensive and 51 the self-directed programs (fig 1). The 2 groups were similar at baseline, except that more participants in the comprehensive group were never married (table 1). The combined mean age of both groups at baseline was 70.6 years, 57% were women, 84% had leg symptoms for >12 months, and the mean maximum distance walked during the SPWT was 328.7 m. The follow-up rate at 12 months was 89%. The discrepancy between the number of participants and the number of participants who performed the SPWT at each follow-up in fig 1 and table 2 was due to missing data (some participants did not perform the SPWT but competed the self-reported outcomes measures).

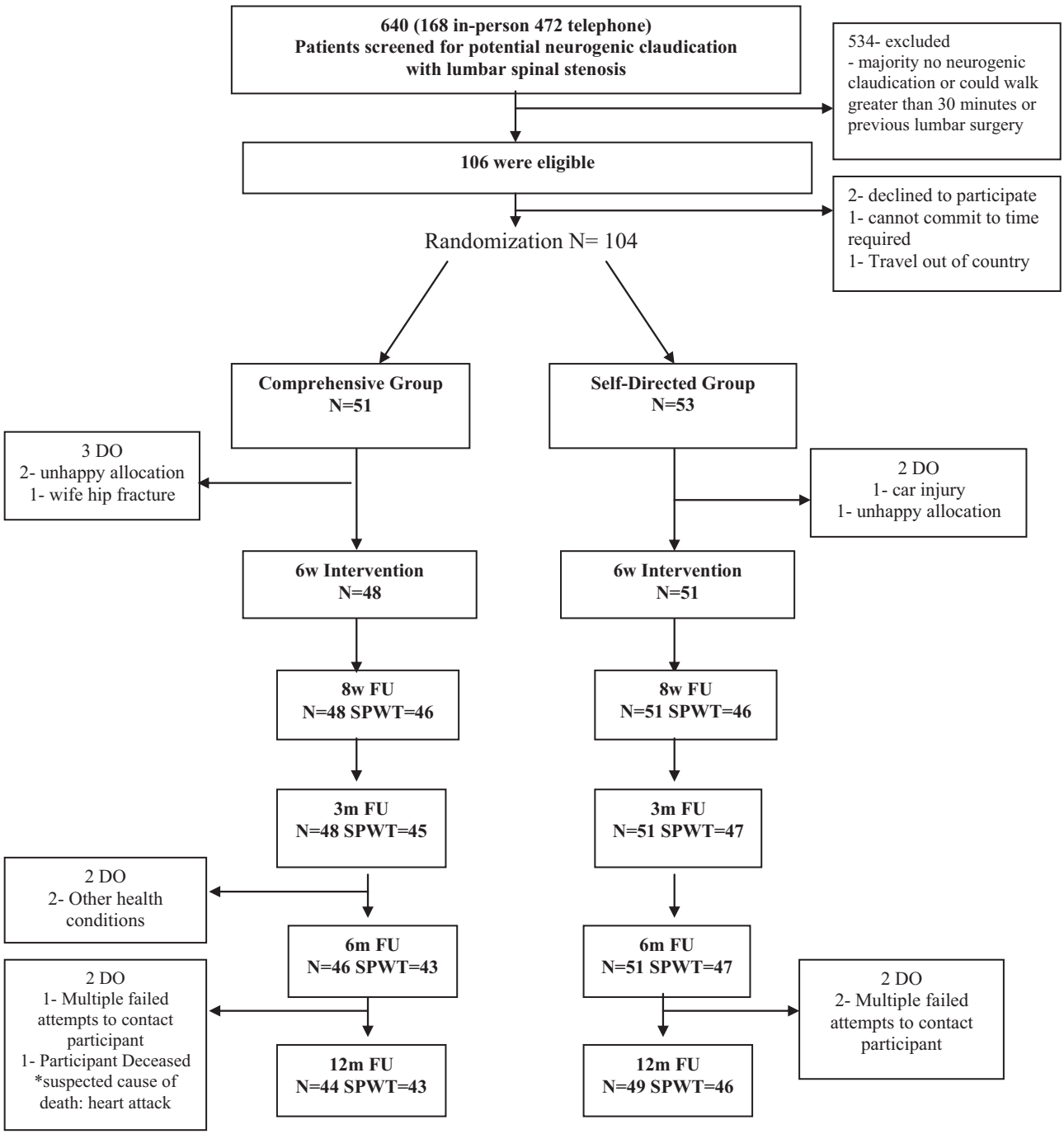

Fig 1 Flow diagram of enrolment, randomization, and follow-up. Abbreviations: DO, dropouts; FU, follow-up.

Table 1 Baseline characteristics of the study participants

Variable	Comprehensive Group (n=51)	Self-Directed Group (n=53)
Age (y)	69.4±7.7	71.7±9.5
Sex—no. (%)		
Men	18 (35)	27 (51)
Women	33 (65)	26 (49)
Marital status—no. (%)		
Single, never married*	8 (16)	0 (0)
Married	29 (57)	30 (57)
Common law	2 (4)	6 (11)
Divorced	7 (14)	8 (15)
Widowed	5 (10)	8 (15)
Separated	0 (0)	1 (2)
Expectations—no. (%)		
Get better soon	12 (24)	8 (15)
Get better slowly	16 (31)	20 (38)
Never get better	6 (12)	8 (15)
Don't know	17 (33)	17 (32)
Global health rating†	67.9±15.7	69.1±14.4
Comorbidities—no. (%)‡		
Yes	37 (73)	38 (72)
No	14 (27)	14 (26)
Unknown	0 (0)	1 (2)
Duration of back pain—no. (%)		
<3 mo	1 (2)	0 (0)
3-12 mo	8 (16)	6 (11)
>12 mo	42 (82)	47 (89)
Duration of leg pain—no. (%)		
3-12 mo	10 (20)	7 (13)
>12 mo	41 (80)	46 (87)
Dominant pain—no. (%)		
Leg	34 (67)	32 (60)
Back	9 (18)	13 (25)
Equal	8 (16)	8 (15)
ZCQ		
ZCQ functional score§	2.3±0.5	2.3±0.5
ZCQ symptoms score‖	2.9±0.6	3.0±0.5
ZCQ function + Symptom score¶	5.2±1.0	5.3±0.8
ODI#	0.4±0.1	0.4±0.1
ODI walk—no. (%)**		
No limitations	0 (0)	0 (0)
2 km	5 (10)	4 (8)
1 km	12 (24)	16 (30)
500 m	32 (63)	33 (62)
Gait aid	2 (4)	0 (0)
Bedridden	0 (0)	0 (0)
NRS		
NRS back pain††	5.2±2.7	5.7±2.6
NRS leg pain‡‡	7.2±2.3	6.9±1.9
Falls Efficacy Scale§§	29.8±20.6	31.6±20.8
SF-36 subscales‖‖		
SF-36-PF	36.8±21.7	38.5±21.8
SF-36-RP	50.5±25.0	49.1±24.6
SF-36-RE	76.8±24.5	78.9±22.6
SF-36-V	47.3±19.5	49.6±18.8
SF-36-MH	70.1±20.7	71.4±16.9
SF-36-SF	65.0±27.4	68.2±26.9
SF-36-BP	38.5±17.3	43.0±17.7
SF-36-GH	57.7±19.0	55.4±19.3
CES-D scale¶¶	11.6±10.1	11.6±9.5
SPWT (m)##	283.6±293.2	372.1±380.7

(*continued on next column*)

(*continued*)

NOTE. Data are expressed as mean ± SD.

Abbreviations: BP, bodily pain; CES-D, Center for Epidemiological Studies-Depression; GH, general health; MH, mental health; NRS, numerical rating scale; PF, physical function; RE, role emotional; RP, role function; SF, social function; V, vitality.

* The difference between the groups was significant ($P=.04$ by the χ^2 test). There were no significant between-group differences in any of the remaining baseline characteristics.

† Global health rating scores range from 0 to 100, with higher scores indicating better health.

‡ Comorbidities include problems with other muscles, bone or joint conditions, allergies, breathing difficulties, hypertension, heart and circulation, digestive system, diabetes, kidney and genitourinary, headaches, neurologic conditions, mental and emotional disorders and cancer.

§ ZCQ functional scores range from 1 to 4, with lower scores indicating less severity.

‖ ZCQ symptom scores range from 1 to 5, with lower scores indicating less severity.

¶ ZCQ functional + ZCQ Symptom scores range from 2 to 9, with lower scores indicating less severity.

ODI scores range from 0 to 1.0, which is the average score of 10 individual scores (sum of 10 scores/50 the maximum score).with lower scores indicating less disability.

** ODI walk allows for 6 possible (0-5) responses on walking ability; no limitations, 2 km, 1 km, 500 m, gait aid, and bedridden.

†† NRS back pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating *pain as bad as you can imagine*.

‡‡ NRS leg pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating *pain as bad as you can imagine*.

§§ Falls Efficacy Scale scores range from 10 to 100, with lower scores indicating less severity.

‖‖ SF-36 subscales range from 0 to 100, with lower scores indicating poorer health.

¶¶ CES-D scores range from 0 to 60, with lower scores indicating less depressive symptomatology.

SPWT measures objective walking distance in meters without stopping due to neurogenic claudication symptoms.

At 8 weeks and 3, 6, and 12 months, both groups demonstrated significant improvement in the SPWT, adding an additional 501.8 versus 201.2 m, 487.4 versus 220.2 m, 564.2 versus 175.0 m, and 674.5 versus 201.3 m, respectively, from baseline. The comprehensive group demonstrated statistically significant and clinically important improvement in the SPWT compared to the self-directed group at each follow-up period (see table 2).

At 6 months, the mean adjusted difference in distance walked between the comprehensive and the self-directed group was 421.0 m; 95%CI, 181.4-660.6; $P=.0006$, and at 12 months this between-group adjusted mean difference was 473.2m; 95% CI, 203.9-742.4; $P=.0007$.

At each follow-up, the proportion of participants who improved their walking distance by at least 30% (MCID) was significantly higher in the comprehensive versus the self-directed group (see table 2). At 6 months, 82% of participants in the comprehensive and 63% in the self-directed group achieved the

Table 2 Intention to treat analysis comparing comprehensive and self-directed treatment

Outcome	Baseline	Comprehensive	Self-Directed	Treatment Effect	*P* Value
		Mean Difference from Baseline		Adjusted with 95% CI	
8 wk					
Primary outcomes					
No. of participants	104	46	46		
SPWT distance (m)*		501.8±610	210.8±401	345.4 (150.0-540.7)	.0005
≥30% improvement in SPWT—no. (%)†		39 (84)	28 (60)	24 (6-40)‡	.011
≥30% improvement in SPWT—no. (%) RR§		39 (84)	28 (60)	1.4 (1.1-1.8)§	.011
Secondary outcomes					
No. of participants	104	47	49		
ZCQS‖		−0.47±0.55	−0.24±0.46	−0.19 (−0.37 to −0.02)	.033
ZCQF¶		−0.43±0.55	−0.37±0.54	−0.02 (−0.22 to 0.17)	.81
ZCQS + ZCQF#		−0.90±0.93	−0.60±0.81	−0.24 (−0.56 to 0.07)	.13
ODI**		−0.1±0.10	−0.1±0.10	−0.02 (−0.07 to 0.02)	.3
ODI walk††		−0.6±0.70	−0.3±0.90	−0.2 (−0.6 to 0.1)	.14
NRS back‡‡		−2.0±2.7	−0.8±2.1	−1.4 (−2.2 to −0.5)	.002
NRS leg§§		−2.1±2.1	−1.2±2.2	−0.7 (−1.5 to 0.1)	.094
≥50% improvement in SPWT—no. (%)†		39 (82)	27 (56)	26 (8-42)‡	.008
≥50% improvement in SPWT—no. (%) RR§		39 (82)	27 (56)	1.5 (1.1-2.0)§	.008
3 mo					
Primary outcomes					
No. of participants	104	45	47		
SPWT distance (m)*		487.4±551	220±571	304.1 (77.9-530.3)	.008
≥30% improvement in SPWT—no. (%)†		40 (88)	31 (67)	21 (4-38)‡	.022
≥30% improvement in SPWT—no. (%) RR§		40 (88)	31 (67)	1.3 (1.0-1.7)§	.022
Secondary outcomes					
No. of participants	104	45	47		
ZCQS‖		−0.53±0.65	−0.32±0.50	−0.15 (−0.37 to 0.08)	.19
ZCQF¶		−0.54±0.65	−0.35±0.50	−0.18 (−0.39 to 0.03)	.09
ZCQS + ZCQF#		−1.07±1.12	−0.67±0.85	−0.36 (−0.75 to 0.03)	.07
ODI**		−0.1±0.1	−0.1±0.1	−0.04 (−0.09 to 0.01)	.13
ODI walk††		-0.8±1.2	−0.4±1.0	−0.4 (−0.9 to 0.03)	.07
NRS back‡‡		-1.4±2.9	−0.9±2.3	−0.6 (−1.4 to 0.3)	.23
NRS leg§§		-2.4±2.6	−1.9±2.8	0.05 (−0.85 to 0.96)	.91
≥50% improvement in SPWT—no. (%)†		34 (76)	27 (57)	19 (−1.0 to 36)‡	.061
≥50% improvement in SPWT—no. (%) RR§		34 (76)	27 (57)	1.3 (0.99-1.8)§	.061
6 mo					
Primary outcomes					
No. of participants	104	43	47		
SPWT distance (m)*		564.2±734	175.0±486	421.0 (181.4-660.6)	.0006
≥30% improvement in SPWT—no. (%)†		35 (82)	30 (63)	19 (2-35)‡	.03
≥30% improvement in SPWT—no. (%) RR§		35 (82)	30 (63)	1.3 (1.04-1.7)§	.03
Secondary outcomes					
No. of participants	104	45	51		
ZCQS‖		−0.44±0.60	−0.36±0.54	−0.02 (−0.22 to 0.19)	.87
ZCQF¶		−0.54±0.63	−0.39±0.66	−0.11 (−0.33 to 0.11)	.34
ZCQS + ZCQF#		−0.98±1.12	−0.75±1.04	−0.23 (−0.58 to 0.12)	.2
ODI**		−0.1±0.1	−0.1±0.1	−0.02 (−0.07 to 0.02)	.34
ODI walk††		−1.1±1.1	−0.3±1.2	−0.9 (−1.3 to −0.4)	<.0001
NRS back‡‡		−1.8±3.0	−1.2±2.6	−0.7 (−1.7 to 0.3)	.16
NRS leg§§		−2.8±2.9	−1.6±2.8	−0.9 (−1.9 to 0.03)	.058
≥50% improvement in SPWT—no. (%)†		32 (70)	27 (52)	17 (−2 to 35)‡	.086
≥50% improvement in SPWT—no. (%) RR§		32 (70)	27 (52)	1.3 (0.97-1.8)§	.086
≥30 min walk in SPWT—no. (%)‖‖ *RR*§		10 (23)	13 (6)	2.3 (0.8-6.8)§	.034
12 mo					
Primary outcomes					
No. of participants	104	43	46		
SPWT distance (m)*		674.5±700	201.3±575	473.2 (203.9-742.4)	.0007

(*continued on next page*)

Table 2 (*continued*)

Outcome	Baseline	Comprehensive	Self-Directed	Treatment Effect	*P* Value
		Mean Difference from Baseline		Adjusted with 95% CI	
≥30% improvement in SPWT—no. (%)[†]		35 (81)	27 (59)	22 (4-39)[‡]	.018
≥30% improvement in SPWT—no. (%) RR[§]		35 (81)	27 (59)	1.4 (1.1-1.8)[§]	.018
Secondary outcomes					
No. of participants	104	43	48		
ZCQS[‖]		−0.66±0.62	−0.36±0.68	−0.22 (−0.47 to 0.02)	.074
ZCQF[¶]		−0.65±0.64	−0.35±0.65	−0.27 (−0.49 to −0.04)	.020
ZCQS + ZCQF[#]		−1.30±1.11	−0.71±1.16	−0.48 (−0.90 to −0.06)	.025
ODI[**]		−0.1±0.1	−0.1±0.1	−0.03 (−0.08 to 0.02)	.3
ODI walk[††]		−0.8±1.2	−0.5±1.2	−0.2 (−0.7 to 0.2)	.32
NRS back[‡‡]		−1.8±2.8	−1.5±2.2	−0.4 (−1.3 to 0.4)	.32
NRS leg[§§]		−2.8±3.1	−2.2±3.3	−0.5 (−1.6 to 0.6)	.37
≥50% improvement in SPWT—no. (%)[†]		32 (74)	24 (51)	24 (5-40)[‡]	.013
≥50% improvement in SPWT—no. (%) RR[§]		32 (74)	24 (51)	1.5 (1.1-2.0)[§]	.013
≥30 min walk in SPWT—no. (%)[‖‖] *RR*[§]		11 (26)	4 (9)	2.7 (1.1-6.9)[§]	.033

Abbreviations: NRS, numeric rating scale; RR, relative risk; ZCQF, Zurich Claudication Questionnaire Functional; ZCQS, Zurich Claudication Questionnaire Symptom Scale.

* SPWT measures walking distance in meters in 30 minutes without stopping due to neurogenic claudication symptoms.

† Improvement in SPWT of 30% or more and 50% or more was calculated at each follow-up. Numbers and percentages are adjusted values.

‡ Adjusted difference in proportion.

§ Adjusted RR.

‖ ZCQS scores range from 1 to 5, with lower scores indicating less severity.

¶ ZCQF scores range from 1 to 4, with lower scores indicating less severity.

ZCQF + ZCQS scores range from 2 to 9, with lower scores indicating less severity.

** ODI scores range from 0 to 1.0, with lower scores indicating less disability.

†† ODI walk allows for 6 possible responses on walking ability; no limitations, 2 km, 1 km, 500 m, gait aid, and bedridden.

‡‡ NRS for back pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating *pain as bad as you can imagine*.

§§ NRS for leg pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating *pain as bad as you can imagine*.

‖‖ Post hoc analysis of number and proportion of participants who were able to complete the SPWT (able to walk for 30min or more).

MCID (adjusted relative risk, 1.3; 95% CI, 1.0-1.7; $P=.03$). The treatment effect persisted at 12 months in favor of the comprehensive group (81% vs 59%, adjusted relative risk, 1.4; 95% CI, 1.1-1.8; $P=.018$).

Significant improvement in pain and function was observed in both groups at each follow-up (see table 2) (fig 2). At 6 months, the comprehensive group showed statistically significant and clinically important improvement in the ODI walk score compared to the self-directed group with a between-group adjusted mean difference of −0·9; 95% CI, −1·3 to −0·4; $P=.0001$. There were no other significant differences in any of the other secondary outcomes at 6 months.

At 12 months, the comprehensive group showed statistically significant improvement in the ZCQ Functional Scale and combined ZCQ Symptom Scale and ZCQ Functional Scale scores compared to the self-directed group with a between-group adjusted mean difference of −0·27; 95% CI, −0·49 to −0·04; $P=.020$, and −0.48; 95% CI, −0.90 to −0.06; $P=.025$, respectively (see table 2). These between-group differences were clinically important.[23] At 12 months, there were significant between-group adjusted mean differences favoring the comprehensive group in the SF-36 physical function score; 8.2; 95% CI, 0.2-16.2; $P=.045$ and the SF-36 bodily pain score, 10.0; 95% CI, 2.1-17.9; $P=.013$ (supplemental table S2, available online only at http://www.archives-pmr.org/). These differences were clinically important.[24]

There were no between-group differences in reported compliance to the exercise programs or cointerventions (table 3). At 6 months, 2 versus 5 participants ($P=.33$) and at 12 months, 0 versus 2 participants ($P=.18$) reported adverse events in the comprehensive and self-directed groups, respectively. Most of the reported adverse events were related to a temporary increase in low back and/or leg symptoms (see table 3). No participants reported cauda equine syndrome.

Discussion

In a trial of nonsurgical treatment for neurogenic claudication due to LSS, we observed statistically significant and clinically important improvements in walking distance favoring a structured 6-week comprehensive program compared to a self-directed approach. The observed magnitude and sustainability of improved walking ability are highly relevant findings for patients with LSS.[4] Walking is the dominant limitation and the most common reason for seeking care in this population.[5] Moreover, the natural history of LSS is favorable for leg and back pain and health-related quality of life, but not for walking ability.[10] Consequently, improved walking distance is a highly meaningful outcome and is a measure more likely attributable to a treatment effect in this population. To our knowledge, this is the first clinical trial to demonstrate a large, sustainable, and clinically important

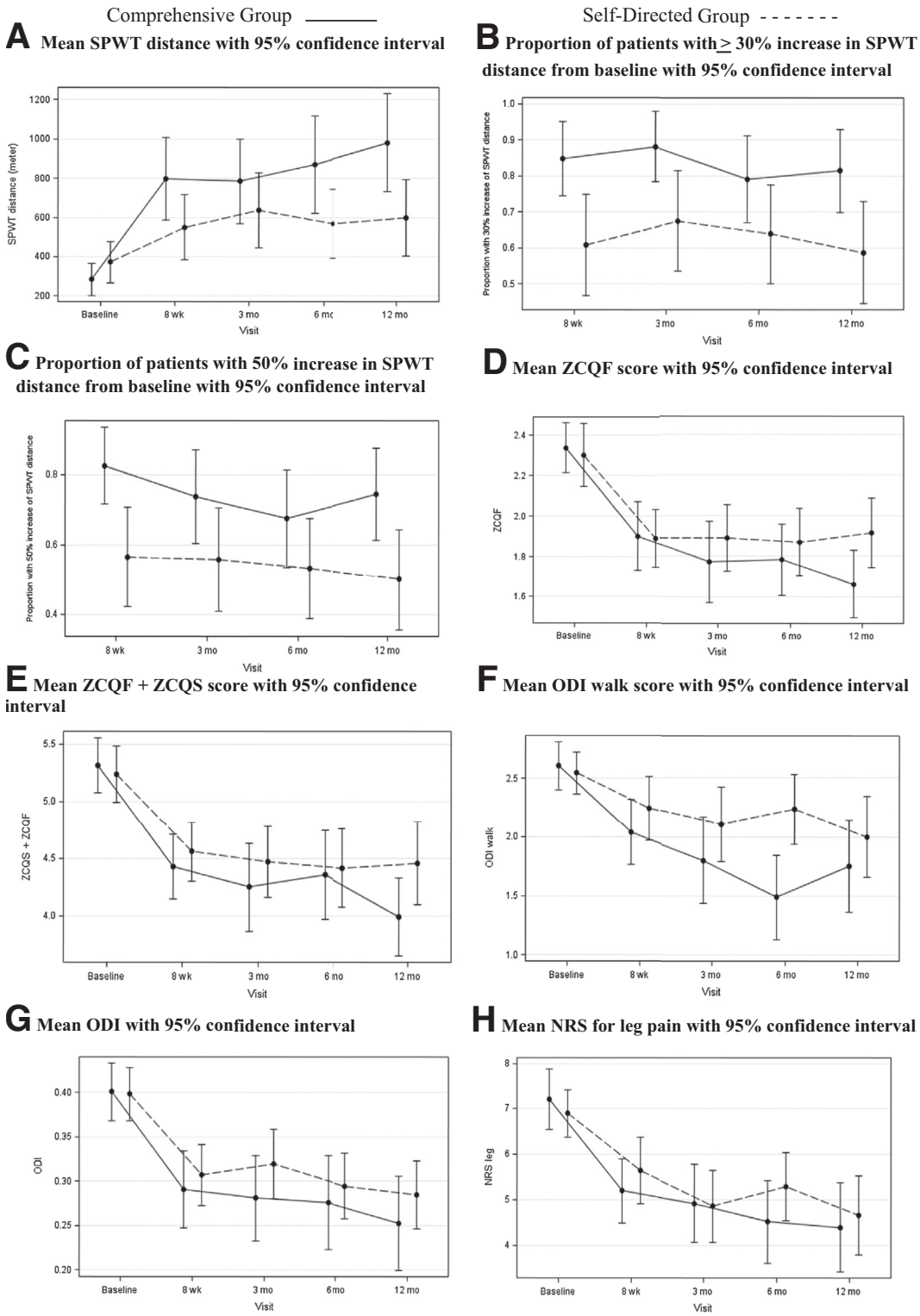

Fig 2 Primary and secondary outcomes for the comprehensive and self-directed groups over 12 mo. Primary outcomes were the mean scores on the SPWT that measure objective walking distance in meters without stopping due to neurogenic claudication symptoms **(A)** and the proportion of participants with 30% or more increase in the SPWT in meters from baseline **(B)**. Secondary outcomes included the proportion of patients with 50% or more increase in the SPWT in meters from baseline **(C)**, the mean scores on the ZCQ Functional (ZCQF) scale **(D)**, the ZCQF plus ZCQ Symptom Scale (ZCQS) (symptom) (ZCQF + ZCQS) **(E)**, the ODI walk scale **(F)**, the ODI **(G)**, and the numeric rating scale for leg pain (NRS leg) **(H)**. The ZCQF scores range from 1 to 4, with lower scores indicating less severity. ZCQF + ZCQS scores range from 2 to 9, with lower scores indicating less severity. ODI scores range from 0 to 1.0, with lower scores indicating less disability. ODI walk allows for 6 possible responses (0-5) on walking ability: no limitations, 2 km, 1 km, 500 m, gait aid, and bedridden. NRS leg pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating *pain as bad as you can imagine*.

Table 3 Cointerventions, compliance, and adverse events

	8 wk			3 mo			6 mo			12 mo		
	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value
Cointerventions*												
Care from other health care provider—no. (%)												
Yes	10 (21)	8 (16)	.53	14 (31)	18 (38)	.47	16 (36)	13 (25)	.28	12 (27)	15 (31)	.72
No	37 (79)	41 (84)		31 (69)	29 (62)		29 (64)	38 (75)		32 (73)	34 (69)	
Spinal injections—no. (%)												
Yes	4 (9)	1 (2)	.15	2 (4)	3 (6)	.68	3 (7)	3 (6)	.89	2 (5)	3 (6)	.74
No	43 (91)	48 (98)		43 (96)	44 (94)		42 (93)	47 (94)		42 (95)	46 (94)	
Lumbar spinal stenosis surgery—no. (%)												
Yes	0 (0)	0 (0)	N/A	1 (2)	1 (2)	.98	1 (2)	0 (0)	.29	1 (2)	6 (12)	.07
No	47 (100)	49 (100)		44 (98)	46 (98)		44 (98)	51 (100)		43 (98)	43 (88)	
Decline	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
Hospital/ED visit—no. (%)												
Yes	0 (0)	0 (0)	N/A	0 (0)	2 (4)	.16	0 (0)	0 (0)	N/A	0 (0)	0 (0)	N/A
No	47 (100)	49 (100)		45 (100)	45 (96)		45 (100)	51 (100)		44 (100)	49 (100)	
Overnight in hospital/ED—no. (%)												
Yes	0 (0)	0 (0)	N/A	0 (0)	0 (0)	N/A	0 (0)	0 (0)	N/A	0 (0)	0 (0)	N/A
No	47 (100)	49 (100)		45 (100)	47 (100)		45 (100)	51 (100)		44 (100)	49 (100)	
Use of prescription medications—no. (%)												
Yes	27 (57)	25 (51)	.53	27 (60)	27 (57)	.80	22 (49)	27 (53)	.69	23 (52)	24 (49)	.75
No	20 (43)	24 (49)		18 (40)	20 (43)		23 (51)	24 (47)		21 (48)	25 (51)	
Compliance*												
To prescribed exercises—no. (%)†												
All of the time	26 (55)	22 (45)	0.32	16 (36)	11 (23)	.19	13 (29)	9 (18)	.58	11 (26)	7 (14)	.16
Most of the time	17 (36)	15 (31)		15 (33)	11 (23)		14 (31)	18 (35)		14 (33)	17 (35)	
Half the time	2 (4)	4 (8)		7 (16)	11 (23)		7 (16)	8 (16)		10 (23)	6 (12)	
Less than half the time	1 (2)	4 (8)		5 (11)	6 (13)		7 (16)	7 (14)		6 (14)	12 (24)	
Not at all	1 (2)	4 (8)		2 (4)	8 (17)		4 (9)	9 (18)		2 (5)	7 (14)	
Adverse events*												
Adverse events experienced—no. (%)												
Yes	9 (19)	10 (20)	.88	4 (9)	7 (15)	.40	2 (5)	5 (10)	.33	0 (0)	2 (4)	.18
No	38 (81)	39 (80)		40 (91)	40 (85)		42 (95)	46 (90)		44 (100)	47 (96)	
Type of adverse event												
Worsened low back pain—no (%)												
Yes	5 (11)	4 (8)	.79	3 (7)	2 (4)	.24	1 (2)	2 (4)	.59	0 (0)	1 (2)	.40
No	4 (9)	6 (12)		1 (2)	5 (11)		1 (2)	3 (6)		0 (0)	1 (2)	
N/A	38 (81)	39 (80)		41 (91)	40 (85)		43 (96)	46 (90)		44 (100)	47 (96)	

(*continued on next page*)

Table 3 (*continued*)

	8 wk			3 mo			6 mo			12 mo		
	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value	Comp	Self-Directed	*P* Value
Worse leg pain/numbness/ tingling—no. (%)												
Yes	0 (0)	3 (6)	.20	3 (7)	2 (4)	.24	2 (4)	1 (2)	.13	0 (0)	0 (0)	.18
No	9 (19)	7 (14)		1 (2)	5 (11)		0 (0)	4 (8)		0 (0)	2 (4)	
N/A	38 (81)	39 (80)		41 (91)	40 (85)		43 (96)	46 (90)		44 (100)	47 (96)	
Worse knee, hip or ankle pain—no. (%)												
Yes	4 (9)	1 (2)	.23	0 (0)	2 (4)	.35	0 (0)	2 (4)	.38	0 (0)	1 (2)	.40
No	5 (11)	9 (18)		4 (9)	5 (11)		2 (4)	3 (6)		0 (0)	1 (2)	
N/A	38 (81)	39 (80)		41 (91)	40 (85)		43 (96)	46 (90)		44 (100)	47 (96)	
Description of adverse event—no. (%)												
Serious‡	1 (2)	0 (0)	.59	0 (0)	1 (2)	.50	0 (0)	0 (0)	.31	0 (0)	0 (0)	.18
Nonserious	8 (17)	9 (18)		4 (9)	6 (13)		2 (4)	5 (10)		0 (0)	2 (4)	
N/A	38 (81)	40 (82)		41 (91)	40 (85)		43 (96)	46 (90)		44 (100)	47 (96)	
Duration of adverse event—no. (%)												
<24 h	1 (2)	2 (4)	.83	0 (0)	2 (4)	.41	1 (2)	1 (2)	.60	0 (0)	0 (0)	.40
24-48 h	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	2 (4)		0 (0)	1 (2)	
3-7 d	3 (7)	2 (4)		0 (0)	0 (0)		0 (0)	1 (2)		0 (0)	0 (0)	
<1 mo	3 (7)	3 (6)		2 (4)	2 (4)		1 (2)	1 (2)		0 (0)	0 (0)	
<6 mo	0 (0)	0 (0)		1 (2)	3 (6)		0 (0)	0 (0)		0 (0)	0 (0)	
>or=6 mo	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	1 (2)	
Permanent	0 (0)	1 (2)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
N/A	38 (84)	39 (83)		41 (91)	40 (85)		43 (96)	46 (90)		44 (100)	47 (96)	

Abbreviations: Comp, comprehensive; ED, emergency department; no., the number of participants.

* Participants were asked to answer questions based on changes since last follow-up.

† Participants were asked to comment on how often they performed exercises as instructed.

‡ Serious adverse events included those that required visits to hospital/ED or overnight stay.

improvement in walking ability in LSS using objective and validated outcomes measures.[25]

We observed significant and clinically important long-term improvements in self-reported back and leg pain and ODI scores, but no between-group differences. This lack of between-group differences may have been influenced by patient adaptation and natural history. Limited walking ability may compel individuals with LSS to modify their environment and activities to match their functional abilities.[26] These adaptations and natural history can contribute to significant reductions in perceived pain and disability[10,26] and may have led to similar group improvements in self-reported outcomes in our study.

Both groups received a pedometer and the same educational materials, exercises, and self-management strategies. The superior improvements observed in the comprehensive group may be related to the supervised and individualized education and instruction received, the regular interactions and support provided to participants, the manual therapy applied, and/or the cognitive behavioral interventions delivered. In chronic low back pain, supervised home exercises, cognitive behavioral therapy, and manual therapy are recommended evidence-based treatments.[27] Although self-reported compliance to exercise appeared similar in both groups, this could not be confirmed objectively. Proficiency in performing all the exercises and self-management strategies, however, was confirmed for the comprehensive but not self-directed group participants, and this may have been a factor contributing to the observed outcomes.

In systematic reviews assessing the effectiveness of nonsurgical treatments for LSS, all 4 randomized controlled trials of physical therapy plus exercise failed to demonstrate improved walking ability.[8,9] One trial suggested that exercise is better than no treatment for leg pain in the short term. Another trial that included manual therapy and exercise showed global improvement only at 6-weeks. All trials were of low methodological quality[8,9]; therefore, no conclusions could be made about the effectiveness of these interventions. A recent trial comparing home exercise, education, and advice to education and advice only reported no difference in the ZCQ or other outcomes at 8 weeks or 12 months.[28] Among large clinical trials comparing physiotherapy to surgery for LSS,[29,30] the 12-month improvement in the primary outcomes SF-36 physical function, bodily pain, and ODI for physiotherapy did not exceed those observed in the comprehensive group in our study.

The strengths of this study were the use of a randomized controlled design, multiple and long-term follow-up assessments, a low dropout rate, masking of the assessors, and the use of a valid and objective primary outcome measure that is highly meaningful to patients with LSS.[4] In addition, the pragmatic nature of the study where participants received care alongside regular patients increased the generalizability and applicability of our findings.

Study limitations

Our trial had limitations. Masking of participants and clinicians was not possible which could have affected the reported outcomes. The SPWT significantly underestimated improvement in walking distance seen in this study, especially for the comprehensive group participants, because improved walking distance beyond 30 minutes was not captured. This is illustrated in a post hoc analysis at 12 months where 26% of participants in the comprehensive and only 9% in the self-directed group ($P=.033$) completed the SPWT. There was a potential for selection bias in our study. We used a simple randomization process and rigorous allocation concealment procedures to reduce this risk, and only the trained research coordinator and not the investigators were involved in treatment allocation. The research coordinator, using strict inclusion-exclusion criteria, also performed participant screening and selection. These strict criteria excluded patients with mild and severe neurogenic claudication and patients with other comorbidities that significantly impacted walking ability. Excluding these patients would limit the generalizability of our findings.

Our study did not include a *no treatment* or *usual care* arm, and therefore it is uncertain whether our findings are superior to the natural history or usual care for LSS. However, in a study of nonsurgical usual care, only 28% of patients were definitely improved at 1 year.[31] In a recent natural history study, about a third of LSS patients showed long-term improvements in symptoms and quality of life (but not walking ability).[10] In our study, a significantly larger proportion of participants in both the comprehensive (81%) and self-directed (59%) groups showed clinically important improvements at 1 year.

Future studies are planned that include testing a similar comprehensive intervention using a peer-to-peer group format for exercises and self-management training rather than one-on-one instruction. A community intervention training field practitioners on how to implement the comprehensive program in their clinics and assessing their patient outcomes is also planned. This would assess the potential effectiveness of the comprehensive program in a real-world setting.

Conclusions

To date, clinicians and patients wanting to make evidence-informed decisions about effective nonsurgical treatment to improve outcomes in LSS, particularly walking ability, were limited by low quality evidence. However, the findings from our study suggest that a comprehensive nonsurgical training program that included clinician instruction and supervision, manual therapy and a cognitive behavioral approach can be an effective and safe option for patients with neurogenic claudication due to LSS.

Suppliers

a. SAS, version 9.3; SAS Institute Inc.
b. Leander 9000 Table; Leander Healthcare Technologies.
c. Pedusa PE-771; Pedometers USA.
d. Lufkin Pro-Series Model PSMW38; Lufkin.

Keywords

Back; Conservative treatment; Randomized controlled trial; Rehabilitation; Spinal stenosis

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Supplemental Table S1 Eligibility criteria

Inclusion criteria

1. Age greater or equal to 50 years
2. Clinical symptoms of back and/or radiating lower limb or buttock pain; fatigue or loss of sensation in the lower limbs aggravated by walking and/or standing and relieved by sitting.
3. Intermittent or persistent pain without progressive neurological dysfunction
4. Duration of symptoms and signs for more than 3 months
5. Imaging confirmed spinal canal narrowing using MRI or CT scan
6. Clinical signs and symptoms corresponding to segmental level of narrowing identified by imaging
7. Patients with degenerative spondylolisthesis are included
8. Not considered to be a surgical candidate (in the next 12 months) or patient unwilling to have surgery
9. Able to perform mild-moderate exercise
10. Able to walk without assistive devices for at least 20 metres and less than 30 minutes continuously
11. Able to give written informed consent and complete interviews and questionnaires in English.

Exclusion criteria

1. Severe degenerative stenosis with intractable pain and progressive neurological dysfunction
2. Lumbar spinal stenosis not caused by degeneration
3. Lumbar herniated disc diagnosed during the last 12 months
4. Previous back surgery for lumbar spinal stenosis or instability
5. Underlying spinal disorder such as ankylosing spondylitis, neoplasm, infection or metabolic disease
6. Intermittent claudication due to vascular disease
7. Severe osteoarthrosis or arthritis of lower extremities causing limited walking ability
8. Neurologic disease causing impaired function of the lower limbs, including diabetes
9. Psychiatric disorders and /or cognitively impaired

Supplemental Table S2 Intention to treat analysis comparing comprehensive and self directed treatment additional secondary outcomes

		Comprehensive	Self-Directed	Treatment Effect	
Outcome	Baseline	Mean Difference from Baseline*		Adjusted with 95% CI	*P* Value
8 weeks					
No. of Participants	104	46	46		
FES†		-4.9±15.1	-3.8±14.7	-1.8 (-6.3 to 2.6)	0.42
SF36-PF‡		19.9±22.3	14.1±21.8	4.2 (-3.9 to 12.4)	0.31
SF36-RP‡		12.9±26.3	10.8±30.2	3.3 (-6.0 to 12.5)	0.49
SF36-RE‡		3.0±18.8	-2.0±20.1	4.6 (-1.8 to 11.0)	0.16
SF36-V‡		6.1±15.3	0.5±16.7	4.4 (-1.6 to 10.3)	0.150
SF36-MH‡		1.9±17.3	-1.7±13.1	3.2 (-2.3 to 8.6)	0.25
SF36-SF‡		9.0±22.4	3.3±23.6	3.2 (-5.0 to 11.4)	0.45
SF36-BP‡		14.4±17.8	9.7±20.0	2.0 (-4.9 to 8.9)	0.57
SF36-GH‡		4.7±13.8	0.3±17.6	6.0 (0.3 to 11.7)	0.038
CES-D§		-1.9±7.8	0.3±9.4	-1.8 (-4.9 to 1.3)	0.26
SPPB total¶		0.2±1.2	0.0±1.4	0.2 (-0.3 to 0.6)	0.44
3 months					
No. of Participants	104	45	47		
FES†		-3.0±16.3	-0.6±18.6	-3.0 (-9.2 to 3.2)	0.35
SF36-PF‡		20.3±24.2	10.0±16.5	9.2 (1.1 to 17.3)	0.027
SF36-RP‡		9.2±32.5	8.2±28.2	0.5 (-9.1 to 10.1)	0.92
SF36-RE‡		1.7±31.1	-3.2±21.7	2.5 (-5.9 to 11.0)	0.56
SF36-V‡		6.7±20.5	1.5±15.3	4.6 (-2.2 to 11.4)	0.19
SF36-MH‡		4.8±19.7	-1.6±15.5	5.1 (-0.9 to 11.1)	0.094
SF36-SF‡		10.6±27.8	3.5±24.0	6.1 (-3.0 to 15.2)	0.19
SF36-BP‡		14.1±27.0	13.4±19.3	-4.5 (-12.4 to 3.5)	0.27
SF36-GH‡		3.4±16.0	-1.2±15.9	5.3 (-0.1 to 10.6)	0.054
CES-D§		-1.2±8.4	0.4±7.6	-0.7 (-3.6 to 2.1)	0.61
SPPB total¶		0.05±1.4	0.02±1.5	0.03 (-0.5 to 0.6)	0.91

(*continued on next page*)

Supplemental Table S2 (*continued*)

Outcome	Baseline	Comprehensive	Self-Directed	Treatment Effect	*P* Value
		Mean Difference from Baseline*		Adjusted with 95% CI	
6 months					
No. of Participants	104	43	47		
FES†		-3.2±16.6	-3.5±15.4	0.2 (-4.6 to 5.0)	0.93
SF36-PF‡		17.0±22.4	10.5±18.4	5.8 (-2.1 to 13.6)	0.15
SF36-RP‡		9.7±30.9	9.9±29.4	2.7 (-7.0 to 12.4)	0.58
SF36-RE‡		3.3±26.3	-2.3±22.7	3.3 (-5.1 to 11.7)	0.44
SF36-V‡		6.5±19.0	0.2±14.8	5.0 (-1.2 to 11.3)	0.12
SF36-MH‡		2.2±18.8	-1.7±13.3	2.4 (-3.5 to 8.4)	0.43
SF36-SF‡		10.0±28.2	2.7±22.3	5.2 (-2.9 to 13.3)	0.2
SF36-BP‡		12.7±22.3	11.2±21.3	-3.3 (-10.2 to 3.6)	0.35
SF36-GH‡		-1.3±14.7	-1.6±12.5	-0.4 (-5.4 to 4.7)	0.89
CES-D§		-0.5±6.9	0.8±7.9	-0.5 (-3.2 to 2.1)	0.68
SPPB total¶		-0.3±1.5	-0.3±1.5	0.1 (-0.4 to 0.7)	0.68
12 months					
No. of Participants	104	43	46		
FES†		-2.8±17.0	-0.7±16.4	-2.6 (-8.4 to 3.2)	0.38
SF36-PF‡		16.9±23.2	5.9±18.9	8.2 (0.2 to 16.2)	0.045
SF36-RP‡		12.8±33.3	9.1±27.6	5.2 (-4.9 to 15.4)	0.31
SF36-RE‡		4.9±26.1	2.4±25.3	-0.8 (-8.7 to 7.2)	0.85
SF36-V‡		11.5±14.5	8.5±16.4	1.2 (-4.1 to 6.5)	0.65
SF36-MH‡		3.2±19.2	-4.3±13.2	4.7 (-0.3 to 9.7)	0.068
SF36-SF‡		13.9±22.3	8.4±24.3	1.2 (-5.9 to 8.4)	0.74
SF36-BP‡		20.1±21.5	8.1±20.7	10.0 (2.1 to 17.9)	0.013
SF36-GH‡		4.0±15.8	3.0±15.3	2.1 (-3.9 to 8.0)	0.50
CES-D§		0.4±8.8	0.4±8.0	0.84 (-1.9 to 3.6)	0.55
SPPB total¶		-0.5±1.7	-0.3±1.7	-0.2 (-0.8 to 0.3)	0.37

* Plus-minus values are means ±SD.

† Falls Efficacy Scale (FES) scores range from 10 to 100, with lower scores indicating less severity.

‡ Short Form 36 (SF36) Health Survey consists of 8 scaled scores, which are weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the less disability. PF= Physical Function, RP= Role Function, RE= Role Emotional, V= Vitality, MH= Mental Health, SF= Social Function, BP= Bodily Pain, GH= General Health.

§ Center for Epidemiological Studies-Depression (CES-D) scale scores range from 0 to 60, with lower scores indicating less depressive symptomatology.

¶ Short Physical Performance Battery (SPPB) total assesses lower extremity function in adults, scores range from 0 (worst performance) to 12 (best performance).