

Treadmill walking with body weight support is no more effective than cycling when added to an exercise program for lumbar spinal stenosis: a randomised controlled trial

Yong-Hao Pua^{1,2}, Cong-Cong Cai¹ and Kian-Chong Lim¹

¹Alexandra Hospital, Singapore ²The University of Melbourne, Australia

Question: Is 6 weeks of treadmill walking with body weight support more effective than cycling in people with lumbar spinal stenosis when added to an exercise program? **Design:** Randomised controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. **Participants:** Sixty-eight patients aged 58 (SD 8) with symptoms of lumbar spinal stenosis for 12 weeks (SD 49). **Intervention:** Participants performed either treadmill with body weight support or cycling, twice weekly, for 6 weeks. Both groups also received an exercise program consisting of heat, lumbar traction, and flexion exercises. **Outcome measures:** The primary outcome was disability measured using the modified Oswestry Disability Index. Secondary outcomes were disability, measured using the Roland-Morris Disability Questionnaire, pain severity, and patient perceived benefit. Measures were collected midway through intervention at 3 weeks and after intervention at 6 weeks. **Results:** There was no difference between the groups in reduction in disability or pain over the 6-week intervention period. The between-group difference in the modified Oswestry Disability Index was 3.2 points (95% CI -3.1 to 7.7) at 6 weeks, and in pain severity was 2 mm on a 100 visual analogue scale (95% CI -5 to 10). Furthermore, the wide confidence intervals associated with estimates of patient benefit are consistent with no difference between the two groups. However, both groups did improve. **Conclusion:** Treadmill with body weight support and cycling may be equally effective in the conservative management of people with lumbar spinal stenosis. However, the improvement observed in both groups was probably a combination of the intervention and the natural course of recovery of lumbar spinal stenosis. [Pua YH, Cai CC, Lim KC (2007) Treadmill walking with body weight support is no more effective than cycling when added to an exercise program for lumbar spinal stenosis: a randomised controlled trial. *Australian Journal of Physiotherapy* 53: 83–89]

Key words: Spinal Stenosis, Walking, Lumbar Region, Low Back Pain, Physiotherapy, Randomized Controlled Trial, Exercise Therapy, Back Pain

Introduction

Lumbar spinal stenosis is the narrowing of the spinal canal, nerve root canal, and/or intervertebral foramen (Arnoldi et al 1976). It is a condition commonly seen in older people, and individuals with symptomatic lumbar spinal stenosis often have significant pain and functional limitations. As the population continues to age, both the prevalence and public health problem of lumbar spinal stenosis are expected to increase (Deyo et al 1992).

Although observational and prospective studies (Johnsson et al 1991, Johnsson et al 1992, Onel et al 1993, Atlas et al 1996, Hurri et al 1998, Amundsen et al 2000, Simotas 2001) have pointed toward the relatively benign and uneventful nature of lumbar spinal stenosis, controversy exists about its management. While surgery has traditionally been the treatment of choice, a trial of conservative management is usually recommended prior to surgery (Fritz et al 1998, Nagler and Hausen 1998, Spivak 1998, Jenis and An 2000). Of the myriad conservative management options, physiotherapy intervention is one of the most common (Fritz et al 1998, Nagler and Hausen 1998). To date, many authors (eg, Rademeyer 2003, Rittenberg and Ross 2003, Whitman et al 2003, Vo et al 2005) have considered a comprehensive rehabilitation program to comprise manual therapy, stretching, and strengthening exercises for the lumbar spine and hip region. Moreover, these authors also

emphasised the importance of endurance exercises to retard the deleterious sequelae of inactivity and deconditioning.

Lumbar spinal stenosis is characterised clinically by an exacerbation of symptoms with lumbar extension or weight bearing postures, and symptom relief with flexion or non-weight bearing postures (Takahashi et al 1995). This postural- and load-dependent nature of lumbar spinal stenosis has, therefore, important implications regarding the appropriate endurance exercises to be prescribed. Based on the observation that cycling on a stationary bicycle does not elicit pain in people with neurogenic claudication (Dyck and Doyle 1977), many authors (Fritz et al 1998, Spivak 1998, Rittenberg and Ross 2003, Vo et al 2005) have traditionally advocated its use as a form of aerobic training. Alternatively, in the past decade, at least three case reports and case series (Fritz et al 1997, Joffe et al 2002, Whitman et al 2003) have reported the use of treadmill walking with body weight support for people with low back pain and lumbar spinal stenosis. Given that reduced walking tolerance is a common limitation in individuals with lumbar spinal stenosis (Onel et al 1993), treadmill walking with body weight support may be a potentially useful intervention as it involves the application of a vertical traction force resulting in a reduction in compressive spinal loading (Fritz et al 1997) during walking. Therefore, the research questions for this trial were:

1. Is 6 weeks of treadmill walking with body weight support more effective than cycling in decreasing pain and disability in people with lumbar spinal stenosis when added to an exercise program?
2. Are any gains apparent by 3 weeks?

Method

Design: This randomised controlled trial was conducted at the physiotherapy outpatient clinic of a large tertiary institution in Singapore. All three authors recruited the participants and allocated them to their groups. We used a computer-generated table of random numbers to perform block randomisation (4 and 6 per block). A staff member not involved in the trial prepared the sequentially-numbered, opaque, sealed envelopes. After confirmation of eligibility, participants completed several self-report measures and then gave a history and underwent a physical examination. After completion of the baseline measurements, the assessor who conducted the measurements opened the next envelope to get the group assignment. Patients were randomly assigned to receive either treadmill with body weight support plus an exercise program (treadmill group) or cycling plus an exercise program (cycling group). Participants in both groups received intervention twice a week for the next 6 weeks, for a total of 12 sessions. As with most trials of physical intervention, the physiotherapists delivering the intervention were unblinded. Blinding of the participants was also not possible because of the informed consent process. An assessor who was blinded to group allocation repeated the measurements at 3 and 6 weeks after randomisation. Participants were instructed not to reveal information about their intervention to the assessor. The study was approved by the local research ethics committee, and each participant gave informed consent.

Participants: Consecutive patients who were referred by the orthopaedic specialists to outpatient physiotherapy for management of degenerative lumbar spinal stenosis were recruited. Patients were included if they were at least 50 years of age, had a history of low back pain (radiating or non-radiating symptoms), had a body mass index less than 38 kg/m² (to enable treadmill walking with body weight support and lumbar traction), had evidence of lumbar spinal stenosis on MRI or radiograph, and had no cognitive impairments. Because the exercise program involved flexion exercises, we added two inclusion criteria to ensure a more homogeneous sample of participants. First, we included patients who reported back or lower extremity pain while walking and during sustained (30 seconds) spinal extension in the quadruped position. Second, we included patients who reported relief of their back or lower extremity symptoms in sitting compared with walking or standing. Patients were excluded if they had symptoms arising from neoplastic conditions, severe osteoporosis, spondylolisthesis with greater than 5 mm of slippage, pulmonary or vascular disease, or had undergone surgery for lumbar spinal stenosis or to the lower extremities.

Intervention: Both groups took part in an exercise program prior to cycling or treadmill walking with body weight support beginning with a 20-minute application of heat therapy using a shortwave diathermy machine^(a). This was followed by 15 minutes of mechanical lumbar traction^(b) with an on/off cycle time of 30:10 seconds with the participant positioned in the Fowler's position. The on traction force was 30–40% of the participant's body weight (Meszaros et

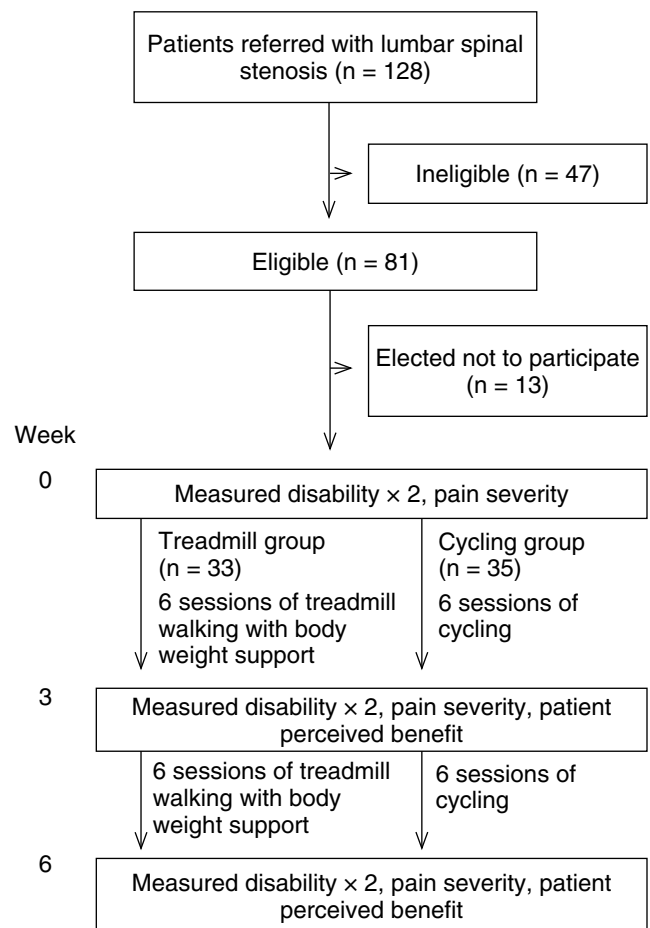


Figure 1. Flow of participants through the trial.

al 2000) depending on his/her response (ie, centralisation or reduction of symptoms) and the off traction force was 10% of body weight. This part of the program was intended to mobilise the lumbar spine prior to more intensive exercise (Spivak 1998). Participants were given a home exercise program (see Appendix 1 on the eAddenda) which comprised 3 flexion, neural mobilisation exercises (Rademeyer 2003, Murphy et al 2006). This part of the exercise program was intended to restore or maintain motion as well as improve circulation in the spinal region via many repetitions of low-intensity exercises. Participants were taught the home exercise program during the first intervention session and were instructed to perform the exercises daily for 6 weeks.

The treadmill group trained with the Biodex unweighting system^(c). During Weeks 1 and 2, participants walked at their comfortable pace. Sufficient traction was applied to achieve a relatively pain-free gait which translated to 30–40% of body weight. In Weeks 3 to 6, participants were encouraged to walk at a moderate intensity which translated to 11–15 points on the Borg Rating of Perceived Exertion Scale (Borg 1982). The duration of each treadmill with body weight support session was limited by participant tolerance or to a maximum of 30 minutes.

The cycling group trained on an upright bicycle. During

Table 1. Participant characteristics.

Characteristic	Treadmill Group (n = 33)	Cycling Group (n = 35)
Age (yr), mean (SD)	58.2 (9)	58.5 (6)
Sex, number of female participants (%)	14 (42)	19 (52)
Body mass index (kg/m^2), mean (SD)	24.7(3.1)	24.2(6.4)
Education < 12 years, number (%)	22 (67)	23 (66)
Diabetes mellitus, number (%)	8 (24)	7 (20)
Spoke only Chinese, number (%)	12 (36)	12 (34)
In employment, number (%)	18 (55)	13 (37)
Current smoker, number (%)	4 (12)	3 (9)
Duration of current episode (wk), median	12	12
Spondylolisthesis, number (%)	5 (15)	4 (11)
Leg pain worse than back pain, number (%)	21 (64)	18 (51)
Pain prevents walking > 400 metres, number (%)	12 (36)	14 (40)
On medication, number (%)	20 (61)	18 (51)
Decreased tendon reflexes, number (%)	6 (18)	13 (37)

Weeks 1 and 2, participants cycled at their comfortable pace at 50 to 60 rpm. Participants were instructed to assume a flexed posture and avoid lumbar extension while cycling. In Weeks 3 to 6, as with the treadmill group, participants were encouraged to exercise at a moderate intensity and the duration of each cycling session was limited by participant tolerance or to a maximum of 30 minutes.

Outcome measures: The primary outcome measure was disability as a result of lumbar spinal stenosis measured using the modified Oswestry Disability Index (Fritz and Irrgang 2001). We used the Chinese version (Chow and Chan 2005) for participants who spoke only Chinese. For the Chinese version (Chow and Chan 2005), we substituted the sex life item with a section regarding employment and home-making to parallel the modified English version. Disability was also measured using the Roland-Morris Disability Questionnaire (Roland and Morris 1983) or the Chinese version (Chen et al 2003) for participants who spoke only Chinese. Participants rated their average pain severity over the previous week using a 100-mm visual analogue scale (Beurskens et al 1996).

The number of participants that had improved after intervention was also calculated. Patient Perceived Benefit was measured by participants rating their change compared with baseline on a 6-point scale (completely better, much better, better, same, worse, much worse). Participants who rated themselves as 'completely better' and 'much better' were categorised as having improved. Participants with at least an 8-point improvement (representing at least a 33% improvement) (Farrar et al 2000) in their modified Oswestry Disability Index scores were also categorised as having improved. Participants who were able to walk at least 800 metres (ie, scored 0 and 1 on the walking item of the modified Oswestry Disability Index) were also categorised as having improved.

Data analysis: We estimated the required sample size *a priori*, assuming a power of 90% and an alpha level of 0.05. Our sample size was calculated to detect a minimal clinically-important change between groups of 8 points in

a population with a standard deviation of 10 points on the modified Oswestry Disability Index, giving an estimated sample size of 32 participants in each group and 64 participants in total.

Baseline measures were summarised for descriptive purposes using means and standard deviations for continuous measures and percentages for categorical measures. Independent sample t-tests and χ^2 tests were used to compare baseline measures between treatment groups. Lilliefors tests for normality were used to test the hypothesis that outcome measures for disability and pain severity were normally distributed. However, the Oswestry Disability Index and the Roland-Morris Disability Questionnaire were not normally distributed at the 3-week follow-up. Although we found the best transformation to achieve normality was square root transformations, we felt that the square root transformed outcomes possessed little intuitive meaning. Given that the results of our subsequent analyses did not differ between the transformed and non-transformed data, we elected to present only the non-transformed results.

The modified Oswestry Disability Index and the Roland-Morris Disability Questionnaire scores at 3 weeks and 6 weeks were analysed with separate analyses of covariance using the baseline scores as covariates. We examined the effect of intervention over all time points using repeated measures analysis of covariance. All significance tests were two-tailed, with an alpha of 0.05 indicating significance. All analyses were performed on an intention-to-treat basis. To address potential biases due to incomplete follow up, we analysed participants with complete data at all time points and those with data at any time point, using the last known value carried forward to replace missing values.

To elucidate the value of incorporating either cycling or treadmill with body weight support into clinical practice, the number of participants who had improved after intervention on Patient Perceived Benefit, modified Oswestry Disability Index, and ability to walk ≥ 800 metres was also calculated. Odds ratios (95% CI) were used to assess the difference between the groups with logistic regression used for adjusted

Table 2. Mean (SD) of each group, mean (SD) difference within groups, and mean (95%CI) differences between groups for disability and pain scores for the treadmill group (n = 33) and the cycling group (n = 35).

Score	Groups						Difference within groups				Difference between groups *	
	Week 0		Week 3		Week 6		Week 3 minus Week 0		Week 6 minus Week 0		Week 3 minus Week 0	Week 6 minus Week 0
	T	C	T	C	T	C	T	C	T	C	T minus C	T minus C
Disability												
ODI (0 to 100)	33.0 (15.8)	31.8 (14.1)	29.3 (16.5)	25.2 (14.7)	25.9 (16.7)	23.0 (14.2)	-3.6 (-9.8)	-6.6 (-11.2)	-7.1 (-13.5)	-8.8 (-11.0)	3.2 (-1.7 to 8.2)	2.1 (-3.1 to 7.7)
RMQ (0 to 24)	8.2 (4.4)	9.6 (5.0)	7.4 (4.4)	7.4 (4.5)	6.8 (4.5)	6.7 (4.2)	-0.8 (-0.6)	-2.1 (-0.6)	-1.5 (-0.7)	-2.9 (-0.6)	0.9 (-0.7 to 2.4)	0.8 (-0.9 to 2.5)
Pain severity												
VAS (0 to 100 mm)	52 (17)	50 (16)	45 (21)	42 (17)	43 (20)	42 (16)	-8 (-15)	-7 (-17)	-10 (16)	-8 (-19)	1 (-6 to 8)	2 (-5 to 10)

*mean and 95% CI are ANCOVA adjusted for baseline scores; T = treadmill group, C = cycling group, ODI = modified Oswestry Disability Index, RMQ = Roland-Morris Disability Questionnaire, VAS = visual analogue scale

comparisons. Finally, the numbers needed to treat (NNT) and numbers needed to harm (NNH) statistics (Altman 1998) were calculated.

Results

Flow of participants through the trial: Between December 2004 and March 2006, 128 patients were referred, and 81 (63%) fulfilled the inclusion criteria. The two most common reasons for exclusion were an absence of back or lower extremity pain while walking and during sustained (30 s) spinal extension in the quadruped position (n = 24, 51%) and being younger than 50 years old (n = 12, 27%). Thirteen of the 81 eligible patients (16%) elected not to participate in the study, leaving 68 participants to be randomised. Subsequently, 33 participants were randomly assigned to the treadmill and 35 to the cycling group (Figure 1).

The mean age of the 68 participants was 58 years (SD 8); 38 (58%) participants were female. The mean duration of symptoms for the current episode of low back and/or lower extremity pain was 12 weeks (SD 49). Twenty-six (38%) participants reported that their back or lower extremity pain prevented them from walking more than 400 metres. Table 1 lists the participants' characteristics, which did not differ between the groups.

Twelve participants (18%) did not complete the Week 3 measurements (Figure 1). One participant in the treadmill group withdrew due to increased pain during treadmill walking; however, she was still measured and analysed as intention-to-treat. Twenty-one participants (29%) did not complete the Week 6 measurements. There were 25 participants in all (37%) who did not attend on at least one measurement occasion. However, these participants did not differ markedly in their baseline characteristics from the participants who attended on all measurement occasions ($p = 0.50$ to 0.80). Furthermore, the proportion of participants

who did not complete all measurements did not differ between the two groups ($p = 0.20$).

Compliance with trial method: Two participants in the treadmill group did not attend any therapy sessions. The proportion of noncompliant participants did not differ between the treadmill (n = 12, 24%) and cycling (n = 14, 20%) group ($p = 0.76$). There was no difference between groups in the number of therapy sessions attended during the 6-week intervention period ($p = 0.29$). On average, by the last week, participants in the treadmill group walked for 20–30 minutes and participants in the cycling group cycled for 20–30 minutes.

Effect of intervention: Group data for disability and pain outcomes are presented in Table 2 while individual data for the three measurement times are presented in Table 3 (see Table 3 on eAddenda for the complete dataset). There was no difference between the groups in reduction in disability or pain between Week 0 and 3 or between Week 0 and 6. Table 2 shows the results derived from the last value carried forward analysis. The repeated analysis of variance of the mean transformed scores revealed that there was no difference between groups in the overall reduction in disability as measured by either the modified Oswestry Disability Index ($p = 0.44$) or the Roland-Morris Disability Questionnaire ($p = 0.31$). However, it did show that when the groups were combined, they reduced their disability on both measures over time ($p < 0.001$).

At 3 weeks, the treadmill group perceived a benefit two-thirds as often (OR = 0.66, 95% CI 0.18 to 2.41) as the cycling group; and at 6 weeks, half as often (OR = 0.50, 95% CI 0.17 to 1.48) as the cycling group (Table 4). Furthermore, the number needed to treat for participants in the treadmill group to perceive a benefit greater than that perceived by the cycling group was -21 (NNT 5 to ∞ to 7 NNH) at 3 weeks and -8 (NNT 3 to ∞ to 11 NNH) at 6 weeks (Table

Table 4. Number of participants (%) in each group categorised as improved, odds ratio (95% CI) and numbers needed to treat (95% CI) of difference between groups for those categorised as improved.

Category	Week 3				Week 6			
	Groups		Difference between groups		Groups		Difference between groups	
	T (n = 33)	C (n = 35)	OR* Exp relative to Con	NNT Exp relative to Con	T (n = 33)	C (n = 35)	OR* Exp relative to Con	NNT Exp relative to Con
Patient Perceived Benefit (> 'better')	5 (15)	7 (20)	0.66 (0.18 to 2.41)	-20.6 (NNT 4.5 to ∞ to 7.4 NNH)	8 (24)	13 (37)	0.50 (0.17 to 1.48)	-7.8 (NNT 3 to ∞ to 11.2 NNH)
ODI (≥ 33%)	8 (24)	11 (31)	0.49 (0.23 to 2.0)	14 (NNT 3.7 to ∞ to 7.2 NNH)	13 (39)	13 (37)	1.10 (0.41 to 2.98)	44 (NNT 4 to ∞ to 5 NNH)
Ability to walk (≥ 800 metres)	17 (52)	17 (49)	1.13 (0.44 to 2.95)	34 (NNT 5 to ∞ to 4 NNH)	18 (55)	18 (51)	1.14 (0.44 to 2.94)	32 (NNT 3.9 to ∞ to 5 NNH)

* = OR from logistic regression adjusted for age; NNT = numbers needed to treat, NNH = numbers needed to harm; T = treadmill group, C = cycling group, ODI = modified Oswestry Disability Index

4). On the basis of the wide confidence intervals associated with estimates of improvement overall (Table 4), our data are consistent with no difference in improvement between the two interventions.

Given the large amount of missing data at Week 6, a per-protocol analysis was performed on data from participants who attended on both measurement occasions (n = 42). Results from the per-protocol analysis were the same as from the intention-to-treat analysis.

Discussion

In this study we compared the benefits of treadmill with body weight support with cycling, in addition to an exercise program, on disability and pain in individuals with lumbar spinal stenosis. The principal finding of this study was that the two groups did not show any differences that we considered clinically meaningful, at least not immediately after the end of intervention. Given that the 95% CI did not cross the minimal clinically-important change between groups of 8 points on the modified Oswestry Disability Index, this finding can be seen as robust.

Six trials (Johnsson et al 1992, Onel et al 1993, Hurri et al 1998, Amundsen et al 2000, Atlas et al 2001, Simotas 2001) have examined various forms of exercise for people with lumbar spinal stenosis. Comparing our results directly with these studies is difficult because most were uncontrolled trials (Onel et al 1993, Amundsen et al 2000, Atlas et al 2001, Simotas 2001) and in some the interventions were described inadequately (Johnsson et al 1992, Hurri et al 1998). Our findings are consistent with those of Iversen and colleagues (2003), who reported that a 12-week cycling program was associated with an improvement in low back symptoms, as measured using the Spinal Stenosis Scale (Stucki et al 1995, Stucki et al 1996). In this pilot study on 26 older adults, all participants had low back, buttock, and/or leg pain that was exacerbated by passive lumbar extension

in standing. Taken together, our results extend the findings of Iversen and colleagues (2003) to include a younger group of participants with lumbar spinal stenosis, and suggest that bicycle cycling may be a viable intervention for individuals who are extension sensitive.

In lumbar spinal stenosis, reduced walking tolerance is often cited as the reason for seeking medical attention (Stucki et al 1994, Porter 1996). Because treadmill with body weight support provides an unloading force while the participant ambulates on the treadmill, we expected the treadmill group to show greater improvement in walking tolerance than the cycling group; however, this was not the case. Although speculative, an explanation may be that 38% of our participants had only a moderate limitation in walking tolerance at baseline, as determined by the self-reported inability to walk more than 400 metres. Ostensibly, the potential number of participants who could improve their walking tolerance substantially from either intervention was reduced, and the trial was not powered to detect differences in subgroups.

We believe a strength of this study resides in the use of impairment-based inclusion criteria to ensure a more homogeneous sample with regard to symptom presentation. Given the relatively high false-positive findings on imaging for lumbar spinal stenosis in approximately 20% of asymptomatic participants (Hitselberger and Witten 1968, Jensen et al 1994), we included only people who reported pain with walking that was relieved with sitting. Moreover, all participants reported back or lower extremity pain with lumbar extension. The additional inclusion criteria, in our view, enabled us not only to compare the effectiveness of two endurance exercise protocols, but also to examine the effects of a regime of flexion exercises targeted on participants who were extension sensitive. Given that both groups showed a reduction in disability at 3 weeks and 6 weeks (Table 2), we believe our impairment-based inclusion criteria fit well with an important rehabilitation principle

in low back pain (Delitto et al 1995, Brennan et al 2006), which is to match an intervention to a group of participants with similar impairments.

Based on the overall similarity in clinical effectiveness between the two groups, it is reasonable to question whether the improvements seen immediately following our interventions could reflect the favourable natural history of lumbar spinal stenosis (Johnsson et al 1992). As well, our results raise the possibility that cycling and treadmill with body weight support did not add anything to the exercise program. However, we consider this possibility to be unlikely because reviews of evidence (van Tulder et al 2000, Hayden et al 2005, Hayden et al 2005) have consistently supported the use of endurance exercises in the management of chronic back pain. Nonetheless, in the absence of a control group, we can only surmise that the outcomes seen in our study were probably a combination of a treatment effect and the natural course of lumbar spinal stenosis.

We acknowledge four limitations of our study. First, our participants may not be similar to the participants with lumbar spinal stenosis included in most other studies as they were quite young (mean age of 58 years) with a relatively short mean duration of symptoms (12 weeks). Second, we measured outcomes only during and immediately after the intervention period, which might have missed a long-term effect. Although we were primarily interested in the short-term improvement in pain and disability, future trials with longer follow-up periods are required to establish whether the interventions used in our study would result in long-term improvement of symptoms. Third, although there were no statistical differences in baseline characteristics between participants who did or did not provide complete data, the internal validity of our study is limited because the overall response rate was only 63%. In the study by Iversen and colleagues (2003) where exercise bicycles were delivered to the participants' residences, only eighteen (63%) of the original 26 participants completed the 12-week cycling protocol. Taken together, these studies highlight the high dropout rate in studies of exercise in older adults with low back symptoms, and researchers should be aware of this when designing similar trials. Finally, although blinding of therapists would not be possible in a study such as this, the potential for bias may have been reduced if therapists had delivered only one treatment or the other.

In this pragmatic trial comparing the effectiveness of treadmill with body weight support with cycling, when added to an exercise program for individuals with lumbar spinal stenosis, clinical outcomes were similar in the short term. Although our findings tend to suggest that treadmill with body weight support and cycling may be equally useful, we emphasise the preliminary nature of this study because the dropout rate was high. Moreover, we cannot exclude the possibility that the overall improvement seen in our study was partially a function of the natural course of lumbar spinal stenosis.

Footnotes: ^(a)Enraf, Curapuls 419, The Netherlands, ^(b)Chattanooga, Triton T-700, ^(c)Biodex Unweighing System, Biodex Co., Shirley, New York.

eAddenda: Appendix 1 and Table 3 available at www.physiotherapy.asn.au/AJP

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Correspondence: Yong-Hao Pua, Centre for Health, Exercise and Sports Medicine, School of Physiotherapy, The University of Melbourne, 202 Berkeley Street, Victoria 3010, Australia. Email: puayonghao@gmail.com

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