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Effects and underlying mechanisms of unstable shoes on chronic low back pain: a randomized controlled trial

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Abstract

Objective: To investigate the effects that wearing unstable shoes has on disability, trunk muscle activity, and lumbar spine range of motion (ROM) in patients with chronic lower back pain (CLBP).

Design: Randomized controlled trial.

Setting: Orthopedic Surgery Service.

Participants: We randomized 40 adults with nonspecific CLBP either to an unstable shoes group ($n = 20$) or to the control group ($n = 20$).

Intervention: The participants in the unstable shoes group were advised to wear these shoes for a minimum of six hours a day for four weeks. Control group participants were asked to continue wearing their regular shoes.

Outcome measures: Our primary outcome was measurement of back-related dysfunction, assessed using the Roland-Morris Disability Questionnaire. Secondary outcomes included changes in electromyographic (EMG) activity of erector spinae (ES), rectus abdominis (RA), internus obliquus (IO), and externus obliquus (EO) muscles, and changes in lumbar spine ROM.

Results: Between-group analysis highlighted a significant decrease in disability in the unstable shoes group compared to the control (−5, 95% confidence interval (CI) = −8.4 to −1.6). Our results revealed a significant increase in the percentage of RA, ES, IO, and EO EMG activity and in lumbar spine ROM in the unstable shoes group compared to the control group. Moreover, our results showed a significant negative correlation between disability and the percentage of ES, RA, and IO muscle activity at the end of the intervention.

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Conclusion: This study shows that the use of unstable shoes contributes to improvements in disability, which are likely related to increased trunk muscle activity and lumbar spine ROM.

Keywords

Chronic low back pain, electromyography, gait, unstable shoes

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Introduction[AQ: 1]

A commonly prescribed treatment for chronic low back pain is exercise training to strengthen the muscles of the spine and improve postural stability.[1,2] However, one of the main problems with conventional exercise training programs is the rate of noncompliance because of patients' other time commitments, or the need for equipment and/or training personnel.[3,4]

One proposal that has not been entirely explored is the use of unstable shoes, which can help to train trunk muscles during the normal activities of daily living, thus promoting lumbar stability. Previous studies have demonstrated significant improvements in the pain and disability measured in low back pain patients who wore these types of shoes.[3–5] The mechanisms involved in these therapeutic effects are still unclear; however, changes in trunk muscle activity and/or in lumbar spine range of motion could be involved.

This study investigates the effect that wearing unstable shoes has on disability, trunk muscle activity, and angular displacement of the lumbar spine in patients with low back pain, as well as the possible association between all of these variables.

Methods

This randomized controlled trial (NCT02606370) was approved by the University Human Ethics Committee and followed the ethical guidelines set out in the Declaration of Helsinki. All participants read an information leaflet and then signed an informed consent statement. The trial was conducted between January 2016 and May 2016, and participants aged between 18 and 65 years with a diagnosis of nonspecific chronic low back pain lasting at least three months were consecutively recruited from the Orthopedic Surgery Service at the Hospital. Exclusion criteria were body mass index ≥30 kg/m^2, the presence of a spinal tumor or infection, spinal fracture, lumbar radiculopathy, systemic disease, fibromyalgia, previous spine surgery, musculoskeletal injuries of the lower limbs, or previous experience with unstable shoes.

Before the start of the trial, Researcher 1, who was not involved in the selection and inclusion of participants, organized the preparation of numbered, opaque, sealed envelopes containing the group allocation. Researcher 2 generated the random sequence (based on simple randomization) using a computerized random number generator; this was concealed from all the study personnel throughout the study duration. Upon enrollment in the study, 40 participants were randomly assigned either to the unstable shoes (n = 20) or control (n = 20) group. All outcome measurements were recorded at baseline and at the end of the study (four weeks) by two trained physiotherapists who were blinded to the group allocation.

The primary outcome of the study was a change in the degree of measured disability produced as a result of low back pain. The degree of disability was measured (before performing the electromyographic (EMG) and kinematic data tests) using the Spanish version of the Roland-Morris Disability Questionnaire,[6] with a score ranging from 0 (no disability) to 24 (maximum disability).

Secondary outcomes were changes in the percentage of EMG activity in the erector spinae,

Figure 1. Side view of the unstable shoe type used in this study.

rectus abdominis, internus obliquus, and externus obliquus muscles (at four weeks minus the baseline value), and changes in the angular displacement of the lumbar spine in the sagittal plane (mean and maximum range of motion at four weeks minus the mean and maximum range of motion at baseline).

The EMG and kinematic tests were conducted in the Biomechanics laboratory at the University. Both unstable shoes and control group participants were tested under two conditions: unstable (Masai Barefoot Technique (MBT)) and flat shoes (John Smith Classic). Prior to testing, an expert spent 15 minutes instructing all the participants on the correct use of the unstable shoes. Subsequently, all participants spent a 20-minute period to habituate to the shoes by walking on a treadmill (BH Fitness Columbia Pro) at the same speed as the experimental procedure; this allowed them to become familiar with the nature of the measurements.[7] After the familiarization stage, and before data collection, the participants performed submaximal voluntary isometric contractions in order to normalize the muscle EMG assessment, according to recommendations for low back pain patients.[8]

The treadmill tests consisted of 2 (MBT and flat shoe–type conditions) × one-minute walking trials at a walking speed of 1.44 m/s. This specific design criterion (fixed speed instead of preferred movement path) is important because it allows speed-independent identification of the EMG and range of motion characteristics of unstable shoes. The data for both shoe-type conditions were acquired in a random order, and the two tests were separated by a minimum of 15 minutes rest so that the participants would not experience left-over fatigue from the previous test.

The EMG signals of the erector spinae, rectus abdominis, internus obliquus, and externus obliquus muscles were recorded for each participant's right side using a electromyography ME6000s Tester. Surface electrodes were positioned on the muscles according to SENIAM recommendations.[9]

A twin-axis electronic goniometer (TSD130A, Biometrics) was integrated to simultaneously collect plantar flexion and plantar dorsiflexion ankle range of motion data and was used to determine the walking cycles. As previously published,[7] each walking cycle was defined as the time from initial foot contact to the following ipsilateral initial contact. The angular displacement of the lumbar spine was recorded using an electromagnetic tracking instrument (3Space Fastrak, Polhemus, Inc.). We derived the angular displacement of the lumbar spine in the sagittal plane from two sensors strapped in place over the sacrum (S1) and L1. Taking into account the specific placement of the sensors of this study, lower negative values indicate more degrees of lumbar extension.

For all the tests, we collected ankle and lumbar spine range of motion and EMG data from the selected muscles during treadmill walking for a total of 60 seconds. The first 10 walking cycles from the middle 20 seconds onward were then analyzed using MegaWin software for Windows. Mean values for this period of 10 walking cycles were calculated in order to analyze the EMG variables. The amplitude of the EMG data was normalized to the maximum signal collected during submaximal voluntary isometric contractions and is expressed as a percentage. The mean and maximum values (measured in degrees) of the lumbar spine range of motion were also calculated.

Participants in the unstable shoes group were provided with MBT model Afiya 5 unstable shoes (Figure 1) for four weeks. This shoe is characterized by its rounded sole in the anterior–posterior direction and a flexible heel which provides an

Table 1. Participant characteristics at baseline.

	Group	
	Unstable shoes	Control
Age	49.1 (±11.5)	50.6 (±13.0)
BMI (kg/m^2)	25.7 (±3.6)	26.8 (±4.0)
Men/women	8/12	12/8

BMI: body mass index.
Data are mean (±standard deviation (SD)).

unstable base of support. Previous studies[7,10] have suggested that these shoes increase instability in the anterior–posterior and medial–lateral directions. The participants in the unstable shoes group were strongly advised to wear these shoes for a minimum of six hours a day for four weeks. Control group participants were asked to continue wearing their regular shoes during the study period. Both the unstable shoes and control group participants were instructed to maintain their usual levels of daily activity and not to add any additional exercise components.

The desired sample size was calculated by an external researcher and determined a priori—based on a preliminary study—to allow at least 80% power to detect a between group effect of three points on Roland-Morris Disability Questionnaire. This difference was chosen to be consistent with the minimum clinically important difference established for this variable.[11] Thus, the recruitment target was 36 participants (G*Power 3.0.10). The sampling size was increased by 10% to compensate for possible alterations in the statistical significance of the results caused by potential participant dropouts. Therefore, we used a final sample size of a total of 40 participants. The statistical analysis was performed according to the intention-to-treat.

Two-way mixed analysis of variance (ANOVA) tests were used to compare the effects of the study variables on disability, using time (baseline vs four weeks) as the within-group factor and the intervention group (unstable shoes vs control) as the between-group factor. Similarly, two-way mixed ANOVA tests were used to compare the study effects on changes in the percentage EMG activity (erector spinae, rectus abdominis, internus obliquus, and externus obliquus muscles) and changes in the angular displacement of the lumbar spine in the sagittal plane, with test condition shoes (MBT vs flat) as the within-group factor and intervention group (unstable shoes vs control) as the between-group factor.

To determine the independent relationship between disability resulting from low back pain and the EMG activity and range of motion outcomes, we also calculated bivariate correlations for all the participants using the Pearson correlation coefficient. In addition, stepwise linear regression analyses were conducted for the whole sample in order to construct a model to identify independent contributors to the disability resulting from low back pain. Prior to the variable selection, the correlation coefficients between the independent variables and the disability were checked, and only those with a significant correlation were chosen for further analysis.

Results

We screened 62 consecutive patients. A total of 22 subjects were not allocated for randomization because they did not meet the inclusion criteria (20) or declined to participate (2). Table 1 shows baseline characteristics of trial participants. Figure 2 shows the progression of the participants through the trial.

The between-group analysis highlighted a significant decrease in Roland-Morris Disability Questionnaire scores in the unstable shoes group compared to the control group (Table 2).

Comparison of the changes in trunk muscle activity and the lumbar spine range of motion between unstable shoes and control groups during the flat and MBT conditions are also shown in Table 2. All of these comparisons showed significantly higher percentage EMG activity and increased lumbar spine extension values in the unstable shoes group compared to control group.

Associations between the Roland-Morris Disability Questionnaire results at four weeks and the independent variables are summarized in Table 3.

The stepwise linear regression analyses revealed that the change (four months minus the

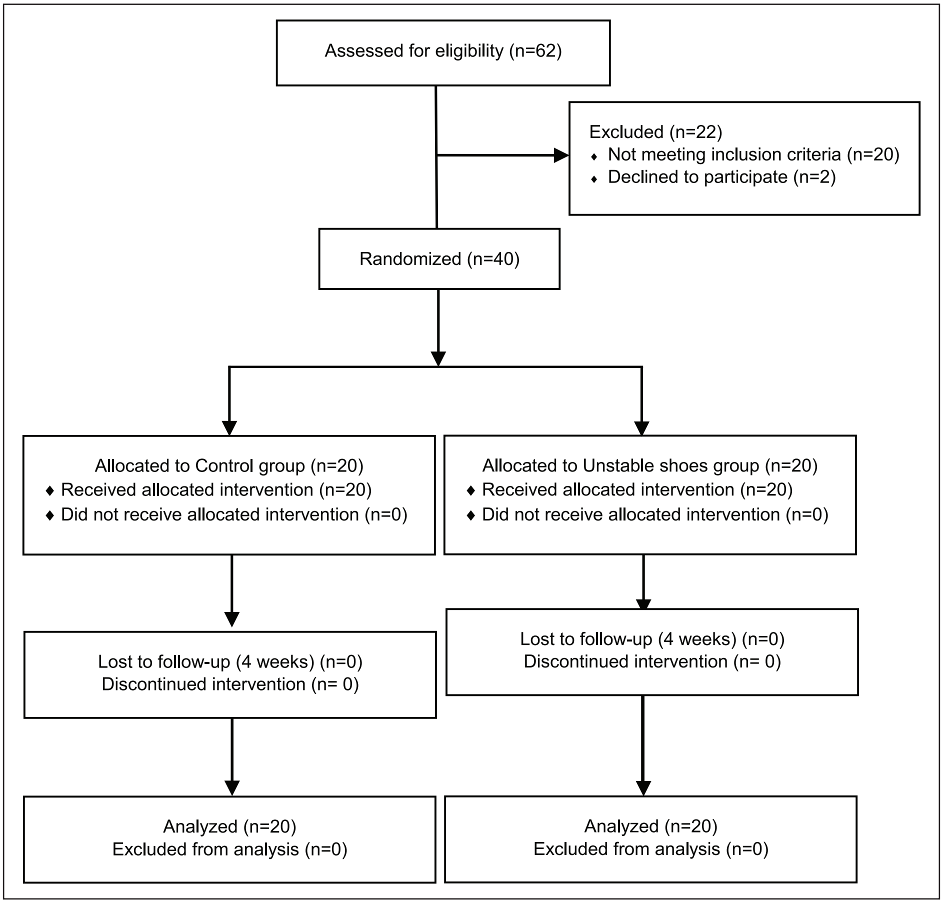

Figure 2. Progression of the participants through the trial.

baseline values) in the percentage EMG activity of the internus obliquus muscle during the flat shoes test condition was the best predictor of the eventual functional disability related to low back pain (Adj. $R^2=0.204$, $\beta=-0.473$, $P<0.05$), and compared with other variables, it explained 22.4% of the variation in low back pain–related functional disability.

Discussion

Our results show that there was a significant decrease in the disability measured in the unstable shoes group compared to the control group. Moreover, the mean difference between groups reached the minimum clinically important difference for this variable,[11] although these results must be carefully interpreted because in this case, the minimum clinically important difference still falls within the confidence interval (CI) boundaries.

These results are consistent with those of Vieira and Brunt,[5] who used the visual analog scale and the Oswestry Low Back Pain Disability Questionnaire to evaluate the effect that wearing unstable shoes for a month had on pain and disability in a sample of 20 nurses. These authors concluded that wearing unstable shoes reduced low back pain and disability and might be helpful as part of the back pain rehabilitation process. However, as these authors state, this study was limited because it implemented a convenience sampling method and

Table 2. Comparison of disability scores between the unstable and control groups at baseline and at four weeks and comparison of electromyographic activity values (%EMG at four weeks minus %EMG at baseline) and lumbar spine sagittal plane range of motion values (degrees at four weeks minus degrees at baseline) between the unstable and control groups during MBT and flat shoes test conditions.

	Outcomes	Group		Unstable minus control	
		Unstable shoes	Control	Diff. (95% CI)	*P* value
	RMDQ (baseline)	8.4 (±4.8)	8.6 (±6.2)	−0.2 (−3.7 to 3.3)	0.909
	RMDQ (four weeks)	5.2 (±4.3)	10.2 (±6.1)	−5 (−8.4 to −1.6)	0.005
Flat shoes test condition	ES (%diff.)	6.3 (±6.8)	−4.1 (±5.2)	10.4 (6.6 to 14.3)	<0.001
	RA (%diff.)	4.9 (±5.7)	−10.3 (±13.0)	15.1 (8.7 to 21.6)	<0.001
	IO (%diff.)	8.9 (±5.7)	−9.7 (±11.5)	18.6 (12.9 to 24.4)	<0.001
	EO (%diff.)	8.6 (±6.3)	−10.7 (±12.7)	19.3 (12.9 to 25.7)	<0.001
	meanROM (°diff.)	−5.0 (±4.1)	4.4 (±5.4)	−9.4 (−12.5 to −6.4)	<0.001
	maxROM (°diff.)	−5.1 (±5)	6.9 (±13.6)	−12 (−18.5 to −5.4)	<0.001
MBT test condition	ES (%diff.)	7.1 (±7.9)	−4.3 (±6.1)	11.4 (6.9 to 16.0)	<0.001
	RA (%diff.)	5.5 (±5.7)	−9.7 (±14.3)	15.2 (8.2 to 22.2)	<0.001
	IO (%diff.)	10.0 (±6.8)	−7.8 (±11.7)	17.8 (11.6 to 23.8)	<0.001
	EO (%diff.)	9.2 (±8.9)	−9.1 (±13.2)	18.3 (11 to 25.5)	<0.001
	meanROM (°diff.)	−5.1 (±5.1)	3.8 (±5.4)	−8.9 (−12.2 to −5.5)	<0.001
	maxROM (°diff.)	−6.7 (±8)	4.4 (±7.2)	−11.2 (−18.5 to −5.4)	<0.001

EMG: electromyographic; MBT: Masai Barefoot Technique; CI: confidence interval; RMDQ: Roland-Morris Disability Questionnaire; ES: erector spinae; RA: rectus abdominis; IO: internus obliquus; EO: externus obliquus; meanROM: lumbar spine sagittal plane mean range of motion; maxROM: lumbar spine sagittal plane maximum range of motion; %diff.: %EMG at four weeks minus %EMG at baseline; °diff.: lumbar spine sagittal plane degrees at four weeks minus lumbar spine sagittal plane degrees at baseline.

recruited only a small number of patients without calculating sample size a priori. In addition, their statistical analysis is unclear and may be limited because it appears they used one-way ANOVA analysis, without studying *time*group* interactions.

Other authors have also analyzed the effects of wearing unstable shoes on low back pain and disability, producing positive results. In another randomized controlled trial, Nigg et al.[4] concluded that unstable shoes can be used to reduce moderate low back pain (measured on a visual analog scale) in a population of golfers. However, the main limitation of this particular study is that authors did not clearly report the inclusion or exclusion criteria (stating that *Forty male golfers with self-reported mild to moderate lower back pain were recruited for this study*), hence the low back pain diagnosis was unclear.

More recently, a randomized controlled trial by Armand et al.[3] concluded that wearing unstable shoes for six weeks significantly decreases pain (measured using a visual analog scale) in health professionals working in a hospital and suffering from chronic low back pain. They also used the Roland-Morris Disability Questionnaire, but unlike us, they reported no significant changes in disability scores. However, it is of note that although no between-group difference was detected, the Roland-Morris Disability Questionnaire score decreased in both the control (−1.3 points) and unstable shoes (−2.4 points) groups. In this study, participants in the control group received new sports shoes, which may have slightly reduced their disability scores and might explain why the difference between groups did not reach statistical significance.

Interestingly, our results revealed a significant increase in erector spinae, rectus abdominis, internus obliquus, and externus obliquus muscle EMG activity in the unstable shoes group compared to the control group (under both MBT and flat shoes test conditions). Furthermore, our results showed a significant negative correlation between disability

Table 3. Correlation coefficients for the Roland-Morris Disability Questionnaire (at four weeks) and independent variables.

	Flat shoes test condition						MBT test condition					
	ES (%diff.)	RA (%diff.)	IO (%diff.)	EO (%diff.)	meanROM (°diff.)	maxROM (°diff.)	ES (%diff.)	RA (%diff.)	IO (%diff.)	EO (%diff.)	meanROM (°diff.)	maxROM (°diff.)
RMDQ	−0.426**	−0.380*	−0.473**	−0.303	0.314*	0.297	−0.387*	−0.333*	−0.398*	−0.144	0.279	0.209

MBT: Masai Barefoot Technique; ES: erector spinae; RA: rectus abdominis; IO: internus obliquus; EO: externus obliquus; meanROM: lumbar spine sagittal plane mean range of motion; maxROM: lumbar spine sagittal plane maximum range of motion; RMDQ: Roland-Morris Disability Questionnaire; %diff.: %EMG at four weeks minus %EMG at baseline; °diff.: lumbar spine sagittal plane degrees at four weeks minus lumbar spine sagittal plane degrees at baseline.
$^{*}P \leq 0.05$; $^{**}P \leq 0.01$.

and the percentage of erector spinae, rectus abdominis, and internus obliquus EMG activity at the end of the intervention, which suggest that trunk muscle changes can explain the improvements in disability that we measured. Accordingly, it is well known that the internus obliquus and externus obliquus muscles are involved in multiple functions, including controlling trunk orientation and stabilizing the pelvis and spine.[12] In addition, the erector spinae and rectus abdominis muscles may be able to generate trunk extensor and flexor moments to control the instability created by the unstable shoes we used in this study (which were characterized by a rounded sole in the anterior–posterior direction).

However, stepwise linear regression analyses revealed that the change (increase) in the percentage EMG activity of the internus obliquus muscle was the best predictor of the eventual functional disability related to low back pain. Effectively, muscles like rectus abdominis and externus obliquus are mostly involved in producing global movements, whereas deeper muscles, including internus obliquus, are essential for stabilizing the lumbosacral spine.[13–16]

Another potential explanation that could help to explain the reduction in disability that we noted was changes in the lumbar spine range of motion in the sagittal plane. Changing the angular displacement of the lumbar spine seems to depend on the abdominal muscles, back muscles, and pelvic/spine ligament function, and this may affect the diagnosis and treatment of low back pain patients.[17] Our results revealed a significant increase in lumbar spine extension values in the unstable shoes group compared to the control group. Moreover, our results showed a significant correlation between the angular position of the lumbar spine and disability (in the flat shoes test condition) at the end of the intervention, which may also suggest that changes in lumbar spine range of motion could explain the improvements in disability we observed.

Finally, we would like to note the limitations of this study. First, it was impossible to blind the participants to their group assignation and so we cannot exclude the possibility that a placebo effect may account for the improvements in functional disability that we measured. However, the concomitant changes in muscle activation and lumbar spine range of motion and its significant association with improvements in disability are evidence against this possibility. Second, the compliance of wearing MBT shoes was not monitored in the unstable shoes group. However, the significant differences in the studied variables between unstable and control groups suggest that the compliance was satisfactory. Finally, although all the participants were asked to maintain any pharmaceutical treatments they were using for low back pain during the duration of the study, we did not specifically monitor this. Thus, we cannot discount the possibility that some subjects may have increased or decreased their pharmaceutical treatments, which would have confounded the effects of the intervention. Nevertheless, this effect, if produced, was likely minimized by the randomized nature of this study.

Despite these limitations, this study is the first to analyze the short-term effects of wearing unstable shoes on disability, trunk muscle activity, and lumbar spine range of motion in patients with low back pain. In summary, our findings show that the use of unstable shoes contributes to improvements in disability, which are likely related to increased trunk muscle activity and lumbar spine extension values.

Future research should investigate in a larger sample of patients with low back pain the long-term effectiveness of this inexpensive treatment option that allows wearers to benefit from the proprioceptive stimuli of training on uneven grounds while performing the activities of normal daily living.

Clinical Messages

- The use of unstable shoes contributes to improvements in disability in chronic lower back pain patients.
- These improvements are likely related to increased trunk muscle activity and lumbar spine range of movement.

Declaration of Conflicting Interests

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