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Original article

Effects of unstable shoes on chronic low back pain in health professionals: A randomized controlled trial



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ABSTRACT

Objective: The aim of this study was to evaluate the effectiveness of unstable shoes in reducing low back pain in health professionals.

Methods: Of a volunteer sample of 144 participants, 40 with nonspecific chronic low back pain were eligible and enrolled in this study. Participants were randomized to an intervention group, who wore unstable shoes (model MBT Fora), or a control group, who wore conventional sports shoes (model Adidas Bigroar). The participants had to wear the study shoes during their work hours, and at least 6 hours per workday, over a period of 6 weeks. The primary outcome was low back pain assessed on a Visual Analog Scale. The secondary outcomes were patient satisfaction, disability evaluated using Roland-Morris questionnaire and quality of life evaluated using EQ-VAS.

Results: The intervention group showed a significant decrease in pain scores compared to the control group. The rate of satisfaction was higher in the intervention group (79%) compared to the control group (25%). There was no significant difference for the Roland-Morris disability questionnaire score and the EQ-VAS scale.

Conclusions: The results of this clinical trial suggest that wearing unstable shoes for 6 weeks significantly decreases low back pain in patients suffering from chronic low back pain but had no significant effect on quality of life and disability scores.

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1. Introduction

Low back pain (LBP) is a very common health problem [1]. LBP is also a very common complaint among hospital workers and health-care professionals [2]. The annual prevalence has been reported to be between 40 and 50% among nurses [3] and two thirds of hospital employees complained of spinal pain during the previous year [4]. Pheasant and Stubbs observed that health professionals who suffer from back pain have 30% higher rate of absenteeism from work compared to the rest of the workforce [5] resulting in an important societal burden [4,6]. Numerous intervention strategies exist for

the management of LBP among which drugs, spinal manipulation, rehabilitation exercises, and surgery are the most widely used [7,8]. Exercise training to strengthen spine muscles is frequently prescribed for LBP and is widely recommended [9]. However, a recent systematic review on the effectiveness of physical and rehabilitation interventions for chronic nonspecific low back pain showed a limited improvement in the intervention group compared to control group [7]. The main criticisms against conventional exercise training studies are the rate of non-compliance due to time commitments, the availability of equipment and the personal high degree of motivation required to sustain the training sessions [10].

Unstable shoes (shoes incorporating a rounded sole to increase instability in the anterior–posterior direction) have been advocated by the brand Masai Barefoot Technology (MBT) since 1996 to reduce LBP, to improve posture and balance, and to increase muscle activity. Nigg et al. argued that these unstable shoes could be an optimal solution for exercise intervention as they are not time consuming to

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use and do not require any equipment apart from the shoes themselves, and can be used in daily life activities [11]. Moreover, in a non-randomized controlled trial Nigg et al. showed a significant reduction of LBP among golfers wearing these types of shoes [11].

Biomechanical studies investigating the effects of unstable shoes during standing, showed a greater excursions center of pressure during standing [12,13], an increased muscle activity of ankle muscles [12–14]. During walking, studies reported an increased dorsiflexion angle at initial contact [12,15], an increased spine movement [16], a shift in pressure towards the front of the foot [17], an increased muscle activity of ankle muscles [15] and low back muscles [16]. Therefore, as unstable shoes modify biomechanical gait and posture parameters at the lower limb and spine, and could reduce LBP in golfers, we hypothesized that employees with a nonspecific LBP, wearing unstable shoes would significantly reduce the level of LBP and related functional disability. Therefore, the aim of this study was to evaluate the effectiveness of unstable shoes in reducing LBP in health professionals.

2. Methods

2.1. Standard protocol approvals, registrations, and patient consents

This study protocol was approved by the ethical committee at Geneva University Hospitals and registered in June 2011 at ClinicalTrials.gov (NCT01384071). All subjects gave written informed consent according to the ethical standards set forth in the declaration of Helsinki (1983).

2.2. Participants and recruitment procedure

2.2.1. Enrolment procedure

Recruitment was done through internal hospital announcements, via an institutional web site and via notice boards.

2.2.2. Eligibility criteria

To be included, participants had to be aged between 30 and 65-years-old, to work in the hospital for at least 80% of the time and to work in a position that required to walk or to be standing at least 50% of working time and to suffer of chronic LBP ($\geq 3/10$ VAS – average pain of the last week). Participants with disabling pain in any other body parts, or recent spine or lower limb surgery were excluded. We further excluded subjects with lumbar radiculopathy, neurological or orthopedic problems affecting the lower limbs, gait and balance disturbances. Finally, participants were excluded if they walked with an assistive device or were unable to walk more than 100 meters. In addition participants who already wore unstable shoes were excluded from this study.

2.2.3. Testing procedure for participant's inclusion

All interested participants were screened for inclusion and exclusion criteria via a first telephone call. Following this, each eligible participant was invited for a clinical examination in the laboratory. During this examination, an experienced clinician performed a basic neurological examination to exclude lumbar radiculopathy. Each participant evaluated the average pain level over the last week on a VAS. Eligible participants were included in the study.

2.3. Randomization and group allocation

Eligible participants were randomized via a computer-generated list into two groups:



Fig. 1. Intervention shoes (a) and control shoes (b).

- an intervention group (IG) that wore unstable shoes;
- a control group (CG) that wore conventional sports shoes.

The allocation was centrally generated and concealed. To limit a placebo effect, participants were not aware of the study hypothesis and their group allocation (control or intervention). All participants were informed that both types of shoes could have a positive effect on their back pain. Both groups were required to wear the shoes every workday for at least 6 hours/day after the first week, over a period of 6 weeks.

2.4. Sample size

A previous study on golfer showed a reduction of back pain of 17.5 (SEM: 3.03) on a 0 to 100 VAS pain after 6 weeks of wearing unstable shoes [11]. Based on this result and to be conservative, we calculated that a 10 (SD: 10) points difference between treatment and control groups would require 40 patients to have 80% chance to detect a difference in LBP, with an alpha error of 0.05%, including a 20% dropout.

2.5. Intervention

At the first evaluation, both groups of participants received a new pair of shoes according to their allocation. Participants in the IG ($n = 20$) received unstable shoes (model MBT Fora, athletic collection SS 2010, Masai Barefoot Technology, Switzerland) (Fig. 1a) and participants in the CG ($n = 20$) received conventional sports shoes (model Adidas, Bigroar, Germany) (Fig. 1b). An expert instructed all of participants during 15 minutes how to use the shoes correctly and advised patients to progressively increase the time wearing the shoes, starting with 2 hours per day and increasing the duration by 1 hour every day. After 1 week, participants were asked to wear the shoes for a minimum of 6 hours a day during their time spent at work.

2.6. Testing protocol and measurements

The outcome measures were assessed at baseline and after 6 weeks by the same evaluator. Moreover the participants fulfilled a diary logbook to indicate the level of LBP and to report any incidents such as falls or experienced instability.

2.6.1. Primary outcome

The pain intensity at the pre- and post-intervention was recorded on the VAS. The scale is determined with a line of 10 cm, with extremities of minimum (0) to maximum (10). As LBP fluctuates during a period of time [18], LBP was assessed with different scores. Firstly, each participant reported the mean intensity of LBP for the last 24 hours. Secondly, pain was assessed during gait analysis in the laboratory while walking barefoot and while walking with allocated shoes. Finally a pain diary was provided and participants were invited to rate their pain at the end of the workday based on the average amount of pain during the workday. We also predefined responders as participants who achieved a reduction of

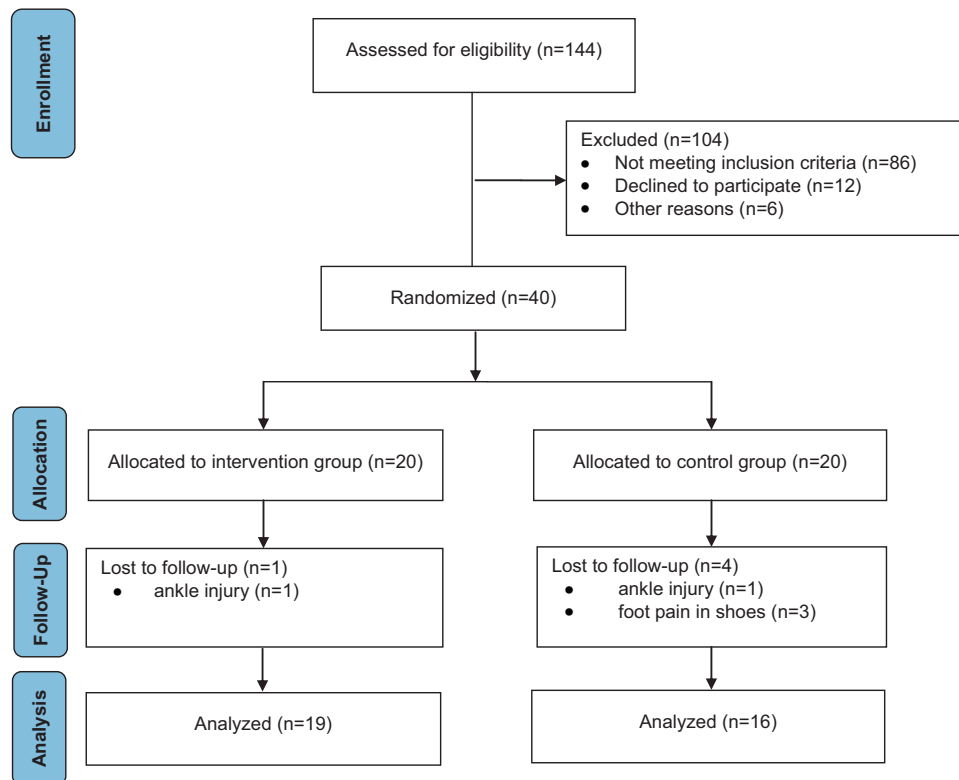


Fig. 2. Flow chart with detailed description of recruitment.

at least 2 points [19] for each pain scale (pain during last 24 h, pain while walking with shoes, pain while walking and pain reported in the daily logbook).

2.6.2. Secondary outcomes

Functional disabilities related to LBP were assessed with the validated French translation [20,21] of the Roland-Morris disability questionnaire (RMDQ) [22]. RMDQ is a 24 items questionnaire (yes/no answer) exploring 24 activities limitation due to LBP. The score ranges from 0 (no limitation) to 24 (full disability). Quality of life was assessed with EQ-VAS scales, which represents health status for the moment of evaluation in the range from 0 (extremely bad) to 100 (excellent quality of life) [23]. A 5-point Likert scale satisfaction question regarding the efficacy of LBP treatment using shoes was given to the participants at the last evaluation.

2.7. Data analysis

Statistical analyses were performed using Statistica 10.0 (Stat-Soft Inc., Tulsa, OK, USA). Means and standard deviations of variables were calculated for descriptive statistics and all data were checked for normality using the Kolmogorov–Smirnov test and for equal variance using the Levene test. The mean change in the IG was compared with the mean change in the CG to determine the effect of unstable shoes on LBP (*t*-test or equivalent non-parametric test: Mann-Whitney U for non-normally distributed outcomes). Differences in proportions between groups were compared with the Fisher exact test. The level of significance was set at $P < 0.05$. An intention to treat analysis with imputation by last observation carried forward was performed when dropouts occurred.

3. Results

A total of 144 subjects showed an interest in participating in this study, of which 40 were randomized. Participants had similar baseline characteristics in both groups for pain, professional and physical activities characteristics (Table 1).

A flow chart (Fig. 2) summarizes the recruitment and the evaluation process. During the 6-week intervention period, there were five dropouts, one in the intervention and four in the CG. One in each group was related to ankle injury (malleolus fracture), occurring during leisure time activities, thus not related to the studied shoes; and three dropouts in the CG were related to a foot pain in the external part of shoes. After 6 weeks, 35 participants reached the end of the intervention and underwent the follow-up evaluation in the 7th week. There were no significant differences in pain scores obtained at baseline between dropouts and other participants ($P > 0.05$). The median and quartile range were respectively for dropouts and other participants for the different pain scores: 24 hours 4.8 [1.9] vs. 3.9 [2.7], in-laboratory pain while walking barefoot 4.0 [4.0] vs. 2.2 [4.0] and with shoes 3.0 [2.0] vs. 1.5 [2.5].

3.1. Primary outcome

Table 2 and Fig. 3 present different LBP pain score assessments (during the previous 24 hours, in-laboratory pain while walking barefoot and with shoes, pain reported in the daily logbook) at inclusion and follow-up visit. Average pain in the last 24 hours was assessed for all participants. There were three missing data sets for pain during walking. The compliance rate for the pain diary was 77% (27 of 35 participants, 5 participants in the IG and 3 participants in the CG did not fulfill correctly the diary logbook).

The IG showed a greater improvement than the CG for all pain scores. The difference between baseline and follow-up for the pain scores: in-lab waking barefoot, in-lab walking with shoes and in

Table 1
Description of participants' characteristics at baseline.

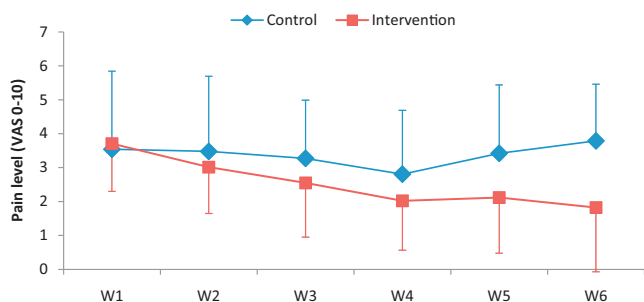
	Intervention group (n=20) n or Mean ± SD (range)	Control group (n=20) n or Mean ± SD (range)
General characteristics		
Gender (female)	19	17
Age (years)	44.5 ± 7.9 (31–58)	46.8 ± 8.8 (32–62)
Height (cm)	162.1 ± 9.1 (144–180)	164.8 ± 7.8 (155–187.7)
Weight (kg)	66.2 ± 11.3 (50–90)	71.6 ± 13.7 (52.5–106)
Body mass index (kg/m ²)	25.1 ± 3.9 (20.1–32.5)	26.5 ± 5.5 (19.1–40.8)
Pain		
Pain last 24 h	4.2 ± 1.9 (1.0–7.4)	4.1 ± 1.8 (0.6–7.6)
In-lab pain during walking with shoes	1.9 ± 1.6 (0–5)	2.3 ± 1.6 (0–5)
In-lab pain during barefoot walking	2.3 ± 1.9 (0–6)	2.7 ± 2.1 (0–7)
Pain killers intake (n)	7	7
NSAIDs (n)	7	6
Muscle relaxants (n)	1	1
Opioids (n)	0	2
Low back pain before this episode (n)	20	18
Pain duration (current episode)		
<7 weeks (n)	4	5
7 weeks–3 months (n)	1	3
3 months–6 months (n)	5	2
6 months–18 months (n)	4	4
>18 months (n)	6	6
Employment status		
Percent of employment (%)	92 ± 8.9 (80–100)	95 ± 8.2 (80–100)
Earlier sickness leave due to low back pain (n)	5	11
Working at night (n)	7	9
Employment type		
Medical doctor (n)	0	1
Nurses (n)	6	6
Nurses assistants (n)	8	5
Midwives (n)	1	4
Administrative staff (n)	1	0
Technical staff (n)	4	4

SD: standard deviation; NSAIDs: non-steroidal anti-inflammatory drugs.

Table 2
Low back pain intensities, functional disability and quality of life at baseline and follow-up for the intervention and control group. Statistical test comparisons between groups were performed on changes over time from baseline to follow-up.

	Intervention group		Mean ± SD	Control group		Mean ± SD	P values(t-test)
	n	Baseline		n	Baseline		
Pain							
Last 24 h (VAS 0–10)	20	4.3 ± 1.9	2.8 ± 2.3	20	4.1 ± 1.8	3.5 ± 2.2	0.199
In-lab walking barefoot	18	2.3 ± 2.0	0.8 ± 1.1	19	2.7 ± 2.1	2.4 ± 2.0	0.037
In-lab walking shoes	18	1.9 ± 1.6	0.3 ± 0.8	19	2.3 ± 1.6	2.4 ± 1.6	0.001
Daily logbook	14	3.7 ± 2.3	1.8 ± 1.7	13	3.5 ± 1.4	3.8 ± 1.9	0.005
Functional disability							
Roland-Morris (0–24)	20	7.5 ± 3.2	5.1 ± 4.9	20	7.6 ± 3.1	6.3 ± 3.5	0.287
Quality of life							
EQ-VAS (0–100)	20	79.0 ± 12.7	81.4 ± 15.5	20	76.6 ± 13.4	79.8 ± 8.4	0.867

SD: standard deviation; VAS: Visual Analog Scale.

**Fig. 3.** Low back pain assessed for 6 weeks with a daily logbook.

the diary showed a statistically significant difference ($P < 0.05$) between the two groups (IG and CG). Only the pain score during the last 24 h was not significant between the two groups ($P = 0.199$).

Although all participants had a mean pain score for the last week ≥ 3 at inclusion, as required in the eligibility criteria, they could have other pain score (e.g. in-lab pain while walking barefoot) lower than 2. In line with the predefined definition of responders (a decrease of at least 2 points), computation of responders' rate had thus to be limited to participants with baseline score ≥ 2 for this specific score. The percentage of responders was higher in the IG compared to the CG for all pain scores (pain during last 24 h: 56.25% [9/16] vs. 33.3% [6/18] $P = 0.16$; pain while

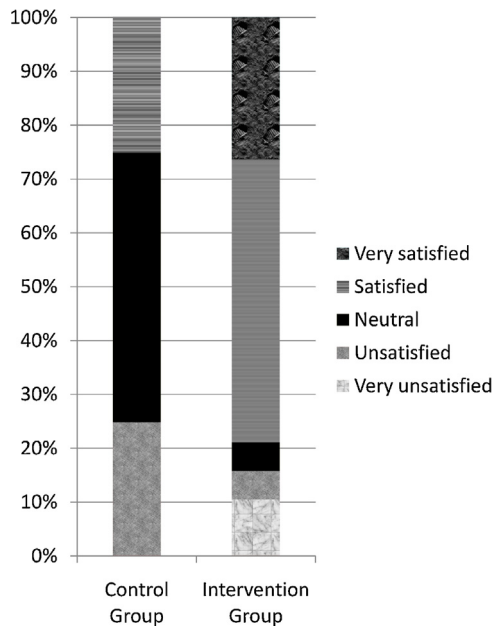


Fig. 4. Pain management satisfaction of the participants at the follow-up.

walking with shoes 80% [4/5] vs. 27.3% [3/11], $P=0.08$; pain while walking barefoot 100% [8/8] vs. 27.3% [3/11], $P=0.002$ and pain reported in the daily logbook: 77.8% [7/9] vs. 7.8% [1/13], $P=0.001$).

3.2. Secondary outcomes

Comparing baseline and follow-up evaluations, the RMDQ score reduced in both groups (1.3 points for CG and 2.4 points in IG). However, no between group difference could be detected ($P=0.287$) (Table 2). There was no significant difference in EQ-VAS scale between the mean change in the IG and the mean change in the CG ($P=0.867$).

Satisfaction result is illustrated on Fig. 4. The rate of satisfaction (satisfied and very satisfied) was 79% in the IG compared to 25% in the CG ($P=0.002$).

4. Discussion

The objective of this RCT was to evaluate the effect of unstable shoes among working health professionals suffering from chronic LBP. The group wearing unstable shoes for 6 weeks showed a superior reduction in pain compared to participants wearing control shoes. The difference was statistically significant for self-reported pain in a diary logbook and pain during walking with unstable shoes and barefoot. A trend was observed for mean pain in the last 24 hours but this result was not statistically significant. In addition, the proportion of responders (predefined as a clinically meaningful reduction of 2 points in VAS pain scores) for all the pain scores and “satisfaction with the pain management” were higher in the IG compared to the CG. This is the first study that showed a significant reduction of LBP in health professionals by wearing unstable shoes. In golfers with chronic LBP, in a non-controlled study, Nigg et al. reported a similar amount of pain reduction (1.75/10 points) after 6 weeks of using unstable shoes [11]. Our results are promising compared to those reported in recent reviews on physical and rehabilitation interventions for LBP [7]. They reported that most of the studies did not reach a difference between IG and CG larger than 10%. Our results showed a difference greater than

20% in all the pain scores, which is defined as a clinically relevant reduction [7].

The initial proposed mechanism for this decrease in LBP is the modification of posture during standing and walking [11,15,24] and more specifically at the pelvis and trunk level [16]. Future research should investigate mechanisms of action of unstable shoes for chronic LBP by identifying posture, gait and muscles activity modifications that could explain reduction of LBP. The present study found no effect on functional disability and on quality of life after the intervention. The absence of a positive effect could be related to the short time of follow-up (6 weeks). Whynes et al. reported that quality of life (EQ-5D index) is less responsive than instruments specific to pain measurement [25]. There were however important differences between the 2 groups in the rate of satisfaction. The most striking difference was the absence of “very satisfied” participant in the CG whereas it was expressed by half of the participants in the unstable shoes group. In addition, there was an absence of “very dissatisfied” in the CG compare to two in the unstable shoes group. It is apparent that unstable shoes seem to induce a more extreme reaction (whether satisfied or not) compared to usual shoes.

As obesity has been identified as a risk factor of low back pain [26], a post-hoc analysis was conducted to explore if obese participants had a different evolution than non-obese participants. Two obese participants (BMI > 30) were included in each group. Due to small numbers, a statistical analysis could not be performed. However, an increase in the different pain scores was reported for the two participants in the CG while a decrease was reported for the two participants in the IG. Studies with a larger number of obese patients should be conducted to confirm these preliminary results.

The major strength of this study was the use of a RCT design to assess the effects of unstable shoes on a chronic LBP population. However, this study has also some limitations. As for most trials that do not investigate drugs, double blinding design was impossible. Albeit participants were not aware that one type of shoes was considered as control shoes and great care was taken to present the “control” shoes in the same way as the intervention shoes, we cannot fully exclude that some of them guessed whether they were allocated to an intervention or a control group. In addition, as the study was conducted in a single institution, there is a potential for a contamination, with some participants exchanging their opinion with others on an observed effect related to the shoes they were wearing. However, as more than 11,000 individuals are working in the institution the risk is relatively low. There is also a lack of generalizability as this study was conducted in a single institution; and on professionals that spent most of their working time walking or standing. This study is as a proof of concept study. The length of follow-up was chosen based on a previous study showing that an effect could already be detected after 6 weeks [11]. However, as with any chronic condition, additional studies with longer follow-up are required before definite conclusion can be drawn. Lastly, the compliance of using shoes (control or intervention) and the compliance with instructions (progressive wearing time, only at work) were only assessed with a logbook.

In summary, we found that the group wearing unstable shoes for 6 weeks showed a superior reduction in pain compared to participants wearing control shoes. The reduction of pain was the most effective during walking with the unstable shoes. Additionally, the rate of satisfaction for pain management and the number of responders were higher in the group wearing unstable shoes. However, the intervention had no effect on functional disability and on quality of life on a period of 6-week. Future studies are needed to determine the effect of unstable shoes on a longer period, on other and larger populations and to determine the profile of responders.

Disclosure of interest

The company Masai Barefoot Technology has offered the shoes for all the participants. Masai Barefoot Technology has not in any way influenced the study design, the measurement procedures, the data analysis, or the interpretation of the results.

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