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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.

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:

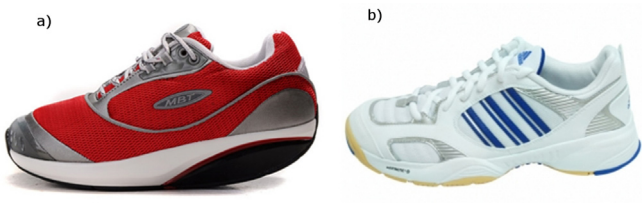

Fig. 1. Intervention shoes (a) and control shoes (b).

- 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