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ORIGINAL ARTICLE

Orthotic insoles do not prevent physical stress-induced low back pain

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Abstract Orthotic insoles are suggested to prevent low back pain. This randomized controlled study assessed if customised orthotic insoles prevent low back pain. Healthy military conscripts ($n = 228$; mean age 19 years, range 18–29) were randomly assigned to use either customised orthotic insoles (treatment group, $n = 73$) or nothing (control group, $n = 147$). The main outcome measure was low back pain requiring a physician visit and resulting in minimum 1 day suspension from military duty. Twenty-four (33%) treated subjects and 42 (27%) control subjects were suspended from duty due to low back pain ($p = 0.37$; risk difference 4.3%; 95% CI: −8.7 to 17.3%). Mean suspension duration was 2 days (range 1–7) in both groups. Four (5%) treated subjects and eight (5%) control subjects were released from duty due to persistent low back pain ($p = 0.92$; risk difference 0%; 95% CI: −6 to 6%). Use of orthotic insoles is therefore not recommended to prevent physical stress-related low back pain.

Keywords Prevention · Lower back pain · rct

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Introduction

Low back pain (LBP) is a common clinical entity among adolescents and adults [5, 6, 9, 10]. The prevalence of LBP is highest in middle age, but high occurrence figures of LBP have also been reported among adolescents and young adult populations [1, 2, 4, 14, 15].

Orthotic insoles are often used with the aim to prevent musculoskeletal disorders such as lower limb overuse injuries and LBP [3, 11, 16]. Several manufacturers advertise the benefits of orthotic insoles, claiming that musculoskeletal overuse injuries, including LBP, can be avoided using orthotic insoles. The proposed preventative function of orthotic insoles is based on two functional mechanisms of orthotic insoles. First, insoles provide a cushion that absorbs shock transmission to the lower limbs and, second, insoles compensate for biomechanical deficiencies of the foot, such as excessive pronation and leg-length discrepancy, which also affect core stability and lumbar vertebrae.

A recent Cochrane review assessed the effect of using orthotic insoles to prevent LBP [11]. Only six randomised controlled trials were found in the literature and the authors concluded that orthotic insoles do not prevent LBP [11]. In addition, a review by Burton and coworkers [2] suggests that insoles do not prevent low back pain. These studies, however, had several limitations: the interventions were heterogeneous, study populations were small, and the outcome measures varied [2, 11]. Some contradictory findings were also reported. For example, Shabat and coworkers [13] suggested that LBP, evaluated by a questionnaire, can be reduced using insoles. To address the weaknesses of the previous studies, we designed a randomised controlled trial to evaluate whether orthotic insoles are useful towards the prevention of LBP in a healthy young adult population with controlled physical exposure.

Methods

Study design

The present study was a part of the EIPM (effectiveness of insoles in preventing musculoskeletal disorders) study protocol. The two arms of the EIPM study aimed to assess the effectiveness of orthotic insoles in the prevention of musculoskeletal disorders related to physical stress (i.e., lower limb overuse injuries and LBP). Study subjects included a healthy young adult population with 18–29 years of age (mean, 19 years) who started their 9-month military service period in the Finnish Defence Forces in January, 2007. The study took place in the Santahamina Garrison's rifle company in Helsinki, Finland, and the first 230 conscripts in the rifle company were invited to participate in the study.

All the subjects had passed their entry medical examination performed by a physician and were considered healthy. Participants were excluded from the study if they already had insoles or if they had ever used any kind of orthotic insoles prescribed by a physician or a physiotherapist ($n = 8$). Subjects with a prior history of LBP were excluded from the study and patients with major orthopaedic or medical conditions (e.g., diabetes, inflammatory arthritis, previous severe trauma) were excluded before even entering the military service.

As military service is compulsory for males in Finland and 75–80% of the men in a specific age group complete their military service, the military conscript sample is considered generalisable to the young adult male population exposed to physical activity. Female conscripts voluntarily participate in the military and represent only a small percentage of the total conscript population; therefore we excluded women from the study analysis.

Randomisation and treatment

The participants were allocated to have either orthotic insoles (treatment group) in their normal army ankle boots or no insoles in their normal army ankle boots (control group), according to a computer-generated random allocation sequence (Fig. 1). The study protocol was previously described in a report on the EIPM study arm that assessed the effectiveness of orthotic insoles in preventing lower limb overuse injuries (paper in press). The customised insoles were made by a single manufacturer (Thermo + Camel) and they were standardised for the whole study. They were fabricated from firm-density polyethylene, and the hard plastic shell was three-quarters the length of the foot. The insole was strong enough to fill the arch area, thus providing support to the mid foot. The insoles were customised for each individual by heating the polyethylene and having the individual stand or walk on the insole, which resulted in the insole assuming the shape of the foot. A single professional nurse individually customised all the insoles.

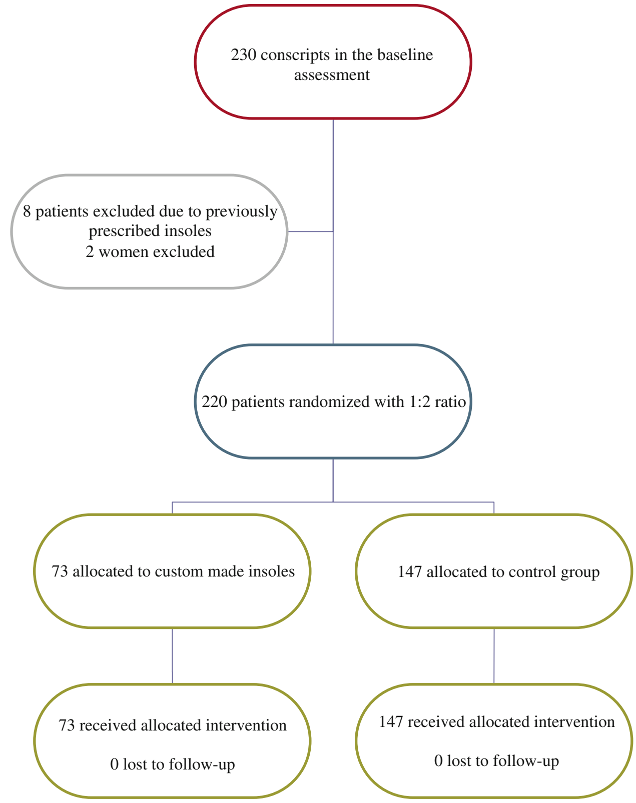

Fig. 1 Flow of participants through trial

The participants were required to use these insoles in their ankle boots during daily service time. The control group was advised to use ankle boots without insoles in the normal manner. The allocation sequence was concealed from the researchers and health care personnel. The participants were considered to have entered the study at the moment their allocations were seen by the researcher. The institutional review board accepting this study was the Medical Ethics Committee of the Finnish Defence Forces. This study was registered as number NCT00922246 at http://www.clinicaltrials.gov.

Baseline measurements

All study subjects had undergone a clinical examination by a physician. Baseline statistics collected included age, measured height and weight, and data on the background variables, such as medical history and physical fitness. Body mass index was calculated. All study subjects underwent physical fitness tests during the first 3 weeks of service performed according to the protocol of the Finnish Defence Forces [12]. Aerobic fitness was measured using the distance covered in a 12-min run. Five measures of muscle strength (horizontal jump distance, and number of sit-ups, push-ups, pull-ups, and back-lifts) were obtained with values ranging from 0 to 3 points, and a muscle strength score was calculated as the sum of these five scores [8].

Clinical protocol

Physical stress exposure

At the beginning of military service, all study subjects participated in a basic training period of 8 weeks, which included various physical activities such as marching, cycling, drill training, and combat training in combat gear. The intensity of military training is structured to increase gradually, and includes an average of 17 h/week of physical training. In addition, conscripts voluntarily perform various physical exercises, such as jogging, team sports, and circuit training for 3–6 h/week, during which they used their personal jogging shoes. The participants were permitted to use the insoles only in their military ankle boots. After the first 8 weeks, the amounts of moderate and high-intensity physical training were maintained at approximately the same level. During the first 6 months of military service, conscripts were expected to complete approximately 450 h of instructed physical training (19 h/week). Approximately 20–40% of conscripts participated in sports during their leisure time.

Outcome measures and follow-up

The main outcome measure in the present study was LBP requiring a visit to the physician and suspension from duty for at least 1 day. LBP included such clinical diagnoses as unspecified LBP and sciatica. The physician was blinded to the treatment, although it is possible that the physician may have seen the insoles in the participants' shoes. A physician based the clinical diagnosis of LBP on clinical examination as well as radiographic studies if they were considered necessary. The secondary outcome in the present study was premature release from military service due to LBP as recommended by a physician.

The follow-up period started on the day the study participants were allocated to either the insole or control group, and ended after 6 months of service or on the day of premature release from military service. Study participants were examined by a physician at the time of study enrolment and after the 6-month follow-up period.

Sample size

The statistical analyses were conducted based on the intention-to-treat principle. The sample size was sufficient to allow us to identify a 50% reduction in the occurrence of LBP in the insole group compared to the control group. Based on previous studies and the authors' unpublished observations, we expected a baseline LBP occurrence of 40% [7]. A total of 192 participants (64 in the insole group and 128 controls) were needed with a power of 80% and an alpha of 0.05. Assuming an attrition of 10%, a minimum of 210 conscripts (70 in the insole group and 140 in the control group) were required to detect an effect of the intervention.

Statistical analyses

Our analysis included all conscripts who were allocated to the insole group or control group, whether or not they had been prematurely released from duty. We compared the proportion of participants absent from duty due to LBP in the insole group to the number of participants absent from duty in the control group by two-way tables and a logistic regression model with 95% confidence intervals (95% CI). The proportions of participants prematurely released from duty were analysed by two-by-two tables, and due to the small number of cases, Fischer's test was used. The duration of absence from duty due to LBP between the groups was evaluated with an independent sample, two-tailed *t* test. For the statistical analyses, SPSS for Windows 15.0 was used.

Results

A total of 220 conscripts was randomised in the study and all of them were included in the analyses (Fig. 1). Table 1 shows the characteristics of the subjects in both groups. Compliance in using the custom made insoles was 80% at the follow-up, based on self-report.

Twenty-four (33%) of the participants in the insole group were suspended from duty due to LBP compared to 42 (27%) in the control group ($p = 0.37$; risk difference 4.3%; 95% CI: −8.7 to 17.3%). Mean duration of suspension was 2 days (range 1–7) in both groups ($p = 0.54$).

Four participants (5%) in the insole group were prematurely released from duty due to a diagnosis of LBP.

Table 1 Baseline characteristics

Baseline characteristics	Insole group ($n = 73$)	Control group ($n = 147$)
No. of patients	73	147
Mean age (years)	19	19
Sex: male	73	147
Height	179	180
Weight	79	79
Body mass index, mean	24.7	24.4
12-min running test (m), mean	2,570	2,560
Muscle strength score[a], mean	8	8

[a] Tests used by the Finnish Defence Forces. Includes five measures of muscle strength (distance of horizontal jump, number of sit-ups, push-ups, pull-ups, and back-lifts), obtained with values ranging from 0 to 3 points

Eight (5%) participants in the control group were prematurely released due to LBP ($p = 0.9$; risk difference 0%; 95% CI: −6 to 6%). The clinical diagnoses included scoliosis, spondylolysis, spondylolisthesis, lumbar disc disease, and unspecified LBP.

When physical fitness (12-min running test and muscle strength) were taken into account in a logistic regression model, the odds ratio for LBP in the insole group was 0.7 (95% CI: 0.4–1.4) compared to the control group.

Discussion

In our study, primary prevention of LBP among healthy male adults was studied using orthotic insoles. The use of orthotic insoles did not prevent sick days taken due to LBP. In addition, insoles did not prevent premature release from duty due to a diagnosis of LBP. Thus, the main finding of the present study was that orthotic insoles do not prevent LBP related to exposure to physical stress. Although there was no observed effect of using orthotic insoles, LBP resulted in a significant clinical entity leading to absence from service among the study subjects.

A recent study described the lifetime prevalence of severe LBP in males aged 18–29 to be 13% in a sample of 7,300 military conscripts [10]. To prevent LBP, some studies have suggested orthotic insoles, but most studies have concluded that using insoles is not associated with a lower rate of LBP [2, 11]. We detected no benefit of using orthotic insoles for preventing LBP in young male adults. The groups were comparable and as all the study subjects were clinically examined by a physician and considered to be healthy adults with equal exposure to physical stress, the sample was not mixed with variables such as a wide age range and degenerative diseases of the lower extremity or pre-existing intervertebral disc disorder.

A limitation of the study was the lack of female study subjects. We excluded women from the study to avoid bias resulting from an inadequate female sex sample size. In addition, due to the study setting, our results can be generalised only to the healthy adult male population. We did not collect any clinical scores related to LBP. At the time of the study enrolment, the subjects were considered healthy based on clinical examination and the lack of physical complaints or deficiencies recorded at that time. As the main outcome measure included suspension from duty due to LBP diagnosed by a physician, we focused on objective evaluation of the study subjects' ability to participate in physical activities. Compliance in using orthotic insoles was slightly lower than expected, but 80% of the subjects in the insole group reported using the insoles. In addition, it must be taken into account that the insoles used did not correct malpositions or deformities of the foot, but were rather made as an imprint of the foot. Insoles of this kind are widely used, however, to prevent musculoskeletal disorders.

Insoles are commonly used among active individuals participating in physical activities. Sometimes, perhaps quite often, the reason behind the decision to start using insoles is not related to a medical condition but is due to commercial marketing advertising various situations in which one should use insoles. Certain clinical conditions such as an acquired flatfoot deformity and overpronation may sometimes require support for the plantar arch and some insoles are based on an existing deformity to correct lower limb positioning affecting core balance. Exposure to physical stress, however, may also predispose a normal lower limb to suffer overuse injuries if the lower limb is not adapted to the increased physical activity. Core stability may be affected through lower limb kinematics, resulting in LBP. The results of this study indicate that in the absence of deformities of the lower leg, the use of an insole with shock absorbing effects does not minimise LPB episodes.

Based on these findings, we recommend orthotic insoles not to be used with an aim toward preventing LBP episodes in young male adults. Using orthotic insoles was not associated with a lower rate of LBP assessed by suspension from duty. LBP comprises a significant amount of morbidity among young adults and is not reducible using orthotic insoles. Methods for reducing LBP episodes warrant further research as the lifetime expectance of LBP among young adults is high.

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