Can Custom-made Biomechanic Shoe Orthoses Prevent Problems in the Back and Lower Extremities? A Randomized, Controlled Intervention Trial of 146 Military Conscripts

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Abstract

Background: Shock-absorbing and biomechanic shoe orthoses are frequently used in the prevention and treatment of back and lower extremity problems. One review concludes that the former is clinically effective in relation to prevention, whereas the latter has been tested in only 1 randomized clinical trial, concluding that stress fractures could be prevented.

Objectives: To investigate if biomechanic shoe orthoses can prevent problems in the back and lower extremities and if reducing the number of days off-duty because of back or lower extremity problems is possible.

Design: Prospective, randomized, controlled intervention trial.

Study Subjects: One female and 145 male military conscripts (aged 18 to 24 years), representing 25% of all new conscripts in a Danish regiment.

Method: Health data were collected by questionnaires at initiation of the study and 3 months later. Custom-made biomechanic shoe orthoses to be worn in military boots were provided to all in the study group during the 3-month intervention period. No intervention was provided for the control group. Differences between the 2 groups were tested with the chi-square test, and statistical significance was accepted at $P < .05$. Risk ratio (RR), risk difference (ARR), numbers needed to prevent (NNP), and cost per successfully prevented case were calculated.

Outcome Variables: Outcome variables included self-reported back and/or lower extremity problems; specific problems in the back or knees or shin splints, Achilles tendonitis, sprained ankle, or other problems in the lower extremity; number of subjects with at least 1 day off-duty because of back or lower extremity problems and total number of days off-duty within the first 3 months of military service because of back or lower extremity problems.

Results: Results were significantly better in an actual-use analysis in the intervention group for total number of subjects with back or lower extremity problems (RR 0.7, ARR 19%, NNP 5, cost US $98); number of subjects with shin splints (RR 0.2, ARR 19%, NNP 5, cost US $101); number of off-duty days because of back or lower extremity problems (RR 0.6, ARR < 1%, NNP 200, cost US $3750). In an intention-to-treat analysis, a significant difference was found for only number of subjects with shin splints (RR 0.3, ARR 18%, NNP 6 cost US $105), whereas a worst-case analysis revealed no significant differences between the study groups.

Conclusions: This study shows that it may be possible to prevent certain musculoskeletal problems in the back or lower extremities among military conscripts by using custom-made biomechanic shoe orthoses. However, because care-seeking for lower extremity problems is rare, using this method of

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prevention in military conscripts would be too costly. We also noted that the choice of statistical approach determined the outcome. (J Manipulative Physiol Ther 2002;25:326-31)

Key Indexing Terms: *Orthosis; Lower Extremity; Low Back Pain; Biomechanics*

Introduction

The prevalence of back and lower extremity problems in general is high,[1] particularly during the first 3 months of military service.[2] The most common musculoskeletal problems in the Danish Army are back problems, knee problems, shin splints, Achilles tendonitis, and sprained ankles.[2] Shock-absorbing and biomechanic shoe orthoses (BSO) are frequently used in the prevention and treatment of back and lower extremity problems. One review concludes that shock-absorbing insoles in footwear reduces the incidence of stress fractures in athletes and military personnel.[3] In several randomized, controlled studies, researchers conclude that preventing overuse injuries in the back and lower extremities by use of shock absorbing insoles is possible.[4-8] We succeeded in finding only 1 randomized clinical trial in which BSO were used for prevention of back and lower extremity problems.[9] According to the results from this study, reducing the incidence of stress fractures with semi-rigid and in particular soft BSO is possible.

The theory behind the use of BSO is that control of the subtalar and midtarsal pronation has a positive effect on the closed kinetic, linked movements in the whole lower extremity and back during walking and running.[10] Prevention of excessive subtalar and midtarsal joint pronation is thought to prevent excessive medial rotation of the tibia, femur, and pelvis, which in turn prevents further mechanical stress on the knee, hip, and back.[10-12] A connection between subtalar and midtarsal joint problems and lower extremity and back problems has been described.[13-18]

The purpose of this trial is to investigate if BSO can prevent problems in the back and lower extremities and if their use can reduce the number of days off-duty during the first 3 months of military service because of back or lower extremity problems.

Material and methods

Study Subjects

The estimated sample size was calculated with MEDSTAT (Version 2.12) to 55 subjects per group, with alpha at 5%, beta at 10%, and least relevant difference at 20%. We expected that 10% of subjects would be unwilling to participate and that we would have a drop-out rate of 10%. Therefore, all 154 male and female conscripts (aged 18 to 24 years) from all over Denmark, who were drafted to start in August 1999 at the Jutland Dragoon Regiment, Holstebro, Denmark, were asked to consider joining the study. All conscripts who agreed to participate in the trial were included. These conscripts all underwent an extended medical examination within 6 months before they were drafted. At that time, all subjects with serious back or lower extremity problems were excluded from military service. Therefore, no conscripts were excluded because of serious back or lower extremity problems at baseline evaluation. A further exclusion criterion was current use of a shoe orthosis. After we obtained informed written consent, we randomly assigned all conscripts into 2 groups by drawing an envelope out of a box with 154 well-shuffled envelopes, with text indicating either BSO or no BSO.

The main study was preceded by a pilot study performed on 37 male and female conscripts, aged 18 to 24 years, from February 1999 to May 1999. Adjustments to the procedure were made according to findings in the pilot study. Data from the pilot study are not included in the main study.

A prospective, randomized, controlled, intervention trial was conducted from August 1999 to November 1999 in cooperation with medical and other health care practitioners at the infirmary. We provided, all conscripts In the intervention group with custom-made BSO. One person experienced in making these BSO provided the orthoses with a heater and FormThotics (Foot Science International Ltd, Christchurch, New Zealand), in this way producing a semi-rigid shoe orthosis. The orthoses were fitted to the inside of the boots and heated while insi de. When the orthoses had the right temperature for molding, the conscripts put on their boots and sat down on a chair, while bearing weight on the outer side of the back of their feet. From this position, they stood up and shifted the weight from the lateral heels to the medial and anterior part of their feet, allowing a controlled pronation at the subtalar and midtarsal joint. The control subjects then stayed in this position for 1 minute while the orthoses cooled down. The conscripts were then told to use the biomechanic orthoses whenever wearing their military boots during the 3-month intervention period. The control group was given no intervention.

Data Collection

Data were collected through questionnaires at baseline evaluation, during medical examination in the first week of military service, and 3 months later at follow-up evaluation, shortly after completion of the 3-month basic education. During the study period, medical and other health care practitioners at the infirmary were not aware of the group allocation, and they were told to treat all conscripts in the normal fashion,

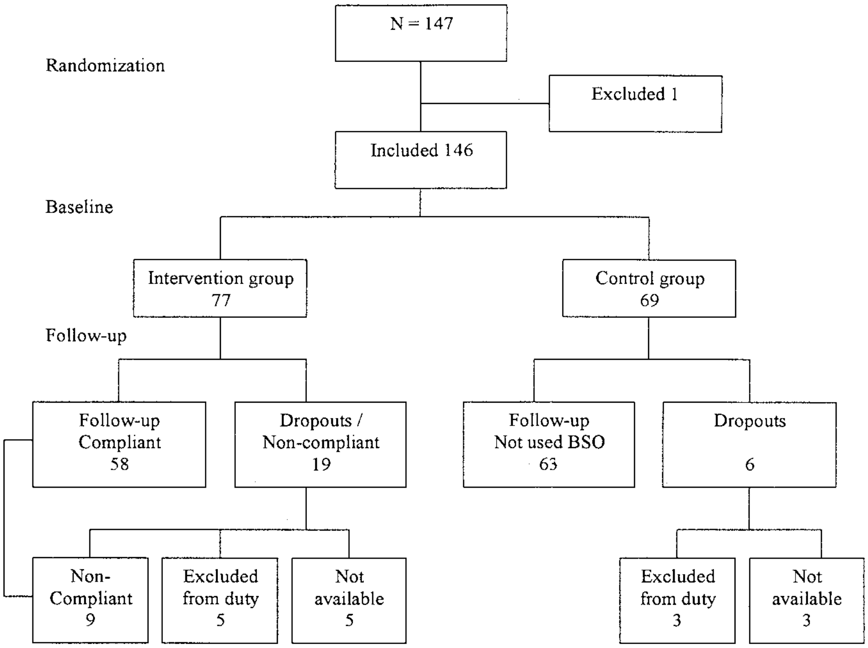

Fig 1. *Number of participants at time of randomization, baseline, and follow-up observation.*

except to refrain from using any type of BSO as a mode of treatment.

Baseline data were collected on self-reported back and/or lower extremity problems and specific problems in the back, knee, shin splints, Achilles tendonitis, sprained ankle, or other problems in the lower extremities within 3 months before military service.

Outcome variables at follow-up evaluation were the same as at baseline evaluation, with the addition of the number of subjects with at least 1 day off-duty because of lower extremity or back problems and total number of off-duty days because of back or lower extremity problems during the past 3 months. In addition, both groups were asked if they had used BSO within the first 3 months of military service to measure their compliance.

Data Handling and Analysis

The same person used the Data Entry Builder software package version 1.0 from SPSS for data entry at two separate times, and discrepancies were corrected according to the raw data. Data were analyzed with the statistical software package SPSS version 9.0 (SPSS, Chicago, Ill), and Stata release 6.0 (College Station, Tex). Chi-square tests were used to compare the 2 groups, accepting a significance level of $P < .05$. Data were analyzed in 3 different ways:

1. An actual-use analysis, including subjects who completed the intervention. Eleven conscripts selected for the Danish Army Sergeants School (4 in the control group and 7 in the intervention group) did not return the follow-up questionnaire but underwent a medical examination at completion of the first 3 months of military service. At this time, they reported not to have had back or lower extremity problems during the intervention period, therefore classified as having no back or lower extremity problems during the intervention period. We assumed that these conscripts had been compliant. Nine conscripts in the intervention group who were not compliant were excluded from this analysis. When calculating the 3-month period prevalence of off-duty days, we assumed that all conscripts had been on-duty for a period of 60 days (Fig 1).
2. An intention-to-treat analysis was conducted for those variables for which significant differences between groups were found in the actual-use analysis, including known data from the 9 conscripts in the intervention group who were not compliant (Fig 1).
3. A worst-case analysis was conducted for those outcome variables that were significantly different in the actual-use analysis. It included the 25 conscripts who were not compliant or dropped out (ie, 9 non-compliant subjects, 8 persons excluded from military service, and 8 subjects who were unavailable at follow-up evaluation). In this analysis, we assumed that conscripts excluded from service and those who were unavailable at follow-up evaluation had problems in back and lower extremity and that all had been off-duty at least 1 day (Fig 1).

The risk ratio (RR) was calculated as the period prevalence rate in the intervention group divided by the period prevalence rate in the control group. The

Table 1. *Actual-use analysis*

	Control group (n = 63)	Intervention group (n = 58)	*P* value for difference between groups
Any problems in back or lower extremities	56 (43–68)	36 (24–50)	.045
Specific problems			
Back problems	9 (4–20)	9 (3–19)	1.000
Knee problems	22 (13–35)	28 (17–41)	.533
Shin splint	24 (14–36)	5 (1–14)	.005
Achilles tendonitis	9 (4–20)	3 (0–12)	.276
Sprained ankle	3 (0–11)	2 (0–9)	1.000
Other lower extremity problems	9 (4–20)	9 (3–19)	1.000
Number of persons off-duty	29 (18–45)	19 (10–31)	.287
Number of days off-duty	1 (1–1)	1 (0–1)	.035

The three-month period prevalence at follow up of 121 military conscripts for any problems in back or lower extremities; specific problems in the back, knee, shin splint, Achilles tendonitis, sprained ankle; number of persons with days missed from work and total number of off-duty days in percent, with 95% confidence limits in brackets.

Table 2. *Actual-use analyses*

	RR	ARR	NNP	Cost
Any problems in back or lower extremities	0.7 (0.4–1.0)	19 (2–37)	5 (3–53)	98 (51–986)
Specific problems: shin splint	0.2 (0.1–0.7)	19 (7–31)	5 (3–15)	101 (62–279)
Number of days off-duty	0.6 (0.4–1.0)	1 (0–1)	200 (111–2500)	3750 (2063–46,875)

The 3-month period prevalence at follow-up for 121 military conscripts of variables with significant differences between groups. Relative risk (RR), absolute risk reduction (ARR), number needed to prevent (NNP), and costs per prevented case in US$ (cost), with 95% confidence limits in brackets for the intervention group.

risk difference (ARR) was calculated as the prevalence in the control group minus the prevalence rate in the intervention group. Numbers needed to prevent (NNP) was calculated as 1 divided by the risk difference.[19] Costs were calculated as NNP multiplied by cost per pair of BSO, which was approximately US $19.

Results

Of the 154 persons drafted, 1 female and 146 male conscripts were available and willing to participate in the trial. One person was excluded because of current use of BSO. After randomization, the two groups consisted of an intervention group of 77 subjects and a control group of 69 subjects (Fig 1). At baseline evaluation, the 3-month period prevalence rates were similar in both groups on all collected data.

At follow-up evaluation, data were collected from 67 (87%) conscripts in the intervention group, and 63 (91%) in the control group, giving a total follow-up rate of 130 (89%) of 146 subjects. A total of 10 conscripts in the intervention group and 6 in the control group were classified as having dropped out of the study (Fig 1).

Actual-use analysis (per protocol). According to the actual-use analysis (ie, including those 58 conscripts who actually used the BSO and the 63 conscripts in the control group), there was a significantly lower 3-month period prevalence of subjects with any problems in the back or lower extremities in the intervention group (36%) compared with the control group (56%). The same applied for specific problems with shin splints (13% vs 24%, respectively) and for number of off-duty days <1% (23 days) vs 1% (43 days), respectively (Table 1). The cost to prevent 1 case of any problem in the back or lower extremities was US $98. The cost for preventing 1 case of shin splints was US $101. To prevent at least 1 case of off-duty days, the cost was US $3750. For further information on RR, ARR, and NNP, please refer to Table 2.

Intention-to-treat analysis. The intention-to-treat analysis included those who entered the study and were available at follow-up evaluation (58 plus 9 who were not compliant, a total of 67 in the intervention and 63 in the control group) and was performed only for the significant variables from the actual-use analysis (any problems in the back or lower extremity, shin splints, and number of off-duty days) (Fig 1). According to this analysis, any problems in back or lower extremity were reported by 6 of the 9 conscripts who were not compliant, giving a non-significantly different 3-month period prevalence in the intervention group compared with the control group (40% vs 56%), a RR of 0.7, and an ARR of 15%. The NNP was 7 at a cost of US $122 per prevented case (Table 3). Shin splints were reported by

Table 3. *Intention-to-treat analysis*

	Control group (n = 63)	Intervention group (n = 67)	
Problems in back or lower extremities	56 (43–68)	40 (29–53)	
P value of difference between groups			.114
RR			0.7 (0.5–1.1)
ARR			15 (2–32)
NNP			6 (3–59)
Cost			122 (58–1103)
Specific problems: shin splints	24 (14–36)	6 (2–15)	
P value for difference between groups			.005
RR			0.3 (0.1–0.7)
ARR			18 (6–30)
NNP			6 (3–17)
Cost			105 (64–317)
No. of off-duty days	1 (0–1)	1 (1–1)	
P value for difference between groups			.828
RR			1.0 (0.6–1.5)
ARR			0
NNP			0
Cost			Infinite

The 3-month period prevalence at follow-up for 130 military conscripts variables with significant differences between groups in the actual-use analysis in percent, with 95% confidence limits in brackets. Relative risk (RR), absolute risk reduction (ARR), number needed to prevent (NNP), and costs per prevented case in US$ (Cost), with 95% confidence limits in brackets for the intervention group.

1 of the conscripts who were not compliant, giving a significantly lower 3-month period prevalence in the intervention group compared with the control group (6% vs 24%), a RR of 0.3, and an ARR of 18%. NNP was 6 at a cost of US $105 (Table 3). An additional 20 off-duty days were reported in the intervention group, giving an equal number of off-duty days of 1% of the duty time in both groups, a RR of 1.0, and no risk difference (Table 3).

Worst-case analysis. The worst-case analysis included the 25 conscripts who were not compliant or who dropped out of the study, for a total of 146 conscripts. The total number of conscripts in the intervention group was 77, and 69 were in the control group (Fig 1). There were no significant differences for any of the outcome variables (any problems in back or lower extremities, shin splints or off-duty days).

Discussion

This study clearly illustrates the different results in relation to the choice of analysis. When the actual use of BSO was tested, results were superior to when the actual intervention was tested (ie, intention-to-treat). All significant results were not present in the worst-case analysis.

In addition, estimates of the NNP put the results in perspective. These ranged from 5 in preventing any problems in the back and lower extremities to 200 in preventing off-duty days. However, when the costs of prevention were calculated, the results were truly tested: to prevent just 1 day off-duty would cost US $3750, according to the actual-use analysis!

Conclusion

Although BSO, in accordance with the study by Finestone et al,[9] has a statistically significant preventive effect on certain musculoskeletal problems in those who actually use them, the fact that relatively few conscripts seek care for this type of injury prevention is not economically feasible.

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