Insoles for prevention and treatment of back pain (Review)

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ABSTRACT

Background
There is lack of theoretical and clinical knowledge of the use of insoles for prevention or treatment of back pain. The high incidence of back pain and the popularity of shoe insoles call for a systematic review of this practice.

Objectives
To determine the effectiveness of shoe insoles in the prevention and treatment of non-specific back pain compared to placebo, no intervention, or other interventions.

Search strategy
We searched the following databases: The Cochrane Back Group Trials Register and The Cochrane Central Register of Controlled Trials (CENTRAL) to March 2005, and MEDLINE, EMBASE, and CINAHL to February 2007; reviewed reference lists in review articles, guidelines and in the included trials; conducted citation tracking; contacted individuals with expertise in this domain.

Selection criteria
We included randomized controlled trials that examined the use of customized or non-customized insoles, for the prevention or treatment of back pain, compared to placebo, no intervention or other interventions. Study outcomes had to include at least one of the following: self-reported incidence or physician diagnosis of back pain; pain intensity; duration of back pain; absenteeism; functional status. Studies of insoles designed to treat limb length inequality were excluded.

Data collection and analysis
One review author conducted the searches and blinded the retrieved references for authors, institution and journal. Two review authors independently selected the relevant articles. Two different review authors independently assessed the methodological quality and clinical relevance and extracted the data from each trial using a standardized form.

Main results
Six randomized controlled trials met inclusion criteria: Three examined prevention of back pain (2061 participants) and three examined mixed populations (256 participants) without being clear whether they were aimed at primary or secondary prevention or treatment. No treatment trials were found. There is strong evidence that the use of insoles does not prevent back pain. There is limited evidence that insoles alleviate back pain or adversely shift the pain to the lower extremities.

Limitations
This review largely reflects limitations of the literature, including low quality studies with heterogeneous interventions and outcome measures, poor blinding and poor reporting.

Authors' conclusions
There is strong evidence that insoles are not effective for the prevention of back pain. The current evidence on insoles as treatment for low-back pain does not allow any conclusions.

High quality trials are required for stronger conclusions.

PLAIN LANGUAGE SUMMARY

Insoles for the prevention and treatment of back pain

Back pain is one of the most common health problems in the industrialized world, with estimates that between 60% and 85% of the population will experience it at some point in their lives. Laboratory trials suggest that the use of shoe insoles might be beneficial in the prevention and treatment of back pain, by absorbing the shock of the foot striking the ground and supporting the foot in proper alignment. There are a variety of insoles available.

We included six trials that studied populations who did extensive standing and walking in the course of their daily jobs. Three prevention studies (2061 participants) examined the effects of both customized and non-customized insoles for the prevention of back pain. Three studies with mixed populations (256 participants) examined the effects of customized insoles for back pain without being clear whether they were aimed at primary or secondary prevention or treatment. None of the studies showed that insoles prevented back pain. No included trials assessed insoles exclusively for treatment for back pain.

Although half of the trials were of high methodological quality and therefore had a low potential for bias, the results should still be read with caution. Most of the trials examined specific young, highly active male populations. Finally, no long-term treatment and prevention data are available.

In conclusion, there is strong evidence that insoles do not prevent back pain, while the current evidence on insoles as treatment for low-back pain does not allow any conclusions. Better trials assessing the association between insoles and back pain are required before professional recommendation for the use of insoles become standard.

BACKGROUND

Back pain is one of the most common health problems in the industrialized world, second only to upper respiratory infection as a reason for physician office visits in the United States. Several studies have estimated the point prevalence of low-back pain in North America to range from 4.4% to 33%, and life-time prevalence is estimated at 60% to 85% of the population (Loney 1999). In North America, back disorders generate direct and indirect costs of more than $100 billion per year in treatment and lost time from work (Andersson 2004).

For over 40 years, researches hypothesized and tested possible biomechanical and skeletal mechanisms of orthotic interventions. Theoretical explanations suggest that the use of shoe insoles might be beneficial in the prevention and treatment of back pain by absorbing shock, preventing excessive pronation and preventing sagittal plane blockade, and enhancing balance and proprioceptive performances (Bird 1999; Ball 2002). Ball and Afheldt (Ball 2002) critically reviewed these explanations and found that both theoretical and clinical knowledge is lacking. The American Veterans Health Administration (VA 1999) supports the use of shoe insoles for the treatment of workers with low-back pain; however, orthopedic and rehabilitation practitioners from the Netherlands do not prescribe orthopedic footwear for back pain (Boer 1998).

There are different kinds of shoe insoles, both customized and non-customized, made from different materials. Several studies have examined their effectiveness in the prevention of back pain.

Studies examining the effects of insoles for limb length inequality have been thoroughly reviewed (Brady 2003). Limb length inequality is a term relating to a cluster of conditions that creates lower limb asymmetry. Brady 2003 reviewed clinical assessment of this situation and possible interventions. In a narrative review, they found controversial and inconsistent results for accurate and useful methods for detection of this condition. They describe disagreement between authors as to what constitutes a significant limb length inequality; some suggest 3 mm to 5 mm of limb length discrepancy is a clinically significant magnitude, others suggest impairment is induced with limb length inequality of 11 mm, 15 mm or 20 mm. They found 12 studies that investigated the link between limb length inequality and low-back pain, but no association was unequivocally found. Special designs of shoe lifts or orthoses were presented as non-invasive techniques to correct scoliosis associated with limb length inequality in younger patients, but a residual curve was found to persist in older patients. Older individuals were shown to experience more adverse events from lift intervention. The topic of insole use for prevention or treatment of back pain, regardless of limb-length asymmetry, was not discussed.

The use of insoles for prevention or treatment of back pain has not been systematically reviewed. The high incidence of back pain and the popularity of shoe insoles call for a systematic review of this practice.

OBJECTIVES

To determine the effectiveness of shoe insoles in the prevention (primary and secondary) and treatment of non-specific back pain compared to placebo, no intervention, or other interventions.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We included randomized controlled trials (RCTs) and cross-over trials. We excluded retrospective reports, cohort studies or studies with no control group. There were no language restrictions.

Types of participants

We includd trials that examined adults, aged 18 years and over, with non-specific low-back pain for treatment and secondary prevention trials, or without low-back pain for primary prevention. Non-specific low-back pain indicates that no identifiable cause has been detected, such as infection, neoplasm, metastases, osteoporosis, arthritis, fracture, inflammatory processes or radicular syndrome (Waddell 1996).

Types of intervention

We included studies that examined the use of customized or non-customized insoles, for the prevention or treatment of low-back pain, compared to placebo, no intervention or other interventions. We excluded studies of special types of insoles that were designed to treat limb length inequality due to the controversies described in Brady 2003 and lack of evidence that limb length inequality is related to back pain.

Types of outcome measures

We included studies that used at least one of the following outcome measures:

- self reported incidence or physician diagnosis of back pain;
- pain intensity (e.g. visual analogue scale (VAS), numerical rating scale (NRS), McGill Pain Questionnaire) and proportion of pain free patients;
- duration of back pain;
- absenteeism (percentage of the population studied, number of days);
- back-pain-specific functional status (e.g. Roland Disability Questionnaire (RDQ), SF-36 (The MOS 36-item short-form survey)).

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Back Group methods used in reviews.

We identified relevant trials by searching the following databases from their earliest manuscript registers to March 2005: The Cochrane Back Group Trials Register and The Cochrane Central Register of Controlled Trials (CENTRAL). MEDLINE, EMBASE and CINAHL, all using Silver Platter, were searched to February 2007.

We used the search strategy recommended by the Cochrane Back Review Group (Robinson 2002; van Tulder 2003) and added terms for prevention and insoles. See Table 01 for our search strategies. In addition, we reviewed reference lists in review articles, guidelines and the included trials and used citation tracking of the relevant trials to search for further trials. AL contacted individuals with expertise in this domain to ensure we did not miss any trials. Though there were no language restrictions, we found no Non-English articles.

METHODS OF THE REVIEW

Trial selection

One review author (TS) conducted the electronic searches and electronically blinded the retrieved references for authors, institution and journal. Two review authors who are specialists in physical therapy and family medicine (DOO & VN) independently screened the references by looking at the titles, abstracts, and keywords (Oxman 1993). If they were not sure whether the reference met the inclusion criteria, a full-text copy of the article was retrieved for final decision. Consensus was used to resolve disagreements.

TS pilot tested the inclusion criteria on a sample of ten articles.

Three studies that appeared to meet the inclusion criteria but were excluded upon review of the full-text are listed in the *Characteristics of excluded studies* table (Dananberg 1999; Sobel 2001; Wosk 1985).

Methodological quality assessment

After blinding the studies for authors, institution, journal, results and conclusions, two review authors (LK & IL), who are specialists in orthopedics and family medicine, independently assessed the methodological quality, using 11 items reflecting internal validity, as recommended by the Cochrane Back Review Group (van Tulder 2003, see Table 02). Each criterion was scored as "yes"(Y), indicating that the criterion was met, "no"(N), indicating it wasn't met, or "don't know"(DK), indicating that it was unclear from the paper if the criterion was or wasn't met. We tried to contact all of the authors and obtain additional information to clarify assessments of 'no' or 'don't know'. We were unable to find addresses of two authors and two other authors did not respond to our attempts to contact them.

The two review authors met and reached consensus on their assessment. When disagreement persisted in one case, a third author (AL) was consulted.

Data extraction

Two review authors (LK & IL) independently extracted the data from each trial using a standardized form, pilot tested by TS and IL,

on a sample of three articles. The authors met to reach consensus. Throughout the pilot data collection process, we examined inter-rater reliability, noting frequency of disagreement for specific data, and modifying the coding instructions accordingly.

The following data were extracted from each study: characteristics of the study population (age, gender, profession), setting, recruitment data (including number of drop-outs or withdrawals), type of insoles used (e.g. customized, non-customized, materials), duration of intervention, characteristics of the control intervention (type and duration), types of outcome measures, results (including statistics and type of analysis), compliance, adverse effects due to intervention, the authors' conclusions and sponsorship of the trial.

Clinical Relevance

Two authors judged the clinical relevance of each trial, using the five questions recommended by Shekelle et al (Shekelle 1994) and the Cochrane Back Review Group (van Tulder 2003):

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

Data analysis

We followed the recommendations of the Cochrane Handbook (Alderson 2003) and the Cochrane Back Review Group (van Tulder 2003) for our statistical analyses and contacted the authors for missing data when possible. All results were calculated and presented separately for prevention and treatment, for each comparison and each important outcome for which data were provided. Separate meta-analyses were planned for:· prevention and treatment, customized or non-customized shoe insoles versus placebo, no intervention, or other treatments. Dichotomous data were analyzed by calculating the Relative Risk (RR) and 95% confidence intervals (95% CI) for each trial. We employed the random-effects (DerSimonian and Laird) model for the meta-analyses, because the assumptions underlying this model are better suited to the field of back pain (van Tulder 2003). We checked for statistical heterogeneity by visually inspecting the graphic presentations of the results of the meta-analyses and by calculating the chi-squared test for heterogeneity.

Analyses were performed for actual trial participants and two forms of sensitivity analysis. The first was calculated assuming that all drop-outs did not develop outcome events. The second analysis was calculated under the assumption that drop-out event rates were similar to those among control subjects.

If data were inadequately presented (not allowing reliable data retrieval), a qualitative analysis was conducted, using a rating system consisting of five levels of evidence (van Tulder 2003):

- strong evidence - consistent findings in multiple high quality RCTs (RCTs meeting at least six of eleven quality criteria);
- moderate evidence - consistent findings among multiple low quality RCTs and/or one high quality RCT;
- limited evidence - one low quality RCT;
- conflicting evidence - inconsistent findings among multiple RCTs;
- no evidence from trials - no RCTs.

Findings were considered consistent when the results of 75% or more of the studies were in the same direction.

DESCRIPTION OF STUDIES

A total of 325 references were identified from the CENTRAL, MEDLINE, EMBASE, and CINAHL searches. No additional references were suggested by experts. After reviewing titles and abstracts, 316 citations were excluded for not meeting the pre-determined inclusion criteria. Nine papers were retrieved in full, three of which were excluded due to improper study design (not RCTs). A total of six studies met the inclusion criteria and were included in this review: Three studied insoles for the prevention of back pain (Larsen 2002; Milgrom 2005; Schwellnus 1990). Three studies examined the use of insoles on a group consisting of subjects both with and without back pain at baseline (Basford 1988; Shabat 2005; Tooms 1987).

Three studies used non-customized insoles (Basford 1988; Schwellnus 1990; Tooms 1987) and two used customized (Larsen 2002; Shabat 2005). In the trials using non-customized insoles, Basford 1988 and Tooms 1987 used viscoelastic polyurethane insoles and Schwellnus 1990 used Neoprene impregnated with nitrogen bubbles. In the trials using customised insoles, Larsen 2002 used semi-rigid insoles and Shabat 2005 used viscoelastic polymer material. Milgrom 2005 included three groups for comparison: one used customized semirigid biomechanical insoles, the second used non-customized soft biomechanical insoles and the third was provided with sham shoe inserts without shock absorbing qualities.

The three largest studies examined prevention among male military recruits (Larsen 2002; Milgrom 2005; Schwellnus 1990). The three studies with a mixed population were on a smaller scale, performed in civilian settings. One study examined 96 women, standing for 75% of their working hours (Basford 1988) and another examined 100 nursing students standing three days a week for eight hours a day (Tooms 1987). Shabat 2005 performed their study on 60 postmen.

Two studies used physician diagnoses to evaluate back pain complaints (Milgrom 2005; Schwellnus 1990). The others only used self reports. Shabat 2005 applied a specific low-back pain scale.

One study reported a high discomfort rate (Basford 1988), and in another there was a high drop-out rate of over 40% in each of the three trial arms (Milgrom 2005). In another trial, there were few cases of alleviation of back pain (Tooms 1987). Instead, subjects reported that the location of pain shifted from the back to the legs. No other adverse effects were reported. All details of each trial are reported in the table of included studies.

No trial reported private funding sources and no author indicated financial ties with an insoles manufacturer. Only the two most recent trials (Larsen 2002; Milgrom 2005) reported no conflict of interest.

METHODOLOGICAL QUALITY

Initially, several ratings for the methodological quality criteria for individual studies varied between authors. There were 26 disagreements on 66 individual ratings, for a raw agreement of 61%. Fifteen of the disagreements resulted from disparate interpretations of the methodological quality items (items 3, 7 and 11) and eleven disagreements resulted from reading errors in the trials. These disagreements were easily resolved through discussion between the raters without the need for a third party. Contact with one primary author clarified five 'don't knows', changing the item to a 'yes'/ 'No' in this trial (Milgrom 2005). Contact with another author did not provide supplementary material (Shabat 2005). As mentioned above, contact was not achieved with the other four authors.

The mean score for methodological quality of the prevention studies was five, with a range of two to eight criteria met. Using a cut-off point of six fulfilled criteria out of 11, three of the six trials (50%) were of high quality (See Table 03). Of note, while fulfilling a high quality assessment, Shabat 2005 has several notable flaws (no intention-to-treat analysis, no clear randomization methods). Both cross-over trials suffered from inadequate statistical analyses (Basford 1988; Shabat 2005). Milgrom 2005 also had a high quality rating but suffered substantial dropout rates (as high as 40%). The main methodological shortcomings of the trials included a lack of reporting of allocation concealment, compliance rates, lack of blinding of the participants, care providers and outcome assessors to the intervention and withdrawal or drop-out rates during the follow-up period. See Table 03 for details.

Clinical relevance

There were five disagreements on 30 individual ratings of clinical relevance, but these were easily resolved during the consensus meeting. Three trials met all five clinical relevance criteria (Larsen 2002; Milgrom 2005;Schwellnus 1990). Three trials did not meet item four regarding a clinically important effect size (Basford 1988; Tooms 1987; Shabat 2005).

RESULTS

Insoles versus no intervention or sham-inserts for primary prevention of back pain

A total of 2061 participants with no back pain were included in three trials, which tested both customized and non-customized insoles versus no intervention or sham-inserts for the prevention of back pain in military settings (Larsen 2002; Milgrom 2005; Schwellnus 1990). The trials lasted five to fourteen weeks. From the data available, we assume that only one of the 2061 participants was a woman. All pooled analyses had a non-significant test for heterogeneity. The pooled RR in favor of the use of insoles was 0.73 (95% CI: 0.43 to 1.22, P = 0.17). Taking the two higher quality studies and excluding Schwellnus 1990, the pooled results were RR 0.77 (95% CI: 0.4 to 1.5, P = 0.45). These analyses include only those trial subjects who actually completed the study.

The sensitivity analyses did not show any different findings (see Graphs 02.01; 03.01; 5.01; 06.01), neither did the stratified analysis for type of insoles used (customized and non-customized) (see Graphs 07.01; 08.01; 09.01; 10.01; 11.01; 12.01).

Overall, there were no statistically significant differences in the rates of prevention of back pain between participants who used insoles compared to those who did not.

Insoles versus no intervention or sham-inserts - trial of mixed populations (primary prevention, secondary prevention and treatment of back pain)

Basford 1988 was a cross-over study, examining non-customized insoles, which utilized the VAS to document the extent of back pain. They presented data that back pain, with insole use, decreased from 4.8 to 2.1 (P < 0.001). Data were not presented and calculated for each phase separately, thus the analysis of the data is not adequate (Sibbald 1998).

Shabat 2005 was a cross-over study, examining customized insoles versus placebo non-customized insoles and used the score of the MILLION questionnaire for evaluation of low-back pain. Back pain decreased from 5.46 to 3.96 with use of the real insole, and to 5.11 with use of the placebo insoles, and the difference was statistically significant (P < 0.0001). However, this difference is not considered clinically significant (Farrar 2001). Although this study fulfilled six of the 11 methodological quality criteria, it has major methodological flaws. For example: unclear inclusion criteria, inappropriate randomization, inappropriate analysis for cross-over trial (data were not presented and calculated for each phase separately), and missing data. Therefore, although the authors reported that customized insoles were more effective than non-customized insoles, we suggest that, at best, there is limited evidence to support this conclusion.

Tooms 1987 conducted a low-quality RCT comparing non-customized insoles versus no intervention. In this study, the authors found that initially 21 (42%) participants had reported back-pain

and lower extremity pain and 26 (52%) reported lower extremity pain. After the intervention, in the insole group, there was a shift of the pain, among those who had back pain to only lower extremity pain - with a total number of participants with lower-extremity pain of 42 (84%). In the control group, the proportions were stable. There is limited evidence that non-customized insoles are more effective than no intervention, but it is unclear whether this is for primary or secondary prevention or treatment.

Data from these three studies could not be pooled because the trials were clinically heterogeneous and we could not stratify subjects according to primary prevention, secondary prevention or treatment since the required data were not presented. Consequently, we assessed the results from each trial individually, using levels of evidence (van Tulder 2003). Therefore, we suggest there are insufficient data to support or refute the effectiveness of insoles over no treatment, for the prevention or treatment of back pain.

Insoles versus no intervention or sham-inserts - trials of back pain treatment.
No RCTs found of participants collected uniquely for treatment of back pain.

DISCUSSION

In this review, we attempted to collect all relevant high quality clinical data, published to date in the medical literature, regarding insoles and their association with either prevention or treatment of low-back pain. Our search identified only six studies which sufficiently met our inclusion criteria. Three of the studies were prevention trials and three included mixed participant populations (and thus had both a prevention and treatment assessment). Adequate data were only provided in the three prevention trials and a meta-analysis of their results showed no significant association between the use of insoles and short term prevention of low-back pain. The three studies with mixed populations were qualitatively summarized. While their data may suggest that insoles do indeed help decrease low-back pain prevalence and magnitude, numerous drawbacks in design and data presentation call into question these conclusions.

Methodological Quality
As mentioned above, three studies were designated as high quality (Larsen 2002; Milgrom 2005; Shabat 2005). Even so, all six studies were lacking in either their design or performance. High dropout rates (when reported), high prevalences of displeasure with the insoles, varying outcomes and inconsistent measuring methods should be noted. We believe that these findings reflect the limited methodological knowledge the study designers had when setting out to perform their studies. Another probable reason is the wide range of insoles available around the world, both customized and non-customized. No financial body stands to gain from protection of a patent, after financing large-scale high quality trials. In the case of insoles, the opposite is true, many small manufacturers capitalize on the lack of clear cut data (which might turn out to show that insoles are not beneficial) and the common lay-person and physician belief that insoles do, in fact, prevent and reduce low-back pain.

Blinding of participants and researches is inherently difficult. Thus, true blinding would decrease the placebo effect and decrease insole efficacy.

Efficacy
All three prevention trials were homogeneous, both methodologically (military settings, male participants) and statistically (Larsen 2002; Milgrom 2005; Schwellnus 1990). The pooled results do not support the claim that insoles prevent low-back-pain. It should be noted that the prevalence of low-back-pain among control patients was around 3%. Thus, even if the RR of insoles was 50%, it would require 67 participants to wear insoles in order to prevent one event of low-back pain. The three studies included over 2000 participants, providing substantial statistical power. Even if, in larger scale studies, insoles were to prove to be significantly efficacious, their absolute effects would probably be small. Two studies with a mixed population provided relief in pain scores from 4.8 to 2.1 (Basford 1988) on a VAS and from 5.46 to 3.96 (Shabat 2005) on a standardized back-pain questionnaire. The clinical significance of these decreases is questionable (Farrar 2001). The third study described a shift of pain from the back to lower extremities and provided little if any actual relief (Tooms 1987).

Clinical relevance
In general, the trials meet the criteria of clinical relevance recommended by the guidelines (van Tulder 2003). But there are still open questions regarding prevention and treatment of back pain in active senior populations, since most of the trials studied younger people. Furthermore, as with most studies of back pain, the data are restricted to high-income countries. However, it is unlikely that the effectiveness of insoles varies among different countries based on their economic characteristics. Given the limited evidence to support this intervention and the limited resources available in these countries to conduct trials, clinical trials in low income countries are not likely. Finally, long-term data are not yet available.

Advantages and drawbacks of this review
The strong side of this review is the comprehensive search strategy and the use of suggested methods for systematic reviews of interventions for low-back pain. On the other hand, this review is limited by the scarcity of trials, especially trials that used insoles as treatment for back pain, and our inability to reach most of the authors for clarifying unclear points regarding the data.

There is strong evidence that insoles are not useful for prevention of back pain. This evidence is stronger for males in military settings. There is limited evidence that insoles might decrease back pain. A proposed adverse event, with limited evidence to support it, is

a shift of pain from the back to the lower extremities following insole use.

AUTHORS' CONCLUSIONS

Implications for practice

There is strong evidence against using insoles for the prevention of back pain.
The current evidence on insoles as treatment for low-back pain does not allow any conclusions.

Implications for research

Additional high quality trials must be done to determine if insoles are effective in the treatment of back pain.
Researchers should improve the quality of methodology and reporting of trials on insoles for back pain.

POTENTIAL CONFLICT OF INTEREST

AL was a co-author of one of the reviewed papers (Milgrom 2005). AL was not involved in the methodological and quality assessment of this publication or in extraction of data from it.

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TABLES

Characteristics of included studies

Study	Basford 1988
Methods	RCT - cross-over No Blinding Mixed population (primary prevention + treatment) - no participant was under medical care for back pain, but 39 had mild-moderate back pain on the initial questionnaire
Participants	United States 96 Women, non-supervisory personnel working in laboratories and patient reception , standing 75% of working hours Average age - 39 (18-68) Drop-outs - 32/96 (33%) Footwear: 66 - Oxford, 19 - Jogging, 11 - other
Interventions	Non Customized insoles materials:Commercially available Viscoelastic polyurethane Duration of intervention: 5 weeks and 5 weeks cross over Control intervention: No treatment
Outcomes	Self reported incidence, pain intensity - visual analogue scale (VAS) - maximum pain relief - 4.8 back pain relief from insole use - 2.1/4.8 (p<.0001) (actual-use analysis)
Notes	adverse affects - 25 refused to participate because feeling unpleasant and too tight . 1/38 - pain increased. We were not able to extract the numbers of patients with or without back pain after each intervention period. The required data were not available.

Characteristics of included studies (*Continued*)

	Methodological quality: low (2/11 criteria) Major methodological flaw - Inappropriate analysis for cross-over trial (One comparison was done instead of two sets of comparisons).
Allocation concealment	C – Inadequate

Study	**Larsen 2002**
Methods	RCT Blinding of health professionals Primary prevention
Participants	Denmark 146 Infantry recruits (M:F - 145:1) Average age - 18-24 Drop-outs - Intervention - 10/77 + 9/77 non-compliant and Control - 6/69
Interventions	Customized insoles Materials: semirigid insoles (Fromthotics) Duration of intervention: 3 months (60 working days) Control intervention: No intervention
Outcomes	self reported incidence and number of days off-duty Back pain - Intervention- 9/63, control 9/58 Differences were not statistically significant in intention to treat analysis and per protocol analysis.
Notes	Military setting Methodological quality: high (8/11)
Allocation concealment	A – Adequate

Study	**Milgrom 2005**
Methods	RCT Blinding Primary prevention
Participants	Israel 404 Male Infantry recruits Average age - 18.8 Drop-outs - group 1 - 78/129, group 2 - 51/126, group 3 - 73/126 Footwear - Standard military footwear (boot with leather upper and rubber sole)
Interventions	Customized insoles Group 1 - customized semirigid biomechanical insoles Group 2 - soft biomechanical insoles Group 3 - sham inserts without supportive or shock absorbing qualities materials: semirigid biomechanical insoles, soft biomechanical insoles Duration of intervention: 14 weeks Control intervention: Simple shoe inserts without supportive or shock absorbing qualities
Outcomes	Review by the senior author every two weeks - questions about back pain + physical examination + monitoring for compliance back pain - Biomechanical - 16/129, Soft custom - 17/126, Placebo - 18/126 Differences were not statistically significant in intention to treat analysis and per protocol analysis
Notes	Military setting Methodological quality: high (6/11 criteria)

Characteristics of included studies (*Continued*)

	Major methodological flaw - very high drop-out rate
Allocation concealment	C – Inadequate

Study	**Schwellnus 1990**
Methods	RCT, No Blinding Primary prevention
Participants	South Africa 1511 military recruits (250 - intervention, 1261- control) Average age - 18.5 Drop-outs - 13/250 and 109/1260 (due to transfers to other units) Footwear - Standard military footwear (boot with leather upper and rubber sole)
Interventions	Non Customized insoles materials: Neoprene - impregnated with nitrogen bubbles covered with stretch nylon Duration of intervention: 9 Weeks Control intervention: No treatment
Outcomes	Physician diagnosis after first complaint by participant Mean incidence per 1000 subjects per week Acute back pain - Intervention - 0.7%, Control - 1.6% Chronic back pain - Intervention - 1.2%, Control - 2.4% Differences were not statistically significant Main outcome - injuries leading to self referral for medical care and confirmed by standardized medical diagnosis.
Notes	Military setting There is a report regarding back pain, but it was not the focus of this study. Took place among South-African army recruits prior to 1990. No data specifying sex ratios were provided and we found that females were recruited to the South-African army since the 1970s (http://en.wikipedia.org/wiki/South_African_Army) Methodological quality: middle (5/11 criteria).
Allocation concealment	B – Unclear

Study	**Shabat 2005**
Methods	RCT - cross over Blinding Mixed population (secondary prevention +treatment)
Participants	Israel 75 postmen whose job includes walking long distances and who reported that they suffered from back pain 60 agreed to participate in the study (M:F - 25:35) Average age - 39.14 Drop-outs - 15 did not agree to participate. 2/60 dropped from follow up Compliance:
Interventions	Customized insoles materials: viscoelastic polymer material Duration of intervention: 5 weeks Control intervention: Placebo non-customized insoles
Outcomes	MILLION questionnaire for evaluation of low back pain + 10-point pain scale

	Scores decreased from 5.46 to 3.96 after use of the real insole, and to 5.11 after use of the placebo insoles (P < 0.0001). Most of the participants said they would have liked to continue with the use of either of the insoles. 81% of them preferred the true insoles over the placebo insoles.
Notes	We were not able to extract the numbers of patients with or without back pain after each intervention period. The required data were not available. Methodological quality: high (6/11 criteria) Major methodological flaw - Inappropriate analysis for cross-over trial (One comparison was done instead of two sets of comparisons).
Allocation concealment	B – Unclear

Study	**Tooms 1987**
Methods	RCT No Blinding Mixed population (primary and secondary prevention + treatment)
Participants	United States 100 Nursing students, standing 3 days a week for 8 hours a day Average age - 22.8 Drop-outs - 1/100
Interventions	Non Customized insoles materials: commercially available Viscoelastic polyurethane Duration of intervention: 5 weeks Control intervention: No intervention
Outcomes	Self reported incidence, pain intensity - visual analogue scale (VAS) Shift of pain from back plus lower extremity to lower extremities only.
Notes	Methodological quality: low (3/11 criteria)
Allocation concealment	C – Inadequate

Characteristics of excluded studies

Study	**Reason for exclusion**
Dananberg 1999	Not a RCT
Sobel 2001	Not a RCT
Wosk 1985	Retrospective report No randomization

ADDITIONAL TABLES

Table 01. Search Strategies

Database	Time span	Search strategy
CENTRAL	current issue of The Cochrane Library	((back and pain) or backache or lumbago) and (shoe or insert or (shock and absorber) or insole or footwear or orthoses)
MEDLINE	1966 - 3/2005	#1 (randomized controlled trial or controlled clinical trial or randomized controlled trials or random allocation or double-blind method or single-blind method or clinical trial or clinical trials or ("clinical trial") or ((singl$ or doubl$ or trebl$ or tripl$) and (mask$ or blind$)) or ("latin square") or placebos or placebo$ or random* or research design or comparative study or evaluation studies or follow-up studies or prospective studies or cross-over studies or control* or prospectiv* or volunteer*) not (animal not human) #2: ((back and pain) or backache or lumbago) and (shoe or insert or (shock and absorber) or insole or footwear or orthoses) # 3: #1 and #2
EMBASE	1980 - 10/2005	#1 (randomized controlled trial or controlled clinical trial or randomized controlled trials or random allocation or double-blind method or single-blind method or clinical trial or clinical trials or ("clinical trial") or ((singl$ or doubl$ or trebl$ or tripl$) and (mask$ or blind$)) or ("latin square") or placebos or placebo$ or random$ or research design or comparative study or evaluation studies or follow-up studies or prospective studies or cross-over studies or control$ or prospectiv$ or volunteer$) not (animal not human) #2: ((back and pain) or backache or lumbago) and (shoe or insert or (shock and absorber) or insole or footwear or orthoses) # 3: #1 and #2
CINAHL	1982 - 3/2005	#1 (randomized controlled trial or controlled clinical trial or randomized controlled trials or random allocation or double-blind method or single-blind method or clinical trial or clinical trials or ("clinical trial") or ((singl$ or doubl$ or trebl$ or tripl$) and (mask$ or blind$)) or ("latin square") or placebos or placebo$ or random$ or research design or comparative study or evaluation studies or follow-up studies or prospective studies or cross-over studies or control$ or prospectiv$ or volunteer$) not (animal not human) #2: ((back and pain) or backache or lumbago) and (shoe or insert or (shock and absorber) or insole or footwear or orthoses) # 3: #1 and #2

Table 02. Methodological quality criteria with operational definitions

Criteria/Definitions

A. Was the method of randomization adequate? A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.
B. Was the treatment allocation concealed? Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
C. Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a "yes," groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurologic

Table 02. Methodological quality criteria with operational definitions (*Continued*)

Criteria/Definitions

symptoms, and value of main outcome measure(s).
D. Was the patient blinded to the intervention? The review author determines if enough information about the blinding is given in order to score a "yes."
E. Was the care provider blinded to the intervention? The review author determines if enough information about the blinding is given in order to score a "yes."
F. Was the outcome assessor blinded to the intervention? The review author determines if enough information about the blinding is given in order to score a "yes."
G. Were co-interventions avoided or similar? Co-interventions should either be avoided in the trial design or be similar between the index and control groups.
H. Was the compliance acceptable in all groups? The review author determines if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).
I. Was the drop-out rate described and acceptable? The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for immediate and short-term follow-ups, 30% for intermediate and long-term follow-ups and does not lead to substantial bias a "yes" is scored.
J. Was the timing of the outcome assessment in all groups similar? Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.
K. Did the analysis include an intention-to-treat analysis? All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.

Table 03. Results of Quality Assessment

Article	Random/Concealed	similar at baseline	blind patient/provid	blind assessor	co-interventions	compliance/drop-out	outcome timing same	ITT	total
Basford 1988	yes/no	unsure	no/no	unsure	yes	no/no	no	no	2/11
Larsen 2002	yes/yes	unsure	no/yes	unsure	yes	yes/yes	yes	yes	8/11
Milgrom 2005	yes/no	yes	no/no	yes	yes	no/no	yes	yes	6/11
Schwellnus 1990	unsure/unsure	yes	no/no	unsure	yes	yes/yes	yes	no	5/11
Shabat 2005	no/unsure	yes	yes/yes	yes	unsure	yes/yes	no	no	6/11
Tooms	unsure/no	yes	no/unsure	unsure	yes	no/no	yes	no	3/11

ANALYSES

Comparison 01. Prevention trials

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	3	1688	Relative Risk (Random) 95% CI	0.73 [0.43, 1.22]

Comparison 02. Prevention trials - ITT Assuming all dropouts did not have back pain

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	3	2061	Relative Risk (Random) 95% CI	0.74 [0.43, 1.27]

Comparison 03. Prevention trials - ITT Assuming dropouts were similar to controls

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	3	2061	Relative Risk (Random) 95% CI	0.85 [0.58, 1.23]

Comparison 04. Prevention trials - High quality

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	300	Relative Risk (Random) 95% CI	0.79 [0.46, 1.39]

Comparison 05. Prevention trials - High quality - ITT Assuming all dropout did not have back pain

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	550	Relative Risk (Random) 95% CI	0.81 [0.46, 1.45]

Comparison 06. Prevention trials - High Quality - ITT Assuming dropouts were similar to controls

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	550	Relative Risk (Random) 95% CI	0.90 [0.61, 1.32]

Comparison 07. Prevention trials - Customized insoles

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	249	Relative Risk (Random) 95% CI	0.74 [0.34, 1.61]

Comparison 08. Prevention trials - Customized insoles - ITT Assuming all dropout did not have back pain

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	414	Relative Risk (Random) 95% CI	0.81 [0.43, 1.52]

Comparison 09. Prevention trials - Customized insoles- ITT Assuming dropouts were similar to controls

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	414	Relative Risk (Random) 95% CI	0.83 [0.53, 1.31]

Comparison 10. Prevention trials - Non customized insoles

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	1492	Relative Risk (Random) 95% CI	0.69 [0.33, 1.43]

Comparison 11. Prevention trials - Not Customized insoles- ITT Assuming all dropout did not have back pain

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	1782	Relative Risk (Random) 95% CI	0.66 [0.31, 1.42]

Comparison 12. Prevention trials - Not Customized insoles- ITT Assuming dropouts were similar to controls

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Insoles vs placebo/No intervention	2	1782	Relative Risk (Random) 95% CI	0.78 [0.37, 1.65]

INDEX TERMS

Medical Subject Headings (MeSH)

Back Pain [prevention & control; *therapy]; *Orthotic Devices; Randomized Controlled Trials as Topic; Shoes

MeSH check words

Humans

COVER SHEET

Title	Insoles for prevention and treatment of back pain
Authors	Sahar T, Cohen MJ, Ne'eman V, Kandel L, Odebiyi DO, Lev I, Brezis M, Lahad A
Contribution of author(s)	idea generation - AL, TS writing protocol - TS; team offered ideas and revisions refinement of inclusion criteria, data extraction form - TS, LK, IL selection of studies - DOO, VN, AL

	quality assessment of studies - IL, LK, MB data extraction - IL, LK, TS, MJC, VN data analysis - TS, IL, AL, MB, MJC interpretation of results - all writing review - TS, MJC; team offered ideas and revisions contact with authors of primary studies - TS
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GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Prevention trials, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 01 Prevention trials

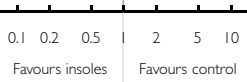
Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/58	9/63		37.0	1.09 [0.46, 2.55]
Milgrom 2005	15/126	10/53		50.0	0.63 [0.30, 1.31]
Schwellnus 1990	2/237	24/1151		13.0	0.40 [0.10, 1.70]
Total (95% CI)	**421**	**1267**		**100.0**	**0.73 [0.43, 1.22]**

Total events: 26 (Insoles), 43 (No Insoles/Sham)

Test for heterogeneity chi-square=1.66 df=2 p=0.44 I^2 =0.0%

Test for overall effect z=1.20 p=0.2



Analysis 02.01. Comparison 02 Prevention trials - ITT Assuming all dropouts did not have back pain, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 02 Prevention trials - ITT Assuming all dropouts did not have back pain

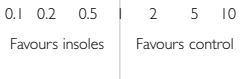
Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/77	9/69		38.2	0.90 [0.38, 2.13]
Milgrom 2005	15/269	10/135		47.9	0.75 [0.35, 1.63]
Schwellnus 1990	2/250	24/1261		13.9	0.42 [0.10, 1.77]
Total (95% CI)	**596**	**1465**		**100.0**	**0.74 [0.43, 1.27]**

Total events: 26 (Insoles), 43 (No Insoles/Sham)

Test for heterogeneity chi-square=0.81 df=2 p=0.67 I^2 =0.0%

Test for overall effect z=1.09 p=0.3



Analysis 03.01. Comparison 03 Prevention trials - ITT Assuming dropouts were similar to controls, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 03 Prevention trials - ITT Assuming dropouts were similar to controls

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	12/77	10/69		23.5	1.08 [0.50, 2.33]
Milgrom 2005	42/269	25/135		69.6	0.84 [0.54, 1.32]
Schwellnus 1990	2/250	26/1261		6.9	0.39 [0.09, 1.62]
Total (95% CI)	**596**	**1465**		**100.0**	**0.85 [0.58, 1.23]**

Total events: 56 (Insoles), 61 (No Insoles/Sham)

Test for heterogeneity chi-square=1.55 df=2 p=0.46 I^2 =0.0%

Test for overall effect z=0.87 p=0.4

Analysis 04.01. Comparison 04 Prevention trials - High quality, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 04 Prevention trials - High quality

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/58	9/63		42.5	1.09 [0.46, 2.55]
Milgrom 2005	15/126	10/53		57.5	0.63 [0.30, 1.31]
Total (95% CI)	**184**	**116**		**100.0**	**0.79 [0.46, 1.39]**

Total events: 24 (Insoles), 19 (No Insoles/Sham)

Test for heterogeneity chi-square=0.90 df=1 p=0.34 I^2 =0.0%

Test for overall effect z=0.81 p=0.4

Analysis 05.01. Comparison 05 Prevention trials - High quality - ITT Assuming all dropout did not have back pain, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 05 Prevention trials - High quality - ITT Assuming all dropout did not have back pain

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/77	9/69		44.4	0.90 [0.38, 2.13]
Milgrom 2005	15/269	10/135		55.6	0.75 [0.35, 1.63]
Total (95% CI)	**346**	**204**		**100.0**	**0.81 [0.46, 1.45]**

Total events: 24 (Insoles), 19 (No Insoles/Sham)

Test for heterogeneity chi-square=0.09 df=1 p=0.77 I^2 =0.0%

Test for overall effect z=0.70 p=0.5

Analysis 06.01. Comparison 06 Prevention trials - High Quality - ITT Assuming dropouts were similar to controls, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 06 Prevention trials - High Quality - ITT Assuming dropouts were similar to controls

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	12/77	10/69		25.3	1.08 [0.50, 2.33]
Milgrom 2005	42/269	25/135		74.7	0.84 [0.54, 1.32]
Total (95% CI)	**346**	**204**		**100.0**	**0.90 [0.61, 1.32]**

Total events: 54 (Insoles), 35 (No Insoles/Sham)

Test for heterogeneity chi-square=0.28 df=1 p=0.59 I^2 =0.0%

Test for overall effect z=0.55 p=0.6

Analysis 07.01. Comparison 07 Prevention trials - Customized insoles, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 07 Prevention trials - Customized insoles

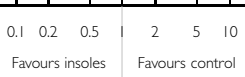
Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/58	9/63		51.7	1.09 [0.46, 2.55]
Milgrom 2005	7/75	10/53		48.3	0.49 [0.20, 1.22]
Total (95% CI)	**133**	**116**		**100.0**	**0.74 [0.34, 1.61]**

Total events: 16 (Insoles), 19 (No Insoles/Sham)

Test for heterogeneity chi-square=1.55 df=1 p=0.21 I^2 =35.4%

Test for overall effect z=0.76 p=0.5



Analysis 08.01. Comparison 08 Prevention trials - Customized insoles - ITT Assuming all dropout did not have back pain, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 08 Prevention trials - Customized insoles - ITT Assuming all dropout did not have back pain

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	9/77	9/69		53.9	0.90 [0.38, 2.13]
Milgrom 2005	7/133	10/135		46.1	0.71 [0.28, 1.81]
Total (95% CI)	**210**	**204**		**100.0**	**0.81 [0.43, 1.52]**

Total events: 16 (Insoles), 19 (No Insoles/Sham)

Test for heterogeneity chi-square=0.13 df=1 p=0.72 I^2 =0.0%

Test for overall effect z=0.67 p=0.5

Analysis 09.01. Comparison 09 Prevention trials - Customized insoles- ITT Assuming dropouts were similar to controls, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 09 Prevention trials - Customized insoles- ITT Assuming dropouts were similar to controls

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Larsen 2002	12/77	10/69		34.1	1.08 [0.50, 2.33]
Milgrom 2005	18/133	25/135		65.9	0.73 [0.42, 1.28]
Total (95% CI)	**210**	**204**		**100.0**	**0.83 [0.53, 1.31]**

Total events: 30 (Insoles), 35 (No Insoles/Sham)

Test for heterogeneity chi-square=0.63 df=1 p=0.43 I^2 =0.0%

Test for overall effect z=0.79 p=0.4

Analysis 10.01. Comparison 10 Prevention trials - Non customized insoles, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 10 Prevention trials - Non customized insoles

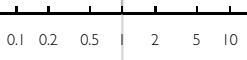
Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Milgrom 2005	8/51	10/53		74.2	0.83 [0.36, 1.94]
Schwellnus 1990	2/237	24/1151		25.8	0.40 [0.10, 1.70]
Total (95% CI)	**288**	**1204**		**100.0**	**0.69 [0.33, 1.43]**

Total events: 10 (Insoles), 34 (No Insoles/Sham)

Test for heterogeneity chi-square=0.76 df=1 p=0.38 I^2 =0.0%

Test for overall effect z=1.00 p=0.3



Analysis 11.01. Comparison 11 Prevention trials - Not Customized insoles- ITT Assuming all dropout did not have back pain, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 11 Prevention trials - Not Customized insoles- ITT Assuming all dropout did not have back pain

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Milgrom 2005	8/136	10/135		71.9	0.79 [0.32, 1.95]
Schwellnus 1990	2/250	24/1261		28.1	0.42 [0.10, 1.77]
Total (95% CI)	**386**	**1396**		**100.0**	**0.66 [0.31, 1.42]**

Total events: 10 (Insoles), 34 (No Insoles/Sham)

Test for heterogeneity chi-square=0.56 df=1 p=0.45 I^2 =0.0%

Test for overall effect z=1.05 p=0.3

Analysis 12.01. Comparison 12 Prevention trials - Not Customized insoles- ITT Assuming dropouts were similar to controls, Outcome 01 Insoles vs placebo/No intervention

Review: Insoles for prevention and treatment of back pain

Comparison: 12 Prevention trials - Not Customized insoles- ITT Assuming dropouts were similar to controls

Outcome: 01 Insoles vs placebo/No intervention

Study	Insoles n/N	No Insoles/Sham n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Milgrom 2005	24/136	25/135		77.5	0.95 [0.57, 1.58]
Schwellnus 1990	2/250	26/1261		22.5	0.39 [0.09, 1.62]
Total (95% CI)	**386**	**1396**		**100.0**	**0.78 [0.37, 1.65]**

Total events: 26 (Insoles), 51 (No Insoles/Sham)

Test for heterogeneity chi-square=1.41 df=1 p=0.23 I^2 =29.2%

Test for overall effect z=0.65 p=0.5