

Effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury: a systematic review and meta-analysis

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ABSTRACT

Objective To investigate the evidence relating to the effectiveness of foot orthoses and shock-absorbing insoles for the prevention of musculoskeletal injury.

Design Systematic review and meta-analysis.

Eligibility criteria for selecting studies Clinical trials evaluating the effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury.

Data sources Cochrane Library, CINAHL, EMBASE, MEDLINE and SPORTDiscus from their inception up to the first week of June 2016.

Results 11 trials that had evaluated foot orthoses and 7 trials that had evaluated shock-absorbing insoles were included. The median Physiotherapy Evidence Database (PEDro) score for trials that had evaluated foot orthoses and shock-absorbing insoles was 5 (range 3–8/10) and 3 (range 1–7/10), respectively. Meta-analysis found that foot orthoses were effective for preventing overall injuries (risk ratio (RR) 0.72, 95% CI 0.55 to 0.94) and stress fractures (RR 0.59, 95% CI 0.45 to 0.76), but not soft-tissue injuries (RR 0.79, 95% CI 0.55 to 1.14). In contrast, shock-absorbing insoles were not effective for preventing overall injuries (RR 0.92, 95% CI 0.73 to 1.16), stress fractures (RR 1.15, 95% CI 0.57 to 2.32) or soft-tissue injuries (RR 0.92, 95% CI 0.74 to 1.15).

Conclusions Foot orthoses were found to be effective for preventing overall injuries and stress fractures but not soft-tissue injuries, while shock-absorbing insoles were not found to be effective for preventing any injury. However, further well-designed trials will assist the accuracy and precision of the estimates of risk reduction as the quality of the included trials varied greatly.

INTRODUCTION

Regular physical activity is known to provide health benefits,¹ but exercise-related injuries are common.^{1–3} The incidence of injuries among long-distance runners and physically active defence force personnel has been reported to range from 19% to 79%.^{2,4} The most common injuries include medial tibial stress syndrome, Achilles tendinopathy, plantar fasciitis and patellofemoral pain.^{1–3} Exercise-related injuries have a detrimental impact on health, reduce the ability to participate in physical activity and can incur financial costs associated with treatment and lost productivity.³ Many interventions have been used in an attempt to prevent injuries, yet only limited evidence supports their effectiveness.^{5,6}

Foot orthoses and shock-absorbing insoles are commonly used for the prevention and

management of many musculoskeletal disorders of the lower extremity.^{7–11} Typically, foot orthoses have a contoured profile and are used with the intention of optimising foot function.¹² Although the specific mechanism by which foot orthoses provide benefits is unclear, they have been shown to alter plantar pressure distribution, sensory feedback, muscle activity and kinematics of the lower limb during walking and running.^{13–17} Comparatively, shock-absorbing insoles have a relatively flat profile, are made from soft materials and are predominantly used to reduce impact forces.^{9,18}

Understanding the mode of action of foot orthoses and shock-absorbing insoles provides insight into how they may work, but summarising the patient-orientated outcomes of clinical trials provides the best indication of their effectiveness. Accordingly, previous systematic reviews have determined that foot orthoses decrease the incidence of lower limb stress fractures^{19,20} and shin splints¹⁹ during initial defence training, yet they were not found to prevent other lower limb soft-tissue injuries^{5,19–21} or back pain.^{22,23} Regarding shock-absorbing insoles, systematic reviews have not found that they prevent injuries of any kind.^{5,19}

The findings of previous systematic reviews need to be considered with the knowledge that some reviews did not use meta-analysis to synthesise data,^{19,20} some reviews included studies that were not clinical trials,²⁰ and some reviews considered foot orthoses and shock-absorbing insoles as the same intervention.^{22,23} Further, several clinical trials evaluating foot orthoses for the prevention of injury have been published in recent years and these are yet to be included in systematic reviews on this topic.^{11,24–26} As such, synthesising all the contemporary literature with meta-analysis would provide clinicians with more accurate estimates of the effectiveness of foot orthoses for preventing injury.

Therefore, the aim of this systematic review was to summarise the literature and apply meta-analysis to estimate the effectiveness of foot orthoses and shock-absorbing insoles for the prevention of musculoskeletal injury.

METHODS

This systematic review and meta-analysis is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.²⁷



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Inclusion and exclusion criteria

Studies were eligible for inclusion if they were randomised or quasirandomised clinical trials investigating the effectiveness of foot orthoses or shock-absorbing insoles for the prevention of musculoskeletal injury. The foot orthoses and shock-absorbing insoles were eligible for inclusion irrespective of their length (full-length insoles, heel inserts, etc). No language restrictions were used. Non-peer-reviewed trials were excluded. Outcome measures included the number of injured participants, or if this was not available, the total number of injuries or conditions causing pain was used. Trials were excluded if the participants had pre-existing injuries at baseline.

Foot orthoses were defined as shoe inserts that had a profile that closely contours the plantar surface of a foot and were used to 'assist, resist, facilitate, stabilise or improve range of motion and functional capacity'.¹² The foot orthosis was further classified as *custom-made* if it was derived from a three-dimensional representation of an individual's foot, otherwise it was considered a *prefabricated* foot orthosis.¹² Shock-absorbing insoles were defined as shoe inserts that had a minimally contoured profile, were made from 'soft' materials (such as viscoelastic polymers, neoprene, polyurethane, etc) and were primarily used to attenuate shock. Material density and Shore A values were not used to determine if the insoles were 'shock-absorbing' as few trials reported such information.

Search strategy

A standardised search strategy was used for the following databases: Cochrane Library, CINAHL, EMBASE, MEDLINE and SPORTDiscus from their inception up to the first week of June 2016 (table 1). The search terms were agreed on by DRB and HBM. All titles and abstracts identified from the search were downloaded to Endnote VX7 (Thomson Reuters, Philadelphia, Pennsylvania, USA). Once all duplicates were removed, the titles and abstracts were independently screened by DRB and HBM to determine the clinical trial's inclusion based on the predetermined eligibility criteria. Once all clinical trials were screened for inclusion, the two authors met and discussed any discrepancies until a consensus was achieved. All clinical trials that met the inclusion and exclusion criteria, as well as previous systematic reviews on related topics had their reference list hand-searched. In addition, citation tracking was performed using Google Scholar.

Methodological quality assessment

Two reviewers (DRB and KBL) independently assessed the quality of the included clinical trials using the Physiotherapy Evidence Database (PEDro) scale.²⁸ The PEDro scale rates the

methodological quality of clinical trials using an 11-item checklist that examines external validity (criterion 1), internal validity or methodological quality (criteria 2–9) and statistical interpretability (criteria 10–11). All criteria were documented as 'yes' if 'clearly satisfied' or 'no' when 'not satisfied'. With the exception of criterion 1, which is not included in the final overall score, each criterion is allocated a score of 1 when 'clearly satisfied'. Accordingly, each trial is provided a score out of 10 with a greater score indicative of a higher quality trial that is less likely to be affected by confounding and bias. According to Maher *et al*,²⁸ a score of ≥ 6 points is indicative of moderate-to-high quality, although this is based on the assumption that each scale item is equally important when determining the methodological quality of clinical trials. The reliability of the total score obtained using the PEDro scale has been shown to be fair to good (intra-class correlation coefficient=0.56, 95% CI 0.47 to 0.65).²⁸ Once all studies were scored, the reviewers met and discussed any discrepancies and a final score was agreed on.

Data analysis

Data from each trial were extracted from the available text. Where the provided data were not sufficient for the purposes of this review, the corresponding author of the trial was contacted via email and relevant data were requested. Meta-analysis was calculated using the Cochrane Collaboration Review Manager V5.3 software. Trials were excluded from meta-analysis if the foot orthoses or shock-absorbing insoles under evaluation were not compared with a control condition. In this review, a control condition was considered either a shoe-alone without modification, no insole or a sham orthosis/insole.²⁹ The data used from each trial included the number of individuals allocated to the intervention and control groups and the number of individuals injured in each group. If the latter information was not available, the number of injuries or conditions causing pain in the intervention and control groups was used (injury definitions used by the included trials are provided in online supplementary file S1). Only lower limb and back musculoskeletal injury data were included in this review. Further, acute or traumatic injuries were not included (eg, ankle sprains). All lower limb and back injury data were broadly grouped as 'overall injuries', and subsequently subgrouped as either 'stress fractures' or 'soft-tissue injuries'. Further subgrouping was performed for specific injuries for foot orthoses (custom-made and prefabricated, combined) and shock-absorbing insoles if the injury data were available from three or more trials. A random-effects model was used for the meta-analyses as we assumed that the true effect size would vary among the included trials, due to differences between the trial design, participants,

Table 1 Search strategy

MEDLINE and EMBASE (Ovid)	CINAHL and SPORTDiscus (EBSCO)	Cochrane Library
1. exp foot orthosis/	1. MH Foot orthoses+	1. MeSH Foot Orthoses exp
2. foot orthoses.mp	2. (orthotic* OR orthosis OR orthoses OR insole* OR heel insert*)	2. (orthotic* or orthos*s or insole* or heel insert*)
3. (orthotic* OR orthosis OR orthoses OR insole* OR heel insert*)	3. #1 or #2	3. #1 or #2
4. #1 or #2 or #3	4. (prevent* OR incidence OR reduce* OR effect*)	4. (prevent* OR incidence OR reduce* OR effect*)
5. (prevent* OR incidence OR reduce* OR effect*)	5. (injur* OR stress fracture\$ OR pain OR soreness)	5. (injur* OR stress fracture\$ OR pain OR soreness)
6. (injur* OR stress fracture\$ OR pain OR soreness)	6. (randomi*ed OR controlled OR prospective OR trial OR clinical evaluation)	6. (randomi*ed OR controlled OR prospective OR trial OR clinical evaluation)
7. (randomi*ed OR controlled OR prospective OR trial OR clinical evaluation)	7. #3 and #4 and #5 and #6	7. #3 and #4 and #5 and #6
8. #4 and #5 and #6 and #7	8. Limit #7 to Human ^α	
9. Limit #8 to Human		

^α=search term # 8 was not used for SPORTDiscus database.

interventions, researchers and setting.³⁰ Risk ratios (RR) with 95% CIs were used to measure the effectiveness of the intervention. Number needed to treat (NNT) was calculated for variables that produced a statistically significant RR. Statistical heterogeneity of the included trials was calculated using the I² statistic, where <25% was classified as low risk of heterogeneity, 25–75% was classified as moderate risk of heterogeneity and >75% was classified as high risk of heterogeneity.³¹

RESULTS

The initial search yielded 1573 titles and abstracts. Seventeen trials were identified for potential inclusion once all citations were screened using the eligibility criteria. Following full-text review, 16 trials were accepted for inclusion. An additional 2 trials were identified for inclusion following citation tracking of the 16 included trials and after the reference lists of previous systematic reviews on related topics were searched.^{5 6 19–23 32} A total of 18 trials were included in this review, with 11 trials evaluating foot orthoses^{11 24–26 33–39} and 7 trials evaluating shock-absorbing insoles^{10 40–45} for the prevention of injury. All decisions regarding the selection of trials were achieved by the two reviewers with consensus. Refer to [figure 1](#) for a flow diagram of the study selection process.

The relevant methods, description of the foot orthoses and shock-absorbing insoles, participant characteristics, and the main outcomes of the included trials are provided in [tables 2](#) and [3](#).

Quality assessment

The specific details of the PEDro quality assessment scale for each trial that evaluated foot orthoses and shock-absorbing insoles are provided in [tables 4](#) and [5](#), respectively. The median

quality score for trials that evaluated foot orthoses was 5 (range 3–8/10), indicating that the general quality of trials is moderate, with there being large variation of quality across the trials. The median quality score for the trials that evaluated shock-absorbing insoles was 3 (range 1–7/10) indicating that the general quality of trials is low, with only one trial being assessed to be of moderately high quality. The criteria that were most commonly ‘not satisfied’ were adequate *allocation concealment* (criterion 3)^{10 24 33 35 37–44} and adequate *blinding of participants*,^{11 24–26 33 34 36 38–45} *therapists*,^{10 11 24–26 33–45} and *assessors*^{10 11 24 33–41 43–45} (criteria 5–7). In addition, several of the shock-absorbing insoles trials did not specify the *participant eligibility criteria* (criterion 1),^{40 42–44} used *quasirandomisation of interventions* (criterion 2),^{10 40–42 44} did not adequately provide the *baseline characteristics* of the intervention groups (criterion 4),^{40 42–44} did not adequately report *key outcome data* (criterion 8)^{41 43 44} and did not *analyse data by intention-to-treat* (criterion 9).^{10 41 43 44}

Foot orthoses

Eleven randomised trials evaluated foot orthoses for the prevention of injury among military personnel undertaking defence training.^{11 24–26 33–39} Eight of the trials evaluated one type of foot orthosis^{11 24–26 33 36 38 39} and three compared multiple foot orthosis types within a single trial.^{34 35 37} A large variety of foot orthoses were used across the trials. Two trials evaluated custom-made foot orthoses,^{34 37} eight trials evaluated prefabricated foot orthoses^{11 24–26 33 36 38 39} and one trial evaluated both prefabricated and custom-made orthoses.³⁵ The materials used in the construction of the foot orthoses included ‘soft’ materials, such as polyethylene foam, and ‘semirigid’ materials such as ortholene and polypropylene. Nine trials

Figure 1 PRISMA flow diagram for the selection of studies.

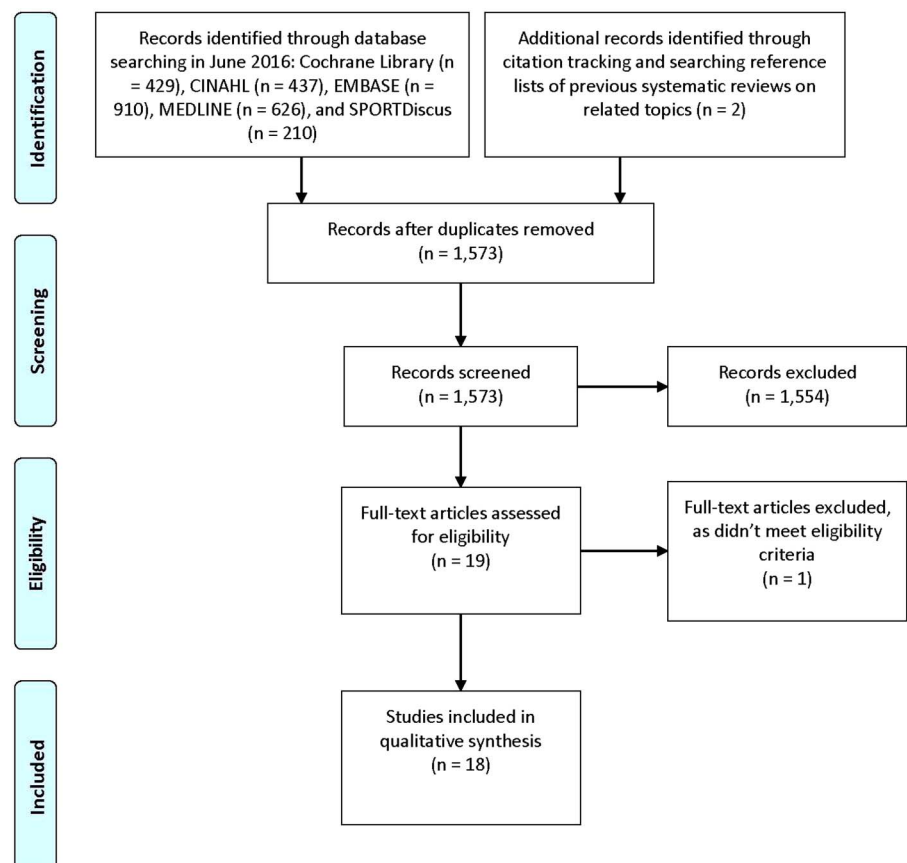


Table 2 Summary of trials evaluating foot orthoses for the prevention of injuries

First author, year	Study design	Participant details and country trial conducted	Intervention details and allocation number	Intervention period	Outcome/s
Esterman, 2005 ³³	Randomised controlled trial	47 Australian Air Force recruits with flat feet	(1) Heat-molded prefabricated three-quarter length flexible foot orthosis (Australian Orthotics Laboratory; n=25) (2) Shoe-alone (control; n=22)	8 weeks of a 10-week basic training course	No significant difference in lower limb injuries between groups. Incidence of lower limb injuries in the (1) foot orthosis and (2) shoe-alone (control) group was 20% and 5%, respectively
Finestone, 1999 ³⁴	Randomised controlled trial	404 Israeli military infantry recruits (only 197 included in analysis following drop-outs)	(1) 'Semirigid' custom-made polypropylene foot orthosis with rearfoot post (n=132) (2) 'Soft' custom-made polyurethane foot orthosis comprised of Shore 80A upper and lower layer and Shore 60A middle layer (n=128) (3) Prefabricated full-length flat insole made of 3 mm polyolefin foam covered with Cambrelle (control; n=126) (4) No insole group (n=18)	14 weeks of basic training	At 14 weeks, the (1) 'semirigid' (15.7%) and (2) 'soft' (10.7%) foot orthoses significantly reduced the incidence of stress fractures compared with the (3) flat insole (control; 24.5%) and (4) no insole group (33.3%)
Finestone, 2004 ³⁵	Randomised controlled trial	874 Israeli military infantry recruits	(1) 'Soft' custom-made polyethylene foot orthosis (1.3 g/cm ³ density top and bottom layer and 1.125 g/cm ³ density middle layer) (2) 'Soft' prefabricated polyurethane foot orthosis (1.3 g/cm ³ density top and bottom layer and 1.125 g/cm ³ density middle layer) (3) 'Semirigid' custom-made orthosis (ortholene shell with acrylic neutral rearfoot posts) (4) 'Semirigid' prefabricated orthosis (ortholene shell with acrylic neutral rearfoot posts)	14 weeks of basic training	No statistically significant difference in the incidence of stress fractures, ankle sprains or foot problems between orthotic groups
Franklyn-Miller, 2011 ¹¹	Randomised controlled trial	400 Royal (UK) Navy new-entry officer cadets classified as being 'high and medium' risk for injury based on the study's screening protocol	(1) Prefabricated foot orthoses individually customised with different densities and arch profiles (<i>D3D</i> ; n=200) (2) Shoe-alone (control)	7 weeks of initial military training	At 7 weeks, the (1) foot orthosis group had a statistically significant lower incidence of injury (10.5%) compared with the (2) shoe-alone (control) group (30.5%; absolute risk reduction 0.49, p<0.0001)
Hesarikia, 2014 ²⁴	Randomised controlled trial	610 Iranian male military recruits	(1) Prefabricated semirigid foot orthosis made from Acrylonitrile Butadiene Styrene (<i>Orthopedy-Fanni-Pishraft Medical Devices Company</i> ; n=300 although only 255 included in analysis) (2) Shoe-alone (control; n=310, although only 301 included in analysis)	2 months of military training	Compared with the (2) shoe-alone (control) group at 2 months, the (1) foot orthosis group experienced significantly less pain and tenderness in the posterior heel (p=0.001), plantar heel (p=0.002), plantar fascia (p=0.04) and metatarsals (p=0.004). Compared with the (2) shoe-alone (control), the (1) orthosis group had increased ankle tenderness (0.02). More recruits in the (2) shoe-alone (control) group were prevented from marching and walking (32.2%) due to injuries compared with the (1) orthosis group (55.8%).
Larsen, 2002 ³⁶	Randomised controlled trial	146 Danish military conscripts	(1) Prefabricated polyethylene orthosis (Formthotics). Heat moulded (n=77) (2) Shoe-alone (control; n=69)	3 months of initial military service	At 3 months, there was no significant difference (p=0.114) for overall injuries in the lower extremities and back for the (1) foot orthosis (40%) and (2) shoe-alone (control) groups (56%; RR 0.7, ARR 15%). However, the (1) orthosis group had a significantly lower number of recruits with shin splints compared with the (2) shoe-alone (control) group (RR 0.3, ARR 18%).
Mattila, 2011a ²⁶	Randomised controlled trial	220 Finnish male military conscripts	(1) Prefabricated firm-density polyethylene three-quarter length foot orthosis (<i>Thermo+Camel</i>). Heat moulded (n=73) (2) Shoe-alone (control; n=147)	6 months (includes 8 weeks of basic training following by military service)	At 6 months, there was no significant difference (p=0.29) in lower limb overuse injury in the (1) foot orthosis (46.6%) and (2) shoe-alone (control; 38.1%) groups. Similarly, there was no significant difference (p=0.56) in the mean days lost to training for the (1) foot orthosis (2.4, SD 2.0) and (2) shoe-alone (control; 1.8, SD 2.0) groups.

Continued

Table 2 Continued

First author, year	Study design	Participant details and country trial conducted	Intervention details and allocation number	Intervention period	Outcome/s
Mattila, 2011b ²⁵	Randomised controlled trial	220 Finnish male military conscripts	(1) Prefabricated firm-density polyethylene three-quarter length foot orthosis (<i>Thermo</i> + <i>Camel</i>). Heat moulded (n=73) (2) Shoe-alone (control; n=147)	6 months (includes 8 weeks of basic training following by military service)	At 6 months, 33% of participants in the (1) foot orthosis group and 27% in the (2) shoe-alone (control) group missed at least 1 day of training due to low back pain (p=0.37). The mean time lost to training was 2 days (range 1–7) in both groups. In summary, there were no differences in rates of low back pain and days lost due to low back pain between the (1) foot orthosis and (2) shoe-alone (control) groups.
Milgrom, 1985 ³⁸	Randomised controlled trial	295 Israel male military recruits	(1) Prefabricated 'military stress' foot orthosis (Langer Biomechanics Group). Shell made from 3.5 mm polyolefin plastic and a 3° varus rubber heel post. 1/8th inch PPT was applied to the heel post and also applied as a shell-length top cover (n=143) (2) Shoe-alone (control; n=152)	14 weeks of basic training	Overall incidence of femoral, tibial and metatarsal fractures was 29.2% in the (1) foot orthosis group and 46% in the (2) shoe-alone (control) group. Regarding specific fractures, the (1) foot orthosis group experienced significantly lower incidence (10% vs 18%) of femoral stress fractures (p<0.05). There was no significant difference in the incidence of tibial and metatarsal fractures between groups.
Milgrom, 2005 ³⁷	Randomised controlled trial	381 Israel military recruits	(1) 'Semirigid' custom-made polypropylene foot orthosis with integrated neutral rearfoot post, with shell thickness determined by the participant's body weight (2) 'Soft' full-length custom-made polyurethane foot orthosis (Shore 80A top layer, Shore 60A middle layer, and Shore 80A bottom layer) (3) Prefabricated full-length flat insole made of 3 mm polyolefin foam covered with Cambrelle (<i>Eshed Advanced Orthopedics</i> ; control)	14 weeks of training	At 14 weeks, the incidence of back pain in the (1) semirigid foot orthosis (12.4%), (2) soft foot orthosis (13.5%) and (3) flat insole (control; 14.3%) was not statistically different (p=0.98).
Simkin, 1989 ³⁹	Randomised controlled trial	295 Israel military recruits Note: 30 recruits dropped out of the orthotic group so they were excluded from analysis	(1) Prefabricated 'military stress' foot orthosis (Langer Biomechanics Group). Shell made from 3.5 mm polyolefin plastic and a 3° varus rubber heel post. 1/8th inch PPT was applied to the heel post and also applied as a shell-length top cover (n=143) (2) Shoe-alone (control; n=152)	14-week training period	Incidence of femoral stress fracture was 5.1% for the (1) foot orthosis group compared with 15.5% in the (2) shoe-alone (control) group. Incidence of metatarsal stress fractures was 0.5% for the (1) foot orthosis group compared with 3.2% in the (2) shoe-alone (control) group. The (1) foot orthosis group experienced a significantly lower rate of femoral stress fractures in recruits with high arches (p=0.003) and metatarsal stress fractures in recruits with low arches (p=0.02).

ARR, adjusted risk ratio; RR, risk ratio.

Table 3 Summary of trials evaluating shock-absorbing insoles for the prevention of injuries

First author, year	Study design	Participant details and country trial conducted	Intervention details and allocation number	Intervention period	Outcome/s
Andrish, 1974 ⁴⁰	Quasirandomised trial (stratified by scholastic and athletic aptitudes)	2777 first-year US male naval midshipmen	(1) Normal training and no intervention (control; n=1453) (2) Heel pad made from 13 mm foam rubber (n=344) (3) 'Heel cord stretches' (n=300) (4) Heel pad and heel cord stretches (n=463) (5) Graduated running programme (n=217)	'Over a summer training programme'. Specific period not provided	No significant differences in incidence of shin splints between groups. Incidence of shin splints in each group was 2.96% for the (1) control, 4.36% for the (2) heel pad, 4.00% for (3) heel cord stretches, 3.03% for (4) heel pad and heel cord stretches, and 6% for (5) graduated running programme.
Fauno, 1993 ⁴¹	Quasirandomised trial (based on birth date)	91 soccer referees (Denmark)	(1) Prefabricated 8 mm 'shock-absorbing heel insert' (<i>action</i> ; n=48) (ii) No intervention (control; n=43)	5-day soccer tournament	Incidence of soreness was reported for the (1) shock-absorbing heel inserts and the (2) no intervention (control) groups (respectively) for each day of the tournament: day 1 (46% vs 65%), day 2 (63% vs 88%), day 3 (63% vs 93%), day 4 (63% vs 93%) and day 5 (44% vs 88%). The (1) heel insert group experienced a significantly lower rate of soreness in the Achilles tendon, calf and back (p<0.05) on days 2–4.
Gardner, 1988 ⁴²	Quasirandomised trial (based on platoon number)	3025 US marine recruits	(1) Prefabricated 'viscoelastic polymer (Sorbothane)' insole (n=1557) (2) Standard mesh insole (control group; n=1468)	12 weeks of training	No significant difference between insoles in preventing stress fractures as 1.35% experienced a stress fracture in the (1) polymer insole group, compared with 1.13% in the (2) standard mesh insole (control) group (relative risk 1.17; 95% CI 0.62 to 2.2).
Schweltnus, 1990 ⁴³	Randomised controlled trial	1388 South African military recruits	(1) Shock-absorbing flat insole made from neoprene impregnated with nitrogen bubbles and covered with stretch nylon (n=250) (2) Standard military footwear (control; n=1261)	9 weeks of training	Compared with the (2) standard military footwear (control) group, the (1) shock-absorbing flat insole group experienced a significantly lower incidence of overuse injuries (p<0.05). The incidence of injury in the (1) shock-absorbing flat insole group was 22.8%, compared with 31.9% in the (2) standard military footwear (control) group.
Sherman, 1996 ¹⁰	Quasirandomised trial (intervention allocation alternated between training units)	1132 US army trainees	(1) Cushioning shoe insert (<i>Spenco Polysorb walker-runner</i> ; n=517) (2) No intervention (control; n=397) (3) Recruits assigned to 'no intervention' but purchased their own cushioning shoe inserts (n=218)	Basic training (exact number of weeks not stated)	No significant differences in lower limb injuries were found between groups, with an incidence of 38% in the (1) cushioning shoe insert group, 29% in the (2) no intervention (control) group, and 38% in the (3) recruits who were not originally allocated inserts but purchased their own.
Smith, 1985 ⁴⁴	Quasirandomised trial (intervention allocation by dividing participants 'into 3 groups')	90 US coast guard recruits (68 included in analysis following drop-outs)	(1) One-eighth inch thick cellular polyurethane insole (<i>Poron</i> ; n=23) (2) One-eighth inch thick closed cellular neoprene polymer insole (<i>Spenco</i> ; n=21) (3) Shoe-alone (control; n=24)	8 weeks of recruit training	Statistical testing was not performed. The (1) Poron (8.7%) and (2) Spenco (8.7%) insole groups both reported lower rates of injuries than the (3) shoe-alone (control) group (29.2%).
Withnall, 2006 ⁴⁵	Randomised controlled trial	1205 Royal (UK) Air Force recruits	(1) Shock-absorbing insole made from moulded 3 mm polyurethane foam with 1 mm viscoelastic polymer in the heel and forefoot region (<i>Sorbothane</i> ; n=421) (2) Shock-absorbing flat insole made from open-cell polyurethane high-density foam (<i>Poron</i> ; n=414) (3) Standard issue Saran insole (control group). Flat insole consisting of a 3 mm base of course weave plastic with a nylon fabric top cover (n=401)	9 weeks	There was no significant difference between the insoles in reducing lower limb injury (OR 1.04, 95% CI 0.75 to 1.44; p=0.87). The incidence of lower limb injury was 18.0% for the (3) Saran insole (control) group, 17.3% for the (1) Sorbothane group and 19.8% for the (2) Poron group. There was no difference in injury incidence between the shock-absorbing insole groups (OR 0.85; 95% CI 0.58 to 1.23; p=0.37).

Table 4 The quality assessment scores (PEDro) of the included trials evaluating foot orthoses for the prevention of injury

First author, year	Eligibility criteria specified	Appropriate randomisation	Allocation concealment	Groups similar at baseline	Participants blinded to intervention	Therapists blinded to intervention	Assessors blinded to intervention	Outcome measures obtained from at least 85% of participants	Intention-to-treat analysis	Between-group statistical comparisons are reported	Point measures and measures of variability are provided	PEDro quality rating (score/10)
Esterman, 2005 ³³	Specified	1	0	0	0	0	0	1	1	1	1	5
Finestone, 1999 ³⁴	Not specified	1	1	0	0	0	0	0	0	1	1	4
Finestone, 2004 ³⁵	Not specified	1	0	0	1	0	0	0	0	1	1	4
Franklyn-Miller, 2011 ¹¹	Specified	1	1	1	0	0	0	1	1	1	1	7
Hesarikia, 2014 ²⁴	Specified	1	0	1	0	0	0	1	0	1	1	5
Larsen, 2002 ³⁶	Not Specified	1	1	0	0	0	0	1	1	1	1	6
Mattila, 2011a ²⁶	Specified	1	1	1	0	0	1	1	1	1	1	8
Mattila, 2011b ²⁵	Specified	1	1	1	0	0	1	1	1	1	1	8
Milgrom, 1985 ³⁸	Not specified	1	0	0	0	0	0	0	0	1	1	3
Milgrom, 2005 ³⁷	Not Specified	1	0	0	1	0	0	1	0	1	1	5
Simkin, 1989 ³⁹	Not Specified	1	0	0	0	0	0	0	0	1	1	3

0=not satisfied, 1=satisfied.
 PEDro, Physiotherapy Evidence Database.

Table 5 The quality assessment scores (PEDro) of the included trials evaluating shock-absorbing insoles for the prevention of injury

First author, year	Eligibility criteria specified	Appropriate randomisation	Allocation concealment	Groups similar at baseline	Participants blinded to intervention	Therapists blinded to intervention	Assessors blinded to intervention	Outcome measures obtained from at least 85% of participants	Intention-to-treat analysis	Between-group statistical comparisons are reported	Point measures and measures of variability are provided	PEDro quality rating (score/10)
Andrish, 1974 ⁴⁰	Not specified	0	0	0	0	0	0	1	1	1	1	4
Fauno, 1993 ⁴¹	Specified	0	0	1	0	0	0	0	0	1	1	3
Gardner, 1988 ⁴²	Not specified	0	0	0	0	0	1	1	1	1	1	5
Schwelinius, 1990 ⁴³	Not specified	1	0	0	0	0	0	0	0	1	1	3
Sheman, 1996 ¹⁰	Specified	0	0	1	1	0	0	1	0	1	1	5
Smith, 1985 ⁴⁴	Not specified	0	0	0	0	0	0	0	0	0	1	1
Withnall, 2006 ⁴⁵	Specified	1	1	1	0	0	0	1	1	1	1	7

0=not satisfied, 1=satisfied.
PEDro, Physiotherapy Evidence Database.

compared foot orthoses to a 'shoe-alone' control condition. Of the remaining trials, one by Milgrom *et al*³⁷ used a flat insole as a control condition, while another by Finestone *et al*³⁵ compared four different foot orthoses (which included custom-made, prefabricated, 'soft' and 'hard' foot orthoses) with each other. The latter trial was included in this systematic review, but it was excluded from the meta-analysis as it did not use a control condition.³⁵

Foot orthoses (custom-made and prefabricated foot orthoses combined)

The data from 10 trials evaluating custom-made and/or prefabricated foot orthoses were pooled, with four yielding results favouring the use of foot orthoses for the prevention of injury compared with a control. No trial favoured the control intervention. The pooled data indicated that foot orthoses are effective for preventing overall injuries (RR 0.72, 95% CI 0.55 to 0.94; NNT 10, 95% CI 7.7 to 13.6), with heterogeneity of results between trials being high ($I^2=75\%$). Regarding stress fractures alone, the data from four trials indicated that foot orthoses are effective for preventing lower limb stress fractures (RR 0.59, 95% CI 0.45 to 0.76; NNT 20, 95% CI 12.8 to 41.1), with heterogeneity of results between trials being low ($I^2=0\%$). In contrast, the data from seven trials indicated that foot orthoses are not effective for preventing soft-tissue injuries (RR 0.79, 95% CI 0.55 to 1.14), with heterogeneity of results between trials being high ($I^2=82\%$; [figure 2](#)).

When specific injuries were considered, the pooled data demonstrated that foot orthoses are effective for preventing metatarsal stress fractures (RR 0.25, 95% CI 0.09 to 0.69; NNT 42, 95% CI 26.0 to 97.7), tibial stress fractures (RR 0.65, 95% CI 0.43 to 0.96; NNT 23, 95% CI 11.9 to 320.9), femoral stress fractures (RR 0.53, 95% CI 0.35 to 0.80; NNT 21, 95% CI 13.1 to 48.1) and shin pain (RR 0.27, 95% CI 0.08 to 0.90; NNT 14, 95% CI 9.1 to 23.1). However, the data showed that foot orthoses are not effective for preventing Achilles pain (RR 0.44, 95% CI 0.18 to 1.04), knee pain (RR 0.94, 95% CI 0.56 to 1.55) or back pain (RR 1.04, 95% CI 0.76 to 1.42; see online supplementary file S2).

Custom-made foot orthoses

The data from two trials evaluating custom-made foot orthoses were pooled,^{34 37} with one trial yielding results favouring the use of custom-made foot orthoses for the prevention of injury compared with a control.³⁴ No trial favoured the control intervention. The pooled data indicated that custom-made foot orthoses are not effective for preventing overall injuries (RR 0.71, 95% CI 0.41 to 1.22), with heterogeneity of results between trials being moderate ($I^2=41\%$). Regarding stress fractures alone, the data from one trial³⁴ indicated that custom-made foot orthoses are effective for preventing lower limb stress fractures (RR 0.52, 95% CI 0.27 to 1.00; NNT 9, 95% CI -88.40 to 4.00). In contrast, the data from one trial³⁷ indicated that custom-made foot orthoses are not effective for preventing soft-tissue injuries (RR 0.91, 95% CI 0.53 to 1.54; see online supplementary file S3).

When specific injuries were considered, the pooled data demonstrated that custom-made foot orthoses are effective for preventing tibial stress fractures (RR 0.46, 95% CI 0.22 to 0.93; NNT 9, 95% CI -755.80 to 4.00). However, the data showed that custom-made foot orthoses are not effective for preventing metatarsal stress fractures (RR 0.14, 95% CI 0.01 to 3.42), femoral stress fractures (RR 0.63, 95% CI 0.24 to 1.68)

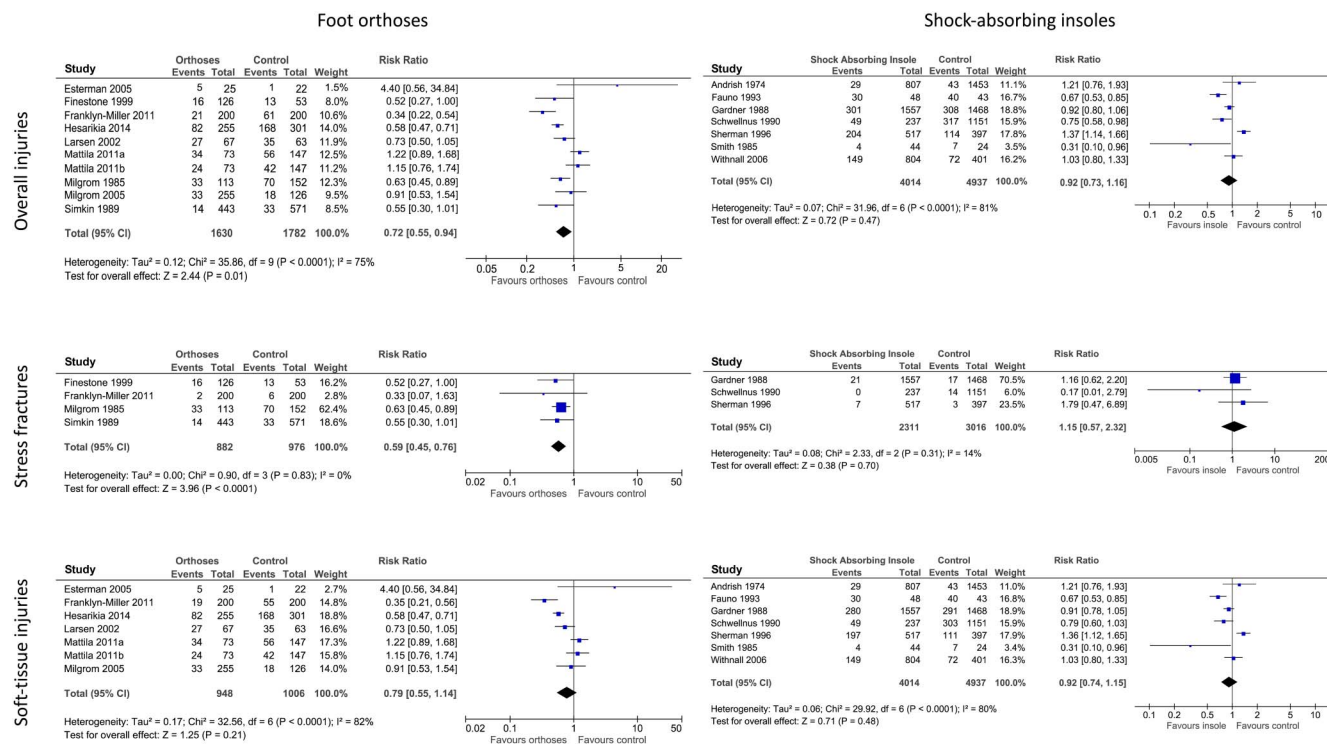


Figure 2 Meta-analysis of overall injuries (top row), stress fractures (middle row) and soft-tissue injuries (bottom row) with foot orthoses (left column) and shock-absorbing insoles (right column).

or back pain (RR 0.91, 95% CI 0.53 to 1.54; see online supplementary file S4).

Prefabricated foot orthoses

The data from eight trials evaluating prefabricated foot orthoses were pooled, with three trials yielding results favouring the use of prefabricated foot orthoses for the prevention of injury compared with a control.^{11 24 38} No trial favoured the control intervention. The pooled data indicated that prefabricated foot orthoses are effective for preventing overall injuries (RR 0.72, 95% CI 0.53 to 0.98; NNT 11, 95% CI 7.7 to 14.8), with heterogeneity of results between trials being high ($I^2=80\%$). Regarding stress fractures alone, the data from three trials^{11 38 39} indicated that prefabricated foot orthoses are effective for preventing lower limb stress fractures (RR 0.60, 95% CI 0.45 to 0.80; NNT 19, 95% CI 12.4 to 38.4), with heterogeneity of results between the trials being low ($I^2=0\%$). In contrast, the data from six trials^{11 24-26 33 36} indicated that prefabricated foot orthoses are not effective for preventing soft-tissue injuries (RR 0.78, 95% CI 0.52 to 1.18), with heterogeneity of results between trials being high ($I^2=84\%$; see online supplementary file S3).

When specific injuries were considered, the pooled data demonstrated that prefabricated foot orthoses are effective for preventing metatarsal stress fractures (RR 0.27, 95% CI 0.09 to 0.78; NNT 42, 95% CI 25.5 to 117.6), femoral stress fractures (RR 0.51, 95% CI 0.33 to 0.80; NNT 20, 95% CI 12.3 to 42.7) and shin pain (RR 0.27, 95% CI 0.08 to 0.90; NNT 14, 95% CI 9.1 to 23.1). However, the data showed that prefabricated foot orthoses are not effective in preventing tibial stress fractures (RR 0.76, 95% CI 0.47 to 1.22), Achilles pain (RR 0.44, 95% CI 0.18 to 1.04), knee pain (RR 0.94, 95% CI 0.56 to 1.55) or back pain (RR 1.12, 95% CI 0.76 to 1.65; see online supplementary file S5).

Shock-absorbing insoles

Seven trials (five quasirandomised^{10 40-42 44} and two randomised^{43 45}) evaluated shock-absorbing insoles for the prevention of injury. Five trials were conducted on military recruits undertaking initial defence training,^{10 40 42 43 45} one on soccer referees working at a 5-day tournament,⁴¹ and another on coast guards attending recruit training.⁴⁴ Five of the trials evaluated a single shock-absorbing insole,^{10 40-43} while two compared a variety of insoles.^{44 45} All of the shock-absorbing insoles had a minimally contoured (relatively flat) profile and were prefabricated or made from a commercially available material. The shock-absorbing insoles were fabricated from 'soft' materials, most commonly polyethylene or neoprene foam. Five trials evaluated full-length shock-absorbing insoles^{10 42-45} and two trials evaluated shock-absorbing heel inserts.^{40 41}

The data from the seven trials evaluating shock-absorbing insoles were pooled, with none yielding results favouring the use of shock-absorbing insoles for the prevention of injury compared with a control. One trial favoured the control intervention.¹⁰ The pooled data indicated that shock-absorbing insoles are not effective for preventing overall injuries (RR 0.92, 95% CI 0.73 to 1.16), with heterogeneity of results between trials being high ($I^2=81\%$). Regarding stress fractures alone, data from three trials^{10 42 43} showed that shock-absorbing insoles are not effective for preventing lower limb stress fractures (RR 1.15, 95% CI 0.57 to 2.32), with heterogeneity of results between trials being low ($I^2=14\%$). Likewise, data from the seven trials demonstrated that shock-absorbing insoles are not effective for preventing soft-tissue injuries (RR 0.92, 95% CI 0.74 to 1.15), with heterogeneity of results between trials being high ($I^2=80\%$; figure 2).

When specific injuries were considered, the pooled data demonstrated that shock-absorbing insoles are not effective for preventing any condition investigated in this meta-analysis,

including soft-tissue foot pain (RR 0.94, 95% CI 0.63 to 0.141), calf pain (RR 0.92, 95% CI 0.47 to 1.81), shin pain (RR 0.89, 95% CI 0.51 to 1.57) and knee pain (RR 1.01, 95% CI 0.78 to 1.32; see online supplementary file S6).

DISCUSSION

The aim of this systematic review was to summarise the literature and apply meta-analysis to estimate the effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury. A total of 18 clinical trials were included in this systematic review, with 11 randomised trials evaluating foot orthoses and 7 trials (randomised and quasirandomised) evaluating shock-absorbing insoles. Meta-analysis found that foot orthoses provide a 28% reduction in the risk of developing an overall injury and a 41% reduction in the risk of developing a lower limb stress fracture, but foot orthoses were not found to reduce the risk of developing a soft-tissue injury. Shock-absorbing insoles were not found to be effective for the prevention of any type of injury.

This review establishes that foot orthoses prevent injuries in a broad sense, but knowing if orthoses prevent specific injuries may be of additional interest (eg, shin pain among distance runners).¹ When considering the prophylactic effect foot orthoses and shock-absorbing insoles have on specific injuries, there is evidence that foot orthoses reduce the risk of developing shin pain by 73% and stress fractures of the tibia, femur and metatarsals by 35%, 47% and 75%, respectively. However, the data from this review showed that foot orthoses do not prevent some specific musculoskeletal injuries, including Achilles pain, knee pain and back pain.¹ Accordingly, the prophylactic use of foot orthoses may be justified in populations that have been identified as experiencing a high incidence of shin pain and lower limb stress fractures, but of limited benefit if attempting to prevent any other specific musculoskeletal injury. In contrast, shock-absorbing insoles were not shown to be effective for preventing injuries of any type and in one trial were shown to have harmful effects, increasing the incidence of injury.¹⁰

Estimating the number of individuals that need to receive foot orthoses to prevent one injury (known as NNT) can provide a clinically useful measure of their relative benefit. The findings of this review found that 10 people need to receive foot orthoses to prevent one lower limb or back injury, while 20 people require foot orthoses to prevent one lower limb stress fracture. Such information provides clinicians, patients, sporting teams and occupational institutions a practical indication associated with using foot orthoses for the prevention of injuries. However, simply using 'NNT' to determine the viability of using foot orthoses as a preventative intervention needs to be contextualised with the knowledge that different types of injuries have different recovery times and associated costs. For example, more individuals need to use foot orthoses to prevent one stress fracture compared with other injuries, but as stress fractures often require a relatively longer period of rehabilitation the benefit of preventing a fracture is likely to be greater.³

This meta-analysis provides evidence that foot orthoses reduce the incidence of some injuries. However, there was a high degree of heterogeneity (measured with the I^2 statistic) for overall injuries and soft-tissue injuries, which indicates a high degree of inconsistency among the trial findings. It is difficult to speculate on the reasons for this but it may be, in part, explained by variations in the study characteristics. Such variations across the trials include differences in participants (although most were military personnel), footwear, foot

orthoses and shock-absorbing insoles, training regimes and definitions of injury. In contrast, there was low heterogeneity regarding the stress fracture data indicating that the findings from the four trials included in this analysis were similar.

When reviewing orthotic research, it is important to consider if the devices being evaluated, and the individuals receiving them, are reflective of contemporary clinical practice. Regarding the 'custom-made' foot orthoses included in this review, all devices were derived from a three-dimensional representation of each individual's foot yet the majority of prescription variables were standardised (eg, same materials, thickness of material, etc).^{34 35 37} This is in contrast to current clinical practice as custom-made foot orthoses are generally prescribed by taking into account an individual's biomechanical and physical characteristics.⁴⁶ Only one trial attempted to individualise the custom-made orthoses by using a thicker material for heavier individuals; although the individualisation was minimal as no other prescription variables were considered.³⁷ Of interest, the only foot orthoses included in this review that were individualised based on biomechanical parameters was a modular prefabricated orthosis, whereby the material density and arch profile was determined from each individual's plantar pressure assessment.¹¹ Further, only 2 of the 11 trials included in this review issued foot orthoses to participants based on individual biomechanical parameters, with one trial only including participants with 'flat feet',³³ while another used a novel plantar pressure analysis to classify military recruits as being 'high or medium' risk of injury.¹¹ As the majority of trials issued foot orthoses to individuals on the premise that they were at risk of injury due to their occupational demands, it seems unlikely that the orthoses were used to address any particular biomechanical variable considered a risk factor for injury. However, it must be noted that it is challenging to identify individuals most likely to benefit from the prophylactic use of foot orthoses and shock-absorbing insoles as the evidence for biomechanical parameters, including impact,⁴⁷ foot posture⁴⁸ and dynamic foot function⁴⁹ as risk factors for injury is limited.

In addition to considering the foot orthoses and shock-absorbing insoles under evaluation in a controlled clinical trial, it is important to assess the control intervention that was used as it may influence the findings. All but one trial included in this review used either a control insole (typically a flat insole) or standard military-issued footwear (shoe-alone) as the comparator condition. The benefits of using a shoe-alone control are that it allows the foot orthoses or shock-absorbing insoles to be directly compared with the standard footwear used at the time of the trial.⁵⁰ However, trials that did not use a control insole may be affected by methodological issues that may confound or bias the findings, such as placebo effect, ascertainment bias and resentful demoralisation.²⁹ Trials that used a control insole may have mitigated these issues, but this is difficult to determine as no trial measured whether participant blinding was successful,⁵¹ whether the interventions were perceived as credible,⁵² or indeed, whether the control interventions had mechanical or physiological effects.^{50 52}

The findings of this review need to be viewed in light of several limitations. First, the majority of clinical trials included in this review were assessed as being of poor quality (only 5 of the 18 trials received a PEDro score of ≥ 6). Of particular note, many of the trials lacked participant, therapist and assessor blinding, allocation concealment, appropriate randomisation and did not use the intention-to-treat principle to analyse data. Such methodological limitations have the potential to bias or confound results, and as such, the findings from the trials need

to be interpreted with some caution. Second, the setting in which the trials were conducted may influence the external validity and generalisability of the findings. The majority of participants in the included trials were defence force personnel who are unlikely to be representative of the general population due to their age, use of military footwear, living arrangements and tightly regulated exercise patterns. Furthermore, four trials were conducted in the Israeli army over a 20-year period (1985–2005) when military recruits were experiencing a high incidence of stress fractures.^{34 35 38 39} In the ensuing 25 years, the same group of researchers reported that there was a 60% decrease in the incidence of stress fractures, which was attributed to enforcing a minimum sleep regimen and lowering cumulative marching distance during training.⁵³ This highlights the need to consider the relevance of trial settings and how the findings can be applied to contemporary defence and sporting populations. Third, as the definition of an injury varied across the included trials it is likely that this affected the reported injury incidence among the trials.⁵⁴ Until standardised injury definitions are established, and used, this will remain an inherent limitation with studies reporting injury incidence.⁵⁴ Finally, future trials that evaluate foot orthoses and shock-absorbing insoles for the prevention of injury should consider including participants who are generalisable to the broader population, provide clear definitions of injury and use the best available methods so they contribute additional evidence of the highest possible quality.⁵⁵ Specifically, future trials should randomise participants appropriately, use an appropriate control intervention, ensure allocation concealment, participant and assessor blinding, and adhere to the intention-to-treat principle to analyse data.

CONCLUSIONS

The findings of this systematic review demonstrate that foot orthoses are effective for preventing overall injuries, shin pain and stress fractures of the metatarsals, tibia and femur. Shock-absorbing insoles were not found to be effective in preventing overall injuries, stress fractures or soft-tissue injuries. However, the findings of this review need to be interpreted with some caution as the methodological quality of the included trials was generally low. Further well-designed trials will assist the accuracy of the estimates of risk reduction and precision obtained in this review.

What are the findings?

- ▶ Foot orthoses were found to be effective for preventing overall injuries and stress fractures, but not soft-tissue injuries.
- ▶ Shock-absorbing insoles were not found to be effective for the prevention of injury.

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Effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury: a systematic review and meta-analysis

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