Interventions for preventing lower limb soft-tissue running injuries (Review)

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[Intervention Review]

Interventions for preventing lower limb soft-tissue running injuries

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ABSTRACT

Background

Overuse soft-tissue injuries occur frequently in runners. Stretching exercises, modification of training schedules, and the use of protective devices such as braces and insoles are often advocated for prevention. This is an update of a review first published in 2001.

Objectives

To assess the effects of interventions for preventing lower limb soft-tissue running injuries.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (March 2011); *The Cochrane Library* 2010, Issue 4; MEDLINE (1966 to January 2011); EMBASE (1980 to January 2011); and international trial registries (17 January 2011).

Selection criteria

Randomised or quasi-randomised trials evaluating interventions to prevent lower limb soft-tissue running injuries.

Data collection and analysis

Two authors independently assessed risk of bias (relating to sequence generation, allocation concealment, blinding, incomplete outcome data) and extracted data. Data were adjusted for clustering if necessary and pooled using the fixed-effect model when appropriate.

Main results

We included 25 trials (30,252 participants). Participants were military recruits (19 trials), runners from the general population (three trials), soccer referees (one trial), and prisoners (two trials). The interventions tested in the included trials fell into four main preventive strategies: exercises, modification of training schedules, use of orthoses, and footwear and socks. All 25 included trials were judged as 'unclear' or 'high' risk of bias for at least one of the four domains listed above.

We found no evidence that stretching reduces lower limb soft-tissue injuries (6 trials; 5130 participants; risk ratio [RR] 0.85, 95% confidence interval [95% CI] 0.65 to 1.12). As with all non-significant results, this is compatible with either a reduction or an increase in soft-tissue injuries. We found no evidence to support a training regimen of conditioning exercises to improve strength, flexibility and coordination (one trial; 1020 participants; RR 1.20, 95% CI 0.77 to 1.87).

We found no evidence that a longer, more gradual increase in training reduces injuries in novice runners (one trial; 486 participants; RR 1.02, 95% CI 0.72 to 1.45). There was some evidence from a poor quality trial that additional training resulted in a significant increase in the number of naval recruits with shin splints (one trial; 1670 participants; RR 2.02, 95% CI 1.11 to 3.70). There was limited evidence that injuries were less frequent in prisoners when running duration (one trial; 69 participants; RR 0.41, 95% CI 0.21 to 0.79) or frequency (one trial; 58 participants; RR 0.19, 95% CI 0.06 to 0.66) were reduced.

Patellofemoral braces appear to be effective for preventing anterior knee pain (two trials; 227 participants; RR 0.41, 95% CI 0.24 to 0.67).

Custom-made biomechanical insoles may be more effective than no insoles for reducing shin splints (medial tibial stress syndrome) in military recruits (one trial; 146 participants; RR 0.24, 95% CI 0.08 to 0.69).

We found no evidence in military recruits that wearing running shoes based on foot shape, rather than standard running shoes, significantly reduced rate of running injuries (2 trials; 5795 participants; Rate Ratio 1.03, 95% CI 0.93 to 1.14).

Authors' conclusions

Overall, the evidence base for the effectiveness of interventions to reduce soft-tissue injury after intensive running is very weak, with few trials at low risk of bias. More well-designed and reported RCTs are needed that test interventions in recreational and competitive runners.

PLAIN LANGUAGE SUMMARY

Interventions for preventing lower limb soft-tissue injuries in runners

Lower limb soft-tissue injuries are common in runners. Most running-related injuries are overuse injuries and the causes of these injuries are often multifactorial. Prevention strategies attempt to target modifiable risk factors. We included 25 trials with 30,252 participants in this review. Only three of the trials recruited runners from the general population, and one recruited soccer referees. Nineteen trials involved service personnel (Army, Marines, Naval personnel etc) undertaking basic training which includes intensive periods of running, along with other activities. Two trials were conducted in prisons.

The included trials tested four categories of interventions: exercises, modification of training schedules, use of orthoses, and footwear and socks.

In the following results, where there is "no evidence" that an intervention worked, the results were compatible with either a reduction or an increase in the number of soft-tissue injuries.

There is no evidence that improving physical attributes by exercises (stretching or conditioning exercises) reduces lower limb soft-tissue injuries.

With regards to the modification of training schedules, there is no evidence that a longer training programme with a gradual increase in the amount of running is more effective than a shorter training programme for preventing injuries in novice runners training for a four-mile recreational run. Having a longer build-up in training intensity may even result in an increase in sore shins in people undergoing military training. There is limited evidence from two poor quality trials conducted in prisons for the effectiveness of decreased frequency or duration of running but these results may not apply to runners in general, or military recruits.

Knee braces may reduce the frequency of anterior knee pain. Custom-made biomechanical insoles may be more effective than no insoles for reducing shin splints (medial tibial stress syndrome) in military recruits. There is no evidence to support the use of shoe insoles for the reduction of other lower limb soft-tissue injuries, whether they are individually prescribed to suit foot shape or off-the-shelf.

There is no evidence that running shoes prescribed to suit individual foot shape are better than standard running shoes for preventing injuries in military recruits.

Overall, the evidence for the effectiveness of interventions to reduce lower-limb pain and injury after intensive running is very weak. More trials, designed, conducted and reported to contemporary standards, would be required to confirm these findings, especially in recreational or competitive runners, rather than military recruits.

BACKGROUND

Description of the condition

Regular physical activities such as running have many beneficial effects including reduction of risk factors for cardiovascular disease. Despite these health benefits, running injuries are common. In a systematic review of reports describing the incidence of lower-extremity running injuries in long distance runners the overall incidence from 17 studies ranged from 19.4% to 79.3% (Van Gent 2007). In a later cohort study of 725 recreational male marathon runners, 54.8% sustained one or more running injuries in the year prior to a marathon (Van Middelkoop 2008a).

Definitions of running injuries differ between studies making comparisons difficult (Van Gent 2007). However, they are generally lower-limb overuse injuries, most commonly soft-tissue injuries and stress fractures. This review focuses on interventions for preventing lower limb soft-tissue injuries, while Rome 2005 summarises the evidence for preventing (and treating) stress fractures and stress reactions of bone in young people.

In Van Gent 2007, the predominant site of lower-extremity injuries was the knee with an incidence ranging from 7.2% to 50.0%. Other common sites were the lower leg (shin, Achilles tendon, calf, and heel), foot (including toes), and upper leg (hamstring, thigh, and quadriceps) with overall incidences ranging from 9.0% to 32.2%, 5.7% to 39.3%, and 3.4% to 38.1% respectively. Iliotibial band syndrome, tibial stress syndrome (often referred to as 'shin splints'), patellofemoral pain syndrome, Achilles tendinitis, posterior tibial tendonitis and plantar fasciitis are some of the commonly diagnosed soft-tissue injuries (Heir 1996; Vleck 1998). These injuries present in a spectrum of severity ranging from inflammation and pain to structural degeneration.

Running- or training-related overuse lower-limb injuries are also common in occupations that involve vigorous repetitive lower-limb activities and training. Army recruits have a high prevalence of lower-limb injury during their initial training with about 25% of men and 50% of women incurring one or more injuries (Jones 1999; Knapik 2006). Sixty to 80 per cent of these injuries are overuse lower-extremity injuries (Bullock 2010). In 2006 in the United States, 743,547 injury-related musculoskeletal conditions were treated in active duty members of the Air Force, Army, Marines, and Navy (Hauret 2010). Thirty-five per cent of these were overuse injuries of the lower extremities (inflammation and pain) (256,268 cases). In a similar study using 2004 statistics, overuse lower-extremity injuries (inflammation, pain and stress fractures) resulted in three million days of limited duty (10,420 person years) (Ruscio 2010). The prevalence of lower-limb injuries in military recruits and infantry soldiers is comparable or even higher than that of endurance athletes (Almeida 1999; Kaufman 2000).

Description of the intervention

Prevention of sports-related injuries should follow four stages (Van Mechelen 1992). The incidence and severity of the sports injury problem should be established, and the aetiology and mechanism of the injuries identified. Appropriate prevention measures (interventions) can then be introduced, and their effectiveness evaluated. Van Gent 2007 identified four categories of risk factors that might predispose to lower-extremity injuries in runners: systemic factors, lifestyle factors, health factors and running/training related factors. Running- and training-related factors include weekly mileage, history of previous running injuries, number of years in running, training characteristics (speed, frequency, surface, timing), training surface, and footwear (Macera 1992; Marti 1988; Taunton 2003; Van Middelkoop 2008b).

Preventive strategies such as modifying the training schedule, the use of stretching or warm-up/cool down exercises, and modification of footwear have been described.

Why it is important to do this review

Soft-tissue running injuries are often severe enough to cause a decrease or cessation of training, and it has been reported that 12% to 44% require medical attention (Brunet 1990; Koplan 1995; Macera 1992; Marti 1988). The impact of injuries among military recruits is also significant. They result in time off work and training, and more importantly, decreased military readiness (Ruscio 2010). These injuries have serious implications in terms of morbidity and costs of medical care therefore effective interventions are required to reduce their impact. This review aims to identify such interventions and is an update of a Cochrane review first published in 2001 (Yeung 2001a).

OBJECTIVES

To assess the effects of interventions for preventing lower limb soft-tissue running injuries.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and quasi-randomised (for example, allocation by date of birth or alternation) controlled trials.

Types of participants

We included trials involving individuals of either gender from adolescence to middle age. Participants had to be involved in running, either recreationally or professionally. We also included trials where the participants were service personnel e.g. soldiers, if they met our other inclusion criteria. We excluded trials where the participants were team members in sports such as soccer, basketball, volleyball, etc. In these sports lower limb soft-tissue injuries are typically acute i.e. caused by actions such as tackling, jumping, pivoting etc, rather than overuse injuries.

Types of interventions

We included trials investigating any intervention to prevent lower limb soft-tissue running injuries i.e. overuse injuries. We excluded trials which targeted the prevention of stress fractures alone, and those testing surgical interventions.

Types of outcome measures

Primary outcomes

1. Number of participants sustaining lower limb soft-tissue overuse injuries (overall and by location in the lower limb). Stress fractures and acute injuries were excluded.
2. Incidence (number) of lower limb soft-tissue overuse injuries (overall and by location in the lower limb), excluding stress fractures and acute injuries.

Secondary outcomes

1. Adverse effects.
2. Compliance.
3. Service utilisation and resource use.

Search methods for identification of studies

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (March 2011); the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 4); MEDLINE (1966 to January 2011); MEDLINE Pending (17 January 2011); EMBASE (1980 to January 2011); CINAHL (1982 to December 2008); SCISEARCH (1991 to December 2008); SPORTDiscus (1975 to December 2008); Current Contents (1991 to December 2008), and reference lists of articles. BIOSIS, Index To Theses, and Dissertation Abstracts were searched for the first version of this review in May 2000.

In MEDLINE the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (Lefebvre 2009) was combined with the subject-specific search terms, and modified for use in other databases (*see* Appendix 1).

We also searched the WHO International Clinical Trials Registry Platform (17 January 2011) for ongoing and recently completed trials.

Data collection and analysis

Selection of studies

All authors screened the titles and abstracts of identified records for possible inclusion, and excluded those obviously not meeting the inclusion criteria. Full text versions of potentially eligible trials were obtained. Two authors (EY, SY) independently screened these for inclusion, and any disagreement was resolved by discussion with the third author (LG). We contacted authors of papers for additional information if necessary.

Data extraction and management

Two authors (EY, SY) independently extracted data using a pretested data extraction form. Disagreement was resolved by discussion, followed if necessary by scrutiny from the third author. Review authors were not blinded to author(s), the institution, or the title of the studies.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias using the recommendations in the Cochrane Handbook (Higgins 2009a) (*see* Differences between protocol and review). The following domains were assessed: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; and incomplete outcome data (*see* Appendix 2). For each domain, the judgement was either 'Low risk', 'High risk', or 'Unclear risk' of bias. Disagreement was resolved by discussion, followed if necessary by scrutiny from the third author. The authors were not blinded to author(s), the institution or the title of the studies.

Measures of treatment effect

For dichotomous outcomes, risk ratios (RR) and 95 per cent confidence intervals (95% CI) were calculated for individual trials. For the calculations we used the number of participants contributing data in each group if this was known; if not reported we used the number randomised to each group.

The generic inverse variance method was used to present data as rate ratios if the events reported in the trial were number of injuries in each group, rather than the number of participants sustaining an injury.

For cluster randomised trials, we performed adjustments for clustering if this was not done in the published report (*see* Unit of analysis issues). Results were then presented using the generic inverse variance method.

Results are presented as risk ratios in the Data and analyses tables unless otherwise stated, i.e. rate ratios.

Unit of analysis issues

When allocation is by group, such as platoons trained by different drill sergeants or physical education instructors, using statistical methods that assume that all participants' chances of injury are independent ignores the possible similarity between outcomes for participants within the same platoon. This may underestimate standard errors and give inappropriately narrow confidence intervals, leading to the possibility of spurious positive findings (Bland 1997).

Therefore, where the results reported from cluster-randomised trials were unadjusted, we used the method described in Higgins 2009b to adjust for clustering. We were unable to identify an intraclass correlation coefficient (ICC) for lower-limb overuse injuries in a trial that cluster randomised military units, therefore we adjusted these data using the ICC of 0.05 for lower-limb injuries in teams of handball players reported in Olsen 2005a.

Assessment of heterogeneity

Heterogeneity between comparable trials was assessed both by inspection of graphical presentations and by performing the Chi^2 and I^2 statistics in RevMan, with significance for the Chi^2 statistic set at P = 0.10.

Data synthesis

Outcomes from included trials were combined using the fixed-effect model in Review Manager 5.1 (RevMan 2011) if appropriate.

Subgroup analysis and investigation of heterogeneity

We minimised heterogeneity as much as possible by grouping trials by type of intervention, and subsequently by type of injury. No additional subgroup analyses were planned. However, stretching regularly outside periods of exercise may have a different effect from stretching prior to exercise (Shrier 2004). We therefore carried out a post-hoc subgroup analysis of stretching interventions and investigated whether the results were significantly different by inspecting the overlap of confidence intervals, and performing the test for subgroup differences and the I^2 statistic available in RevMan. The I^2 statistic describes the percentage of the variability in effect estimates from the different subgroups that is due to genuine subgroup differences rather than sampling error (chance).

Sensitivity analysis

For cluster-randomised trials, we carried out a sensitivity analysis to explore the effect of using an ICC smaller or larger than 0.05 on the width of confidence intervals, and thus the significance of the results.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

Results of the search

The search strategy developed for the original review was highly sensitive, but precision was very low (i.e. it identified a large number of false positive results). For this update the strategy was revised to improve precision while maintaining sensitivity. The revised strategy identifies all previously included studies indexed in the main databases. Some databases were not searched for this update due to unavailability, and because none of the previously included studies were solely indexed in them.

The current search identified 552 records (including duplicates) (*see* Appendix 1).

Included studies

We included 25 trials involving a total of 30,252 participants. All trials were English language apart from Liu 2008, which was published in a Chinese journal. Most were indexed in MEDLINE or EMBASE but two (Bensel 1976; Bensel 1986) were identified in CENTRAL, and Bensel 1983 was identified by checking references. Study details are provided in the Characteristics of included studies and are briefly summarized below.

Design

Seventeen included studies were individually randomised trials, and seven trials involving recruits undergoing basic military training (Air Force, Army, Marines, National Guard, Navy) were cluster-randomised by platoon (Brushøj 2008; Gardner 1988; Pope 1998; Pope 2000; Rudzki 1997; Van Tiggelen 2009) or company (Hartig 1999). It is unclear whether the randomisation in Andrish 1974 was by individual or cluster but we have treated it as an individually randomised trial.

None of the cluster-randomised trials adjusted for clustering in their analyses.

Setting and participants

Nineteen trials (Andrish 1974; Bensel 1976; Bensel 1983; Bensel 1986; Brushøj 2008; Finestone 2004a; Finestone 2004b; Gardner 1988; Hartig 1999; Knapik 2009; Knapik 2010a; Larsen 2002; Liu 2008; Pope 1998; Pope 2000; Rudzki 1997; Van Tiggelen 2004; Van Tiggelen 2009; Withnall 2006) involved recruits undergoing basic military training in seven countries. Two papers contained reports of two trials, each consisting of a different pair

of interventions carried out in different locations: two Army bases (Finestone 2004a; Finestone 2004b) and two prisons (Pollock 1977a; Pollock 1977b). Soccer referees were recruited in Fauno 1993. The remaining three trials (BenGal 1997; Buist 2008; Van Mechelen 1993) drew runners from the general population.

Eight trials (BenGal 1997; Bensel 1983; Buist 2008; Larsen 2002; Knapik 2009; Knapik 2010a; Van Tiggelen 2004; Withnall 2006) included both male (N = 8427) and female (N = 3517) participants, although Larsen 2002 only included one female recruit. Bensel 1986 enrolled only female trainees (N = 555). The source population of soccer referees in Fauno 1993 (N = 127) contained two women, but it is unclear whether they met the inclusion criteria and were randomised. The participants in the remaining trials were all male. Thus only 12.5% of the participants included in this review were female.

Although participant ages in the included trials ranged from 16 to 65 years, the majority of trials only included young adults.

Interventions

The interventions can be grouped into four main categories: exercises, modification of training schedules, use of orthoses (shoe inserts and knee braces), and interventions relating to footwear and socks. Some trials contained more than one intervention arm: Andrish 1974 compared interventions from several different categories with a control group, while five other trials compared two interventions from within the same category with a control group (Bensel 1986; Pollock 1977a; Pollock 1977b; Van Tiggelen 2009; Withnall 2006).

The duration of intervention in 24 trials ranged from six to 20 weeks, and one (Fauno 1993) covered five days of refereeing in a soccer tournament. The intensity of training schedules in the included trials also varied. Duration and intensity of interventions are summarized in Appendix 3.

Exercises

Six trials evaluated the effect of stretching exercises in the prevention of injuries (Andrish 1974; Hartig 1999; Liu 2008; Pope 1998; Pope 2000; Van Mechelen 1993). Three trials assessed the effect of gastrocnemius and soleus stretching exercises (Andrish 1974; Liu 2008; Pope 1998). The intervention in Pope 2000 included stretches to gastrocnemius, soleus, hamstrings, quadriceps, hip adductor and hip flexor muscle groups. In addition to static stretching of the iliopsoas, quadriceps, hamstrings, soleus and gastrocnemius muscles Van Mechelen 1993 also incorporated warm-up and cool-down exercises in the intervention procedure. In Hartig 1999, only hamstring muscles were involved in the stretching routine. Stretching was carried out prior to exercising in three trials (Pope 1998; Pope 2000; Van Mechelen 1993). In the remaining three trials stretching was carried out at regular intervals during the day as part of a training programme (Andrish 1974; Hartig 1999; Liu 2008).

Brushøj 2008 compared an exercise programme with an emphasis on lower-limb muscle strength, coordination and flexibility (conditioning exercises) with exercises for the arms and upper body in Army recruits undergoing 12 weeks of military training.

Modification of training schedules

Five trials (Andrish 1974; Buist 2008; Pollock 1977a; Pollock 1977b; Rudzki 1997) described training schedule modifications. Andrish 1974 utilised a graduated running programme in one intervention group to examine the prevention of shin splints. Buist 2008 evaluated the prevalence of running-related injuries in novice runners training for a four-mile race by comparing a graded training programme that followed the 10% training rule for 13 weeks with a standard training programme for eight weeks. Pollock 1977a examined the effect of duration of training (15, 30 and 45 minutes per day), while Pollock 1977b examined the effect of frequency of training (one, three and five days per week) on attrition and running-related injuries in prisoners. In Rudzki 1997, the intervention group received a modified weight-loaded walking programme which was compared with a running programme in the control group.

Use of orthoses

Three trials investigated the effect of various types of insoles compared with no insoles: shock-absorbing heel insoles (Andrish 1974; Fauno 1993) and custom-made shock-absorbing biomechanical insoles (Larsen 2002). Five trials compared different types of insoles: custom-made versus prefabricated soft foot orthoses (Finestone 2004a); custom-made biomechanical semi-rigid foot orthoses versus prefabricated semi-rigid foot orthoses (Finestone 2004b); shock-absorbing insoles versus non shock-absorbing insoles (Bensel 1986; Gardner 1988; Withnall 2006).

BenGal 1997 and Van Tiggelen 2004 examined the use of knee braces for preventing anterior knee (patellofemoral joint) pain.

Footwear and socks

Two trials in military personnel compared a tropical combat boot with a leather combat boot for the basic training course (Bensel 1976; Bensel 1983). Two trials evaluated the effectiveness of prescribing running shoes based on foot shape for Army (Knapik 2009) and Air Force (Knapik 2010a) recruits undergoing a nine-week training programme. One trial with three arms evaluated the effects of a padded polyester sock or the use of double socks compared with the standard issue sock for preventing overuse injuries in Army recruits (Van Tiggelen 2009).

Outcomes

Primary outcomes

Twenty-two trials reported the number of participants sustaining lower limb soft-tissue overuse injuries either by location or by type of injury. Three trials reported a rate of injury based on the number of injuries in a specified time: Knapik 2009 and Knapik 2010a reported a Training Injury Index based on the number of lower extremity overuse injuries per 1000 person-days (for male and female participants separately), while Van Mechelen 1993 reported number of injuries per 1000 hours of running.

The diagnosis and definition of qualifying soft-tissue overuse injuries differed between trials (*see* Characteristics of included studies for details). The method of ascertaining injury outcomes was not stated in three trials (Liu 2008; Pollock 1977a; Pollock 1977b). For the remaining 22 trials, diagnosis was made by self-reporting and subsequently confirmed by medical consultation. Six trials specified a level of severity for an injury to qualify as an outcome (Buist 2008; Pollock 1977a; Pope 1998; Pope 2000; Van Mechelen 1993; Withnall 2006).

Secondary outcomes

No trials reported adverse effects from the interventions.

Thirteen trials monitored compliance with the interventions using a variety of methods (*see* Appendix 4 for details), but only five reported levels of compliance (Brushøj 2008; Finestone 2004a; Finestone 2004b; Larsen 2002; Van Mechelen 1993).

Although Rudzki 1997 reported number of restricted duty days per injury, not fit for duty days per injury and hospital bed days per injury, this trial included injuries other than lower limb soft-tissue injuries.

Excluded studies

Thirty-eight studies that initially appeared to meet the inclusion criteria were excluded from this review. Sixteen were not randomised or quasi-randomised, 18 were excluded because the injury outcomes were not running related soft-tissues injuries, and four reported interventions for treating soft-tissue conditions relating to overuse. Three previously included studies (Milgrom 1992; Schwellnus 1990; Smith 1985) were excluded from this update because, after reviewing their methods, we judged that they were not randomised or quasi-randomised trials. Further details of excluded studies that initially appeared to meet the inclusion criteria are provided in the Characteristics of excluded studies.

Ongoing studies

We identified four ongoing trials in which the participants are military recruits (ACTRN12607000076471; NCT00922246) and recreational runners (NCT00832195; NTR1906) (*see* the Characteristics of ongoing studies for details).

Studies awaiting classification

We updated our search prior to submission and identified two additional trials (Knapik 2010b; Sherman 1996) which will be included in the next review update (*see* the Characteristics of studies awaiting classification for details).

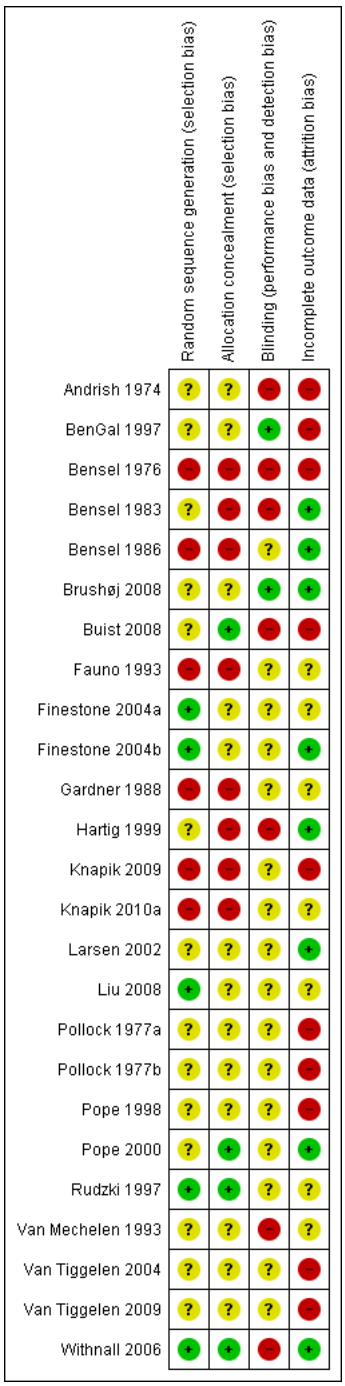
New studies found at this update

Fifteen additional trials have been included in this update (Bensel 1976; Bensel 1983; Bensel 1986; Brushøj 2008; Buist 2008; Finestone 2004a; Finestone 2004b; Gardner 1988; Knapik 2009; Knapik 2010a; Larsen 2002; Liu 2008; Van Tiggelen 2004; Van Tiggelen 2009; Withnall 2006). One previously included trial has been included as two separate trials (Pollock 1977a; Pollock 1977b).

Risk of bias in included studies

Details of the risk of bias assessment for each trial are shown in the Characteristics of included studies. Summary results are shown in Figure 1.

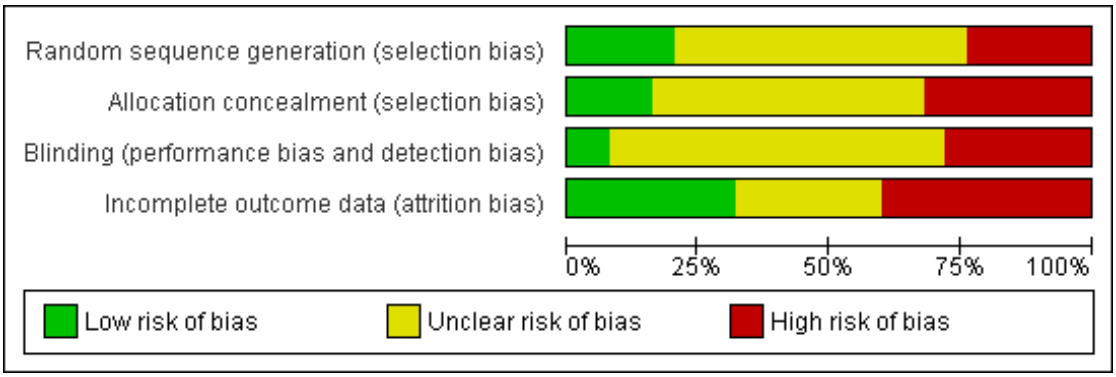
Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

We assessed risk of bias relating to adequacy of sequence generation as low in only 20% of studies (five trials), high in 24% (six trials), and unclear in the remaining trials. Concealment of allocation prior to group assignment was judged to carry low risk of bias in just 16% of studies (four trials), high in 32% (eight trials), and to be unclear in the reports of the remaining 52% of studies (13 trials) (*see* Figure 2). Only two trials were at low risk of selection bias based on both the adequacy of sequence generation and concealment of allocation prior to group assignment (Rudzki 1997; Withnall 2006). Six trials (all quasi-randomised) were at high risk of bias based on these two criteria (Bensel 1976; Bensel 1986; Fauno 1993; Gardner 1988; Knapik 2009; Knapik 2010a).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Blinding

We assessed the risk and potential impact of bias as a result of unblinding of participants or outcome assessors to be low in only 8% of included studies (two trials), high in 28% (seven trials), and unclear in the remaining trials (*see* Figure 2). In the two trials assessed as being at low risk of bias (BenGal 1997; Brushøj 2008), the outcome assessors were blinded to the participants' group assignment, but the participants were not. This was not considered to be a likely cause of bias in these trials.

Incomplete outcome data

We assessed 32% of studies (eight trials) as being at low risk of bias from incomplete outcome data, and 40% (10 trials) as at high risk of bias. In the remainder, risk of bias was unclear (*see* Figure 2). In seven of the trials in which attrition bias was high (BenGal 1997; Bensel 1976; Buist 2008; Pollock 1977a; Pollock 1977b; Pope 1998; Van Tiggelen 2009), the attrition rate was different between the intervention and control groups. Andrish 1974 stated that platoons not carrying out the intervention were placed in the control group for analyses; however, raw data are available as randomised. In Knapik 2009, participants not wearing the prescribed shoes were excluded from the analysis. In Van Tiggelen 2004, drop-outs were excluded from analysis. Reasons for dropping out included "other traumatic lesion" (N = 1 brace group and N = 7 control group); bias could be introduced by these different losses in the two groups.

Effects of interventions

In presenting the results, comparisons are grouped into four main

preventive strategies: exercises (stretching exercises and conditioning exercises); modification of training schedules; use of orthoses (insoles and knee braces); and footwear and socks.

Data from seven randomised trials (Brushøj 2008; Gardner 1988; Hartig 1999; Pope 1998; Pope 2000; Rudzki 1997; Van Tiggelen 2009) were adjusted for clustering using an ICC of 0.05 (*see* Appendix 5).

There were limited opportunities to pool data due to the heterogeneity of comparisons studied and outcomes reported.

Where results are not statistically significant i.e. the 95% confidence intervals include the null, the results are compatible with either a reduction or an increase in soft-tissue injuries.

Exercises

Stretching exercises

Six trials (5130 participants) are included in this comparison. Participants were military recruits in five trials (Andrish 1974; Hartig 1999; Liu 2008; Pope 1998; Pope 2000), and recreational runners in one (Van Mechelen 1993). Pooling of these six trials showed no significant benefit (RR 0.85, 95% CI 0.65 to 1.12; Analysis 1.1), a result which is compatible with either a reduction or an increase in lower limb soft-tissue injuries. Andrish 1974 only reported on shin splints. The pooled result remains non significant if this trial is removed from the analysis. In a post-hoc subgroup analysis there was no significant reduction in soft-tissue injuries in either the subgroup stretching prior to exercise (three trials; 2957 participants; RR 0.95, 95% CI 0.67 to 1.36; Analysis 1.1.1) or the subgroup stretching regularly outside periods of exercise (three trials; 2176 participants; RR 0.74, 95% CI 0.49 to 1.11; Analysis 1.1.2). The confidence intervals for the two subgroups overlap considerably, the test for subgroup differences is not significant ($Chi^2 = 0.85$, $P = 0.36$), and $I^2 = 0\%$. The included trials provide no evidence that the two regimens for implementing stretching have a different effect.

The stretching protocols differed between trials (*see* Appendix 6 for details). For completeness, they are reported individually.

We found no evidence that stretching all major lower-limb muscle groups reduces the number of people sustaining lower limb soft-tissue injuries (Pope 2000; 1538 participants; Analysis 2.1), or the rate of lower limb soft-tissue injury in novice runners (Van Mechelen 1993; 326 participants; Analysis 2.2). Van Mechelen 1993 reported that only 46.6% of participants in the intervention group carried out stretching exercises as prescribed

We found no evidence that hamstring stretches carried out three times a day significantly reduces risk of lower limb soft-tissue injury (Hartig 1999; 298 participants; Analysis 3.1).

Two trials tested the effect of gastrocnemius and soleus stretching but measured different outcomes. Liu 2008 (122 participants), despite its small size, was the only study of stretching reporting a significant reduction in injury risk. It found that supplementary stretches carried out before lunch, supper and bedtime, in addition to "routine" gastrocnemius stretches prior to training, were associated with a significant reduction in the risk of lower-limb injuries (RR 0.47, 95% CI 0.23 to 0.96; Analysis 4.1). However, these data from this trial include both soft-tissue injuries and stress fractures. Therefore we conducted a sensitivity analysis. The general assumption was that soft-tissue injuries are commoner than stress fractures, in a ratio of 2:1 to 3:1 (see for example Pope 1998 and Pope 2000). For each of the two assumptions (two thirds of the events, or three quarters of the events in each group were soft-tissue injuries), entering the imputed number of events for Liu 2008 resulted in loss of statistical significance (data not shown). This confirms that the overall finding of no significant effect from stretching in Analysis 1.1 is robust.

We found no evidence that gastrocnemius and soleus stretching prior to training is effective in reducing risk of lower limb soft-tissue injuries (Pope 1998; 1093 participants; Analysis 4.1).

We found no evidence that supplementary gastrocnemius and soleus stretching reduces the risk of shin splints (Andrish 1974; 445 participants; Analysis 4.2).

Conditioning exercises

We found no evidence that an exercise programme with an emphasis on lower-limb muscle strength, coordination and flexibility, compared with an exercise programme for arms and upper body reduced risk of lower limb soft-tissue injuries overall during military training (Brushøj 2008; 1020 participants; RR 1.20, 95% CI 0.77 to 1.87; Analysis 5.1), or knee injuries, medial tibial stress syndrome, Achilles tendonitis or ankle sprains (*see* Analysis 5.2). On average, 27 out of 36 training sessions were completed (an overall compliance rate of 75%) with no difference between groups.

Modification of training schedules

Five trials examined the effect of training intensity on the risk of injury (Andrish 1974; Buist 2008; Pollock 1977a; Pollock 1977b; Rudzki 1997). Implementation of the training protocols differed between trials (*see* Appendix 7 for details).

We found no evidence that a 13-week training programme utilising a 10% training rule reduced lower limb soft-tissue injuries in novice runners training for a four-mile run (Buist 2008; 486 participants; RR 1.02, 95% CI 0.72 to 1.45; Analysis 6.1). There was also no evidence that a two-week graduated running programme prior to the standard training programme for naval recruits reduced the incidence of shin splints (Andrish 1974;1670 participants; RR 2.02, 95% CI 1.11 to 3.70; Analysis 6.2). The results suggest instead that the additional two weeks of running may result in a significant increase in the number of people with shin splints; however, this should be interpreted with caution as this trial is at high risk of bias.

In prison populations, reducing duration of training significantly reduced lower limb soft-tissue injuries (RR 0.41, 95% CI 0.21 to 0.79; Analysis 7.1; 69 participants), as did reducing frequency of training (RR 0.19, 95% CI 0.06 to 0.66; Analysis 8.1; 58 participants). These two trials (Pollock 1977a; Pollock 1977b) carried high risk of bias and the results should be interpreted with caution.

We found no evidence that decreasing running distance by substituting weight-loaded walking for running significantly reduced lower limb soft-tissue injuries overall (Rudzki 1997; 340 participants; RR 0.80, 95% CI 0.51 to 1.25; Analysis 9.1), or in any specific locations (Analysis 9.2).

Use of orthoses

Insoles versus no insoles

The three trials in this comparison tested different types of insoles in different populations.

Larsen 2002 (146 participants) found that wearing custom-made biomechanical shoe orthoses in military boots significantly reduced the incidence of shin splints in Army recruits (RR 0.24, 95% CI 0.08 to 0.69; Analysis 10.1) but not soft-tissue injuries in other locations (e.g. knee problems; event data in the intervention group only available from the 58 participants who wore the insoles: RR 1.02, 95% CI 0.54 to 1.94; Analysis 10.1). Thick foam rubber heel pads inserted into tennis shoes for running activities did not reduce the incidence of shin splints in 1797 midshipmen during Naval Academy training (Andrish 1974; Analysis 10.1). The interventions were clearly different in these two trials. Exploratory analysis confirmed considerable statistical heterogeneity (I^2 = 89%; P = 0.002) and the data were not pooled.

Fauno 1993 (91 participants) showed that the use of shock-absorbing heel inserts effectively decreased soreness in the lower extremities experienced by soccer referees running for an average of 870 minutes during a five-day soccer tournament (RR 0.67, 95% CI 0.53 to 0.85; Analysis 10.2). The number of participants with lower-limb soreness was collected each day. Data from day four was used in the analysis as they were the same as data from day three, and not all referees participated on day five of the tournament.

Comparison of different insoles

Finestone 2004a (417 participants) compared custom-made with prefabricated soft-foot orthoses and found no significant difference in ankle sprains (RR 0.91, 95% CI 0.51 to 1.60; Analysis 11.1.1) or foot injuries (RR 0.87, 95% CI 0.58 to 1.31; Analysis 11.1.2). Seventy-two percent of the intervention group were still wearing their custom-made soft-foot orthoses at the end of their training, and 57% of the control group still wore their prefabricated orthoses.

Finestone 2004b (352 participants) compared custom-made mechanical semi-rigid orthoses with prefabricated semi-rigid foot orthoses inserted into standard Army boots, and found no significant difference in ankle sprains RR 1.16, 95% CI 0.59 to 2.28; Analysis 12.1.1) or foot injuries (RR 0.68, 95% CI 0.43 to 1.09; Analysis 12.1.2). Seventy-five percent of the intervention group were still wearing their custom-made semi-rigid orthoses at the end of their training, and 82% of the control group still wore their prefabricated orthoses.

Three trials compared shock-absorbing with non shock-absorbing insoles (Bensel 1986; Gardner 1988; Withnall 2006). Bensel 1986 and Withnall 2006 compared two types of shock-absorbing insoles with a control group and for each of these trials we combined data from the two intervention groups given shock-absorbing insoles. Use of shock-absorbing insoles did not result in a significant reduction in all lower limb soft-tissue injuries (4032 participants; RR 1.02, 95% CI 0.81 to 1.29; Analysis 13.1), or injuries in any specific location (Analysis 13.2).

Knee brace versus no brace

Two trials (227 participants) evaluated the effect of knee braces for preventing anterior knee pain: BenGal 1997 used a silicon patellar ring support, and Van Tiggelen 2004 used a dynamic patellofemoral knee brace. We found a statistically significant reduction in the number of participants with anterior knee pain (RR 0.41, 95% CI 0.24 to 0.67; Analysis 14.1).

Footwear and socks

Footwear

Two trials (2185 participants) compared the effect of a boot with a cotton/nylon blend upper (tropical/hot weather boot) with a leather combat boot (Bensel 1976; Bensel 1983). Pooled data showed no significant reduction in lower limb soft-tissue injuries in any location (Analysis 15.1). Although the test for heterogeneity was significant for both Achilles tendonitis and plantar fascial strain the confidence intervals overlapped substantially and the results were not statistically significant. There was no statistical heterogeneity in Analysis 15.1.4 which showed no significant effect on ankle sprains (RR 0.93, 95% CI 0.60 to 1.44).

Two trials (Knapik 2009; Knapik 2010a) compared prescription of running shoes based on foot shape with regular running shoes and found no significant reduction in rate of lower limb soft-tissues injuries in military personnel undergoing basic training (5795 participants; Rate Ratio 1.03, 95% CI 0.93 to 1.14; Analysis 16.1). Data are presented in subgroups by gender in Analysis 16.1 because a combined statistic (or data) were not available in the trial reports. Although we did not state a priori that we would compare

results by gender, this does provide us with an opportunity to do so and the test for subgroup differences shows no significant difference between genders (I^2 = 0%; P = 0.57).

Socks

One trial with three arms (Van Tiggelen 2009) compared a padded polyester sock with a regular army sock and found no significant difference in lower limb soft-tissue injuries in any location (130 participants; RR 0.54, 95% CI 0.27 to 1.08; Analysis 17.1). The same trial compared a double layer sock with a regular army sock and found no evidence of effect on lower limb soft-tissue injuries (124 participants; RR 0.91, 95% CI 0.53 to 1.56; Analysis 18.1).

DISCUSSION

Summary of main results

We included 25 trials testing interventions for preventing running-related lower limb soft-tissue injuries. Few trials could be pooled, since the interventions were heterogeneous, and classification and ascertainment of outcomes varied considerably. Most participants were military recruits. Most included trials failed to find significant effects of the interventions studied. The interventions tested by the included trials fell into four main preventive strategies: exercises (stretching exercises and conditioning exercises); modification of training schedules; use of orthoses (insoles and knee braces); and footwear and socks.

We found no evidence to support stretching prior to exercising or stretching regularly outside of exercising for preventing soft-tissue injuries. There was also no evidence to support a training regimen of conditioning exercises to improve strength, flexibility and coordination.

We found no evidence to support modification of training schedules; i.e. gradual increase in weekly training or a decrease in running mileage, for preventing running injuries. Although two trials in a prison population showed a significant reduction in lower limb soft-tissue injuries when running duration (Pollock 1977a) or frequency (Pollock 1977b) were reduced, both trials were at "high" risk of bias.

Wearing a patellofemoral brace appears to be effective for preventing anterior knee pain. Although the brace designs and the sampling frame for participants were different, both trials in this category reported significant reductions with a similar effect size (BenGal 1997; Van Tiggelen 2004). However, both trials were at "high" risk of bias.

Five trials with 5356 participants investigated the use of insoles and there is very little evidence to support the use of insoles for preventing running-related injuries. Although one trial (Larsen 2002) comparing custom-made insoles in Army boots with no insoles achieved a significant reduction in shin splints (medial tibial stress syndrome) in military recruits, there was no significant effect on other sites (knee, ankle, and Achilles tendonitis) and the risk of bias in this trial was "unclear". One trial (Fauno 1993) at "high" risk of bias, comparing shock-absorbing heel insoles with no insoles found significantly fewer soccer referees with lower-limb soreness after four days of a tournament when each had refereed four or five 50 minute matches per day. However, trials comparing shock-absorbing with non shock-absorbing insoles did not find a significant reduction in all lower limb soft-tissue injuries (Bensel 1986; Gardner 1988; Withnall 2006), and two trials with a total of 4032 participants (Gardner 1988; Withnall 2006) found no significant difference in all lower limb soft-tissue injuries when comparing shock-absorbing and non shock-absorbing insoles, and there was also no evidence of effect on any specific injuries. There is also no evidence to suggest that prescribed soft or semi-rigid insoles are more effective than off-the-shelf insoles.

There is also no evidence from trials of military personnel undergoing basic training that using a prescription running shoe based on foot shape or combat boot with soft uppers reduces injury compared to a standard running shoe, or a standard leather combat boot respectively. Also in this population there is no evidence that polyester socks or wearing double socks reduces lower limb overuse injuries.

Overall completeness and applicability of evidence

In interpreting the results of this review, one should be aware of the variation in the participants, setting, duration, focus and the type of intervention administered. More might have been expected from the participation of more than 30,000 young people in clinical trials of interventions.

The included participants were predominantly young, active males; less than 13% were female. Although the anatomical and physiological differences between female and male athletes might account for unique patterns of musculoskeletal injury, the limited data and analysis of female participants in the included trials means we cannot provide separate evidence of effectiveness for each gender other than for the effectiveness of using prescription running shoes based on foot shape in male and female Army recruits (Knapik 2009; Knapik 2010a). In this case the intervention was not effective and the results for male and female recruits were not significantly different. The significant results for the effectiveness of knee braces came from trials that included both male and female participants and may therefore be generalisable to both genders. The remaining significant results came from trials in which the participants were entirely or predominantly male.

Only three trials drew runners from the general population (BenGal 1997; Buist 2008; Van Mechelen 1993). In 19 trials the participants were military recruits undergoing training programmes which were very intensive compared with the activity

levels of the general population, although no more so than professional or high-performance athletes. Motivation and physical condition at study onset may be important confounders of outcome. Trials conducted in one setting may not be generalisable to another.

Stretching before a training session or competition is perhaps the most commonly prescribed strategy for the prevention of sports injuries. We included six trials evaluating different stretching regimens for reducing overuse injuries in army recruits or novice runners. Although Liu 2008 found supplementary stretches on top of "routine" gastrocnemius stretches significantly reduced the risk of lower limb soft-tissue injuries and stress fractures, inclusion of this trial did not alter the overall result of the pooled analysis; the non-significant result of which is compatible with a small beneficial effect, no effect, or a small increase in soft-tissue injury.

Despite the fact that retrospective studies have shown a correlation between risk of injury and modifiable risk factors such as poor muscle strength, coordination, or joint flexibility (Fredericson 2000; Knapik 2006; Niemuth 2005), we identified only one RCT that investigated interventions to reduce their impact (Brushøj 2008) and the results indicated no significant protection against injury.

Intensity and frequency of training are plausibly associated with overuse injury. Although it has been suggested that sudden changes in training habit or running distance predispose to injuries (Van Middelkoop 2008b), we found little evidence for effectiveness of reduction in intensity, duration, or speed of build-up of running activity outside the prison setting (where the motivation and physical condition of participants might be different). However, looking in detail at the data from Buist 2008 and Rudzki 1997 there appeared to be two peak periods where most running-related injuries occurred; one at the beginning of the first two weeks of training, and another in the middle of training when the intensity increased. This observation is compatible with Van Middelkoop 2008b and suggests that there may be one or more thresholds in training volume around which participants are more prone to injuries. Future research is needed in this area.

The use of shock-absorbing insoles is also a plausible preventive strategy. However, high-quality evidence of its effectiveness in the prevention of running related soft-tissue lower-limb injuries is limited. Larsen 2002 produced evidence that custom-made biomechanical shoe orthoses can effectively reduce the incidence of shin splints in Army recruits. Fauno 1993, a study assessed as having high risk of bias, found that referees wearing shock-absorbing heel inserts reported significantly less soreness on both day three and day four of a tournament. Further research in this area would be justified.

The two trials supporting the use of knee braces for preventing running-related anterior knee pain contained participants of both genders who were fit young athletes (BenGal 1997; 33% female) and officer cadets (Van Tiggelen 2004: about 20% female).

While runners are frequently advised to select their running shoes based on their foot shapes, two trials (Knapik 2009; Knapik 2010a) appear to provide convincing evidence that prescription of running shoes to recruits based on foot shape does not significantly reduce overuse lower limb soft-tissues injuries. However, both these trials were assessed as at high risk of bias, and their findings, while consistent, should be interpreted cautiously.

Although no trials reported on adverse effects, serious adverse effects would be unlikely to result from the types of interventions included in this review.

Lack of compliance can clearly impact on the results. Only 13 trials described methods for monitoring or ensuring compliance, and only five of these reported on levels of compliance.

Although no trials included an economic evaluation evidence about resource use or service utilisation would be more important if there were more significant results.

Consistent with our focus on soft-tissue overuse injuries, we purposefully excluded results for stress fractures and other injuries. Given that injuries sustained during running could include these other injuries, this leaves open the question as to the effect of the interventions tested here on the overall incidence of lower-limb injuries. This is not addressed in this review, nor by several of the included trials. Related issues that hamper interpretation of the results include the variation in the diagnosis and definition of qualifying soft-tissue overuse injuries in the included trials.

Quality of the evidence

The quality of the evidence is disappointing. Each included trial was assessed for risk of bias in four domains (sequence generation, allocation concealment, blinding, and incomplete outcome data). In 49 of the 100 assessments, there was insufficient information to make a judgement, particularly in the domain of sequence generation and allocation concealment. None of the 25 included trials were assessed as low risk of bias in all four domains, and 18 were assessed as at high risk of bias in one or more of the four domains. Although it is true that blinding of both participants and researchers can rarely be achieved in non-pharmaceutical trials, steps can be taken to ensure blinding of outcomes assessors. Only two trials (BenGal 1997; Brushøj 2008) did so.

Of the six trials that evaluated stretching for the reduction of overuse injuries, only Liu 2008 described an adequate random sequence generation procedure, and there was insufficient information to assess risk of bias in the remaining five trials. Only Pope 2000 described adequate allocation concealment, and the rest were either rated as high risk of bias (Hartig 1999) or we were unable to assess bias because of insufficient information. Risk of bias was also unclear for both domains in Brushøj 2008, which tested conditioning exercises. Of the five trials that evaluated the effects of modification of training schedules, and the 10 trials on the use of orthosis, only Rudzki 1997 and Withnall 2006 reported both adequate random sequence generation procedure and allocation concealment. For trials testing footwear and socks, three out of

the five trials were rated as high risk of bias, while the other two provided insufficient information to rate the level of risk of bias. Admittedly, this assessment of bias relies on the adequate reporting of the trial methods. None of the seven cluster-randomised trials were adjusted for clustering in their analyses, hence none reported ICCs. In future research, authors and editors should strive to achieve the standards set out in the relevant CONSORT statements (Boutron 2008; Campbell 2004).

Potential biases in the review process

We attempted to minimise publication bias by carrying out a sensitive search of multiple bibliographic databases. Although our search was comprehensive, and we included trials identified in languages other than English, we cannot rule out the possibility that some trials have been missed.

We minimised bias in the review process by having at least two authors independently screening studies for inclusion, assessing risk of bias and extracting data and data entry has been checked.

Agreements and disagreements with other studies or reviews

We draw attention to four other Cochrane reviews (Goldman 2010; Handoll 2001; Herbert 2007; Rome 2005) and one published protocol (Susta 2010) which are relevant to the prevention of injury in runners, and may have areas of overlap with this review.

We found six other relevant systematic reviews (Bullock 2010; Herbert 2002; Hootman 2007; Shrier 1999; Thacker 2004; Weldon 2003).

Bullock 2010 reported the findings of an expedited systematic review used to gather evidence for recommendations to reduce physical training related injuries during and after initial military training within the four US military services. Compared with our review, it was of much wider scope in respect of interventions and outcomes, and also included non-randomised quasi-experimental intervention studies. Surprisingly, of the 25 trials included in our review, Bullock 2010 included only four (Buist 2008; Pollock 1977a; Pollock 1977b; Rudzki 1997) amongst 328 referenced reports. However, they concluded, as we have, that there is no reliable evidence for the effectiveness of muscle stretching, wearing shock-absorbing insoles, or using running shoes prescribed on the basis of individual foot shape.

Bullock 2010 recommended two interventions for which we did not find strong support in the RCT evidence. The first was prevention of over-training. However, it is a strategy that seems self-evident and it would be foolish to ignore it. The evidence from the two RCTs in prison communities (Pollock 1977a; Pollock 1977b) is unlikely to be generalisable, but Bullock 2010 draws attention to a number of quasi-experimental intervention trials in military training contexts. Rudzki 1997 reported a significant reduction in injury in military recruits allocated to weighted marching, compared with running, but when account was taken of clustering, we found that the effect was not statistically significant.

Bullock 2010 stated that the effectiveness of wearing knee braces had not yet been reviewed. We found that they were effective in preventing anterior knee pain in two different populations (runners in BenGal 1997 and military recruits in Van Tiggelen 2004).

Hootman 2007 included a wide range of sport and recreation activities, both individual and team, at a range of levels, thus including tennis, skiing, volleyball, soccer, rugby, football, etc) but excluded fall-related hip fractures, military populations specifically in recruit training, and bicycling and other wheeled activities. Only one included study (Van Mechelen 1993) was conducted in runners and was common to our review.

Four systematic reviews focusing on the effectiveness of stretching exercises in the prevention of injuries (Herbert 2002; Shrier 1999; Thacker 2004; Weldon 2003), found, as we have, no reliable evidence for the effectiveness of stretching.

AUTHORS' CONCLUSIONS

Implications for practice

In the prevention of running-related soft-tissue injuries in the lower limbs (interventions grouped by four main preventive strategies):

Exercises (stretching exercises and conditioning exercises)

- there is no evidence that stretching exercises reduce running-related soft-tissue injuries;
- there is no evidence that prior conditioning exercises are effective in individuals who are already physically fit;

Modification of training schedules

- there is limited evidence, which may not be generalisable beyond a prison population, that reducing duration and frequency of running may be effective;
- there is no evidence that a graded i.e. longer, training programme is more effective than a regular training programme for preventing injuries in novice runners, and may even result in an increase in shin splints in military recruits;

Use of orthoses (insoles and knee braces)

- there is evidence to support the use of a patellofemoral brace for preventing anterior knee pain;

- there is limited evidence that shock-absorbing heel inserts can reduce the incidence of lower extremity soreness during periods of high intensity running;

- there is no evidence that using insoles is more effective than not using them;

- there is no evidence that individually prescribed insoles are more effective than off-the-shelf insoles;

- there is no evidence that shock-absorbing insoles are more effective than non shock-absorbing insoles;

Footwear and socks

- there is no evidence that the prescription of running shoes based on assessment of foot shape, when compared with standard running shoes, offers additional protection in military recruits;

- there is no evidence that the use of padded polyester or double layer socks, when compared with standard socks, are effective in reducing soft-tissue injuries in military recruits.

Implications for research

Controlled investigations of running-related injuries are difficult due to variations in the definition of injury, study population, and outcome measures used. More well-designed and reported randomised controlled trials are needed to shed light on possible interventions for the prevention of lower limb soft-tissue injuries in recreational and competitive runners, as opposed to military recruits. This includes testing of interventions such as stretching, modification of training schedules, use of orthoses, and prescription running shoes. The evaluation of interventions over a longer period and adequate monitoring and reporting of compliance and adverse effects are also required. Trials are needed involving participants with differing levels of ability and more information is needed regarding the effectiveness of interventions in female runners.

The interacting effects of the training frequency, duration, distance and intensity in the prevention of running injuries should be considered and carefully addressed in the design of further trials.

Design, conduct, and reporting of trials should meet the contemporary standards of the CONSORT statement (Boutron 2008), including those for cluster-randomised trials (Campbell 2004).

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Andrish 1974

Methods	RCT Unclear whether individual or cluster randomisation. Period of study: summer of 1972 and 1973
Participants	Location: United States Naval Academy, USA. 2777 first year midshipmen undergoing summer training programme Age: not stated Exclusion criteria: none stated
Interventions	Four intervention groups: 1. Use of heel pad in tennis shoes for running (N = 344) 2. Stretching exercises to gastrocnemius and soleus for 3 min x3 per day (N = 300) 3. Use of heel pad and stretching exercises (N = 463) 4. Graduated running programme for 2 wks prior to normal physical education programme (N = 217) 5. Control group (N = 1453): normal physical education programme with no additional intervention
Outcomes	1. Incidence of shin splints through self-reporting during training 2. Compliance
Notes	Data for stress fracture to tibia and foot excluded from analysis. Heel pad consisted of 1.3 cm thick foam rubber, hand cut to size and shape for insertion into tennis shoe and taped into place

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "a total of 2777 first-year midshipmen were randomly placed in prophylactic and treatment groups, equalized according to previously tested scholastic and athletic aptitudes" Quote: "For the purpose of the study of prophylactic regimens, the classes were divided into five groups as follows" Comment: insufficient information to allow judgement.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to allow judgement.

Andrish 1974 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "All members of the classes were briefed on shin splints and urged to seek medical consultation for leg pains". Comment: participants not blind to the purpose of the study or to intervention. Not stated whether medical staff blind to intervention group
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Those platoons found not to have carried out the prophylactic regimens were placed in the control group for purposes of statistical analysis" Comment: 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation

BenGal 1997

Methods	RCT Individually randomised
Participants	Location: Israel 80 fit young athletes (33% female) enrolled in an 8-week intensive physical training programme which included middle- and long-distance running Age: range 18 to 25 years. Exclusion criteria: inability to pass the preliminary fitness test, past history of anterior knee pain
Interventions	1. Intervention group (N = 40): knee brace with silicon patellar support 2. Control group (N = 40): no knee brace
Outcomes	Incidence of anterior knee pain. Diagnosis made by pain levels, orthopaedic examination, physical fitness test measured at 1st and 8th week of training
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "There were 54 men and 26 women randomized into two groups of 40" Comment: insufficient information to allow judgement.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to allow judgement.

BenGal 1997 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Data were collected in the 1st and 8th week of the study by investigators blinded to the identity of the candidates." Comment: participants not blinded but this is unlikely to bias results
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "20 volunteers (11 men and 9 women) dropped out soon after the start of the study because of personal reasons and incompatibility with the requirements needed to meet the theoretical studies" Comment: lost a larger proportion of women (20% of the men and 35% of the women), and greater losses from brace group (13/40) compared with non-brace group (7/40)

Bensel 1976

Methods	CCT Individually randomised Period of study: from 22 June 1975
Participants	Location: US Marine Corps Recruit Depot, San Diego, USA 990 male Marine Corps recruits on 12 weeks training course. Age: not stated. Exclusion criteria: none stated.
Interventions	1. Intervention group (N = 372): tropical/hot weather combat boots (cotton/nylon uppers) 2. Control group (N = 414): half leather combat boots All participants received two pairs of boots.
Outcomes	Foot problems. Examined four times by podiatrist (prior to boot issue, at week 5 after 15 mile hike, at week 8 of training, and week 12 of training). Also identified by medical staff if presenting at Sick Call with a foot problem
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote: "each platoon within a series was randomly divided into two footwear groups and approximately one half a platoon was issued tropical combat boots and the other half leather combat boots." Quote: "Those recruits receiving odd-

		numbered sheets were to be issued leather combat boots, while those receiving even-numbered sheets were to be issued with tropical boots." Comment: this is a systematic non-random method of sequence generation
Allocation concealment (selection bias)	High risk	Quote: "Those recruits receiving odd-numbered sheets were to be issued leather combat boots, while those receiving even-numbered sheets were to be issued with tropical boots." Comment: these Individual Record Sheets were numbered 1 to 1000 in the upper left corner. Allocation was by alternation. Thus, allocation was not concealed
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "Individual Record Sheets and Sick Call Stamps were distributed to those drill instructors responsible for the 12 platoons of test participants." Comment: unclear whether the medical officer had access to the Individual Record Sheets which showed type of boot worn, however, recruits likely to be wearing boots when attending Sick Call. The podiatrist carrying out foot examinations recorded the outcomes on the Individual Record Sheet, and was therefore not blinded to allocation. Participants could not be blinded to type of boot.
Incomplete outcome data (attrition bias) All outcomes	High risk	Of the 990 recruits enrolled, Individual Record Sheets were returned for 879 recruits (372 in the tropical combat boot group and 414 in the leather combat boot group). Unclear whether losses were equally distributed across groups, or reasons for loss to follow-up, which could have been related to the outcome of interest

Bensel 1983

Methods	CCT Individually randomised Period of study: June to August 1980
Participants	Location: US Army Training Center, Fort Jackson, USA 2841 Army recruits (27% female) on 8 weeks basic training course. Age: range 16 to 41 years (only available for 1291 participants) Exclusion criteria: if foot size greater or smaller than issue boots
Interventions	1. Intervention group (N = 1070; 32% female): hot weather combat boot. 2. Control group (N =1771; 24% female): black leather combat boot. All participants received two pairs of boots.
Outcomes	Anterior knee pain, shin splints, achilles tendonitis, ankle sprain plus other outcomes not meeting the inclusion criteria of this review. Examined four times by podiatrist or podiatrist assistant: prior to boot issue, at week 3, at week 6, and week 8 (final week of training). Also identified by medical staff if presenting at Sick Call with lower extremity disorders
Notes	Same type of hot weather boot used in Bensel 1976 (cotton/nylon blend uppers)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the 2,074 men and the 767 women serving as test participants were randomly divided into two footwear groups" Quote: "Each study record sheet had previously been marked to indicate which of the two types of boots being tested was to be issued to the trainee; the hot weather boot was identified for issue on every second sheet and the sheets were distributed at random among the trainees." Comment: insufficient information to determine the sequence generation process
Allocation concealment (selection bias)	High risk	Quote: "A trainee who was to receive the hot weather boot, but who could not be properly fitted with the limited stock of this boot on hand, was fitted for and issued the black leather boot in an appropriate size. The trainee was then replaced by another who was to have received the leather boot, but who could be fitted in a hot weather boot." Comment: selection of replacement partic-

Bensel 1983 (*Continued*)

		ipants not concealed
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "Medical personnel examined the lower extremities of the study participants for indications of foot or lower leg problems. Each individual's study record was completed to denote the occurrence of the exam and the presence of disorders, if any. " Comment: medical staff would be aware of the allocation status of the subject as this was noted on the individual's study record. It is also likely that recruits would wear uniform for study examinations and sick call visits. Recruits could not be blinded to allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	357 left the study due to being transferred to a different battalion, or due to discharge from the Army (intervention group N = 127, 82 men, 45 women; control group N = 230, 152 men, 78 women). Data from podiatrist examinations or sick calls included up until time of transfer Comment: similar proportion from intervention group (127/1070) and control group (230/1771). Thus, loss to follow-up unlikely to introduce bias

Bensel 1986

Methods	CCT Individually randomised
Participants	Location: US Army Training Centre, Fort Jackson, South Carolina, USA. 555 female recruits in the Regular Army, the National Guard, or the Enlisted Reserves, on 9 week training course. Age: not stated. Exclusion criteria: none stated.
Interventions	Two intervention groups: 1. Intervention group (N = 186): boot insert with urethane foam material and fibreboard boot backing 2. Intervention group (N = 198): boot insert with moulded network of lever-like projections attached at the back to material in the form of a grid. Smooth grid surface is closest to the foot. 3. Control group (N = 171): standard ventilating boot insert. All participants received two pairs of boots with two identical pairs of inserts

Bensel 1986 (*Continued*)

Outcomes	Incidence of lower extremity disorders identified during examinations or sick calls. Three examinations of the test participants' knee, lower legs and feet carried out by medical personnel during 3rd, 5th, and final (9th) weeks of training. Augmented by data from those reporting sick
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The type of insert placed in the boots was determined by a letter code (A, B, or C) on the participant's study form. Prior to the initiation of the study, the codes for each type of insert had been entered on an equal number of forms and the forms were then collated in the order A, B, C, A, B, C, and so forth. During the study, the forms were randomly distributed among the participants." Comment: this should result in an equal number of participants in each group, but A: N = 186, B: N = 198 and C: N = 171
Allocation concealment (selection bias)	High risk	Comment: forms collated A, B, C, A, B, C so allocation of next participant was visible and predicable
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Comment: participants were not blind to allocated group. There is no mention whether the assessors were blinded to the inserts of the participants. It only stated information regarding lower extremity problems acquired through the medical exams was augmented by sick-call data
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: medically discharged N = 24, but total number randomised included in the analysis

Brushøj 2008

Methods	RCT Cluster randomised by platoon (N = 24) Period of study: 2004 to 2005
Participants	Location: Royal Danish Life Guards, Frederiksborg County, Denmark 1020 male recruits undergoing 12 weeks of basic military training (24.25 hours of training per week) Age: range 19 to 26 years Exclusion criteria: none stated

Interventions	1. Intervention group (N = 507, 12 platoons): exercise programme with emphasis on lower-limb muscle strength, coordination and flexibility (5 exercises performed in 3 sets of 5-25 repetitions, 3 times per week. The load was progressed every 2 weeks) 2. Control group (N = 513, 12 platoons): exercise programme for arms and upper body (placebo training)
Outcomes	1. Number of people with overuse knee injuries (patellofemoral pain syndrome, iliotibial band friction syndrome, jumper's knee), medial tibial stress syndrome, muscle strains and other overuse injuries of the lower limb. Participants examined every second week by one of the authors 2. Compliance.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The conscripts were randomly divided (by personal registration number) into 8 companies each consisting of 3 platoons." "Each company consisted of 125 subjects, and each platoon consisted of 40 subjects." Comment: 40 x 3 = 120, not 125. Quote: "to avoid any unknown differences between companies, a cluster randomization was performed between platoons. In each of the 2 companies beginning every fourth month, 2 platoons were allocated to one type of training, and 1 platoon to another type of training, making 3 platoons allocated to each type of training every fourth month." Comment: insufficient information to allow judgement.
Allocation concealment (selection bias)	Unclear risk	Quote: "The recruits were randomly divided (by personal registration number) into 8 companies.." Quote: "The randomization [of companies] was performed by the head nurse, who otherwise did not participate in the study." Comment: insufficient information to allow judgement.
Blinding (performance bias and detection bias)	Low risk	Quote: "All subjects with knee pain or shin pain were examined every second week by

Brushøj 2008 (*Continued*)

All outcomes		one of the authors (C.B.) who was blinded to training group allocation. Before their examination, the patients were informed by the nurse not to reveal what exercise group they were allocated to." Comment: participants were not blind to allocated group, but the assessor was
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: loss to follow-up unlikely to introduce bias (20 in intervention group, 23 in control group "for reasons not related to the present study)

Buist 2008

Methods	RCT Individually randomised (stratified on the basis of sporting activities status, previous injury, and gender) Period of study: 2005
Participants	Location: The Netherlands 532 novice runners (58% female) preparing for a four-mile run. Age: mean 39.8 years Inclusion criteria: aged 18 to 65 years. Exclusion criteria: history of lower extremity injury in previous 3 months, history of running on a regular basis in previous 12 months, vigorous physical exercise contraindicated, or unwilling to keep running diary
Interventions	1. Intervention group (N = 264): graded training programme for 13 weeks, based on the 10% training rule 2. Control group (N = 268): standard training programme for 8 weeks
Outcomes	Incidence of running related injury (self reported). To qualify an injury had to result in restriction in running for at least a week i.e. three or more training sessions
Notes	10% training rule refers to an increase in training volume of no more than 10% per week

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "From each stratum participants were allocated to intervention or control group by drawing a sealed opaque envelope. Each stratum box contained equal numbers of control and intervention envelopes." Comment: insufficient information to al-

Buist 2008 (*Continued*)

		low judgement.
Allocation concealment (selection bias)	Low risk	Comment: see above. Not sequentially numbered envelopes, but they were sealed and opaque
Blinding (performance bias and detection bias) All outcomes	High risk	Comment: self-reported injuries. Runners reported on their running activities and injuries via an Internet-based training log
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "A participant was lost to follow-up (i.e., excluded from the final analysis) if she or he did not start running or if no exposure data were available. Significantly more participants of the standard training program group were lost to follow-up because they did not start running-32 of 268 (11.9%) versus 14 of 264 (5.3%) of the graded training program group." Comment: could introduce bias.

Fauno 1993

Methods	CCT Individually randomised Period of study: 1989
Participants	Location: Denmark 121 soccer referees undergoing 5 days of refereeing in a tournament (gender not stated; original sample included 2 female referees and 6 people were excluded). For the first four days each referee participated in 4-5 matches each lasting 50 minutes. Age: range 17 to 65 (mean 35.9) years Exclusion criteria: problems with soreness in lower limbs prior to intervention
Interventions	1. Intervention group (N = 62): use of shock-absorbing heel insoles 2. Control group (N = 59): no insoles
Outcomes	Incidence of lower-limb soreness. Diagnosis made by the research team.
Notes	Paper reports the number of referees with soreness on each day of the competition. Data from day four used in the analysis (same as day three)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Fauno 1993 (*Continued*)

Random sequence generation (selection bias)	High risk	Quote: "A birth date dependent randomization procedure was used for the sake of simplicity. Referees born in the period 1st to 15th of each month were randomized to wear 8mm thick shock-absorbing heel inserts" "referees born in the period from 16th to 31st of their birth month acted as the control group." Comment: non-random component in the sequence generation process
Allocation concealment (selection bias)	High risk	Comment: see above. Investigators enrolling participants could foresee assignments as this was based on date of birth
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: participants asked to "record each day the number of matches refereed and to give information about injuries and soreness if any, and anatomical site of symptoms." Asked to contact medical staff (author) if any symptoms reported. Assessment examiner "was not informed whether the referees were wearing the SAH or not, but strict blindness of the examiner was, of course, not possible." Comment: self-reporting of injuries by participants not blind to allocation, but some attempt to blind assessor
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Thirty referees either did not attend a clinical examination or did not complete the questionnaire (fourteen from SAH group and sixteen controls)" Comment: losses 14/62 in intervention group (23%), 16/59 (27%) in control group. Unclear whether this would introduce bias

Finestone 2004a

Methods	RCT Individually randomised
Participants	Location: Israel 451 male infantry recruits on a 14 week basic training course Age: mean age 18.74 (SD 0.72) years Exclusion criteria: none stated

Finestone 2004a (*Continued*)

Interventions	Standard infantry boots were wore by all recruits. Foot impressions were made to each recruit but only used in the custom-made group. 1. Intervention group (N = 227): soft custom-made orthoses 2. Control group (N = 224): soft prefabricated orthoses
Outcomes	1. Incidence of stress fracture, ankle sprains and foot problems Diagnosed by clinical examination. 2. Compliance
Notes	Stress fracture data excluded from analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Before beginning basic training, recruits were assigned to one of two groups according to a randomization program written on Excel." Comment: implies random component to the sequence generation process
Allocation concealment (selection bias)	Unclear risk	Comment: see above. Insufficient information to allow judgement
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "Recruits were blinded in this study as to whether they trained in custom orthoses or prefabricated orthoses since both were made of identical materials." Comment: unclear whether orthopaedists carrying out 3-weekly examinations were blinded, but unlikely as recruits had to remove shoes at each review to monitor compliance with orthoses usage
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: losses 23 in soft custom-made orthoses group (10%), 11 in soft prefabricated orthoses group (5%). Comment: unclear whether this would have introduced bias

Finestone 2004b

Methods	RCT Individually randomised
Participants	Location: Israel 423 male infantry recruits undergoing 14 weeks of basic training at a different base from those in Finestone 2004a Age: mean 18.91 (SD 1.1) years Exclusion criteria: none stated

Finestone 2004b (*Continued*)

Interventions	Standard infantry boots were wore by all recruits. Foot impressions were made to each recruit but only used in the custom-made group. 1. Intervention group (N = 215): semirigid biomechanical orthoses 2. Control group (N = 208): prefabricated semirigid orthoses
Outcomes	1. Incidence of stress fracture, ankle sprains and foot problems. Diagnosed by clinical examination. 2. Compliance
Notes	Stress fracture data excluded from analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Before beginning basic training, recruits were assigned to one of two groups according to a randomization program written on Excel." Comment: implies random component to the sequence generation process
Allocation concealment (selection bias)	Unclear risk	Comment: see above. Insufficient information to allow judgement
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "In this study, subjects were blinded as to whether they received custom or prefabricated orthoses" Comment: unclear whether orthopaedists carrying out 3-weekly examinations were blinded, but unlikely as recruits had to remove shoes at each review to monitor compliance with orthoses usage
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: losses 35 (16%) in semirigid biomechanical orthoses group, 36 (17%) in semirigid prefabricated orthoses group. Unlikely to introduce bias in relation to injury outcomes

Gardner 1988

Methods	CCT Cluster randomised by platoon.
Participants	Location: US Marine Training Center, Parris Island (CA), USA 3025 male marine recruits, undergoing 12 weeks of training Age: range 18 to 41 (mean 20, SD 0.02) years Exclusion criteria: none stated

Gardner 1988 (*Continued*)

Interventions	1. Intervention group (N = 1557): Sorbothane shock absorbent viscoelastic polymer insoles in standard marine boots 2. Control group (N = 1468): standard mesh insoles
Outcomes	Incidence of lower extremity injuries (planter fasciitis, ankle sprains, knee strains and sprains, achilles tendonitis) Primary outcome stress fracture, but data on stress fracture excluded from analysis Diagnosis made by clinical evaluation and radiological examination
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote: "Boots with polymer insoles were issued to trainees who were assigned to even-numbered platoons. Boots with a standard mesh insole were issued to members of odd numbered platoons" Comment: there is a non-random component in the sequence generation process (odd/even numbered platoons)
Allocation concealment (selection bias)	High risk	Comment: see above. Allocation concealment not possible.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "recruits who had lower extremity injuries were evaluated at a medical clinic on Parris Island. Injury information for this study was recorded on clinical data forms at the time of clinic visit. Patients were transferred to Beaufort Naval Hospital for lower extremity x-rays. Both radiologists were blinded with respect to insole status and the second review was blinded concerning the primary evaluation." Comment: unclear whether clinic personnel were blind to allocation, but possibly not. Radiologists were blinded, but this relates to stress fracture outcome, which is not included in this review
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: there is no report of any loss to follow-up.

Hartig 1999

Methods	RCT Cluster randomised by company (N = 2)
Participants	Location: Fort Benning, Georgia, USA 298 male Army recruits undergoing 13-week basic training course Age: mean 20 years Exclusion criteria: none stated
Interventions	1. Intervention group (N = 150, 1 company): routine stretching before training plus 3 hamstring stretching sessions daily (before lunch, dinner and bedtime). Stretching routine: 5 x 30 seconds 2. Control group (N = 148, 1 company): routine stretching before training
Outcomes	1. Incidence of lower-limb overuse injuries. Diagnosis made by weekly review of the log-in sheets at the medical clinic
Notes	Reported as number of injuries, but the number of injuries appears to equal the number of subjects injured

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The two companies designated as either the control or intervention group were assigned randomly before basic training. Also, there was no special system to randomize subjects to either company other than the Army's routine assignment. " Comment: insufficient information about the sequence generation process
Allocation concealment (selection bias)	High risk	Quote: "The two companies assigned as either the control or intervention group were assigned randomly before basic training." Comment: because there were only two companies the allocation of the second group would be obvious once the first one had been allocated
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "Recording and monitoring of lower extremity overuse injuries were done by weekly reviews of the log-in sheets at the troop medical clinic and review of the medical records to determine the diagnosis of any subject seen. Commanders of each company were contacted weekly to make sure there were no injuries that were unac-

Hartig 1999 (*Continued*)

		counted for by the troop medical clinic or medical records." Comment: blinding of clinic personnel not mentioned. Commanders would have been aware of their company's allocation Blinding of participants not possible as the intervention group carried out three stretching sessions (before lunch, dinner and bed time) in addition to the standard fitness programme
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "The results included all subjects, even though 10 in the control group and 18 in the intervention group left training early for various reasons other than overuse lower extremity injuries" Comment: reasons for missing outcome data unlikely to be related to true outcome

Knapik 2009

Methods	CCT Individually randomised Period of study: 2007	
Participants	Location: Fort Jackson, South Carolina, USA. 3952 Army recruits (32% female) undergoing 9 weeks of training Age: mean ± SD (men 23 ± 5, women 23 ± 6) years Exclusion criteria: none stated, but excluded from analysis if participants could not obtain the prescribed shoe or if they did not wear the prescribed shoe for all physical training during the basic combat training	
Interventions	1. Intervention group (N = 1346 male and 633 female): participants were prescribed a type of running shoes (stability, cushion or motion control) based on the plantar shape 2. Control group (N = 1343 male and 630 female): standard stability shoes	
Outcomes	Lower extremity overuse injuries (using the Training Injury Index Knapik 2010a) Diagnosis made by clinical evaluation and radiological examination. Recruits attended the outpatient medical clinics either within military treatment facilities or outside facilities that are paid for by the Department of Defence. Injury classification based on Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM). Data retrieved from the Defence Medical Surveillance System (DMSS)	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Knapik 2009 (*Continued*)

Random sequence generation (selection bias)	High risk	Quote: "Subjects were randomized into a control (C) or experimental (E) group in sequential order (alternately in order of arrival for testing)." Comment: this is a systematic non-random method of sequence generation
Allocation concealment (selection bias)	High risk	Comment: see above. Assignment could be foreseen.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Comment: the outcomes were retrieved from the Defence Medical Surveillance System which captured data from outpatient encounters. Unclear whether people inputting data (clinicians) were aware of assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	Excluded individuals from analysis because prescribed shoe not available at Post Exchange (store), or because the participant changed shoes during training: 521 male and 312 female (264 male and 147 female in control group (20%), 257 male and 165 female in intervention group (21%) Comment: similar proportion lost from control and intervention groups, but not an intention to treat analysis. Reason for changing shoes might have been related to the outcome of the study

Knapik 2010a

Methods	CCT Individually randomised
Participants	Location: Lackland Air Force Base, Texas, USA 3021 Air Force recruits (28% female) undergoing 6 weeks training Age: not stated, but subgrouped into 18-19, 20-24, and $\geq$ 25 years for analysis. Exclusion criteria: none stated.
Interventions	1. Intervention group (N = 1417; 26% female): prescribed a type of running shoes (stability, cushion or motion control) based on the plantar shape 2. Control group (N = 1259; 27% female): standard stability shoes
Outcomes	Lower extremity overuse injuries (using the Training Injury Index) Diagnosis made by clinical evaluation and radiological examination. Recruits attended the outpatient medical clinics either within military treatment facilities or outside facilities that are paid for by the Department of Defence. Injury classification based on Clas-

Knapik 2010a (*Continued*)

	sification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM). Data based on the Defence Medical Surveillance System (DMSS)
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote: "Study participants were randomly assigned to either an experimental (E) or a control (C) group, based on order of arrival for testing." Comment: this is systematic non-random method of sequence generation
Allocation concealment (selection bias)	High risk	Comment: see above. Allocation concealment not possible.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Comment: the outcomes were retrieved from the Defence Medical Surveillance System which captured data from outpatient encounters. Unclear whether people inputting data (clinicians) were aware of assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "113 (60 men and 53 women) did not enter BMT [basic military training] for medical or administrative reasons and were not considered in the analyses. There were 206 subjects (128 men, 78 women) who did not complete training with the unit to which they were originally assigned...and were not considered for subsequent analysis." Quote: "Not all subjects had complete measurements on all variables ... primarily because data were not available in the DMSS databases, subjects did not provide a response to the questionnaire, or the training unit did not have the information. Therefore, the tables indicate the sample size for each variable." Comment: the attrition rate is similar among the experimental and control group. Unclear whether losses would have introduced bias

Larsen 2002

Methods	RCT Individually randomised Period of study: 1999
Participants	Location: Jutland Dragoon Regiment, Holestebro, Denmark 146 Army recruits (1 female) undergoing 3-month training Aged 18 to 24 years Exclusion criteria: serious back or lower extremity problems or current use of shoe orthosis
Interventions	1. Intervention group (N = 77): military boots + custom-made biomechanic shoe orthoses 2. Control group (N = 69): military boots and no inserts
Outcomes	1. Incidence of back and lower-limb injuries. Self-reported back and lower-limb injuries with at least one day off from duty. 2. Compliance
Notes	Back injuries data excluded from analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "we randomly assigned all conscripts into 2 groups by drawing an envelope out of a box with 154 well-shuffled envelopes, with text indicating either BSO or no BSO" Comment: no description of sequence generation process i.e. ratio of biomechanic shoe orthoses (BSO) to no BSO
Allocation concealment (selection bias)	Unclear risk	Comment: see above. Insufficient information to judge. Not described as sealed, opaque, sequentially numbered envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "..medical and other health care practitioners at the infirmary were not aware of the group allocation, and they were told to treat all conscripts in the normal fashion, except to refrain from using any type of BSO as a mode of treatment." However, outcome data was self-reported at the end of three months by the participants who were not blind to allocated group
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "At follow up evaluation, data were collected from 67 (87%) conscripts in the intervention group, and 63 (91%) in the

Larsen 2002 (*Continued*)

		control group, giving a total follow-up rate of 130 (89%) of 146 subjects. A total of 10 conscripts in the intervention group and 6 in the control group were classified as having dropped out of the study" Comment: actual-use analysis, intention-to-treat analysis, and worst-case analysis were reported in the study

Liu 2008

Methods	RCT Individually randomised Period of study: November 2006 to March 2007	
Participants	Location: PLA Institute of Physical Education, Guangzhou, China 122 male Army recruits undergoing 12 weeks of training Age range 17 to 19 years Exclusion: previous injury between the time of the recruiting medical examination and arrival at the Army site	
Interventions	1. Intervention group (N = 61): routine daily morning gastrocnemius stretches plus three more sessions of stretching before lunch, supper and sleep. 2. Control group (N = 61): routine daily morning gastrocnemius stretching exercises. Stretching routine: 5 x 30 seconds static stretches bilateral limbs	
Outcomes	Incidence of overuse lower-limb injuries (include patellofemoral joint pain syndrome, tendinopathy, muscle injuries, shin splints, foot injuries and stress fracture) Diagnosis made by weekly review of the recruits' daily dairy and cases were confirmed by staff in the medical clinic	
Notes	Data includes stress fractures. Email sent to authors requesting data without stress fractures. No reply received	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "divided randomly using random digits table" Comment: this is a random component in the sequence generation process
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to judge any method of concealment

Liu 2008 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding of participants not possible as the intervention group, on top of the routine exercise regimen, added three stretching sessions before lunch, dinner and bed time Blinding of assessors not mentioned in this study.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Lost three from control and one from intervention group (medical reason) but the article did not mention whether these four participants were included in the analysis

Pollock 1977a

Methods	RCT Individually randomised
Participants	Location: California Men's Colony, San Luis Obispo (medium security prison in the USA) 87 male prison inmates undergoing training programmes of different duration for 20 weeks Age: range 20 to 35 years Inclusion criteria: healthy, sedentary, free from drugs
Interventions	Training 3 days/week for 20 weeks on a square, 440 yd asphalt track. Four groups: 1. Train 15 minutes/day (N = 20) 2. Train 30 minutes/day (N = 25) 3. Train 45 minutes/day (N = 24) 4. Control group (N = 18) Note: Exercise intensity at 85-90% maximal heart rate
Outcomes	Incidence of training related injury which prevented participants from running for at least one week. "Incidence of injury was accurately recorded" but method not stated To qualify, injury had to be a training related incident that prevented a participant from jogging for at least one week
Notes	Analysis of incidence of injuries by location in the body not possible

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "... the subjects were assigned on a random basis to one of four groups at each study site." Comment: there is no information about the ran-

Pollock 1977a (*Continued*)

		domisation process
Allocation concealment (selection bias)	Unclear risk	Quote: "... the subjects were assigned on a random basis to one of four groups at each study site." Comment: insufficient information to permit judgement.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	There is no mention of blinding process in the study.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The overall attrition rate was 29.9%" "more injury-related dropouts in the 45-min duration group. " "In general the drop-out rate from uninjured subjects was similar for all training groups, but significantly higher for the training groups as compared to their respective control groups" Comment: uneven losses across intervention groups and greater losses in the intervention groups than the control group (control group: 2/18 (11%), 15 min group: 5/20 (25%), 30 min group: 8/25 (32%), 45 min group: 11/24 (45%))

Pollock 1977b

Methods	RCT Individually randomised
Participants	Harris County Jail, Houston, Texas, USA 70 male prison inmates undergoing training programmes of different frequency for 20 weeks Age: range 20 to 35 years Inclusion criteria: healthy, sedentary, free from drugs
Interventions	Run on treadmill 30 minutes. Three intervention groups: 1. 1 day/week (N = 15) 2. 3 days/week (N = 25) 3. 5 days/week (N = 18) 4. Control group (N = 13) Note: progression of running to 9.75 mph
Outcomes	Incidence of training related injury which prevented participants from running for at least one week. "Incidence of injury was accurately recorded" but method not stated To qualify injury had to be a training related incident that prevented a participant from jogging for at least one week
Notes	Analysis of incidence of injuries by location in the body not possible

Pollock 1977b (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "... the subjects were assigned on a random basis to one of four groups at each study site." Comment: There is no information about the randomisation process
Allocation concealment (selection bias)	Unclear risk	Quote: "... the subjects were assigned on a random basis to one of four groups at each study site." Comment: insufficient information to permit judgement.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	There is no mention of blinding process in the study.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The overall attrition rate was ...21.4%" "In general the drop-out rate from uninjured subjects was similar for all training groups, but significantly higher for the training groups as compared to their respective control groups" Comment: greater losses in the intervention groups than the control (control group: 1/13, 1 day/week group: 4/15, 3 days/week group: 5/25, 5 days/week group: 5/18)

Pope 1998

Methods	CCT Cluster randomised by platoon (N = 26) Period of study: September 1992 to May 1993
Participants	Location: 1st Recruit Training Battalion, Kapooka, NSW, Australia 1093 male Army recruits undergoing 11 weeks of intensive training (average 47 hours per week) Age: range 17 to 35 years Exclusion criteria: previous injury between the time of the recruiting medical examination and arrival at the Army site
Interventions	1. Intervention group (N = 549): stretches to the gastrocnemius and soleus muscles before training 2. Control group (N = 544): stretches to the wrist flexors and triceps muscle. Stretching routine for both groups: 2 x 20 seconds static stretches

Outcomes	Incidence of soft-tissue injuries: ankle sprains, Achilles tendonitis, tibia periostitis, anterior compartment syndrome. Self-report and diagnosis confirmed by regimental officer and physiotherapist's examination To qualify injuries had to be more than trivial or result in an Inability to resume full duties without signs and symptoms within three days
Notes	Data for stress fractures of the tibia and foot excluded from analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "As male recruits arrived....they were split into one of two platoons on the basis of surnames. Recruits with surnames commencing with the same letter were equally split between the two platoons. In addition, where possible, recruits with the same surname were allocated to alternate platoons." Quote: "Pairs of platoons were then randomly allocated to control and stretch groups for this study." "Systematic differences were made even more unlikely through truly random allocation of the platoons to control or stretch groups." Comment: sequence generation for randomisation of platoons not stated
Allocation concealment (selection bias)	Unclear risk	Comment: see above. Insufficient information relating to allocation concealment to judge
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "Diagnosis was made by either the regimental medical officer or by one of the two physiotherapists." The physiotherapists were researchers Comment: there is no mention of whether the assessors were blinded to group assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Of the 1093 participating recruits, 162 (15 per cent) were discharged or back-squadded before the end of the training program, or before they experienced one of the five injuries of interest. Ninety-eight of these were from the stretch group and

		64 from the control group. A further 48 subjects (4 per cent), all from the control group, withdrew from the study; most withdrawals occurred at the end of the first half of the training programme." Comment: greater losses in the control versus intervention group (control group 112/544 (20.6%); intervention group 98/549 (17.9%)). The missing data might introduce bias

Pope 2000

Methods	CCT Cluster randomised by platoon (N = 39) Period of study: January to December 1994
Participants	Location: 1st Recruit Training Battalion, Kapooka, NSW, Australia 1538 male Army recruits undergoing 11 weeks of training (40 sessions totaling 50 hours) Age: range 17 to 35 years Inclusion criteria: absence of any significant injury, good general health
Interventions	1. Intervention group (N = 735 recruits, 19 platoons): stretches to gastrocnemius, soleus, hamstrings, quadriceps, hip adductor and hip flexor muscle groups, interspersed with 4 minute warm up activities before training. Stretching routine: 1 x 20 seconds stretch for each muscle group 2. Control group (N = 803 recruits, 20 platoons): only warm up activities but no stretching exercises
Outcomes	Incidence of lower-limb injuries by area and by type: joint injury, ligament sprain, muscle strain, tendinitis, periostitis, compartment syndrome. Self-report and diagnosis confirmed by regimental medical officer To qualify injuries had to be more than trivial or result in an Inability to resume full duties without signs and symptoms within three days
Notes	Stress fractures not included in the analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "As the male recruits arrived...they were assigned to platoons on the basis of surnames, by administrative staff. Recruits with surnames commencing with the same letter were equally split between platoons. In addition, where possible, recruits with the same surname were allocated to differ-

		ent platoons. No other conditions influenced allocation to platoons." Quote: "Pairs of platoons,..., were then randomly allocated to stretch or control groups..., so that one platoon from each pair was allocated to each group." Quote: "There were an odd number of platoons because the last platoon intake within the study period was not matched with an accompanying platoon." Comment: insufficient information to judge.
Allocation concealment (selection bias)	Low risk	Comment: see above. Allocation of cluster units (platoons) was performed after individual participant recruitment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "The RMO (regimental medical officer), who was masked to patient allocation, categorized all injuries by area and type.." referred all injured recruits to the researchers Comment: the participants were not blind to allocated group.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Of the 1538 participating recruits, 170 (11%; 69 from the stretch group, and 101 from the control group) were discharged or transferred to officer training before the end of the training program and without suffering a lower-limb injury. Censored training times for each of these 170 subjects were included in the overall analysis." Quote: "Eighty-nine subjects (5.8%; 46 control subjects and 43 subjects from the stretch group) were backsquadded to another platoon during the course of training. A further 94 subjects (6.1%), all from the control group, withdrew from the study. These subjects reported that they wished to perform lower-limb muscle stretches before exercise and withdrew within the first 3 wk of training. At the time of withdrawal or backsquadding, none had suffered a lower limb injury. Injury data were still available for these subjects, so their data were analysed by intention to treat."

		Comment: survival analysis and intention-to-treat analysis were done in this study

Rudzki 1997

Methods	Cluster randomised by platoon (N = 8) Period of study: March to July 1989
Participants	Location: 1st Recruit Training Battalion, Wagga Wagga, NSW, Australia 350 male Army recruits undergoing 12 weeks of training (average of 41.3 hours per week) Age: range 17 to 31 years Exclusion criteria: none stated
Interventions	1. Walk group (N = 170, 4 platoons): substitute running with walking plus added weight 2. Run group (N = 180, 4 platoons): uninterrupted programme of training Note: run group ran 16.5 km more than the walk group
Outcomes	Number of people with lower-limb injuries overall and by location (hamstring/thigh/hip/groin, knee injuries, shin/calf injuries, ankle and foot injuries) Injury data collected from attendance records maintained by treating medical facility or military hospital
Notes	Injuries to upper limb, back and stress fractures are excluded from the analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "The training clerk allotted names to a platoon on an "as received basis", i.e. , the names of recruits were entered onto platoon nominal rolls as the faxes were received. Once a platoon quota was filled, a second platoon was raised." Quote: "Two paired platoon groups were enrolled during a given week, and a platoon was randomly assigned to be either a Walk or a Run group by being drawn from a hat by the author, who was blind to the composition of the groups." Comment: a random component in the sequence generation process
Allocation concealment (selection bias)	Low risk	Comment: see above. Allocation of cluster units (platoons) was performed after individual participant recruitment

Rudzki 1997 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "Injury data were collected from attendance records maintained by the treating medical facility (regimental aid post) as well as the nearby military hospital." Comment: no mention of blinding, but nothing to suggest that medical facilities would be aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "The wastage rates (all causes) were 23.5% and 19.4% for the Walk and Run groups, respectively." "The rate of medical discharge was higher in the Run group (8.9%) than in the Walk group (5.9%)." "but this difference was not statistically significant (p = 0.07)." "The number of administrative discharges and backsquadding was higher in the Walk group, and the reasons for this were unclear. " Comment: unclear whether these losses were related to the outcome of interest

Van Mechelen 1993

Methods	Individually randomised Period of study: September 1988 to January 1989
Participants	Location: Amsterdam, Netherlands 421 male civil servants (recreational runners) Age: not stated Inclusion: healthy, no current injury, not home from work on sick leave, running at least 10 km/week all year round, not performing sports as their profession
Interventions	1. Intervention group (N = 210): information on warm up / cool down and stretching exercises, explained by coach and performance of these exercises before and after each running session. Protocol: warm up of 6 minutes of running exercises, 3 minutes of loosening exercises, 10 minutes of stretching exercises to major lower-limb muscles (3 x 10 seconds static stretches) 2. Control group (N = 211): no intervention
Outcomes	1. Rate of lower limb soft-tissue injury per 1000 hours of running 2. Number of people with lower limb soft-tissue injuries. Self report (if matched with the running injury definition), followed by physicians' confirmation of medical diagnosis To qualify the injury had to be a running injury and result in one or more of the following: 1) the subject had to stop running, 2) the subject could not run on the next occasion, 3) the subject could not go to work the next day, 4) the subject needed medical attention,

Van Mechelen 1993 (*Continued*)

	or 5) the subject suffered from pain or stiffness during 10 subsequent days while running. 3. Compliance	
Notes		

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Participants divided into one of three categories by age, into one of three categories by estimated running distance per week, and one of five categories by score on a knowledge questionnaire i.e. 45 cells with 2 to 18 participants per cell Quote: "From each cell, subjects were randomly selected for intervention (N = 210) or the control group (N = 211)." Comment: the randomisation process is unclear.
Allocation concealment (selection bias)	Unclear risk	Quote: "From each cell, subjects were randomly selected for intervention (N = 210) or the control group (N = 211)." Comment: method of randomisation not described.
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "Any injury that met this definition was to be noted in the daily running diary. Every injury was also to be reported by a special postage-paid reply form." Comment: blinding not possible as data collected by self reporting
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "The total drop-out rate after 16 weeks was 94/421 = 22.3%" Comment: there is no mention of the reasons for drop out or number that dropped out from each group. Unclear whether this would introduce bias

Van Tiggelen 2004

Methods	RCT Individually randomised
Participants	Location: Belgian Royal Military Academy, Brussels, Belgium 200 male and female officer cadets undergoing 6 weeks basic military training Age: range 17 to 26 years Exclusion criterion: history of knee complaints.
Interventions	1. Intervention group (N = 61; 20% female in the analysis): dynamic patellofemoral knee brace. 2. Control group (N = 139; 17% female in the analysis): no brace
Outcomes	Incidence of anterior knee pain diagnosed by the military physician
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "167 military recruits without history of knee pain were randomized into two groups." Quote: "Fifty four volunteers ... were randomized to the experimental group, and 113 ... served as controls. " Comment: flow chart shows 61 in braced group and 139 in the control group. Insufficient information about the randomisation process
Allocation concealment (selection bias)	Unclear risk	Comment: see above. No method of allocation concealment is described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "An experienced military physician diagnosis all the anterior knee pain syndrome during the BMT (basic military training). " Comment: there is no mention of blinding of the assessors, but brace only to be used during physical activities, so possibly not worn when reporting sick
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Thirty three of the 200 officer cadets dropped out due to different reasons described in Table 1. Therefore, 167 persons (32 females, 135 males) participated in the study." Comment: drop-outs removed from the study. Reasons for dropping out included "other traumatic lesion" N = 1 brace group and N = 7 control group. Bias could be introduced by losses

Van Tiggelen 2009

Methods	RCT Cluster randomised by platoon (N = 6)
Participants	Location: Belgian Royal Military Academy, Brussels, Belgium 189 male and female officer cadets undergoing 6 weeks of basic military training (BMT) . Age: not stated. Exclusion criteria: none stated
Interventions	Two intervention groups: 1. Intervention group (N = 65, 15% female): padded polyester socks (88% polyester, 11% polyamide and 1% elastane). 2. Intervention group (N = 59, 17% female): wore a thin inner sock (45% polyester, 45% viscose, 8% polyamide, and 2% elastane) under a thick cotton-wool stock (40% cotton, 40% wool, 18% polyamide, and 2% elastane) 3. Control group (N = 65, 15% female): regular Army socks (70% combing wool and 30% polyamide)
Outcomes	Overuse injuries of the knee (e.g. patellofemoral pain and fat pad impingement, iliotibial band syndrome, patellar tendinopathy), ankle and knee sprain, achilles tendinopathy, shin splints and tibial stress reactions Participants kept a diary of their injuries during the BMT, and undertook a clinical assessment after the BMT to register the injuries
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The six platoons were randomly divided into two intervention groups and one control group on a 2:2:2 basis." Comment: there is no mention on the randomisation process.
Allocation concealment (selection bias)	Unclear risk	Comment: there is no description of allocation concealment.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "Subjects kept a diary of their injuries and foot blisters during the BMT. They also undertook a clinical assessment after the MBT to register the injuries." Comment: self-report and the participants could not be blinded, and it is not stated whether the assessors were blind to allocation status

Van Tiggelen 2009 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "During the BMT, nine officer cadets were discharged from the RMA for nonmedical reasons. Seven others did not participated in all training sessions because of illnesses. The data of 173 recruits were used for further statistical analysis" Comment: drop outs unevenly distributed across groups (control N = 5, polyester group N = 7, double sock group N = 4) . Some drop outs could be related to outcome, and not included in the analysis

Withnall 2006

Methods	RCT Individually randomised Period of study: Sept 2003 to April 2004
Participants	Location: RAF Halton, Aylesbury, UK 1300 Royal Air Force recruits (22% female) undergoing 9-week basic training program. Age: range 16 to 35, mean 20 years. Exclusion criteria: past medical history of lower-limb injury, any ongoing medical problems, current pregnancy
Interventions	Two intervention groups: 1. Intervention group (N = 421, 22% female): Sorbothane shock-absorbing insoles 2. Intervention group (N = 383, 22% female): Poron shock-absorbing insoles 3. Control group (N = 401, 23% female): Saran non shock-absorbing insoles
Outcomes	Serious lower-limb injuries necessitating withdrawal from training. Overall and by location (thigh, knee, shin and calf, ankle, foot and achilles tendon) Diagnosed by the Medical Centre doctors, nurses or physiotherapists
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "A randomization code was generated using a simple three-way randomization algorithm programmed in Microsoft Access and stratified by flight." Quote: "Participants were randomized to receive Saran (control), Sorbothane or Poron SAIs by 1:1:1 proportion." Comment: adequate sequence generation.

Withnall 2006 (*Continued*)

Allocation concealment (selection bias)	Low risk	Quote: "Random allocation was through a concealed process, in which details of all recruits expected to attend RAF Halton were sent to the randomization centre at the University of Birmingham during the week before their planned arrival." Quote: "Participants were recruited in RAF Halton by staff blinded to the allocation of participants." Comment: randomisation done off site prior to receiving consent. Consent obtained by someone blind to participant's allocation
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "The three insoles utilized in this study are not identical in design, and thus blinding of investigators and participants was not possible"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Participants who did not complete phase 1 training were included in the study until they left the service." Quote: "During the period of the trial 98 participant withdrew from basic training. These participants were included until they left the service, at which point they were declared medically fit." Quote: "During the study there were 221 withdrawals from training that met the criteria for primary outcome events." Comment: data for all participants included until they left the service

CCT: quasi-randomised controlled trial
mph: miles per hour
RAF: Royal Air Force
RCT: randomised controlled trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Amako 2003	Not a RCT. Stretching to prevent training injuries. Recruits randomly assigned to companies, but companies not randomised to intervention or control groups

(*Continued*)

Askling 2003	RCT. Preseason training to prevent hamstring muscle strain in soccer players. Injury mechanism in soccer players differs from runners
Barrett 1993	RCT. This study examines high- versus low-top shoes in the prevention of ankle sprains in basketball players. This type of intervention (high-top shoes) is directed toward prevention of acute ankle sprains. Injury mechanism different from running-associated ankle injuries (overuse)
Cabry 2000	RCT. Effect of hamstring stretches on high school athletes. Email from second author confirmed subjects were playing team games rather than participating in athletics i.e. running or sprinting. Injury mechanisms likely to be different from running-associated injuries
Emery 2007	RCT. This study examines the protective effect of the wobble-board training programme in reducing injuries in basketball players. The injury mechanism for this sport is very different from runners
Esterman 2005	Purports to be an RCT but intervention group "selected at random" and remaining recruits with flat feet acted as controls. Orthotics for the treatment of flat feet in Australian Air Force recruits. Not a preventive strategy
Finestone 1993	RCT. Effect of knee braces in the treatment of people with patellofemoral pain. Not a preventive strategy
Gabbe 2006	RCT. This study examines the effectiveness of pre-season eccentric training in the prevention of hamstring injuries in Australian Football players. Mechanism of injury in this sport different from runners
Garrick 2005	RCT. This study investigates the effect of a structured warm-up programme in reducing knee and ankle injuries in teenage handball players. The primary outcome measure was an acute injury to the knee or ankle during a match or training session
Gudeman 1997	RCT. Use of iontophoresis of 0.4% of dexamethasone for treating plantar fasciitis. Not a preventive strategy
Hagglund 2007	RCT. This study examines a coach-controlled rehabilitation programme in reducing injury in male soccer players. Injury mechanism in soccer players very different from runners
Herring 1990	Not a RCT. Effect of sock fibre composition in the prevention of friction blisters in long distance runners. Not related to soft-tissue injury
Herring 1993	Not a RCT. Effect of sock fibre composition in the prevention of friction blisters in long distance runners. Not related to soft-tissue injury
Impellizzeri 2008	Quasi-randomised study. This study examines effect of plyometric training on different surfaces to improving performance (vertical jump height and sprinting ability). Muscle soreness was measured but this not a soft-tissue injury per se
Jagoda 1981	RCT. Comparison of different socks in the prevention of friction blisters. Not related to soft-tissue injury
Jakobsen 1994	Not a RCT. Effects of prevention and training programmes in the reduction of injury incidence
Junge 2002	Not a RCT. This study evaluates the effects of a prevention programme on the incidence of soccer injuries in young male amateur players

(*Continued*)

Kingsley 2006	Not RCT. The primary outcome for this study were delayed onset muscle soreness (DOMS) evaluated by markers of muscle damage, inflammation and oxidation stress. DOMS is not considered as an 'injury' per se
Knapik 2001	Not a RCT. Pre-post intervention study of Army recruits receiving running shoe prescription based on evaluation of foot arch and flexibility
Knapik 2005	Not a RCT. Non-randomised controlled trial evaluating a newly designed physical training programme for Army recruits
Mickel 2006	RCT. Participants randomly assigned to bilateral ankle brace or taping for preventing ankle sprains in high school football players. Not overuse injuries in runners
Milgrom 1992	Not a RCT. Not randomised to intervention or control. Two pairs of modified basketball shoes were given "at random" to 187 of the recruits (intervention group), and the remaining 203 recruits in the study received standard infantry boots (control group). This trial was included in the first version but now reassessed as non RCT
Milgrom 2003	Not a RCT. Epidemiological study investigating the effect of cold weather training on incidence of achilles paratendinitis
Mundermann 2001	RCT. Military recruits randomly assigned to either insert or control group, but people in the intervention group selected one of six shoe inserts based on comfort. Primary outcome was comfort, and only 79/206 returned injury questionnaires
Myklebust 2007	Not a RCT. This study examined the effect of neuromuscular training programme on anterior cruciate ligament (ACL) injuries in handball players. ACL injuries are typically acute and very different from overuse-injuries in runners
Olsen 2005	RCT. Evaluation of the effect of structured warm-up programmes on the prevalence of acute injuries to the knee or ankle in handball players. Not directly related to runners
Pasanen 2008	RCT. This study investigates whether a neuromuscular training programme is effective in preventing acute non-contact leg injuries in female football players. The injury mechanism in this sport is different from overuse running injuries
Petersen 2002	Controlled study. Method of allocation not clear. This study examined proprioceptive and neuromuscular training for injury prevention in handball players. The primary outcome measure is acute lower-limb injuries
Popovich 2000	Not a RCT. Six companies of Army recruits. Each company assigned to a specific training schedule. Two companies (controls), one company (increased running mileage), three companies assigned to a week of rest from running during the second, third, or fourth week of training respectively. No mention of random allocation, and an uneven number of companies in intervention and control groups
Rompe 2003	RCT. Intervention of shock wave therapy in runners that have already developed plantar fasciitis. Not a preventive strategy

(*Continued*)

Schwellnus 1990	Not a RCT. One thousand five hundred and eleven military recruits from which 250 were "randomly selected" to be the intervention group (shock-absorbing insoles), and the remainder acted as controls. Outcome was overuse injuries. This trial was included in the first version but now reassessed as non RCT
Schwellnus 1992	Not a RCT. One thousand five hundred and eleven military recruits from which 250 were randomly selected to be the intervention group (calcium supplementation), and the remainder acted as controls. Outcome was overuse injuries
Smith 1985	Not a RCT. Ninety randomly selected US Coast Guard recruits divided into three groups. No mention of randomisation or quasi-randomisation. This trial was included in the first version but now reassessed as non RCT
Soderman 2000	RCT. This study examined balance board training to reduce traumatic injuries in female soccer players. The outcome is acute traumatic injuries with injury mechanism very different from running-associated injuries
Torkki 2002	RCT. Shock-absorbing footwear for newspaper carriers with overuse injuries. Not a preventive strategy
Verhagen 2004	Quasi-randomised trial. This study examined a proprioceptive training programme to reduce ankle sprains in volleyball players. Running is not the primary focus in this sport
Wang 2004	RCT. Seventy-five soldiers randomly divided into a reinforced training group and a normal training group. Despite the title (Effect of reinforcing scientific training on constitution and injury incidence) the authors state that data on overuse injuries was not collected. Outcome physiological changes
Wedderkopp 1999	RCT. Intervention programme designed to reduce the number of injuries in young female players in European handball. Running is not the primary focus of the sport

RCT: randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Knapik 2010b

Methods	RCT Individually randomised
Participants	Location: Marine Corps Recruit Depots, USA (San Diego, California (male recruits) and Parris Island, South Carolina (female recruits)) 1411 Marine Corps recruits (40% female) undergoing 12 week basic training including about 40 miles of running Age: mean ± SD (men 21± 2, women 19 ± 2) years Inclusion criteria: volunteered for the study Exclusion criteria: none stated
Interventions	1. Intervention group (N = 408 male, 314 female): participants were prescribed a type of running shoes (stability, cushion or motion control) based on the plantar shape 2. Control group (N = 432 male, 257 female): stability shoes

Knapik 2010b (*Continued*)

Outcomes	1. Lower extremity overuse injuries (using the Training-Related Injury Index, a person-time injury incidence rate (injured subjects/ 1000 person-days)) Data obtained from the Armed Forces Health Surveillance Center which systematically collects all outpatient medical visits. Injury classification based on International Classification of Diseases, Version 9, Clinical Modification (ICD-9-CM). Diagnosis made by clinical evaluation and radiological examination
Notes	Results: no significant difference in injury rates between groups in men or women

Sherman 1996

Methods	CCT (alternation) Cluster randomised
Participants	Location: "a US Army post" 1132 male Army recruits undergoing basic training (duration not stated) Age: mean ± SD (19.9 ± 2.6) years Inclusion criteria: consenting Exclusion criteria: none stated
Interventions	1. Intervention group (N = 517): shock-absorbing shoe insert (Spenco Polysorb walker-runner) 2. Control group (N = 615): no insert, although N = 218 purchased them
Outcomes	1. Lower limb soft-tissue injuries by location 2. Lower limb pain
Notes	Results: no significant difference in the number of participants with pain

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12607000076471

Trial name or title	A randomised controlled trial of a neuromuscular control training program designed to prevent knee and ankle injury in Australian Army recruits
Methods	Cluster randomised trial
Participants	Location: Australian Army Recruit Training Centre 830 regular Army recruits (male and female) undergoing recruit training. Inclusion criteria: aged 17 to 50 years and consenting Exclusion criteria: not consenting
Interventions	Intervention: neuromuscular control training program consisting of balance training conducted for up to five minutes post warmup and prior to every physical training lesson (approximately 46 lessons during recruit

ACTRN12607000076471 (*Continued*)

	training). Agility training conducted three times a week for up to five minutes (drills in cutting and turning, jumping and landing, and stopping and propping). Control: normal physical training program delivered to Australian Army recruits
Outcomes	All knee and/or ankle injuries during the standard 80-day training period
Starting date	January 2007 to August 2007 (completed)
Contact information	Rod Goodall Headquarters Land Warfare Centre Canungra, QLD 4275 Australia rod.goodall@defence.gov.au
Notes	

NCT00832195

Trial name or title	Footwear Prevention Study: Investigating the effects of running shoe pronation control on the risk of injury
Methods	Randomised controlled trial
Participants	Location: Canada 70 people undertaking a 13 week running programme. Male or female, aged 18-50 Exclusion criteria: currently injured; history of surgery to the lower extremity
Interventions	Intervention: footwear with motion controlling elements built into construction in order to reduce pronation of the foot and ankle during running (running shoe with thermoplastic mid-foot shank stiffener, denser durometer foam on medial aspect of mid-sole, reinforced heel counter, wider sole-plate, and lateral foam crash-pad). Control: footwear with standard neutral stabilization elements for the foot and ankle during running (standard running shoe with single density mid-sole foam)
Outcomes	Primary outcome: injury status measured at baseline, 6 weeks, and at the end of the 13-week programme Secondary outcome: pain levels measured at baseline, 6 weeks, and at the end of the 13-week programme
Starting date	March 2009 Estimated completion date: August 2010
Contact information	Dr Jack E Taunton University of British Columbia
Notes	

NCT00922246

Trial name or title	Prevention of lower-limb overuse injuries by using custom made insoles: A randomized controlled trial of 230 patients
Methods	Randomised controlled trial
Participants	Location: Finland 230 male defence force conscripts undergoing basic training Inclusion criteria: aged 18-29 years, male, no deformity of the lower limb Exclusion criteria: major orthopaedic or medical conditions (e.g., diabetes, inflammatory arthritis, previous severe trauma (exclusion criteria for the military service); already wearing prescribed insoles
Interventions	Intervention: custom-made insoles (Thermo+Camel: three quarter length, firm-density polyethylene with hard plastic shell) Control: no intervention
Outcomes	Lower-limb overuse injuries requiring a visit at the garrison physician and requiring suspension from the duty Follow-up: 6 months
Starting date	January 2007 to May 2008
Contact information	Centre of Military Medicine Helsinki, Finland
Notes	

NTR1906

Trial name or title	The GROningen NOvice RUNing 2 (GRONORUN 2) study
Methods	Randomised controlled trial
Participants	Location: Groningen, The Netherlands Healthy novice runners aged 18-65 (N = 432) Exclusion criteria: running experience in the 12 months prior to the start of the study; lower-limb or lower back injury in the 3 months prior to start of the study; absolute contraindications for vigorous physical activities according to the American College of Sports Medicine (ACSM)
Interventions	Intervention: preconditioning program of 4 weeks prior to a 10 week training program Control: 10 week training program without preconditioning.
Outcomes	Primary outcomes: incidence of running related injuries Secondary outcomes: severity of running related injuries; compliance with the training program; compliance with running in the following year 13 week follow-up
Starting date	July 2008 until Groningen 4 mile run in 2009

NTR1906 (*Continued*)

Contact information	SW Bredeweg University Center of Sport, Exercise and Health, University Medical Center Groningen, Hanzeplein 1, 9700 RB Groningen The Netherlands
Notes	

DATA AND ANALYSES

Comparison 1. Stretching exercises: all stretching interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries (risk ratio)	6	5130	Risk Ratio (Fixed, 95% CI)	0.85 [0.65, 1.12]
1.1 Stretching prior to exercise	3	2957	Risk Ratio (Fixed, 95% CI)	0.95 [0.67, 1.36]
1.2 Stretching as part of a training programme (3-4 times/day)	3	2173	Risk Ratio (Fixed, 95% CI)	0.74 [0.49, 1.11]

Comparison 2. Stretching exercises: major lower limb muscle groups vs control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries (risk ratio)	1	1538	Risk Ratio (Fixed, 95% CI)	0.92 [0.60, 1.40]
2 All lower limb soft-tissue injuries (rate ratio)	1	326	Rate Ratio (Fixed, 95% CI)	0.11 [-0.68, 0.90]

Comparison 3. Stretching exercises: hamstrings vs control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	298	Risk Ratio (Fixed, 95% CI)	0.57 [0.25, 1.29]

Comparison 4. Stretching exercises: gastrocnemius and soleus vs control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	2		Risk Ratio (Fixed, 95% CI)	Subtotals only
1.1 Soft-tissue injuries + stress fractures	1	122	Risk Ratio (Fixed, 95% CI)	0.47 [0.23, 0.96]
1.2 Soft-tissue injuries alone	1	1093	Risk Ratio (Fixed, 95% CI)	0.87 [0.27, 2.82]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

2.1 Lower leg (shin splints)	1	1753	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.66, 2.43]

Comparison 5. Conditioning exercises vs placebo exercises

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	1020	Risk Ratio (Fixed, 95% CI)	1.20 [0.77, 1.87]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (Fixed, 95% CI)	Subtotals only
2.1 Knee injuries	1	1020	Risk Ratio (Fixed, 95% CI)	1.17 [0.56, 2.45]
2.2 Medial tibial stress syndrome	1	1020	Risk Ratio (Fixed, 95% CI)	0.93 [0.35, 2.45]
2.3 Achilles tendonitis	1	1020	Risk Ratio (Fixed, 95% CI)	3.04 [0.31, 29.93]
2.4 Ankle sprain	1	1020	Risk Ratio (Fixed, 95% CI)	1.21 [0.37, 3.95]

Comparison 6. Graded running programme vs standard training

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	486	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.72, 1.45]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Lower leg (shin splints)	1	1670	Risk Ratio (M-H, Fixed, 95% CI)	2.02 [1.11, 3.70]

Comparison 7. Reduction in training duration (15-30 minutes/day) vs 45 minutes/day

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	69	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.21, 0.79]

Comparison 8. Reduction in training frequency (1-3 days/week) vs 5 days/week

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	58	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.06, 0.66]

Comparison 9. Reduction in running distance (walking with weights) vs running

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	350	Risk Ratio (Fixed, 95% CI)	0.80 [0.51, 1.25]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (Fixed, 95% CI)	Subtotals only
2.1 Hamstring, thigh, hip, groin injuries	1	350	Risk Ratio (Fixed, 95% CI)	0.87 [0.19, 4.01]
2.2 Knee injuries	1	350	Risk Ratio (Fixed, 95% CI)	0.47 [0.17, 1.33]
2.3 Lower leg injuries	1	350	Risk Ratio (Fixed, 95% CI)	1.06 [0.19, 5.83]
2.4 Ankle and foot injuries	1	350	Risk Ratio (Fixed, 95% CI)	0.78 [0.30, 2.03]

Comparison 10. Insoles vs control (no insoles)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lower limb soft-tissue injuries by location	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Knee problems	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Lower leg (shin splints)	2		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Ankle sprains	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 Achilles tendonitis	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Lower extremity soreness on day 4 in soccer referees	1	91	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.53, 0.85]

Comparison 11. Insoles: custom-made vs prefabricated soft foot orthoses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lower limb soft-tissue injuries by location	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Ankle sprains	1	417	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.51, 1.60]
1.2 Foot injuries	1	417	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.58, 1.31]

Comparison 12. Insoles: custom-made biomechanical vs prefabricated semi-rigid foot orthoses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lower limb soft-tissue injuries by location	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Ankle sprains	1	352	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.59, 2.28]
1.2 Foot injuries	1	352	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.43, 1.09]

Comparison 13. Insoles: shock-absorbing polymer vs non shock-absorbing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	2	4032	Risk Ratio (Fixed, 95% CI)	1.02 [0.81, 1.29]
2 Lower limb soft-tissue injuries by location	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Thigh injuries	1	1205	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.47, 3.61]
2.2 Knee injuries	2	1760	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.85, 1.80]
2.3 Lower leg injuries	2	1760	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.55, 1.47]
2.4 Ankle injuries	2	1760	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.64, 1.28]
2.5 Achilles tendonitis	2	1760	Risk Ratio (M-H, Fixed, 95% CI)	1.56 [0.81, 3.01]
2.6 Foot injuries	1	555	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.56, 2.15]

Comparison 14. Knee brace vs control (no brace)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lower limb soft-tissue injuries by location	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Anterior knee pain	2	227	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.24, 0.67]

Comparison 15. Footwear: tropical combat boot vs leather combat boot

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lower limb soft-tissue injuries by location	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Anterior knee pain	1	2841	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.39, 1.24]
1.2 Lower leg (shin splints)	1	2841	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.53, 2.44]
1.3 Achilles tendonitis	2	3627	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.73, 1.95]
1.4 Ankle sprain	2	3627	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.60, 1.44]
1.5 Plantar fascial strain	2	3627	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.33, 2.13]

Comparison 16. Footwear: prescription of running shoes based on foot shape vs regular running shoe

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries (rate ratio)	2	5795	Rate Ratio (Fixed, 95% CI)	1.03 [0.93, 1.14]
1.1 Men	2	4123	Rate Ratio (Fixed, 95% CI)	1.00 [0.88, 1.15]
1.2 Women	2	1672	Rate Ratio (Fixed, 95% CI)	1.06 [0.92, 1.23]

Comparison 17. Socks: padded polyester vs regular army sock

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	130	Risk Ratio (Fixed, 95% CI)	0.54 [0.27, 1.08]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (Fixed, 95% CI)	Subtotals only
2.1 Knee injuries	1	130	Risk Ratio (Fixed, 95% CI)	0.27 [0.07, 1.00]
2.2 Lower leg (shin splints and tibial stress reactions)	1	130	Risk Ratio (Fixed, 95% CI)	1.0 [0.08, 11.81]

2.3 Achilles tendonitis	1	130	Risk Ratio (Fixed, 95% CI)	1.0 [0.23, 4.26]

Comparison 18. Socks: double layer vs regular army sock

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All lower limb soft-tissue injuries	1	124	Risk Ratio (Fixed, 95% CI)	0.91 [0.53, 1.56]
2 Lower limb soft-tissue injuries by location	1		Risk Ratio (Fixed, 95% CI)	Subtotals only
2.1 Knee injuries	1	124	Risk Ratio (Fixed, 95% CI)	0.80 [0.34, 1.86]
2.2 Lower leg (shin splints and tibial stress syndrome)	1	124	Risk Ratio (Fixed, 95% CI)	0.73 [0.05, 11.48]
2.3 Achilles tendonitis	1	124	Risk Ratio (Fixed, 95% CI)	1.24 [0.31, 5.03]

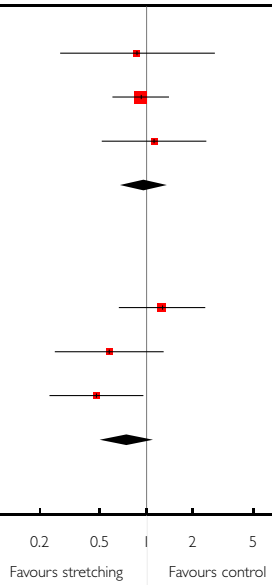
Analysis 1.1. Comparison 1 Stretching exercises: all stretching interventions, Outcome 1 All lower limb soft-tissue injuries (risk ratio).

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 1 Stretching exercises: all stretching interventions

Outcome: 1 All lower limb soft-tissue injuries (risk ratio)

Study or subgroup	Stretching N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
1 Stretching prior to exercise						
Pope 1998	549	544	-0.1393 (0.5999)		5.2 %	0.87 [0.27, 2.82]
Pope 2000	735	803	-0.0834 (0.2142)		41.0 %	0.92 [0.60, 1.40]
Van Mechelen 1993	159	167	0.1133 (0.4032)		11.6 %	1.12 [0.51, 2.47]
Subtotal (95% CI)					**57.8 %**	**0.95 [0.67, 1.36]**
Heterogeneity: Chi² = 0.21, df = 2 (P = 0.90); I² =0.0%						
Test for overall effect: Z = 0.27 (P = 0.79)						
2 Stretching as part of a training programme (3-4 times/day)						
Andrish 1974	300	1453	0.239 (0.3325)		17.0 %	1.27 [0.66, 2.44]
Hartig 1999	150	148	-0.5621 (0.4159)		10.9 %	0.57 [0.25, 1.29]
Liu 2008	61	61	-0.755 (0.3618)		14.4 %	0.47 [0.23, 0.96]
Subtotal (95% CI)					**42.2 %**	**0.74 [0.49, 1.11]**
Heterogeneity: Chi² = 4.61, df = 2 (P = 0.10); I² =57%						



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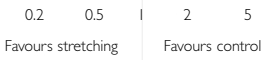
Study or subgroup	Stretching N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Test for overall effect: Z = 1.45 (P = 0.15)						
Total (95% CI)					**100.0 %**	**0.85 [0.65, 1.12]**
Heterogeneity: Chi^2 = 5.67, df = 5 (P = 0.34); I^2 =12%						
Test for overall effect: Z = 1.15 (P = 0.25)						
Test for subgroup differences: Chi^2 = 0.85, df = 1 (P = 0.36), I^2 =0.0%						



Analysis 2.1. Comparison 2 Stretching exercises: major lower limb muscle groups vs control, Outcome 1 All lower limb soft-tissue injuries (risk ratio).

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 2 Stretching exercises: major lower limb muscle groups vs control

Outcome: 1 All lower limb soft-tissue injuries (risk ratio)

Study or subgroup	Stretching N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Pope 2000	735	803	-0.0834 (0.2142)		100.0 %	0.92 [0.60, 1.40]
Total (95% CI)					**100.0 %**	**0.92 [0.60, 1.40]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.39 (P = 0.70)						
Test for subgroup differences: Not applicable						

Analysis 2.2. Comparison 2 Stretching exercises: major lower limb muscle groups vs control, Outcome 2 All lower limb soft-tissue injuries (rate ratio).

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 2 Stretching exercises: major lower limb muscle groups vs control

Outcome: 2 All lower limb soft-tissue injuries (rate ratio)

Study or subgroup	Stretching N	Control N	Rate Ratio (SE)	Rate Ratio IV,Fixed,95% CI	Weight	Rate Ratio IV,Fixed,95% CI
Van Mechelen 1993	159	167	0.1133 (0.4032)		100.0 %	0.11 [-0.68, 0.90]
Total (95% CI)					**100.0 %**	**0.11 [-0.68, 0.90]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.28 (P = 0.78)

Test for subgroup differences: Not applicable

Analysis 3.1. Comparison 3 Stretching exercises: hamstrings vs control, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 3 Stretching exercises: hamstrings vs control

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Stretching N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Hartig 1999	150	148	-0.5621 (0.4159)		100.0 %	0.57 [0.25, 1.29]
Total (95% CI)					**100.0 %**	**0.57 [0.25, 1.29]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.35 (P = 0.18)

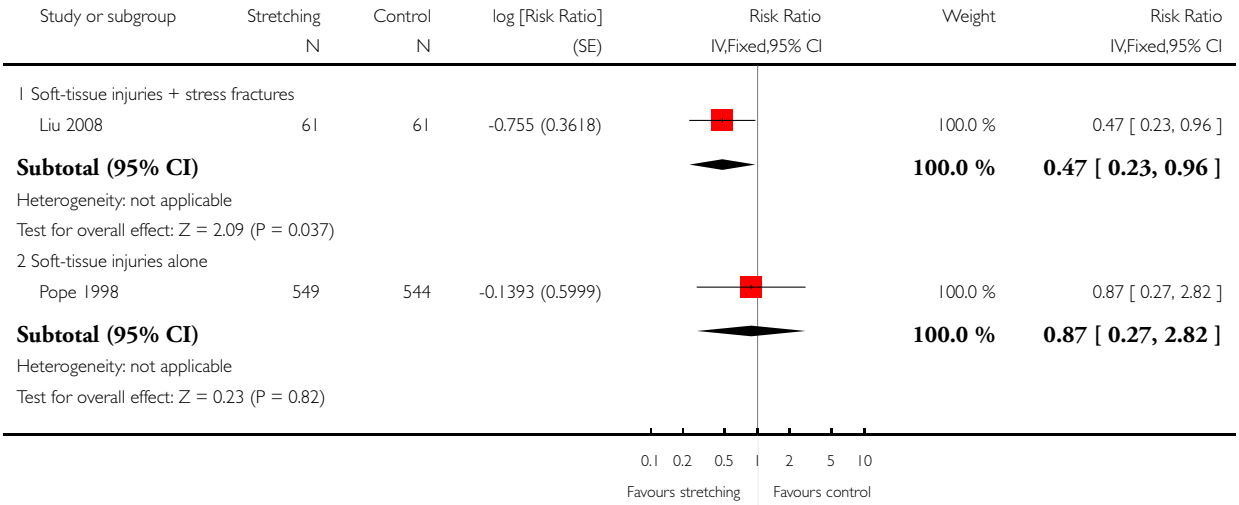
Test for subgroup differences: Not applicable

Analysis 4.1. Comparison 4 Stretching exercises: gastrocnemius and soleus vs control, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 4 Stretching exercises: gastrocnemius and soleus vs control

Outcome: 1 All lower limb soft-tissue injuries

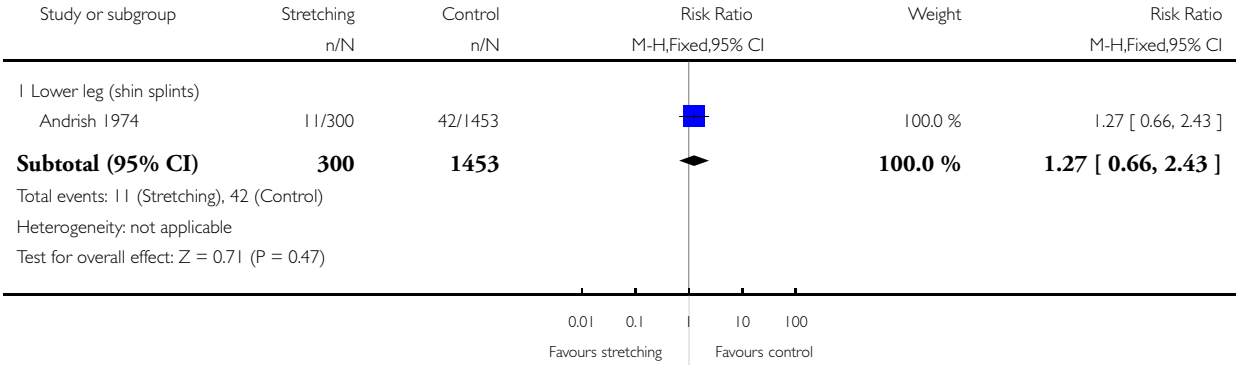


Analysis 4.2. Comparison 4 Stretching exercises: gastrocnemius and soleus vs control, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 4 Stretching exercises: gastrocnemius and soleus vs control

Outcome: 2 Lower limb soft-tissue injuries by location

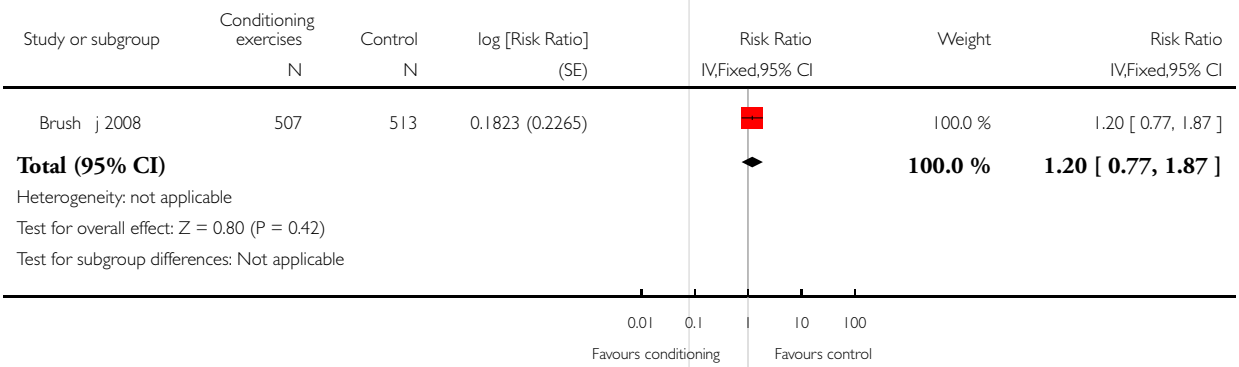


Analysis 5.1. Comparison 5 Conditioning exercises vs placebo exercises, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 5 Conditioning exercises vs placebo exercises

Outcome: 1 All lower limb soft-tissue injuries

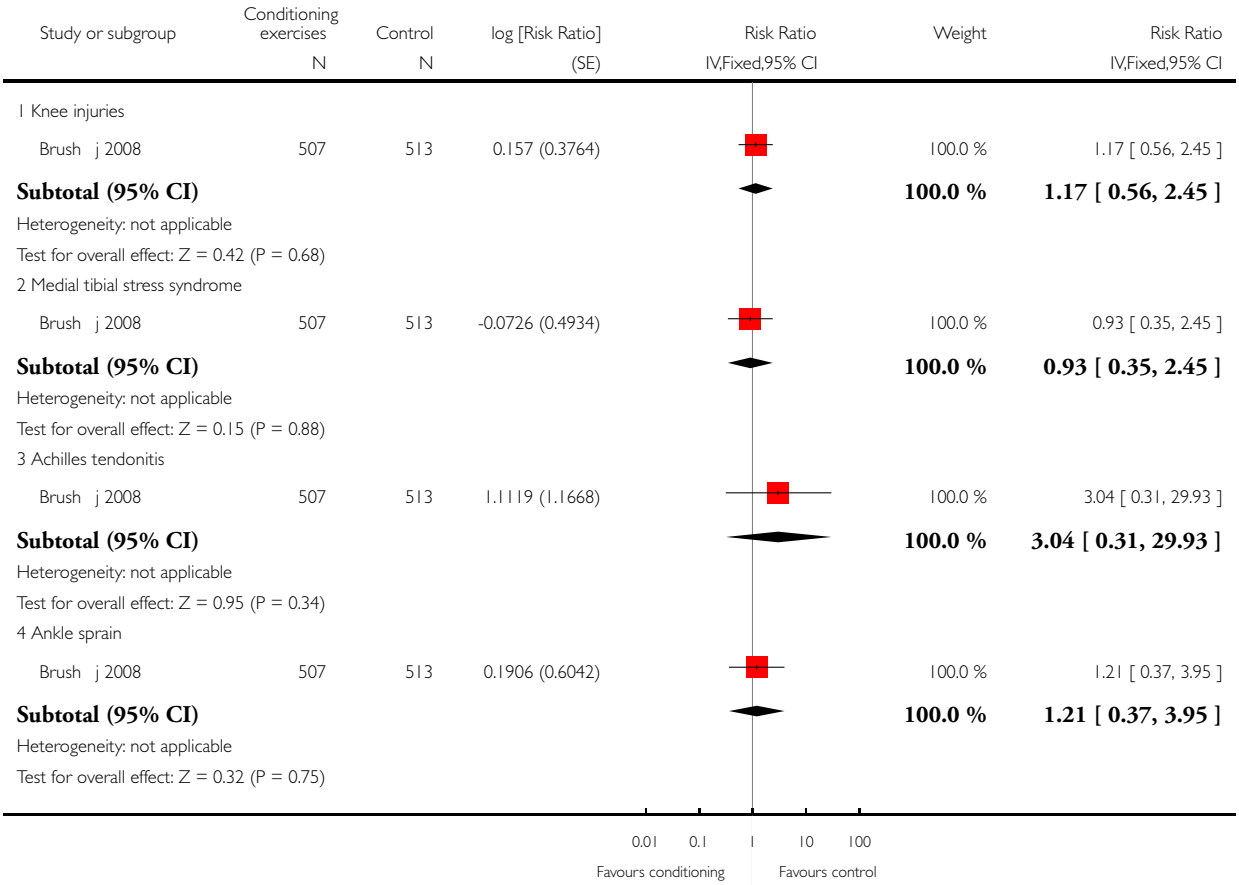


Analysis 5.2. Comparison 5 Conditioning exercises vs placebo exercises, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 5 Conditioning exercises vs placebo exercises

Outcome: 2 Lower limb soft-tissue injuries by location

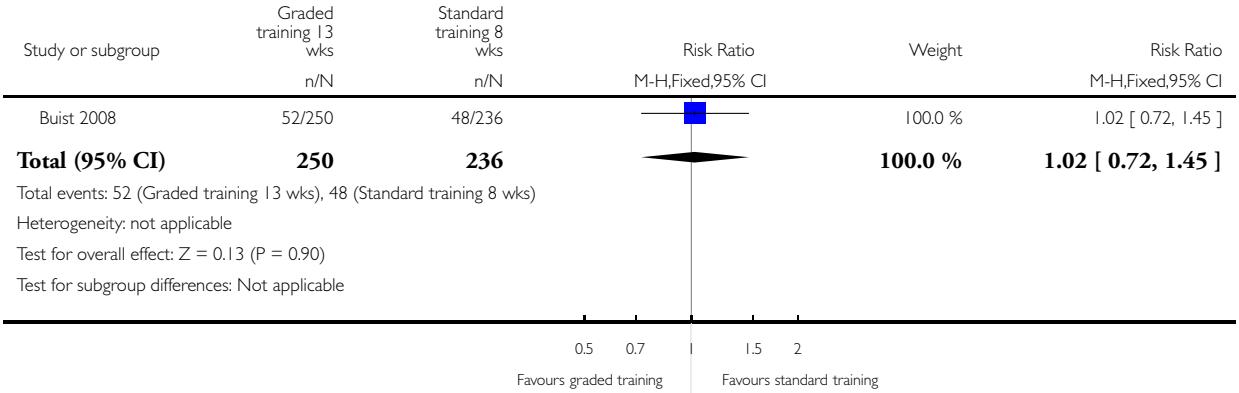


Analysis 6.1. Comparison 6 Graded running programme vs standard training, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 6 Graded running programme vs standard training

Outcome: 1 All lower limb soft-tissue injuries

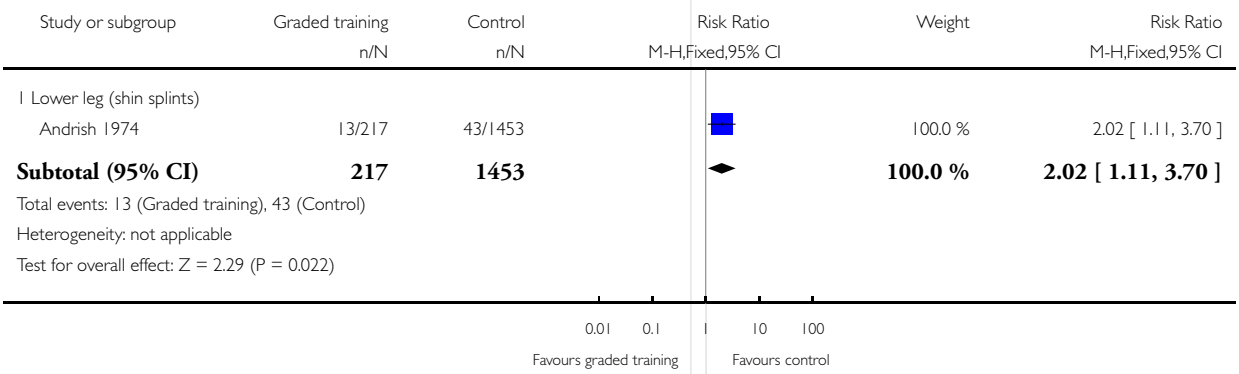


Analysis 6.2. Comparison 6 Graded running programme vs standard training, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 6 Graded running programme vs standard training

Outcome: 2 Lower limb soft-tissue injuries by location



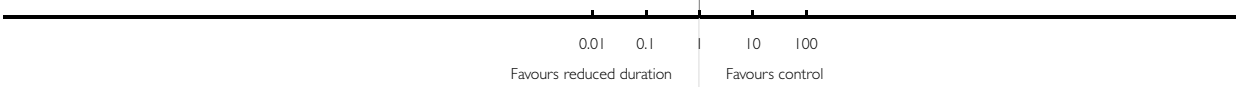
Analysis 7.1. Comparison 7 Reduction in training duration (15-30 minutes/day) vs 45 minutes/day, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 7 Reduction in training duration (15-30 minutes/day) vs 45 minutes/day

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Reduced duration n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Pollock 1977a	10/45	13/24		100.0 %	0.41 [0.21, 0.79]
Total (95% CI)	**45**	**24**		**100.0 %**	**0.41 [0.21, 0.79]**
Total events: 10 (Reduced duration), 13 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.65 (P = 0.0080)					
Test for subgroup differences: Not applicable					



Analysis 8.1. Comparison 8 Reduction in training frequency (1-3 days/week) vs 5 days/week, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 8 Reduction in training frequency (1-3 days/week) vs 5 days/week

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Reduced frequency n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Pollock 1977b	3/40	7/18		100.0 %	0.19 [0.06, 0.66]
Total (95% CI)	**40**	**18**		**100.0 %**	**0.19 [0.06, 0.66]**

Total events: 3 (Reduced frequency), 7 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 2.62 (P = 0.0089)
Test for subgroup differences: Not applicable

Analysis 9.1. Comparison 9 Reduction in running distance (walking with weights) vs running, Outcome 1 All lower limb soft-tissue injuries.

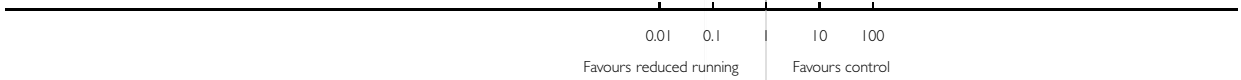
Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 9 Reduction in running distance (walking with weights) vs running

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Reduced running N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Rudzki 1997	170	180	-0.2231 (0.2272)		100.0 %	0.80 [0.51, 1.25]
Total (95% CI)					**100.0 %**	**0.80 [0.51, 1.25]**

Heterogeneity: not applicable
Test for overall effect: Z = 0.98 (P = 0.33)
Test for subgroup differences: Not applicable

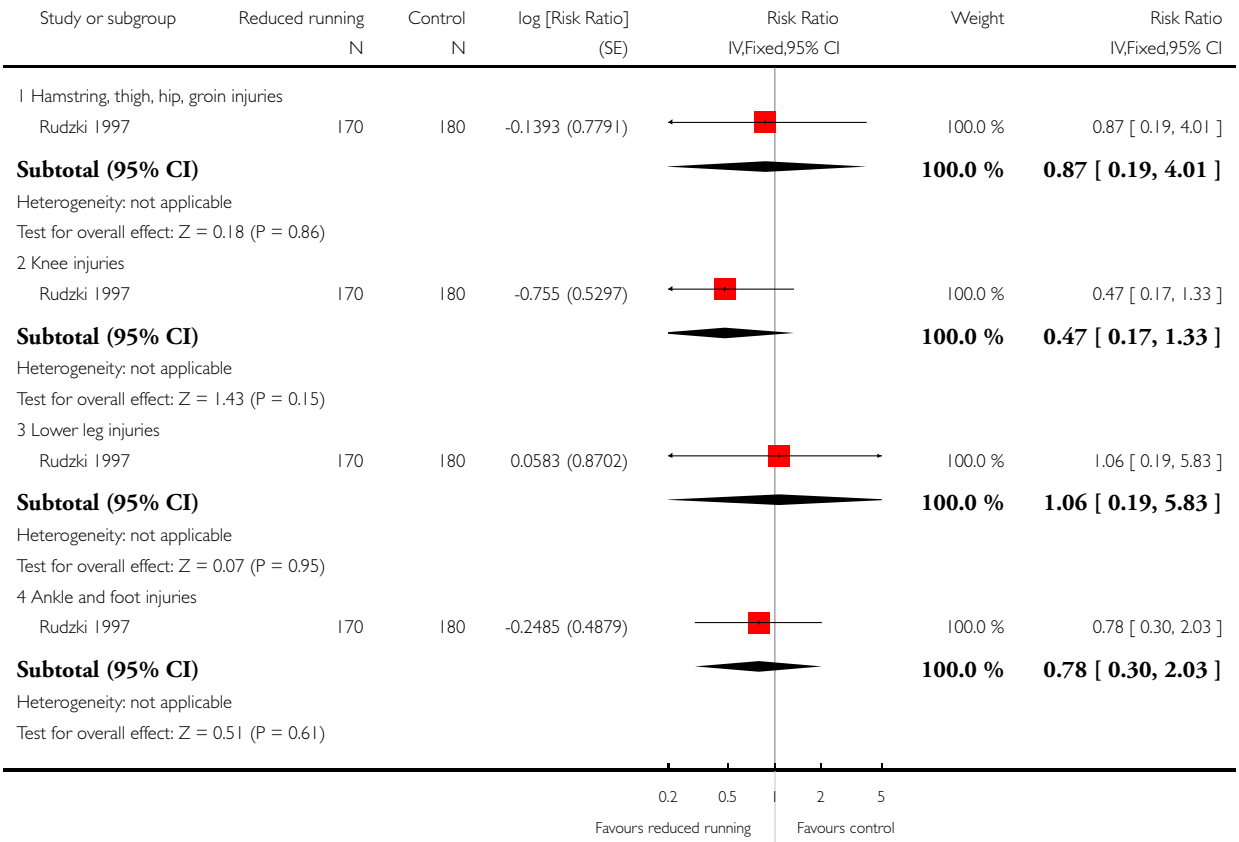


Analysis 9.2. Comparison 9 Reduction in running distance (walking with weights) vs running, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 9 Reduction in running distance (walking with weights) vs running

Outcome: 2 Lower limb soft-tissue injuries by location



Analysis 10.1. Comparison 10 Insoles vs control (no insoles), Outcome 1 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 10 Insoles vs control (no insoles)

Outcome: 1 Lower limb soft-tissue injuries by location

Study or subgroup	Favours insoles n/N	No insoles n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Knee problems				
Larsen 2002 (1)	16/77	14/69		1.02 [0.54, 1.94]
2 Lower leg (shin splints)				
Andrish 1974	15/344	42/1453		1.51 [0.85, 2.69]
Larsen 2002 (2)	4/77	15/69		0.24 [0.08, 0.69]
3 Ankle sprains				
Larsen 2002 (3)	1/77	2/69		0.45 [0.04, 4.83]
4 Achilles tendonitis				
Larsen 2002 (4)	2/77	6/69		0.30 [0.06, 1.43]

(1) "Actual use" analysis (event data only available in paper for compliant participants)

(2) "Intention to treat analysis" (event data available for compliant and non-compliant participants)

(3) "Actual use" analysis (data only available in paper for compliant participants)

(4) "Actual use" analysis (data only available in paper for compliant participants)

Analysis 10.2. Comparison 10 Insoles vs control (no insoles), Outcome 2 Lower extremity soreness on day 4 in soccer referees.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 10 Insoles vs control (no insoles)

Outcome: 2 Lower extremity soreness on day 4 in soccer referees

Study or subgroup	Insoles n/N	No insoles n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Fauno 1993	30/48	40/43		100.0 %	0.67 [0.53, 0.85]
Total (95% CI)	**48**	**43**		**100.0 %**	**0.67 [0.53, 0.85]**

Total events: 30 (Insoles), 40 (No insoles)

Heterogeneity: not applicable

Test for overall effect: Z = 3.33 (P = 0.00086)

Test for subgroup differences: Not applicable

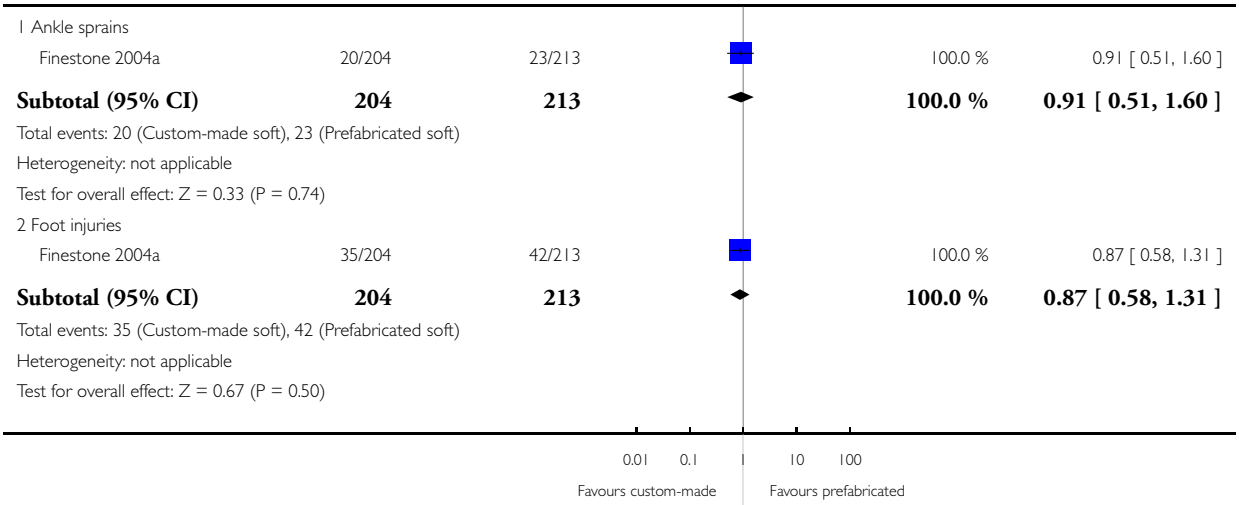
Analysis 11.1. Comparison 11 Insoles: custom-made vs prefabricated soft foot orthoses, Outcome 1 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 11 Insoles: custom-made vs prefabricated soft foot orthoses

Outcome: 1 Lower limb soft-tissue injuries by location

Study or subgroup	Custom-made soft n/N	Prefabricated soft n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Ankle sprains					
Finestone 2004a	20/204	23/213		100.0 %	0.91 [0.51, 1.60]
Subtotal (95% CI)	**204**	**213**		**100.0 %**	**0.91 [0.51, 1.60]**
Total events: 20 (Custom-made soft), 23 (Prefabricated soft)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.33 (P = 0.74)					
2 Foot injuries					
Finestone 2004a	35/204	42/213		100.0 %	0.87 [0.58, 1.31]
Subtotal (95% CI)	**204**	**213**		**100.0 %**	**0.87 [0.58, 1.31]**
Total events: 35 (Custom-made soft), 42 (Prefabricated soft)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.67 (P = 0.50)					



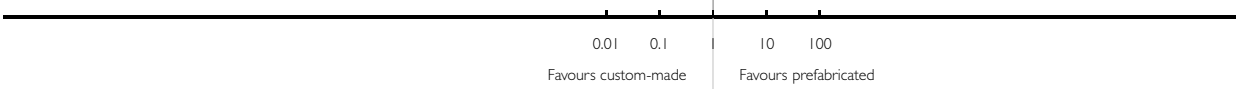
Analysis 12.1. Comparison 12 Insoles: custom-made biomechanical vs prefabricated semi-rigid foot orthoses, Outcome 1 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 12 Insoles: custom-made biomechanical vs prefabricated semi-rigid foot orthoses

Outcome: 1 Lower limb soft-tissue injuries by location

Study or subgroup	Custom-made biomechanical n/N	Prefabricated semi-rigid n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Ankle sprains					
Finestone 2004b	17/180	14/172		100.0 %	1.16 [0.59, 2.28]
Subtotal (95% CI)	**180**	**172**		**100.0 %**	**1.16 [0.59, 2.28]**
Total events: 17 (Custom-made biomechanical), 14 (Prefabricated semi-rigid)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.43 (P = 0.67)					
2 Foot injuries					
Finestone 2004b	25/180	35/172		100.0 %	0.68 [0.43, 1.09]
Subtotal (95% CI)	**180**	**172**		**100.0 %**	**0.68 [0.43, 1.09]**
Total events: 25 (Custom-made biomechanical), 35 (Prefabricated semi-rigid)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.60 (P = 0.11)					



Analysis 13.1. Comparison 13 Insoles: shock-absorbing polymer vs non shock-absorbing, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 13 Insoles: shock-absorbing polymer vs non shock-absorbing

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Shock absorbing N	Non shock-absorbing N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Gardner 1988	1456	1371	-0.0202 (0.2795)		17.7 %	0.98 [0.57, 1.69]
Withnall 2006	804	401	0.0296 (0.1297)		82.3 %	1.03 [0.80, 1.33]
Total (95% CI)					**100.0 %**	**1.02 [0.81, 1.29]**

Heterogeneity: $Chi^2 = 0.03$, df = 1 (P = 0.87); $I^2 = 0.0\%$

Test for overall effect: Z = 0.18 (P = 0.86)

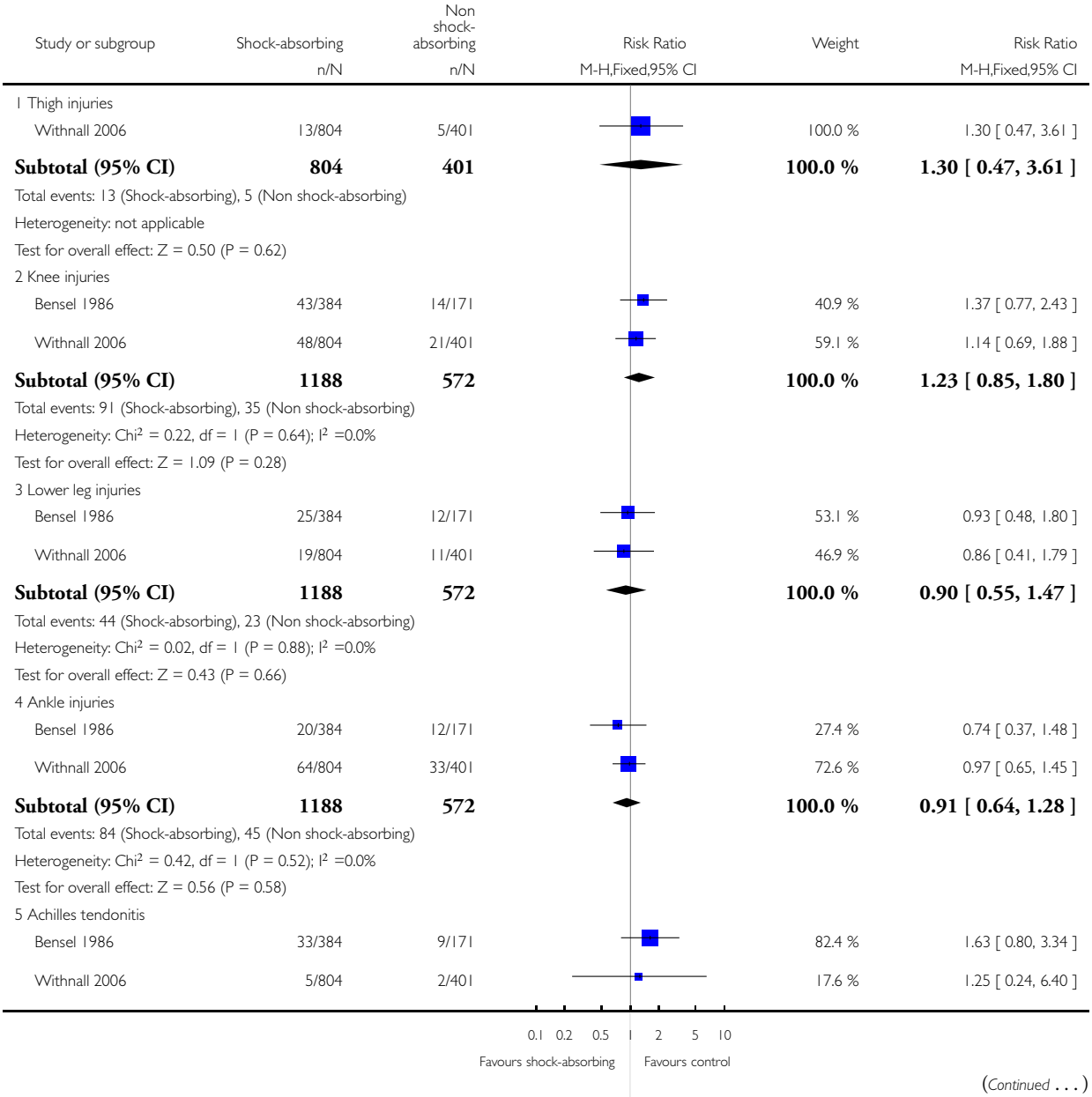
Test for subgroup differences: Not applicable

Analysis 13.2. Comparison 13 Insoles: shock-absorbing polymer vs non shock-absorbing, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 13 Insoles: shock-absorbing polymer vs non shock-absorbing

Outcome: 2 Lower limb soft-tissue injuries by location



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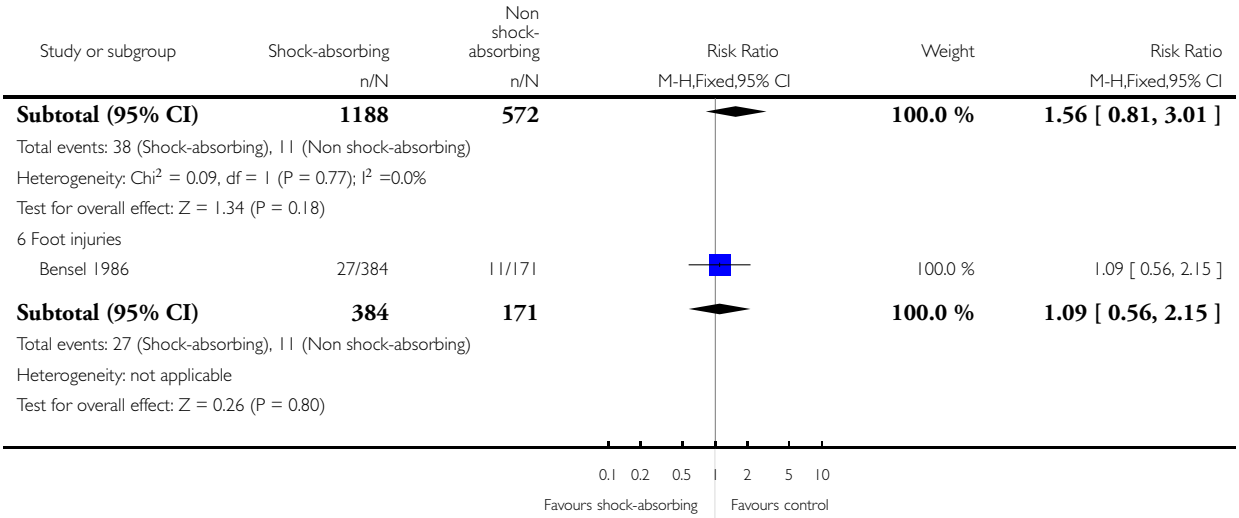
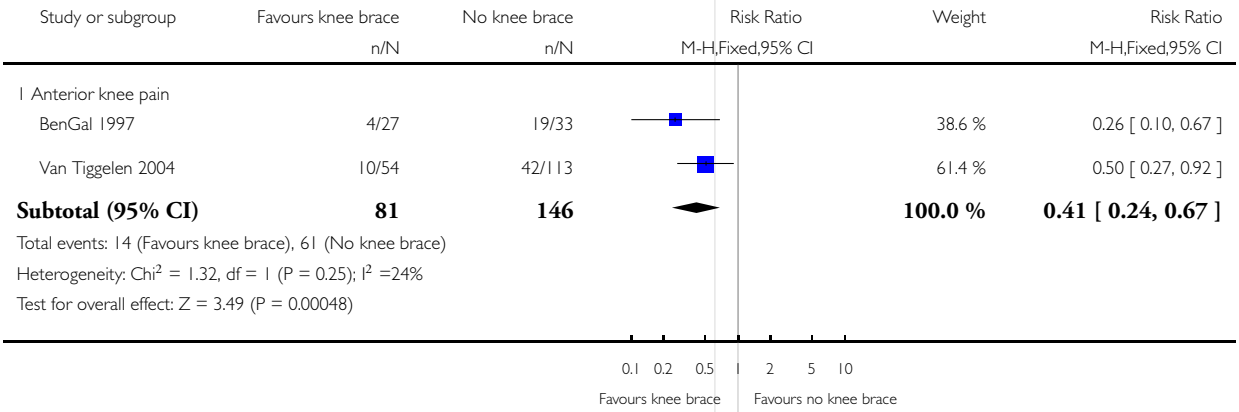


Analysis 14.1. Comparison 14 Knee brace vs control (no brace), Outcome 1 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 14 Knee brace vs control (no brace)

Outcome: 1 Lower limb soft-tissue injuries by location

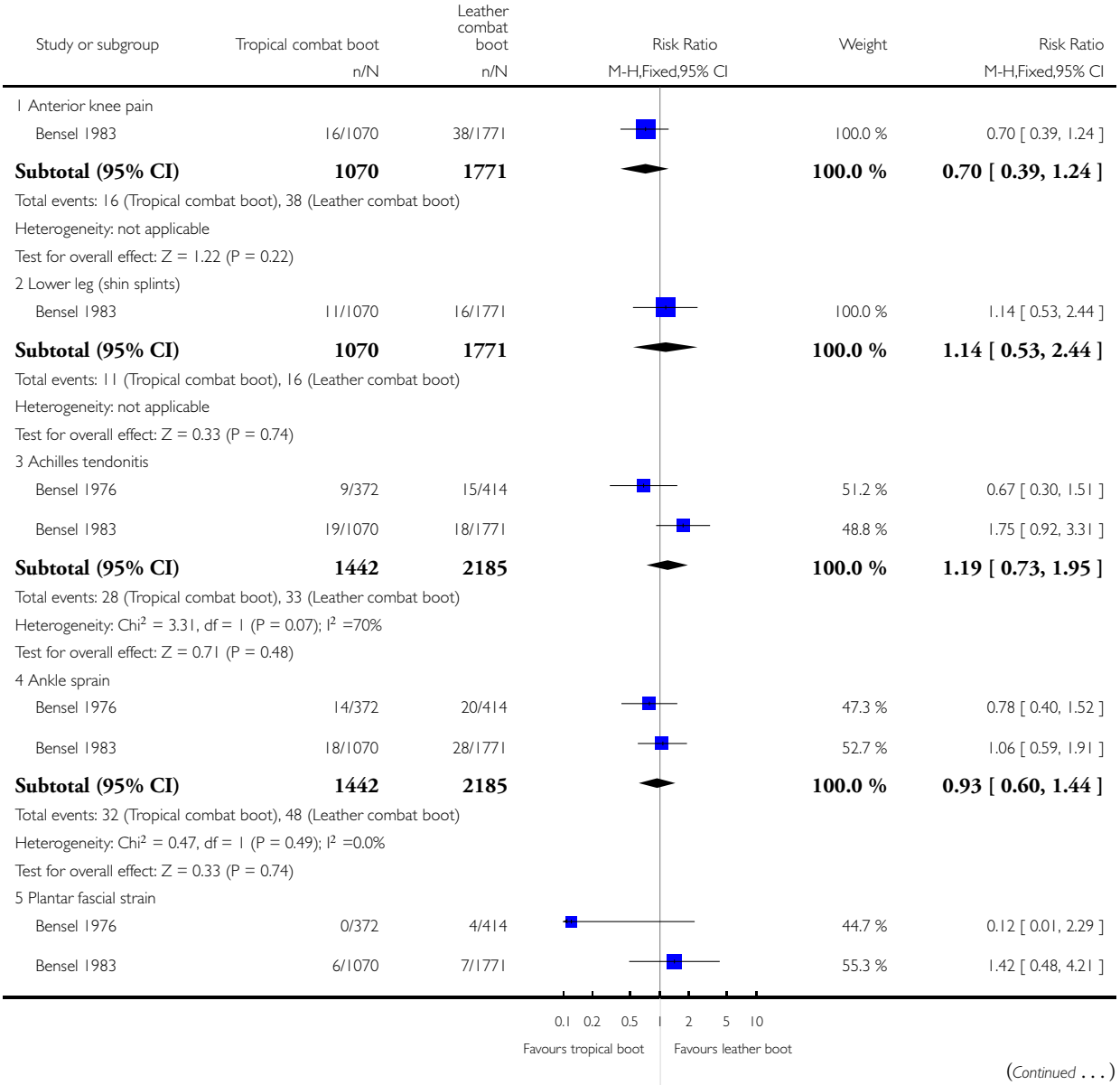


Analysis 15.1. Comparison 15 Footwear: tropical combat boot vs leather combat boot, Outcome 1 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 15 Footwear: tropical combat boot vs leather combat boot

Outcome: 1 Lower limb soft-tissue injuries by location



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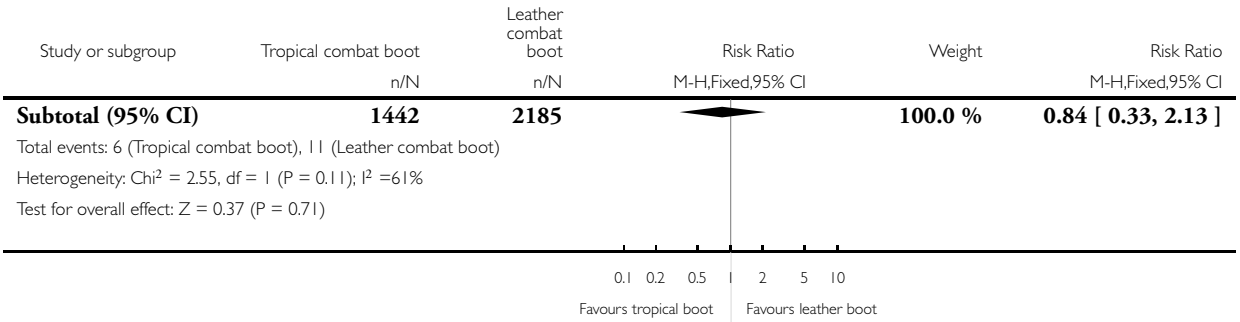
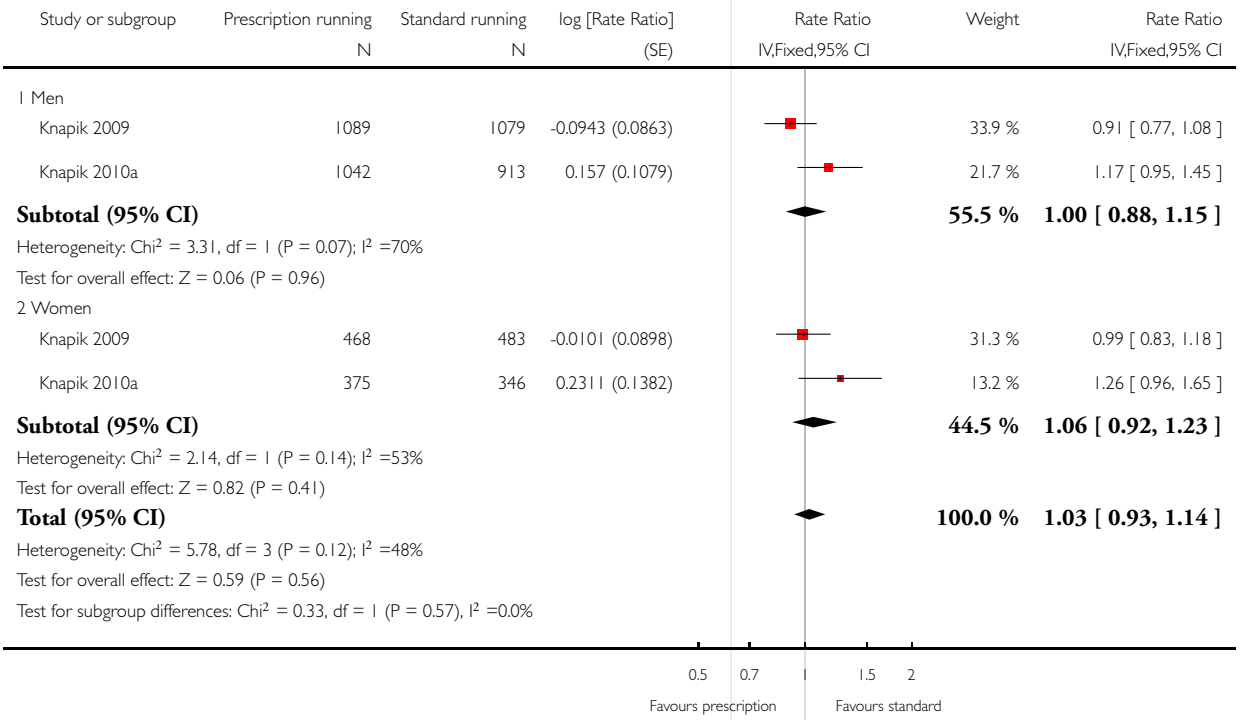


Analysis 16.1. Comparison 16 Footwear: prescription of running shoes based on foot shape vs regular running shoe, Outcome 1 All lower limb soft-tissue injuries (rate ratio).

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 16 Footwear: prescription of running shoes based on foot shape vs regular running shoe

Outcome: 1 All lower limb soft-tissue injuries (rate ratio)



Analysis 17.1. Comparison 17 Socks: padded polyester vs regular army sock, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 17 Socks: padded polyester vs regular army sock

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Polyester N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Van Tiggelen 2009	65	65	-0.6162 (0.3531)		100.0 %	0.54 [0.27, 1.08]
Total (95% CI)					**100.0 %**	**0.54 [0.27, 1.08]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.75 (P = 0.081)

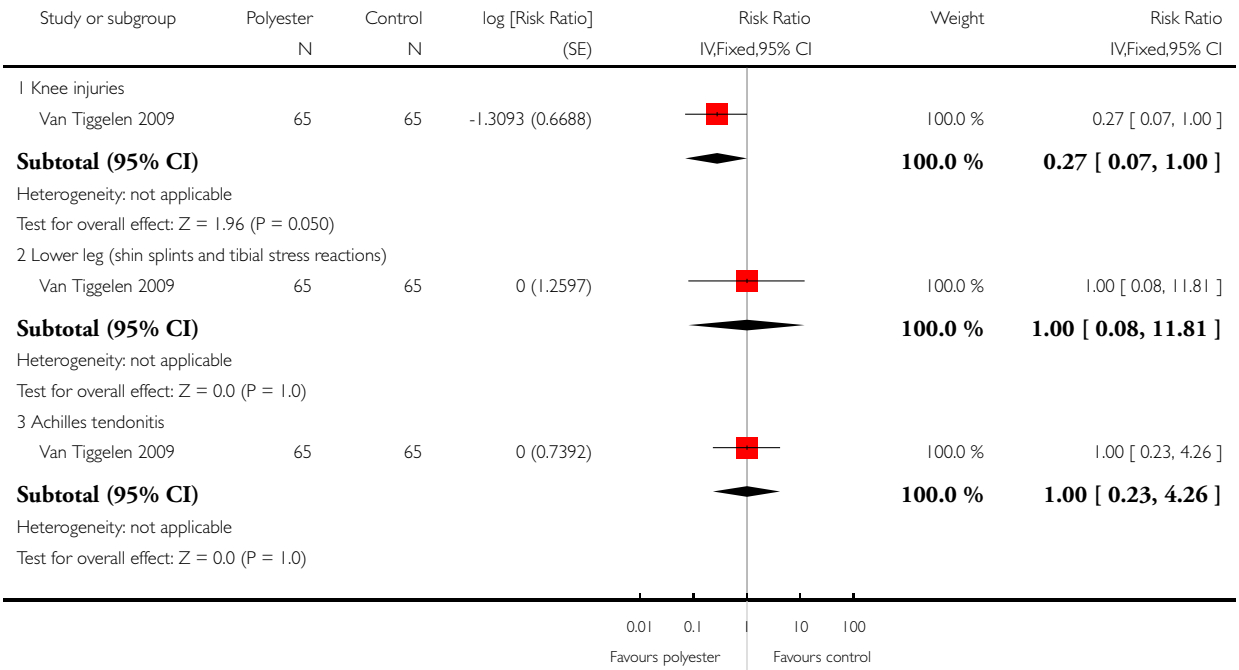
Test for subgroup differences: Not applicable

Analysis 17.2. Comparison 17 Socks: padded polyester vs regular army sock, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 17 Socks: padded polyester vs regular army sock

Outcome: 2 Lower limb soft-tissue injuries by location



Analysis 18.1. Comparison 18 Socks: double layer vs regular army sock, Outcome 1 All lower limb soft-tissue injuries.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 18 Socks: double layer vs regular army sock

Outcome: 1 All lower limb soft-tissue injuries

Study or subgroup	Double layer N	Control N	log [Risk Ratio] (SE)	Risk Ratio IV,Fixed,95% CI	Weight	Risk Ratio IV,Fixed,95% CI
Van Tiggelen 2009	59	65	-0.0943 (0.2765)		100.0 %	0.91 [0.53, 1.56]
Total (95% CI)					**100.0 %**	**0.91 [0.53, 1.56]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.34 (P = 0.73)

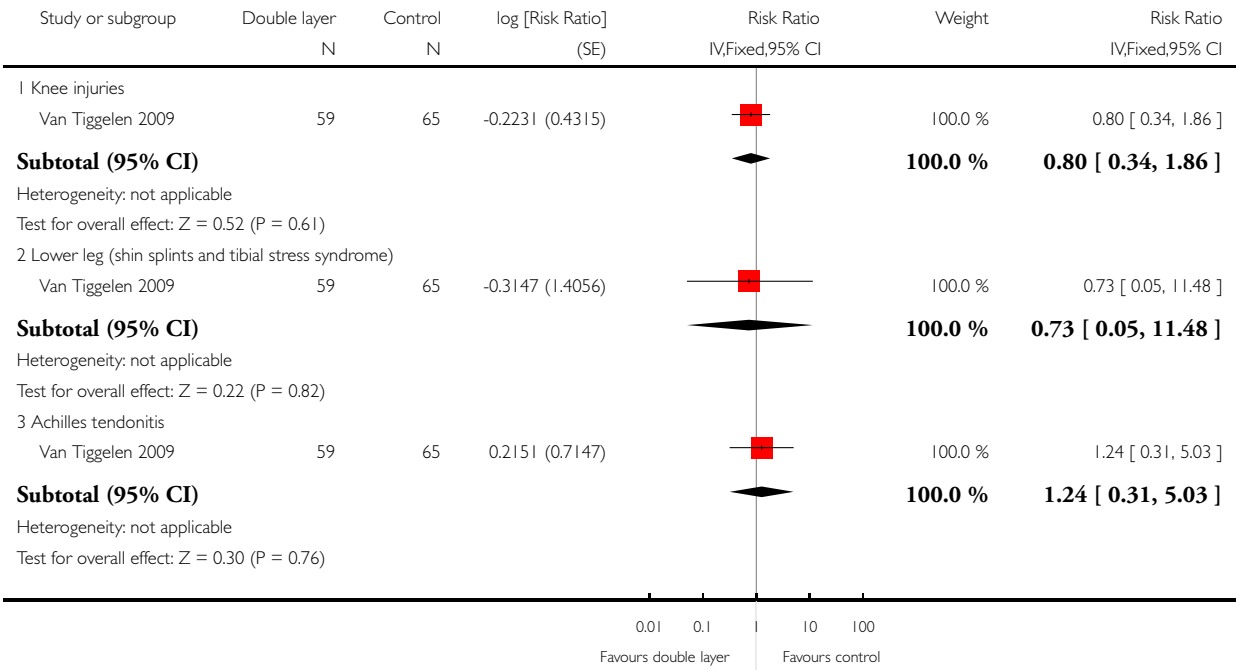
Test for subgroup differences: Not applicable

Analysis 18.2. Comparison 18 Socks: double layer vs regular army sock, Outcome 2 Lower limb soft-tissue injuries by location.

Review: Interventions for preventing lower limb soft-tissue running injuries

Comparison: 18 Socks: double layer vs regular army sock

Outcome: 2 Lower limb soft-tissue injuries by location



APPENDICES

Appendix 1. Current search strategies

Cochrane Central Register of Controlled Trials (OvidSP EBM Reviews interface)

1. Sports/ or "Track and Field"/ or exp Running/ or Athletes/
2. Military Personnel/ or Naval Medicine/ or Military Medicine/
3. (overuse$ or runn$ or jogg$ or sprint$ or athletic$ or recruit$1 or platoon$1 or (basic adj2 training)).tw.
4. or/1-3
5. "Physical Education and Training"/ or Physical Fitness/ or Shoes/ or Orthotic Devices/ or Braces/
6. (prevent$ or stretch$).tw.
7. pc.fs.
8. or/5-7

9. Athletic Injuries/ or Pain/
10. Soft Tissue Injuries/ or "Sprains and Strains"/
11. Cumulative Trauma Disorders/
12. Tendinitis/ or Tendinopathy/ or Fasciitis/ or Fasciitis, Plantar/
13. Leg Injuries/ or Hip Injuries/ or Knee Injuries/ or Ankle Injuries/ or Foot injuries/
14. exp Lower Extremity/in and (leg or knee or hip or thigh or foot or (lower adj (limb or extremity))).tw.
15. ((injur$ adj (athletic$1 or overuse or soft tissue$1)) or (tend#n$ not tendon$1) or fasciitis).tw.
16. (injur$ adj (leg$1 or hip$1 or knee$1 or ankle$1 or foot or lower limb$1)).tw.
17. (plantar fasciitis or (pain adj (heel or knee)) or shin splint$1 or tibial stress syndrome).tw.
18. or/9-17
19. and/4,8,18 (157 records)

MEDLINE (OvidSP interface)

1. Sports/ or "Track and Field"/ or exp Running/ or Athletes/
2. Military Personnel/ or Naval Medicine/ or Military Medicine/
3. (overuse$ or runn$ or jogg$ or sprint$ or athletic$ or recruit$1 or platoon$1 or (basic adj2 training)).tw.
4. or/1-3
5. "Physical Education and Training"/ or Physical Fitness/ or Shoes/ or Orthotic Devices/ or Braces/
6. (prevent$ or stretch$).tw.
7. pc.fs.
8. or/5-7
9. Athletic Injuries/ or Pain/
10. Soft Tissue Injuries/ or "Sprains and Strains"/
11. Cumulative Trauma Disorders/
12. Tendinitis/ or Tendinopathy/ or Fasciitis/ or Fasciitis, Plantar/
13. Leg Injuries/ or Hip Injuries/ or Knee Injuries/ or Ankle Injuries/ or Foot injuries/
14. exp Lower Extremity/in and (leg or knee or hip or thigh or foot or (lower adj (limb or extremity))).tw.
15. ((injur$ adj (athletic$1 or overuse or soft tissue$1)) or (tend#n$ not tendon$1) or fasciitis).tw.
16. (injur$ adj (leg$1 or hip$1 or knee$1 or ankle$1 or foot or lower limb$1)).tw.
17. (plantar fasciitis or (pain adj (heel or knee)) or shin splint$1 or tibial stress syndrome).tw.
18. or/9-17
19. and/4,8,18
20. Randomized controlled trial.pt.
21. Controlled clinical trial.pt.
22. randomized.ab.
23. placebo.ab.
24. Clinical Trials as Topic/
25. randomly.ab.
26. trial.ti.
27. or/20-26
28. exp Animals/ not Humans/
29. 27 not 28
30. and/19,29
31. (2000$ or 2001$ or 2002$ or 2003$ or 2004$ or 2005$ or 2006$ or 2007$ or 2008$ or 2009$ or 2010$ or 2011$).ed.
32. and/30-31 (145 records)

EMBASE (OvidSP interface)

1. Sport/ or Jogging/ or Running/ or Triathlon/
2. Soldier/ or Navy/ or Military Medicine/ or Military Service/
3. (overuse$ or runn$ or jogg$ or sprint$ or athletic$ or soldier$1 or recruit$1 or platoon$1 or (basic adj2 training)).tw.
4. or/1-3

5. Training/ or Physical Education/ or Fitness/ or Shoe/ or Foot Sole/ or Orthotics/ or Knee Brace/
6. (prevent$ or stretch$).tw.
7. pc.fs.
8. or/5-7
9. Sport injury/ or Pain/
10. Soft Tissue Injury/ or exp Musculoskeletal Injury/
11. exp Cumulative Trauma Disorders/
12. exp Tendinitis/ or Fasciitis/
13. Leg Injury/ or Hip Injury/ or Knee Injury/ or Ankle Injury/ or Foot injury/
14. Plantar Fasciitis/ or Footshock/
15. exp Leg/ and exp Injury/
16. ((injur$ adj (athletic$1 or overuse or soft tissue$1)) or (tend#n$ not tendon$1) or fasciitis).tw.
17. (injur$ adj (leg$1 or hip$1 or knee$1 or ankle$1 or foot or lower limb$1)).tw.
18. (plantar fasciitis or (pain adj (heel or knee)) or shin splint$1 or tibial stress syndrome).tw.
19. or/9-18
20. and/4,8,19
21. (random$ or factorial$ or crossover$ or "cross over$" or "cross-over$" or placebo$ or (doubl$ adj blind$) or (singl$ adj blind$) or assign$ or allocat$ or volunteer$).tw.
22. Crossover-procedure/ or Double-blind Procedure/ or Randomized Controlled Trial/ or Single-blind Procedure/
23. or/21-22
24. and/20,23
25. (2000$ or 2001$ or 2002$ or 2003$ or 2004$ or 2005$ or 2006$ or 2007$ or 2008$ or 2009$ or 2010$ or 2011$).em.
26. and/24-25 (250 records)

WHO International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/Default.aspx)

Searched using the 'Advanced Search' facility and the following terms:
(running OR runners OR athletic% OR sport% OR army OR military OR recruit) in the 'Title' field AND
(lower limb OR injur OR overuse) in the 'Condition' field AND
ALL in the 'Recruitment Status' field

Appendix 2. Tool for assessing risk of bias

Domain	Description	Review authors' judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors	Describe all measures used, if any, to blind study participants and personnel from	Was knowledge of the allocated intervention adequately prevented during the

(*Continued*)

	knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	study?
Incomplete outcome data	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors	Were incomplete outcome data adequately addressed?

Appendix 3. Duration and intensity of interventions

Study ID	Duration of intervention (weeks)	Exposure per week (hours)	Total exposure (hours)
Andrish 1974	NA "summer training programme"	NA	NA
BenGal 1997	8	36	288
Bensel 1976	12	NA	NA
Bensel 1983	8	NA	NA
Bensel 1986	9	NA	NA
Brushøj 2008	12	24.25	291
Buist 2008	Intervention: 13 Control: 8	Intervention: 0.99 to 1.55 Control: 1 to 1.85	Intervention: 14.44 Control: 9.55
Fauno 1993	5 days	NA	14.5
Finestone 2004a	14	NA	NA
Finestone 2004b	14	NA	NA
Gardner 1988	12	9.54	Physical training (excluding swimming): 73 Drill and ceremony: 41.5
Hartig 1999	13	NA	NA

(*Continued*)

Knapik 2009	9	NA	NA
Knapik 2010a	9	NA	NA
Larsen 2002	12	NA	NA
Liu 2008	12	NA	NA
Pollock 1977a	20	0.75 to 2.25	15 to 45
Pollock 1977b	20	0.5 to 2.5	10 to 50
Pope 1998	11	47	517
Pope 2000	11	50	550
Rudzki 1997	12	41.3	495.6
Van Mechelen 1993	16	1.74 ± 1.32 to 1.85 ± 1.24	27.85 ± 21.15 to 29.58 ± 19.89
Van Tiggelen 2004	6	NA	NA
Van Tiggelen 2009	6	NA	NA
Withnall 2006	9	NA	NA

Footnotes

NA: not available

Appendix 4. Compliance with interventions

Study ID	Methods for monitoring or improving compliance in trials which did so	Reported compliance
Andrish 1974	Checks from platoon leaders.	Not reported
Brushøj 2008	Supervised by the Army sergeants and the recruit in charge.	Platoons on average performed 27 of 36 planned training sessions resulting in a 75% compliance rate. There was no difference in compliance rates between groups
Finestone 2004a	Based on percentage of recruits who finished the basic training with the assigned orthoses	Intervention group (soft custom insole): 72% Control group (soft prefabricated insole): 57%

(*Continued*)

Finestone 2004b	Based on percentage of recruits who finished the basic training with the assigned orthoses	Intervention group (semirigid biomechanical insole): 75% Control group (semirigid prefabricated insole): 82%
Gardner 1988	Inspection of the insoles to enforce compliance.	Not reported
Hartig 1999	Checks from platoon leaders.	Not reported
Larsen 2002	Intervention group "asked if they had used BSO within the first 3 months of military service" in questionnaire at 3 months	11% were not compliant
Pollock 1977a	Monitored closely during the entire 20-week programme.	Not reported
Pollock 1977b	Monitored closely during the entire 20-week programme.	Not reported
Pope 1998	Physical training instructors.	Not reported
Pope 2000	Research team members.	Not reported
Rudzki 1997	The intervention group was specifically forbidden to run during route marches to control the volume of running	Not reported
Van Mechelen 1993	Intervention group participants completed daily diaries recording compliance with prescribed exercises	Intervention group (stretching): 46.6%

Appendix 5. Adjustment of cluster randomised trials

Study ID	RR unadjusted	Lower 95%CI	Upper 95%CI	Average cluster size	ICC	Design effect	RR adjusted for clustering	Lower 95%CI	Upper 95%CI
Brushøj 2008 all injuries	1.20	0.93	1.54	42	0.05	3.05	1.20	0.77	1.87
Brushøj 2008 knee injuries	1.17	0.77	1.78	42	0.05	3.05	1.17	0.56	2.45

(*Continued*)

Brushøj 2008 MTSS	0.93	0.54	1.62	42	0.05	3.05	0.93	0.35	2.45
Brushøj 2008 Achilles tendonitis	3.04	0.83	11.15	42	0.05	3.05	3.04	0.31	29.93
Brushøj 2008 ankle sprain	1.21	0.62	2.38	42	0.05	3.05	1.21	0.37	3.95
Gardner 1988 all injuries	0.98	0.75	1.28	65	0.05	3.20	0.98	0.57	1.69
Hartig 1999 all injuries[a]	0.57	0.37	0.89	50	0.05	3.45	0.57	0.25	1.29
Pope 1998 all injuries	0.87	0.44	1.73	40	0.05	2.95	0.87	0.27	2.82
Pope 2000 all injuries	0.92	0.72	1.16	39	0.05	2.90	0.92	0.60	1.40
Rudzki 1997 all injuries	0.8	0.62	1.02	44	0.05	3.15	0.80	0.51	1.25
Rudzki 1997 hamstring/ thigh/hip/ groin	0.87	0.37	2.04	44	0.05	3.15	0.87	0.19	4.01
Rudzki 1997 knee injuries[a]	0.47	0.26	0.83	44	0.05	3.15	0.47	0.17	1.33
Rudzki 1997 lower leg injuries	1.06	0.41	2.76	44	0.05	3.15	1.06	0.19	5.83
Rudzki 1997 ankle/foot in-	0.78	0.46	1.34	44	0.05	3.15	0.78	0.30	2.03

(*Continued*)

juries									
Van Tiggelen 2009 double layer socks: all injuries	0.91	0.65	1.29	31	0.05	2.50	0.91	0.53	1.56
Van Tiggelen 2009 padded socks: all injuries[b]	0.54	0.35	0.84	31	0.05	2.50	0.54	0.27	1.08
Van Tiggelen 2009 double layer socks: knee injuries	0.80	0.47	1.37	31	0.05	2.50	0.80	0.34	1.86
Van Tiggelen 2009 padded socks: knee injuries[c]	0.27	0.12	0.63	31	0.05	2.50	0.27	0.07	1.00
Van Tiggelen 2009 double layer socks: shin splits/ tibial stress reactions	0.73	0.13	4.24	31	0.05	2.50	0.73	0.05	11.48
Van Tiggelen 2009 padded socks: shin splints/ tibial stress reactions	1.00	0.21	4.77	31	0.05	2.50	1.00	0.08	11.81

(*Continued*)

Van Tiggelen 2009 double layer socks: achilles tendonitis	1.24	0.51	3.00	31	0.05	2.50	1.24	0.31	5.03
Van Tiggelen 2009 padded socks: Achilles tendonitis	1.00	0.40	2.50	31	0.05	2.50	1.00	0.23	4.26

Footnotes

ICC: intraclass correlation co-efficient
MTSS: medial tibial stress syndrome
RR: risk ratio
[a] Adjustment using ICC of 0.03, 0.05 or 0.07 results in loss of statistical significance
[b] Adjustment using ICC of 0.03 retains statistical significance (RR 0.54; 95% CI 0.30 to 0.99) which is lost using an ICC of 0.05 or 0.07
[c] Adjustment using ICC of 0.03 retains statistical significance (RR 0.27; 95% CI 0.09 to 0.85) which is lost using an ICC of 0.05 or 0.07

Appendix 6. Stretching protocols

Study ID	Target muscle group	Stretch protocol (Intervention)	Stretch protocol (Control)
Andrish 1974	Gastrocnemius and soleus	3 min, 3x per day, outside training session	NA
Hartig 1999	Hamstrings	5x30 sec, 3x per day, outside training session	All recruits had normal routine stretching
Liu 2008	Gastrocnemius and soleus	5x30 sec, 3x per day, outside training session	Routine normal stretching including gastrocnemius and soleus
Pope 1998	Gastrocnemius and soleus	2x20 sec, before training	Stretching other muscle groups (wrist flexors and triceps)

(*Continued*)

Pope 2000	Hip adductors, hip flexors, quadriceps, hamstrings, gastrocnemius and soleus	1x20 sec, before training	Only warm up exercises, no stretching
Van Mechelen 1993	Iliopsoas, quadriceps, hamstrings, gastrocnemius and soleus	3x10 sec for 10 min, before running	Some form of daily stretching performed

Footnotes

min: minutes
NA: not available
sec: seconds

Appendix 7. Running distance per week

Study ID		Distance (km) per week	Total distance (km)
Pollock 1977a	***Intervention groups: differing duration of exercise***		
	15 min/day	2.41 to 2.81	48.27 to 56.31
	30 min/day	4.66 to 5.23	93.2 to 104.58
	45 min/day	6.60 to 8.21	131.94 to 164.12
Pollock 1977b	***Intervention groups: differing frequency of exercise***		
	1 day/week	4.34 to 5.63	86.80 to 112.60
	3 days/week	13.02 to 16.89	260.40 to 337.80
	5 days/week	21.70 to 28.15	434.00 to 563.00
Rudzki 1997	***Intervention group: walk group***	6.83	82
	Control group: run group	23.33	280

Footnotes

km: kilometres
min: minutes

FEEDBACK

Minor corrections, 1 August 2011

Summary

The authors have created a table where they list the distances covered in km/week by the subjects in the Pollock 1977 trial. For the frequency group, the original article states that the subjects in this group ran 2.7 - 3.5 miles/workout in 30 min. The frequency group that runs for 30 min once a week must then cover 4.32 - 5.6 km/week (conversion factor 1.6) but the authors have written 4.56 - 9.68km. For the 3 days a week the authors have 13.67 - 29.00 km/week, which according to my calculations should be 12.96 - 16.8 km (which is 2.7 miles x 1.6 x 3 and 3.5 miles x 1.6 x 3). The 5 days a week does not match my calculations either. Is this a mathematical error?
Additionally, I see that the authors state that the race in the Buist 2008 trial is 10 km. This is incorrect - it is 4 miles (or 6.7 km).

Reply

We would like to thank Dr Schelde for his very thorough observations about our review. He rightly points out our calculation errors where we attempted to convert the mileage in Pollock's study into km - the correct conversion factor should be 1.609 and we have corrected this in Appendix 7 in this version of the review. We have also corrected our error in the study by Buist in which participants are training for a 4 mile race and not 10 km as stated in our review.
Nonetheless, these descriptive errors do not have any effect on our analysis and the evidence that we have concluded from this updated review remain unchanged.

Contributors

Comment from: Dr Jacob Schelde
Reply from: Dr Simon Yeung, Hong Kong

WHAT'S NEW

Last assessed as up-to-date: 16 April 2011.

Date	Event	Description
10 August 2011	Feedback has been incorporated	Feedback incorporated and minor corrections made.

HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 3, 2001

Date	Event	Description
9 June 2011	New citation required and conclusions have changed	1. The addition of evidence from 15 new trials and updated methodology have led to additional conclusions and modifications to pre-existing conclusions 2. An additional author has been added to the byline.
9 June 2011	New search has been performed	For this update, published in Issue 7, 2011, the following changes were made: 1. Converted to new review format, requiring changes to text throughout. 2. Background updated. 3. Search updated to January 2011. 4. Fifteen additional trials have been included (Bensel 1976; Bensel 1983; Bensel 1986; Brushøj 2008; Buist 2008; Finestone 2004a; Finestone 2004b; Gardner 1988; Knapik 2009; Knapik 2010a; Larsen 2002; Liu 2008; Van Tiggelen 2004; Van Tiggelen 2009; Withnall 2006). 5. One previously included trial (Pollock 1977) has been included as two separate trials (Pollock 1977a; Pollock 1977b). 6. Three previously included trials have been excluded (Milgrom 1992; Schwellnus 1990; Smith 1985). 7. Risk of bias assessment has replaced previous methodological quality assessment. 8. Analysis methods have been revised; cluster randomised trials adjusted for clustering
24 December 2009	New search has been performed	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Ella Yeung (EY) and Simon Yeung (SY), initiated and designed the review.

This first update was initiated by EY who carried out screening of papers for inclusion, independent data extraction and risk of bias assessment, data entry and analysis, and wrote the first draft of the review. EY provided a clinical perspective.

SY carried out screening of papers for inclusion, independent data extraction and risk of bias assessment, data entry and analysis, and wrote subsequent drafts of the review. SY provided a clinical perspective and is guarantor of the review.

Lesley Gillespie (LG) revised search strategies and updated searches in 2010/11; contributed to screening of papers for inclusion; assisted with risk of bias assessment and data extraction, data entry and analysis, and contributed to writing subsequent drafts of the review. LG provided a methodological perspective.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Hong Kong Polytechnic University, Hong Kong.

Computing, administration and library services (SY, EY)

- University of Otago, Dunedin, New Zealand.

Library services (LDG)

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This update differs from the published protocol in a number of respects.

- The 'Background' has been revised to include information relating to soft-tissue injuries in military recruits.

- In the protocol and first version of this review the outcome "Incidence (overall and by bodily location) of lower-limb injuries" was defined as the number of people with injuries. In this update we have discriminated between the number of people with injuries and the number of injuries in each study group. The later have been reported as rate ratios.

- In the protocol and first version of the review "Severity of injury" was listed under 'Types of outcome measures'. This has been removed as it was not an outcome of the review. It relates to the definition of an injury in some trials where the injuries had to be of a certain level of severity before they qualified for inclusion as an outcome. These descriptions are included in the Characteristics of included studies.

- We have replaced the outcome "Complication of interventions" with "Adverse effects" as the Handbook 14.1.2. states that "Complications" relate to "adverse events or effects following surgical and other invasive interventions" which is not the case in this review.

- In the protocol and first version of the review we assessed methodological quality using the Cochrane Bone, Joint and Muscle Trauma Group's generic quality assessment tool. For this update we have adopted The Cochrane Collaboration's 'Risk of bias' tool which was implemented along with Review Manager 5 (RevMan 2011).

- Data from cluster-randomised trials have been adjusted for clustering.

INDEX TERMS

Medical Subject Headings (MeSH)

Cumulative Trauma Disorders [*prevention & control]; Leg Injuries [*prevention & control]; Military Personnel; Orthotic Devices; Prisoners; Randomized Controlled Trials as Topic; Running [*injuries]; Soccer [injuries]; Soft Tissue Injuries [prevention & control]

MeSH check words

Humans