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Running shoes for preventing lower limb running injuries in adults (Review)

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[Intervention Review]

Running shoes for preventing lower limb running injuries in adults

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ABSTRACT

Background

Lower-limb running injuries are common. Running shoes have been proposed as one means of reducing injury risk. However, there is uncertainty as to how effective running shoes are for the prevention of injury. It is also unclear how the effects of different characteristics of running shoes prevent injury.

Objectives

To assess the effects (benefits and harms) of running shoes for preventing lower-limb running injuries in adult runners.

Search methods

We searched the following databases: CENTRAL, MEDLINE, Embase, AMED, CINAHL Plus and SPORTDiscus plus trial registers WHO ICTRP and ClinicalTrials.gov. We also searched additional sources for published and unpublished trials. The date of the search was June 2021.

Selection criteria

We included randomised controlled trials (RCTs) and quasi-RCTs involving runners or military personnel in basic training that either compared a) a running shoe with a non-running shoe; b) different types of running shoes (minimalist, neutral/cushioned, motion control, stability, soft midsole, hard midsole); or c) footwear recommended and selected on foot posture versus footwear not recommended and not selected on foot posture for preventing lower-limb running injuries. Our primary outcomes were number of people sustaining a lower-limb running injury and number of lower-limb running injuries. Our secondary outcomes were number of runners who failed to return to running or their previous level of running, runner satisfaction with footwear, adverse events other than musculoskeletal injuries, and number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event.

Data collection and analysis

Two review authors independently assessed study eligibility and performed data extraction and risk of bias assessment. The certainty of the included evidence was assessed using GRADE methodology.

Main results

We included 12 trials in the analysis which included a total of 11,240 participants, in trials that lasted from 6 to 26 weeks and were carried out in North America, Europe, Australia and South Africa. Most of the evidence was low or very low certainty as it was not possible to blind runners to their allocated running shoe, there was variation in the definition of an injury and characteristics of footwear, and there were too few studies for most comparisons.

We did not find any trials that compared running shoes with non-running shoes.

Neutral/cushioned versus minimalist (5 studies, 766 participants)

Neutral/cushioned shoes may make little or no difference to the number of runners sustaining a lower-limb running injuries when compared with minimalist shoes (low-certainty evidence) (risk ratio (RR) 0.77, 95% confidence interval (CI) 0.59 to 1.01).

One trial reported that 67% and 92% of runners were satisfied with their neutral/cushioned or minimalist running shoes, respectively (RR 0.73, 95% CI 0.47 to 1.12). Another trial reported mean satisfaction scores ranged from 4.0 to 4.3 in the neutral/ cushioned group and 3.6 to 3.9 in the minimalist running shoe group out of a total of 5. Hence neutral/cushioned running shoes may make little or no difference to runner satisfaction with footwear (low-certainty evidence).

Motion control versus neutral / cushioned (2 studies, 421 participants)

It is uncertain whether or not motion control shoes reduce the number of runners sustaining a lower-limb running injuries when compared with neutral / cushioned shoes because the quality of the evidence has been assessed as very low certainty (RR 0.92, 95% CI 0.30 to 2.81).

Soft midsole versus hard midsole (2 studies, 1095 participants)

Soft midsole shoes may make little or no difference to the number of runners sustaining a lower-limb running injuries when compared with hard midsole shoes (low-certainty of evidence) (RR 0.82, 95% CI 0.61 to 1.10).

Stability versus neutral / cushioned (1 study, 57 participants)

It is uncertain whether or not stability shoes reduce the number of runners sustaining a lower-limb running injuries when compared with neutral/cushioned shoes because the quality of the evidence has been assessed as very low certainty (RR 0.49, 95% CI 0.18 to 1.31).

Motion control versus stability (1 study, 56 participants)

It is uncertain whether or not motion control shoes reduce the number of runners sustaining a lower-limb running injuries when compared with stability shoes because the quality of the evidence has been assessed as very low certainty (RR 3.47, 95% CI 1.43 to 8.40).

Running shoes prescribed and selected on foot posture (3 studies, 7203 participants)

There was no evidence that running shoes prescribed based on static foot posture reduced the number of injuries compared with those who received a shoe not prescribed based on foot posture in military recruits (Rate Ratio 1.03, 95% CI 0.94 to 1.13). Subgroup analysis confirmed these findings were consistent between males and females. Therefore, prescribing running shoes and selecting on foot posture probably makes little or no difference to lower-limb running injuries (moderate-certainty evidence).

Data were not available for all other review outcomes.

Authors' conclusions

Most evidence demonstrates no reduction in lower-limb running injuries in adults when comparing different types of running shoes. Overall, the certainty of the evidence determining whether different types of running shoes influence running injury rates was very low to low, and as such we are uncertain as to the true effects of different types of running shoes upon injury rates.

There is no evidence that prescribing footwear based on foot type reduces running-related lower-limb injures in adults. The evidence for this comparison was rated as moderate and as such we can have more certainty when interpreting these findings. However, all three trials included in this comparison used military populations and as such the findings may differ in recreational runners.

Future researchers should develop a consensus definition of running shoe design to help standardise classification. The definition of a running injury should also be used consistently and confirmed via health practitioners. More researchers should consider a RCT design to increase the evidence in this area. Lastly, future work should look to explore the influence of different types or running shoes upon injury rates in specific subgroups.

PLAIN LANGUAGE SUMMARY

Running shoes for preventing lower-limb running injuries in adults

Title

Do different types of running shoes change the risk of developing a lower-limb injury?

Key messages

Neutral/cushioned shoes may make little or no difference to the number of runners sustaining injuries or footwear satisfaction compared with minimalist shoes.

It is uncertain if motion control shoes reduce the number of runners sustaining injuries compared with neutral/ cushioned shoes.

Soft midsole shoes may make little or no difference to the number of runners sustaining injuries compared with hard midsole shoes.

It is uncertain if stability shoes reduce the number of runners sustaining injuries compared with neutral/cushioned shoes.

It is uncertain whether or not motion control shoes reduce the number of runners sustaining a lower-limb running injuries when compared with stability shoes.

Prescribing running shoes and selecting on foot posture probably makes little or no difference to running injuries

Future researchers should develop a consensus definition of running shoe design to help standardise classification. The definition of a running injury should be used consistently and confirmed via health practitioners. Researchers should consider a randomised controlled trial design to increase the evidence in this area and explore the influence of different types or running shoes upon injury rates in specific subgroups.

Running shoes and running injuries

Running shoes are designed with features that look to reduce foot motion or how much force is applied to the body, with a view to reducing running-injury risk. Based upon their design features running shoes may be broadly classified as; motion control, stability or neutral/ cushioned and as minimalist if they look to provide little movement control or cushioning features.

What did we want to find out?

We wanted to find out:

whether different types of running shoes could reduce the risk of developing lower-limb running injuries

whether prescribed running shoes could reduce the risk of developing lower-limb running injuries compared to non-prescribed running shoes

What did we do?

We searched for studies that compared running-injury rates (number of runners injured or total number of injuries) between groups of runners or military personnel who wore different types of running shoes.

We compared and summarised their results, and rated our confidence in the evidence, based on factors such as study methods.

What did we find?

We found 12 studies, nine of which assessed leisure or recreational runners and three in military populations. A total of 11,240 participants were included across all studies, with the largest study including 3952 participants and the smallest 24. The following comparisons were made.

- Neutral/ cushioned compared to minimalist running shoes (5 studies, 766 participants)

- Motion control compared to neutral/ cushioned running shoes (2 studies, 421 participants)

- Soft compared to hard running shoes (2 studies, 1095 participants)

- Stability compared to neutral/ cushioned running shoes (1 study, 57 participants)

- Motion control compared to stability running shoes (1 study, 56 participants)

- Prescribed compared to non-prescribed running shoes (3 studies, 7203 participants)

The studies did not use the same definition of injury and some used definitions of injury that included injuries to parts of the body other than just the lower limb.

Main results

We found the following within our review.

Neutral/cushioned shoes may make little or no difference to the number of runners sustaining a lower-limb running injuries or runner satisfaction with footwear when compared with minimalist shoes (low-certainty evidence).

It is uncertain whether or not motion control shoes reduce the number of runners sustaining lower-limb running injuries when compared with neutral/cushioned shoes because the certainty of the evidence was very low.

Soft midsole shoes may make little or no difference to the number of runners sustaining lower-limb running injuries when compared with hard midsole shoes (low-certainty evidence).

It is uncertain whether or not stability shoes reduce the number of runners sustaining lower-limb running injuries when compared with neutral/cushioned shoes because the certainty of the evidence was very low.

It is uncertain whether or not motion control shoes reduce the number of runners sustaining lower-limb running injuries when compared with stability shoes because the certainty of the evidence was very low.

Prescribing running shoes and selecting on foot posture probably makes little or no difference to lower-limb running injuries (moderate-certainty evidence).

What are the limitations of the evidence?

We were moderately confident in the evidence from studies comparing prescribed and non-prescribed running shoes, but this evidence was limited by the fact participants knew what types of running shoes they were receiving.

We have little confidence in the evidence that compared different types of running shoes as the participants often knew what type of running shoe they were receiving, the number of participants taking part in the study were small and there were often not enough studies comparing each type of running shoe with another.

How up to date is this evidence?

The evidence is up to date to June 2021.

Summary of findings 1. Neutral / cushioned versus minimalist running shoes for preventing lower-limb running injuries in adults

Neutral / cushioned versus minimalist running shoes for preventing lower-limb running injuries in adults

Population: healthy adults participating in recreational running
Setting: runners doing training and competitive events over a 3 to 6.5 month period
Intervention: Neutral / cushioned running shoe
Comparison: Minimalist running shoe

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with minimalist running shoe	Risk with neutral / cushioned running shoe				
Number of runners sustaining a lower-limb running injury[a] (Follow-up: 3 to 6.5 months)	Study population 273 per 1,000[b]	210 per 1000 (161 to 276)	RR 0.77 (0.59 to 1.01)	766 runners (5 studies)	⊕⊕⊖⊖ LOW[c]	Only 3 studies reported the location of the injury. Six included injuries were reported in the lower back / pelvis region. Only 1 study reported the type of injury, with 90% of 136 being overuse.
Number of lower-limb running injuries	See comment		-	-	-	Not reported over a specific period. Trials reported on the first running-related injury.
Number of runners who failed to return to running or their previous level of running	See comment		-	-	-	Outcome was not reported. Of note is that one study (61 participants) reported that the median number of training days lost to injury was 13 [IQR 7 to 25 days] in the neutral / cushioned group and 14 [IQR 10 to 27 days] in the minimalist group. One study (553 participants) reported 46 injuries (out of 136 reported) were severe enough to require taking over 28 days off from running.

Runner satisfaction with footwear	67% (8/12) and 92% (11/12) of runners were satisfied with their neutral / cushioned or minimalist running shoes respectively using a dichotomous question in one study.	RR 0.73 (0.47 to 1.12)	24 runners (1 study)	⊕⊕⊖⊖ LOW[d]	Mean satisfaction scores from 1 (very dissatisfied) to 5 (very satisfied) at 0, 4, 8 and 12 weeks were reported in one additional trial. Average scores ranged from 4.0 to 4.3 in the neutral / cushioned group and 3.6 to 3.9 in the minimalist running shoe group and these were not statistically significantly different in one study (29 participants).
Adverse events (e.g. skin complaints) other than musculoskeletal injuries	See comment	-	-	-	Outcome was not reported
Number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event	See comment	-	-	-	Outcome was not reported

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval;**IQR:** interquartile range; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a] All trials reported on the first running-related injury however, there was inconsistency in the definition of a running-related injury. One trials's definition was unclear, however if runners reported pain, this was followed up by a sports medicine physician blinded to assigned group. One trial defined this as "any musculoskeletal problem severe enough to cause a visit to a health professional, use of medication, or reduced weekly training". One trial's definition was "any physical pain located at the lower limbs or lower back region, sustained during or as a result of running practice and impeding planned running activity for at least 1 day (time loss definition)". Another trial defined this as "any reported muscle, joint or bone problem/ injury of lower limb resulting from running training that required the runner to miss at least one training day or a training session". A final trial defined this as "three consecutive missed run work-outs secondary to running-related pain.
[b] Risk is the pooled risk of the control groups.
[c] The certainty of the evidence was downgraded one level for serious risk of bias, reflecting the lack of blinding of outcome assessment, and one level for serious imprecision, reflecting the wide confidence interval crossing the line of no effect.
[d]The certainty of evidence was downgraded one level for serious risk of bias, due to the lack of blinding and one level for imprecision, due to small number of runners and hence events.

Summary of findings 2. Motion control versus neutral / cushioned running shoes for preventing lower-limb running injuries in adults

Motion control versus neutral / cushioned running shoes for preventing lower-limb running injuries in adults

Population: healthy adults participating in recreational running
Setting: runners doing training and competitive events over a 3 to 6 month period
Intervention: Motion control running shoe
Comparison: Neutral / cushioned shoe

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with neutral / cushioned running shoe	Risk with motion control running shoe				
Number of runners sustaining a lower-limb running injury[a] (Follow-up: 3 to 6 months)	Study population		RR 0.92 (0.30 to 2.81)	421 (2 studies)	⊕⊖⊖⊖ VERY LOW[c]	The majority of injuries were lower-limb injuries. Two included injuries were in the lower back / pelvis region. One study (372 participants) reported 72 injuries (out of 93 injuries) as progressive injuries.
	324 per 1,000[b]	298 per 1,000 (97 to 910)				
Number of lower-limb running injuries	See comment		-	-	-	Not reported over a specific period. Both trials reported on the first running-related injury
Number of runners who failed to return to running or their previous level of running	See comment		-	-	-	Outcome was not reported. Of note is that 21 (18% of 114) of injuries were severe enough to require taking over 28 days off from running.
Runner satisfaction with footwear	See comment		-	-	-	Outcome was not reported
Adverse events (e.g. skin complaints) other than musculoskeletal injuries	See comment		-	-	-	Outcome was not reported
Number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event	See comment		-	-	-	Outcome was not reported

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a] Both trials reported on the first running-related injury. However, one trial defined this as "any physical pain located at the lower limbs or lower back region, sustained during or as a result of running practice, and impeding planned running activity for at least 1 day (time-loss definition)". The other trial defined a running-related injury (RRI) as "a missed training day due to running-related pain".
[b] Risk is the pooled risk of the two control groups.
[c] The certainty of the evidence was downgraded one level for serious risk of bias, reflecting the lack of blinding of outcome assessment, one level for serious imprecision, reflecting the wide confidence interval crossing the line of no effect, one level for inconsistency, reflecting the substantial statistical heterogeneity (I^2 = 88%) and one level for indirectness as the outcome for one trial was pain, not injury.

Summary of findings 3. Soft versus hard running shoes for preventing lower-limb running injuries in adults

Soft versus hard running shoes for preventing lower-limb running injuries in adults

Population: healthy adults participating in recreational running
Setting: runners doing training and competitive events over a 5 to 6 month period
Intervention: Soft running shoe (shoes with a more compliant midsole)
Comparison: Hard running shoe (shoes with a stiffer midsole)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with hard running shoe	Risk with soft running shoe				
Number of runners sustaining a lower-limb running injury[a] (Follow-up: 5 to 6 months)	Study population 199 per 1000[b]	163 per 1000 (121 to 219)	RR 0.82, 95% (CI 0.61 to 1.10)	1095 runners (2 studies)	⊕⊕⊖⊖ LOW[c]	The majority of injuries (94.4% of 197) were lower-limb injuries and overuse injuries (79%). One injury was in the shoulder / collarbone, 1 in the head/ neck, 7 in the trunk and 2 in the lower back region

Number of lower-limb running injuries	See comment	-	-	-	Not reported over a specific period. Both trials reported on the first running-related injury
Number of runners who failed to return to running or their previous level of running	See comment	-	-	-	Outcome was not reported. Of note is that 69 (35% of 197) of injuries were severe enough to require taking over 28 days off from running
Runner satisfaction with footwear	See comment	-	-	-	Outcome was not reported
Adverse events (e.g. skin complaints) other than musculoskeletal injuries	See comment	-	-	-	Outcome was not reported
Number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event	See comment	-	-	-	Outcome was not reported

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a] Both trials reported on the first running-related injury. However, one trial defined this as "running-related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least seven days or three consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional first injury only". The other trial defined a running-related injury (RRI) as " physical pain or a complaint sustained during or as a result of running practice and impeding normal running activity for at least 1 day (time-loss definition)".
[b] Risk is the pooled risk of the two control groups.
[c] The certainty of the evidence was downgraded one level for serious risk of bias, reflecting the lack of blinding of outcome assessment, and one level for serious imprecision, reflecting the wide confidence interval crossing the line of no effect.

Summary of findings 4. Running shoes recommended and selected on foot posture versus running shoes not recommended and selected on foot posture for preventing lower-limb running injuries in adults

Running shoes recommended and selected on foot posture versus running shoes not recommended and selected on foot posture for preventing lower-limb running injuries in adults

Population: military personnel
Setting: military personnel in basic combat training over 6 to 12 weeks
Intervention: prescribed running shoes
Comparison: non-prescribed running shoes

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Non-prescribed running shoes	Risk with Prescribed Running Shoes				
Injury Incidence Rate (injuries / 1000 person-days)[a]	Study population 226 per 1000[b]	233 per 1000 (213 to 256)	Rate ratio 1.03 (0.94 to 1.13)	7203 (3 studies)	⊕⊕⊕⊖ MODERATE	Injury definition consistent in all trials. No details on location and severity provided. Subgroup analysis revealed no differences between male and females.
Number of runners sustaining a lower-limb running injury	See comment		-	-	-	Outcome was not reported.
Number of runners who failed to return to running or their previous level of running	See comment		-	-	-	Outcome was not reported.
Runner satisfaction with footwear	See comment		-	-	-	Outcome was not reported.
Adverse events (e.g. skin complaints) other than musculoskeletal injuries	See comment		-	-	-	Outcome was not reported.
Number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event	See comment		-	-	-	Outcome was not reported

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

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[a]All trials defined an injury using the International Classification of Diseases, Version 9, Clinical Modification (ICD-9-CM). The first 4 diagnoses of an injury were considered although "a single visit usually included only one diagnosis". The index data used in this analysis was the Training Injury Index, which is the number of lower extremity injuries per 1000 person-days as the most appropriate measure of running exposure.
[b]Risk is calculated from the median control group risk taken from the included studies. Raw data was provided by the author. The median risk with non-prescribed shoes was 226 per 1000.
[c]The certainty of evidence was downgraded one level for serious risk of bias, reflecting the lack of blinding and appropriate random sequence generation.

BACKGROUND

Description of the condition

Running is amongst the top three most popular adult sport and leisure physical activities globally (Hulteen 2017). It has various health benefits: for example, runners have a 30% lower risk of all-cause mortality and a 45% lower risk of cardiovascular mortality compared with non-runners (Lee 2014). However, running can also result in musculoskeletal and soft tissue injuries.

It has been estimated between 19.4% and 79% of runners sustain an injury, of which the great majority (around 97%) are in the lower limb and are evenly distributed across the knee, lower leg, and foot and ankle (Lun 2004; Malisoux 2015; Taunton 2002; Tonoli 2010; Van Gent 2007; Van Middelkoop 2008). Running injury incidence rates of 17.8% for novice runners, 7.7% for recreational runners and 3.5% for elite or professional runners per 1000 hours of running have been reported (Begizew 2018; Vidbæk 2015). Furthermore, between 10 and 35 injuries per 100 recruits per month occur in military populations who run as part of their training (Kaufman 2000).

A general definition of injury is a significant complaint perceived and defined by the athlete (Parkkari 2004). Common running injuries include muscle and tendon strains and tears, ligament sprains, tendinopathies, specific knee injuries (patellofemoral pain, chondromalacia patella and meniscal damage), stress fractures, medial tibial stress syndrome (or 'shin splints'), plantar fasciitis (pain in the underside of the foot) and iliotibial band syndrome (pain in the tissue between the hip and the knee) (Bird 1997; Lopes 2012; Lemont 2003; Reinking 2012). Severity of injury has been considered in terms of: 1) social and health impacts, for example, work days lost (Van Mechelen 1997), loss of employment or military career (Hespanhol 2015; Kaufman 2000); and loss of health impacts due to long-term reduction in physical activity (Van der Worp 2015); 2) impacts on running, for example, level of ability to continue to run (Marti 1988), or lost running days (Van Mechelen 1997); and 3) clinical impacts such as grading systems for strains and sprains (Lynch 1999; Mueller-Wohlfahrt 2013).

The cause of running injuries is complex and multifactorial (Bertelsen 2017). However, the process that immediately precedes injury concerns the involved structure's capacity being exceeded (Bertelsen 2017; Hulme 2017). Overuse injuries, such as stress fractures, accumulate over time and arise from micro-traumas that create damage (Ferber 2009; Saragiotto 2014). Acute trauma injuries occur after a sudden event such as forceful ankle movement leading to an ankle sprain (Van Mechelen 1997).

Description of the intervention

There are many types of running shoes available. These generally incorporate design features that may reduce the risk of lower-limb injuries (Davis 2014). Recently Ramsey 2019 has categorised these characteristics into nomenclature, measurements, qualitative features and subjective features.

Most studies have used the running shoe types listed in the nomenclature category. They include neutral and cushioned shoes (typically used interchangeably in practice and, for the purpose of this review, we will use neutral / cushioned) designed to reduce the load when striking the ground (Davis 2014; Langley 2015); motion control shoes, designed to reduce the amount or rate, or both, of rearfoot and midfoot motion during ground contact (Davis 2014; Langley 2015); stability shoes designed to offer some motion control and cushioning (Davis 2014; Langley 2015); and minimalist running shoes that aim to mimic barefoot running and are designed with high levels of flexibility and lack of motion control or stability features (Esculier 2015). However, the combination of features included in a particular type of running shoe often vary both within and between brands and may overlap. Although other, less common types of nomenclature are reported in Ramsey 2019, the typical design features of the most commonly reported shoes are detailed in Table 1.

The measurements category provided by Ramsey 2019 lists objective detail on the structure of the shoe (e.g. heel-toe drop); the qualitative features category provides visual inspection details (e.g. outer-sole wear patterns), and the subjective features include comfort and cost. However, these are not characteristics unique to running shoes. Shoe prescription based on assessment of lower-limb alignment is also included in the subjective features category (Ramsey 2019). Furthermore, running shoes have been recommended to runners based upon a scale of foot type measurements known as foot posture (Napier 2018). In general, runners tend to be prescribed shoes that have some aspect of elevated cushioned heels and subtalar motion control features (Richards 2009). However, more specifically, motion control shoes may be recommended for runners with an excessively pronated foot (the foot tends to roll inwards), stability shoes for those with a pronated to neutral foot posture and neutral./cushioned running shoes for neutral to supinated (the foot tends to roll outwards) foot posture (Table 1) (Davis 2014).

How the intervention might work

Running shoes are designed to prevent overuse injuries; it is unclear if acute injuries are also prevented. Shoes can be designed with motion control and cushioning features (Davis 2014; Reinschmidt 2000). Motion control features aim to reduce excessive foot motion and hence increase the efficiency of the foot during the stance phase with cushioning features modifying the impact forces and reducing the amount or rate of force application to the body (Butler 2007; Clarke 1983; Davis 2014; Dinato 2015; Milani 1997; Perry 1995; Reinschmidt 2000; TenBroek 2014). There may be differences in (rear) foot and knee movement (Cheung 2007; Hutchison 2015; Langley 2018; Langley 2019; Lilley 2013; Rose 2011), changes in foot striking patterns (which part of the foot makes contact with the ground first), and modification of impact forces when wearing different types of running shoes (Sinclair 2013; Squadrone 2009). As each running shoe design may modify different lower-limb movements, it is possible that specific injuries may be reduced for each of these footwear designs. For example, the inclusion of an elevated heel in running shoes may reduce Achilles tendon strains and thus Achilles tendon injury (Rabusin 2019). Subtalar motion control characteristics are thought to reduce injuries that occur medially, including medial tibial stress syndrome and patellofemoral pain (McKenzie 1985; Messier 1988). There has also been some limited evidence that older running shoes may be less likely to reduce injuries due to the deterioration of design features (Gardner 1988). Modifications attributed to running shoes may reduce injury risk; however, injury rates are not typically reported in the literature.

Footwear design appears to have been based upon theory of how the foot should function (Root 1971; Root 1977). Root suggested that the foot has an optimum position about which it should

move and deviations away from this would increase injury risk (Root 1971; Root 1977). This concept gave rise to a wide range of running shoe adaptations which aimed to control foot function, primarily by reducing foot motion. Kirby proposed an alternative concept, which detailed how the external forces acting upon a foot would influence the loading of the structures within the foot and may explain how shoes provide a means of modifying injury risk without movement adaptations (Kirby 1987; Kirby 1989; Kirby 1992). More recently, two alternative injury theories have been proposed: the muscle tuning paradigm and the preferred movement pathway theory (Nigg 2015; Nigg 2017). The muscle tuning paradigm suggests that muscles vibrate as a result of impact and the muscular activation required to stop this increases the rate of fatigue and then injury risk. The preferred movement pathway theory suggests that runners have their own preferred movement pathway and that footwear may reduce muscle activation levels by working with rather than against this natural pattern of movement.

Why it is important to do this review

Running injuries have a societal and individual economic impact through loss of productivity and associated costs of health care (Hespanhol 2015), and can lead to a reduction in physical activity entirely (Buist 2010; Van der Worp 2015). As there is a clear link between regular physical activity and increased health and well-being, running-related injury prevention is an important public health issue. Running injuries can also have negative consequences for professional populations such as for military recruits due to a decrease in military readiness (Bullock 2010). Runners attribute injury to their footwear (Rothschild 2012; Saragiotto 2014), and specific features of a running shoe are claimed to reduce the risk of injury (Nigg 2017). This has partly driven the now multi-billion dollar sports footwear industry. However, due to the continuous evolution of injury risk theories surrounding foot position, footwear design and injury risk, the evidence to support running shoes as an injury prevention method must also be continuously evaluated; albeit that, inevitably, evidence about running shoe prescription will lag behind the adoption of theory (Richards 2009).

A previous Cochrane Review on all interventions to prevent running injury concluded that, "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" (Yeung 2011). Furthermore, Leppänen 2014 reported that basketball boots, rugby footwear and infantry boots did not reduce lower-limb injury in professional sports people and military recruits, but their review did not consider running shoes. Therefore, there is a need for decisions and advice on running footwear to be based on high-certainty evidence of the effectiveness of specific running shoes for injury prevention in all types of runners. This review focused specifically on running shoes in a broad population of adult runners. The aim of this review was to evaluate and update the current evidence on the effectiveness of running shoes for preventing lower-limb running injuries in adult runners.

OBJECTIVES

To assess the effects (benefits and harms) of running shoes for preventing lower-limb running injuries in adult runners.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomised controlled trials (RCTs), quasi-RCTs (studies similar to RCTs in design but without a truly random method for assigning participants to intervention groups) and cluster-RCTs. We reported studies irrespective of their publication status: full text, abstract only and non-published data.

Types of participants

Reflecting on the lack of consensus on the classification of runners, we included all runners as defined by study authors: for example, novice, recreational and professional or elite, including service personnel (e.g. military who run as part of their training), adult runners. Participation in running was confirmed by self-report, professional occupation or both. We excluded track athletes as this population use specialist running footwear (i.e. spikes) not included in this review. Due to factors relating to skeletal immaturity, we also excluded studies focusing on children from the review (Adirim 2003; Difiori 1999). No studies included a mix of adults and children.

Types of interventions

Due to inconsistencies in running shoe definitions (see Description of the intervention), we included any type of running shoe defined as such by the study author. However, we expected to find the most common types and characteristics of footwear similar to those presented in Table 1. We contacted study authors if more information on the footwear characteristics was required. We aimed to compare running shoes with shoes defined by study authors as not running shoes. We included studies that compared one type of running shoe with a different type of running shoe (e.g. motion-control running shoes versus stability running shoes). We also included studies that had compared footwear recommended and selected on foot posture with footwear not recommended and not selected on foot posture. We excluded non-sporting footwear and footwear that has cleats or studs such as football boots.

1. Running shoe versus shoes not defined as a running shoe by the study author (e.g. motion control (intervention) versus tennis shoe (control)).
2. Different types of running shoes. In these comparisons, we selected the control group based on the shoe with the least features that are thought to influence lower-limb function. For example, stability (intervention) versus neutral/cushioned (control) and motion control (intervention) versus stability (control). An alternative control group may also be the runner's own running shoe.
3. Prescribed running shoes based on foot posture (intervention) versus non-prescribed running shoes (control).

Types of outcome measures

A Delphi consensus study defined a running injury as follows: “Running related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least 7 days or 3 consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional” (Yamato 2015). However, given that this definition was unavailable until

recently, we recorded lower-limb injuries as reported and defined by study authors. Likewise, as there is no consistency in the literature regarding reporting of lower-limb running injuries, we used the study authors' criteria for all outcome measures. As the author definitions of lower-limb running injuries have been used within the review there may be instances where injuries other than those reported within the lower extremities are included in the data reported. We planned to report outcomes for different time periods: short (e.g. within 12 weeks), intermediate (e.g. up to six months) and long term (e.g. longer than six months) where this detail was provided. However, we found that often studies did not report information about time points for our outcomes (see Differences between protocol and review).

Primary outcomes

1. Number of runners sustaining a lower-limb running injury.
2. Number of lower-limb running injuries.

Where possible, we also categorised these by overuse injuries or acute injuries; specific type of injury (e.g. stress fracture, ligament sprain, patellofemoral pain, shin splints); and location of injury (e.g. the hamstrings).

Secondary outcomes

1. Number of runners who failed to return to running or their previous level of running.
2. Runner satisfaction with footwear. This may relate to comfort or subjective impression of performance.
3. Adverse events other than musculoskeletal injuries. For example, skin complaints, blisters, nail pathology (e.g. onychocryptosis, subungual haematoma, nail loss), infections such as athlete's foot.
4. Number of runners requiring hospital admission or surgery, or both, for musculoskeletal injury or adverse event

Economic and resource outcomes

We planned to record resource use (e.g. cost of footwear; days off work; cost of treatment of injury; number of outpatient visits), other costs and findings of included studies reporting cost-effectiveness analysis where it was included.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL (CRS Web) 28 May 2021, Issue 5), MEDLINE (Ovid MEDLINE(R) 1946 to 27 May 2021), Embase (1980 to 28 May 2021), AMED (1985 to 28 May 2021), CINAHL Plus (1937 to 1 June 2021) and SPORTDiscus (1985 to 1 June 2021). The search strategies can be found in Appendix 1.

At the time of the search, CENTRAL was fully up-to-date with all records from the BJMT Group's Specialised Register and so it was not necessary to search this separately.

To find ongoing and recently completed studies, we searched the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP) search portal (1 June 2021) and ClinicalTrials.gov (the US National Institute of Health Clinical Trials search portal) (1 June 2021).

We applied no restrictions to language or date of publication.

Searching other resources

We searched the reference lists of all primary studies and review articles, and also relevant manufacturers' websites for study references and information. We searched PubMed for errata or retractions from included studies published in full text. We also searched for conference abstracts from key meetings (e.g. International Conference on Biomechanics in Sport, International Conference on Foot and Ankle Biomechanics). Finally, we searched the journal entitled 'Footwear Science' as it is not indexed in the included databases.

Data collection and analysis

Selection of studies

Two review authors (NR and BL) independently screened titles and abstracts for inclusion of all potential studies identified as a result of the search and coded them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We retrieved full-text publications and two review authors (NR and BL) then independently screened the full texts to identify studies for inclusion and record reasons for exclusion of ineligible studies. If required, we attempted to contact study authors to establish study methods and characteristics to help make a decision on eligibility. We resolved disagreements by consensus or by consultation with a third review author (HG or PD). We identified and collated multiple reports of the same study, so that each study rather than each report is the unit of interest in the review. We reported the study selection process using a PRISMA flow diagram and tabulated reasons for exclusion (Moher 2009).

Data extraction and management

We used a data collection form, piloted on one study in the review (Malisoux 2016a), to extract the following study characteristics and outcome data.

1. Methods: study design, total study duration, number of centres and their locations, study settings, randomisation procedure, allocation method, blinding, withdrawals, dates the study was carried out and unit of analysis
2. Participants: number of participants, age (mean, standard deviation (SD) and range), sex, type of runner, running experience, running experience classification criteria, injury history, running terrain, running habits, inclusion and exclusion criteria
3. Interventions and comparisons: intervention (type and characteristics of running shoe, prescribed running shoe, brand), comparison (an alternative type of running shoe or another type of shoe or not prescribed running shoe), running distance, running duration, running frequency, use and type of other injury prevention interventions (e.g. stretching, running socks, cool down)
4. Outcomes: primary and secondary outcomes reported, including who by (self-report or other, such as, a physician), and follow-up time points
5. Notes: funding source and notable conflicts of interest of study authors and any unit of analysis issues.

Two review authors (NR and HG) independently extracted outcome data, and study characteristics of interest including participant

characteristics, intervention and comparison details; and reported them in the characteristics of included studies table. We also recorded where data were not suitable for inclusion in the analyses or where they were otherwise unusable. We resolved disagreements by consensus or by consultation with a third review author (RA). One review author (NR) transferred data into a Review Manager 5 file (RevMan 2014), and a second review author (PG) validated the information.

Assessment of risk of bias in included studies

Two review authors (NR and RA) independently assessed the risk of bias in each study against the following domains, using criteria in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017).

1. Random sequence generation (selection bias)
2. Allocation concealment (selection bias)
3. Blinding of participants and personnel (performance bias)
4. Blinding of outcome assessment (detection bias)
5. Incomplete outcome data (attrition bias)
6. Selective outcome reporting (reporting bias)
7. Other bias

We resolved disagreements by consensus or through a third review author (SS). We considered assessing the bias of subjective (e.g. shoe satisfaction) and objective (e.g. number of injuries) outcome measures separately for performance bias, detection bias and attrition bias; however, there were insufficient data. As no studies used cluster randomisation, we did not need to consider such studies separately.

We graded each domain as high, low, or unclear risk of bias (Higgins 2017), provided information from the study, and recorded our grades in a risk of bias table. We then summarised the risk of bias for each domain across included studies and reported these in the risk of bias summary tables and figures. We contacted study authors for further information about study characteristics when necessary, and noted correspondence in the risk of bias tables and references.

Measures of treatment effect

We reported risk ratios (RR) with 95% confidence intervals (CIs) for dichotomous data (e.g. injured or not injured).

We presented rate ratios with 95% CIs when the events reported in the study were number of injuries in each group over a given time period (e.g. a year).

If studies collected continuous data using the same scale, we reported mean differences (MDs) with 95% CIs. If studies used different scales to measure the same outcome, we used the standardised mean differences (SMDs) and 95% CIs. We used final scores in preference to change scores if both were presented.

Unit of analysis issues

While we anticipated that the unit of randomisation would be individual runners in most studies, we were aware that allocation may have been by group or cluster, such as platoons trained by different drill sergeants or physical education instructors. If cluster-randomised trials met eligibility criteria, they were to be unadjusted for unit of analysis using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017).

Our primary outcome was the number of runners sustaining one or more lower-limb running injuries. Where studies report injuries rather than number of runners with injuries, we reported these as rate ratios (e.g. number of injuries per person-year), or where rate ratios could be calculated from the raw data. We used adjusted data as first choice, where available (e.g. rate ratios from Poisson regression models, mean differences from analysis of variance (ANOVAs)).

Where a single study included multiple study arms, we only included the relevant arms. We avoided double-counting where two comparisons are combined in the same meta-analysis (e.g. neutral/cushioned running shoes were compared with both partial minimalist and full minimalist running shoes). Thus, we combined the active arms.

There were no cross-over trials.

Dealing with missing data

We planned to contact study investigators to verify key study characteristics if required and to obtain missing numerical outcome data (e.g. instances where only the abstract was available). When this was not possible, and we considered missing data would introduce serious bias, we planned to explore the impact of including such studies in the results by performing a sensitivity analysis. However, no sensitivity analysis was required as data missing from baseline were well accounted for in the included studies and hence, we felt it did not introduce serious bias.

Where data were missing in the study text, details available in graphical format were utilised, but only if this was a reliable representation of the study findings. If a study did not report SDs for continuous outcomes, we calculated these from standard errors, (SEs) CIs, or exact probability (P) values, where possible. We did not plan to impute missing SDs. However, again, these actions were not required.

We also considered if the study data were analysed on an intention-to-treat basis whenever possible. This sensitivity analysis was performed in one comparison only: neutral/cushioned shoes versus minimalist shoes.

Assessment of heterogeneity

We assessed clinical heterogeneity of study populations, interventions and outcomes qualitatively and by visually inspecting forest plots (Deeks 2017). We used both the I^2 (Higgins 2003), and Chi^2 statistics to measure statistical heterogeneity among studies in each analysis (Deeks 2017). We interpreted I^2 statistic values using recommendations from Deeks 2017; 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial heterogeneity.

Assessment of reporting biases

We reduced publication bias in our search methods by including published and unpublished studies without language or date restrictions. We also checked reported study data against any available published protocols. Furthermore, we dedicated one

section of the risk of bias assessment to selective outcome reporting. We also searched for unpublished studies, including documentation on shoe manufacturers' websites, and contacted shoe manufacturers if needed to reduce publication bias. If the meta-analysis including more than 10 studies, we planned to create and examine a funnel plot to explore the potential effects of small studies and publication biases (Sterne 2017). However, no comparisons included more than four studies.

Data synthesis

When considered appropriate, we pooled the results of comparable studies using both fixed-effect and random-effects models. Model choice was guided by careful consideration of the extent of heterogeneity and whether it could be explained, in addition to other factors such as the number and size of included studies. We used 95% CIs throughout. We considered reporting non-aggregated data where there was substantial heterogeneity ($I^2 \geq 75\%$) that was not explained by the diversity of methodological or clinical features among studies. Where pooling was inappropriate, we presented data in analyses or tables for illustration and reported results narratively in the text.

When considered appropriate, we pooled data using the generic inverse variance method in Review Manager 5 (RevMan 2014). This method enabled pooling of adjusted and unadjusted treatment effect estimates (e.g. rate ratios) reported in the individual studies or calculated from data presented in the published article.

Subgroup analysis and investigation of heterogeneity

We planned to conduct the following subgroup analyses for outcomes with a sufficient number of studies using Review Manager's test for subgroup differences alongside visual inspection of confidence intervals (RevMan 2014). However, there were insufficient data in the review to perform subgroup analyses in this way. As such we have provided a narrative review of subgroup information where provided within each study. Subgroup analysis is provided for the following.

1. Type of runner (e.g. novice, recreational, elite/professional). There is conflicting evidence that the type of runner is associated with higher injury rates (Van Gent 2007). Although there is no consensus definition for this classification provisional definitions of these three categories are:
   a. novice runners may have no experience, less than two years' regular running experience, or may have run for less than a total of 10 km in the previous 12 months (Baltich 2017; Buist 2008; Buist 2010; Ramskov 2015);
   b. recreational runners may have run at least once a week for 12 months, at least 10 km per week annually, or have run an average of 10- to 11-minute miles (Malisoux 2015; Van Mechelen 1993; Wen 1998);
   c. professional or elite runners are typically full-time athletes and include military recruits who run during basic training (Kornaat 2014; Yeung 2011).
2. Footwear type definition criteria (e.g. motion control, stability, cushioned/neutral) or not defined (e.g. simply referred to as a running shoe) when compared with non-running shoes.
3. Footwear assigned on foot posture (e.g. excessive pronation, neutral, supination). Traditional guidance from some health professionals recommend runners seek expert advice to select the most appropriate shoe for their foot posture (Asplund 2005). However, Richards 2009 stated that there may be no evidence to support the prescription of running footwear on foot posture.
4. Running distance (e.g. training distance per week). A previous systematic review reported that some lower-limb running injuries may be related to greater weekly training distances (Van Gent 2007). However, evidence also suggests that running distance can be a protective factor (Van Gent 2007), with suggestive thresholds of 30 km per training week for 21 km distance runners and 45 km per training week for 42 km distance runners (Besomi 2019).
5. Running terrain (e.g. treadmill, road).
6. Injury report and confirmation method (e.g. by a physician or healthcare professional or self-reported by the runner).
7. Sex: female runners may be more at risk of overall lower-limb running injuries, but these differences may not be apparent when considering specific types of injury, such as hamstring or calf injuries (Van Gent 2007).
8. Age: Van Gent 2007 reported conflicted evidence to suggest that older age is associated with an increase in running injuries. However, we used a provisional threshold of 40 years of age (Satterthwaite 1999).
9. Studies completed pre- and post-Yamato 2015 injury definition.
10. Body mass: increased body mass has been associated with increased risk of developing running-related injuries (Bertelsen 2018).

Sensitivity analysis

We set out the following a priori sensitivity analyses to assess whether the results of the review were robust to the decisions made during the review process based on the following approaches. Most, such as those for cluster-RCTs and mixed-population studies, were not applicable for this version of the review. Those carried out are reported in the Results.

1. Excluding studies that did not use intention-to-treat analysis
2. Excluded studies that did not provide a clear injury definition
3. Excluding studies at high or unclear risk of bias, primarily selection bias, detection bias and attrition bias
4. Excluding studies published in conference proceedings or abstracts only
5. Excluding studies with data that have not been systematically collected and have been poorly reported
6. Excluding studies where there are potential or known unit of analysis issues
7. Excluding mixed population studies
8. Excluding studies that do not describe the characteristics of the footwear using recognised criteria (Table 1; Ramsey 2019)
9. Excluding studies that report on specific types of injury (e.g. stress fractures) instead of overall running injuries
10. Adjusting for missing data
11. Using different ICCs (intraclass correlation coefficients) for adjusting the results of cluster-RCTs
12. Using fixed-effect versus random-effects models for pooling data

Summary of findings and assessment of the certainty of the evidence

We created a summary of findings table for each of our main comparisons, where data were available from more than a single study, using the following review outcomes where available: number of runners sustaining a lower-limb running injury, number of lower-limb running injuries; number of runners who failed to return to running or their previous level of running; runner satisfaction with footwear; and adverse effects.

We used the five GRADE criteria (study limitations, inconsistency of effect, imprecision, indirectness and publication bias) to downgrade our overall confidence in the strength of evidence that contributed to this outcome. We used methods and recommendations described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017) and performed grading using GRADEproGDT software (GRADEpro GDT). We also recorded justification for our assessment of the certainty of evidence for individual outcomes.

RESULTS

Description of studies

Results of the search

We screened a total of 2929 records from the following databases: Cochrane Central Register of Controlled Trials (367), MEDLINE (388), Embase (736), AMED (78), CINAHL Plus (515), SPORTDiscus (586), the WHO International Clinical Trials Registry Platform (97) and Clinicaltrials.gov (162). We handsearched The International Conference of Biomechanics in Sport (1983 to 2019) (781), The International Conference of Foot and Ankle Biomechanics (2008 to 2018) (398) and reference lists of included studies. We also handsearched Footwear Science (472), as it was not included in any of the databases. A total of 3567 records were screened following removal of duplicates. We excluded 3505 records based on titles and abstracts and obtained the full text for the remaining 62 records. Following scrutiny of full texts we excluded 38 records that did not meet the review inclusion criteria (see Characteristics of excluded studies). We identified one ongoing study (ACTRN12613000612718) and one study awaiting classification (Ryan 2019a).

Records pertaining to the same study were linked under a single study ID. We contacted three authors who confirmed that a number of abstracts were from the same studies reported in full papers (Fuller 2017a; Malisoux 2016b; Ryan 2014) and these were listed under the relevant study ID. Five records from clinical trial registries (e.g. clinicaltrials.gov) (Fuller 2017a; Malisoux 2020; Marshall 2013; Ryan 2011; Ryan 2014) and two trial protocols (Fuller 2017a; Malisoux 2020) were also listed under the relevant study ID. The main publication was selected as the primary reference for these studies. One author confirmed that data from an unpublished thesis (Marshall 2013) had not been submitted for publication.

Ultimately, we included 12 studies (22 records) all of which were reported in English. For a further summary, see the study flow diagram (Figure 1).

Figure 1. Study flow diagram.

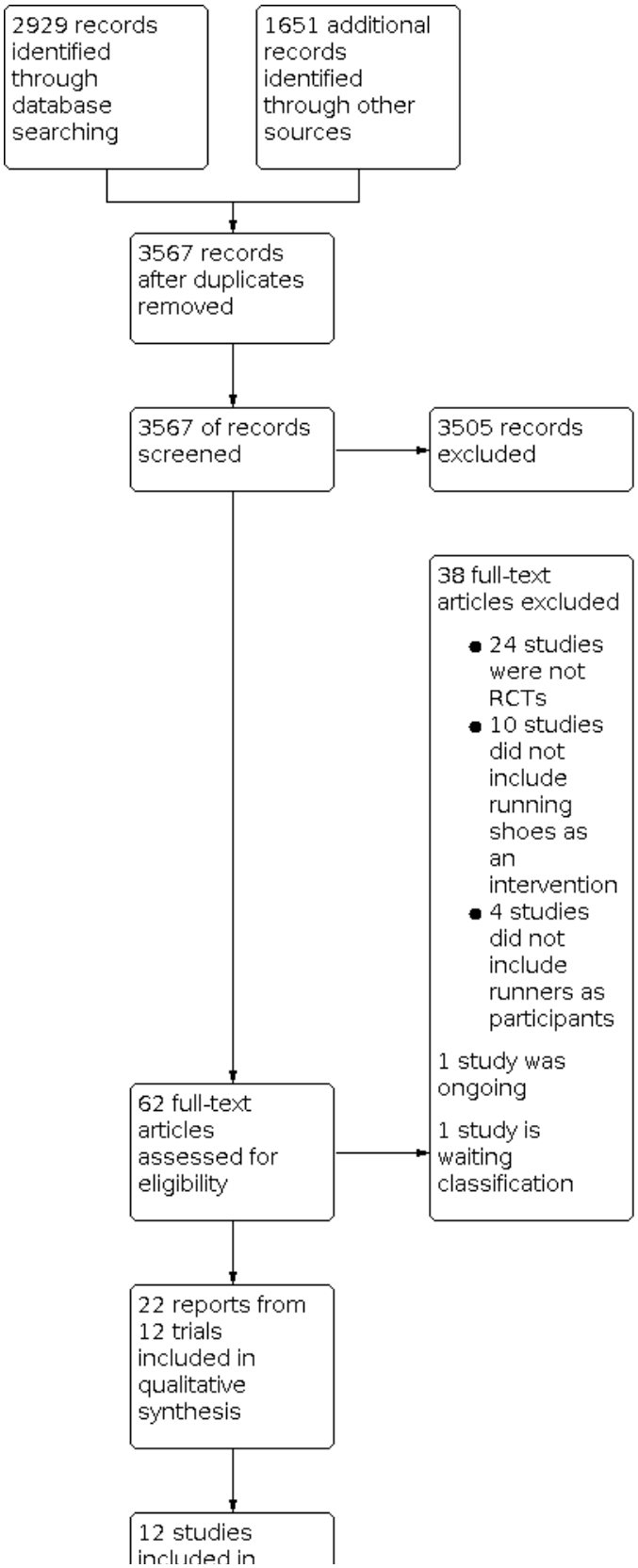
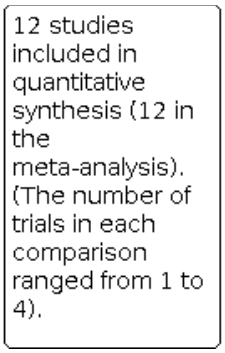


Figure 1. (Continued)



Included studies

We included 12 trials involving a total of 11,240 participants. Details of the individual trials are provided in Characteristics of included studies.

Trial design, size and setting

Seven studies were two-arm parallel-group randomised controlled trials (RCTs) comparing intervention versus control (Dubois 2015; Fuller 2017a; Knapik 2010b; Malisoux 2016b; Malisoux 2020; Marshall 2013; Theisen 2014) and two studies were two-arm parallel-group quasi-RCTs (Knapik 2009; Knapik 2010a). There were three three-armed parallel-group trials (Malisoux 2016a; Ryan 2011; Ryan 2014). Of the 12 trials, four trials attempted to blind participants to footwear manufacturer by concealing the brand (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014).

Participants were both the unit of randomisation and analysis in all trials. Ten of the trials used stratified randomisation based on: foot posture alone (Knapik 2009; Knapik 2010a; Knapik 2010b; Ryan 2011), training history and age (Marshall 2013), 5 km time trial (Fuller 2017a), minimalist shoe experience (Malisoux 2016a), sex (Malisoux 2020), age, sex, body mass index (BMI) and recent regular running practice (Theisen 2014) and age, BMI and foot posture (Malisoux 2016b). Stratification was not mentioned in the remaining two trials (Dubois 2015; Ryan 2014).

The median number of randomised participants was 299 (interquartile range (IQR) 103 to 874), ranging from 24 (Dubois 2015) to 3119 (Knapik 2009). We contacted one author who confirmed the trial sample size (Knapik 2010a). Seven studies reported sample size calculations. These were based on a change in running performance in Fuller 2017a, Malisoux 2016a, Malisoux 2016b and Malisoux 2020; on risk of a running injury in Theisen 2014 and Ryan 2011; and on a change in pain scores Ryan 2014.

Trials were conducted in either North America, Europe, Australia or South Africa. Eight trials were conducted exclusively in a single country; Canada (Dubois 2015; Ryan 2011; Ryan 2014) Australia (Fuller 2017a), USA (Knapik 2009; Knapik 2010a; Knapik 2010b) and South Africa (Marshall 2013). The remaining four trials were conducted in four bordering countries: Luxembourg, France, Belgium and Germany (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014).

Participants

A total of 11,240 runners were randomised in the included trials. Two trials included only male runners (Fuller 2017a; Marshall 2013) and one trial only female runners (Ryan 2011). Four trials only reported gender for participants who completed the study: 40% (800/2025) were female (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014). In the remaining five studies 33% (2867/8654) of randomised participants were female (Dubois 2015; Knapik 2009; Knapik 2010a; Knapik 2010b; Ryan 2014).

Participant ages were variously reported as means, medians or ranges. Eight trials reported mean ages separately for study groups, ranging from 29 to 41.8 years in the control groups and 26 to 41.8 years in the intervention groups (Dubois 2015; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013; Ryan 2011; Ryan 2014; Theisen 2014). One trial reported a mean age of 23 years for both men and women (Knapik 2009). Fuller 2017a reported an overall mean age of 27 years for all runners. Knapik 2010b reported the mean age by both study group and gender, ranging from 19.1 years for females and 20.7 years for males in the intervention groups. One trial did not report participants' age (Knapik 2010a).

Runners were not consistently defined in the included studies. Four trials described runners using a time or distance threshold: Dubois 2015 included recreational runners who could run continuously for 20 minutes; Fuller 2017a included distance runners who could cover 5 km in less than 23 minutes; Marshall 2013 included endurance runners who ran 40 to 60 km a week and Ryan 2011 included runners who could run continuously for 60 minutes. Four trials described participants as leisure or recreational runners regardless of fitness level, experience and/or body mass (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014). Two trials included runners enrolled on training programmes leading to a competitive event; either a 10 km (Ryan 2014) or half marathon (Ryan 2011). Ryan 2014 used more detailed criteria, including greater than five years running experience, being able to run continuously for 60 minutes and able to tolerate 20 to 40 km per week. Three trials involved military personnel who were in basic combat training including army recruits on a nine-week course (Knapik 2009), air force recruits on a six-week course (Knapik 2010a) and marine recruits on a 12-week course (Knapik 2010b).

Where available, inclusion/exclusion criteria for each trial are reported in Characteristics of included studies.

Interventions

Duration of the intervention was six weeks (Knapik 2010a), nine weeks (Knapik 2009), 12 weeks (Knapik 2010b; Marshall 2013; Ryan 2014), 13 weeks (Ryan 2011), 16 weeks (Dubois 2015), five months (Theisen 2014), six months (Malisoux 2016a; Malisoux 2016b; Malisoux 2020) and 26 weeks (Fuller 2017a). In addition, Fuller 2017a and Ryan 2011 included a six-week and one-week familiarisation period for allocated shoes, respectively.

No trials compared a running shoe with a non-running shoe.

Nine trials compared one type of running shoe with another type of running shoe. Of these, five trials compared neutral/cushioned running shoes with minimalist running shoes (Dubois 2015; Fuller 2017a; Malisoux 2016a; Marshall 2013; Ryan 2014). Furthermore, Malisoux 2016a and Ryan 2014 compared neutral/cushioned shoes to two different types of minimalist shoe, with minimalist versus minimalist comparisons also reported within these studies. Two trials compared motion-control running shoes with neutral/cushioned running shoes (Malisoux 2016b; Ryan 2011). Two trials described and compared running shoes as soft versus hard (Malisoux 2020; Theisen 2014). The soft running shoes in these papers had a more compliant midsoles and the hard had stiffer midsoles. One trial compared stability running shoes with neutral/cushioned running shoes and motion-control running shoes with stability running shoes (Ryan 2011). Therefore, Ryan 2011 compared neutral/cushioned, stability and motion-control shoes in their trial.

Three trials involving military personnel compared prescribed running shoes based on foot posture (intervention) versus non-prescribed running shoes (control). They included three types of running shoes; motion control, stability and neutral/cushioned, prescribed to each participant based on plantar shape measurements, high arched, normal arched or low arched (Knapik 2009; Knapik 2010a; Knapik 2010b).

Details of running shoes included in each trial are in Table 2.

Outcomes

All but one trial collected injury data at the point the injury was reported by the runner, throughout the duration of the intervention and then reported total number of runners injured by the end of the intervention. Ryan 2014 collected injury data at 2, 4, 8 and 12 weeks intervals: in this trial, the total number of injuries at the end of the intervention was included in the meta-analysis.

Two trials included all injury data from runners who were randomised and allocated footwear in their final analysis and hence completed true intention-to-treat (ITT) analysis (Dubois 2015; Fuller 2017a). Knapik 2010a reported that participants who failed to complete the military training programme were excluded from the analysis, but it was unclear if the allocated running shoes were the reason for this failure. It was also unclear if the participants not involved in the final analysis due to loss to follow-up was due to shoe allocation in the study by Knapik 2010b. Runners reported dropout reasons not related to the shoe and were not included in the analysis in two trials (Marshall 2013; Ryan 2014). Four trials included those runners who were censored for severe disease and an injury unrelated to running in their final analysis, but not those runners lost to follow-up (Malisoux 2016a; Malisoux 2016b; Malisoux 2020;Theisen 2014). Five trials stated some of the dropout or exclusion reasons were related to the running shoe, but did not include all participants who were randomised in their analysis (Knapik 2009, Malisoux 2016a, Malisoux 2016b; Ryan 2011, Theisen 2014).

Eight trials reported the number of runners sustaining a lower-limb running injury, one of our primary outcomes, (Dubois 2015; Fuller 2017a; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013; Ryan 2014; Theisen 2014). One trial reported the number of runners reporting a missed training day due to running-related pain (Ryan 2011) and for the purpose of the review this was assumed consequent to a running injury.

Three trials (Knapik 2009; Knapik 2010a; Knapik 2010b) reported injuries based on type of activity; for this review we have used the reported Training Injury Index, which is the number of lower extremity injuries per 1000 person-days as the most appropriate measure of running exposure. The following measures were also reported in the trials: the Installation Injury Index based on total time in military training; a modified Installation Injury Index used to capture a broader range of injuries than the Installation Injury Index; the Overuse Injury Index based on the number of musculoskeletal injuries from cumulative micro-trauma; and the Comprehensive Injury Index, that included all International Statistical Classification of Diseases and Related Health Problems (ICD) 9 codes (Knapik 2009; Knapik 2010a; Knapik 2010b).

Methods of injury diagnosis and reporting varied between studies (see Characteristics of included studies for details). Nine trials used self-reported diary cards (Dubois 2015; Fuller 2017a; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013; Ryan 2011; Ryan 2014; Theisen 2014), but this was confirmed by an appropriately qualified professional in only one trial (Dubois 2015). One of these trials also collected outcome data following a weekly group run (Ryan 2011). In three trials, injuries were confirmed by a military treatment facility, but it was unclear whether this was by a trained professional (Knapik 2009; Knapik 2010a; Knapik 2010b). The anatomical location of the injury was reported in eight trials (Dubois 2015; Fuller 2017a; Knapik 2010b; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013, Theisen 2014). Malisoux 2016a; Malisoux 2016b Malisoux 2020 and Theisen 2014 also reported the category (acute or overuse), type and severity of the injury (based on the number of days injured).

One trial (Dubois 2015), reported runner satisfaction with running shoe using a yes/no question: "Were you satisfied with your footwear?". Another trial reported shoe satisfaction using a scale from 1 (very dissatisfied) to 5 (very satisfied) at 0, 4, 8 and 12 weeks (Marshall 2013).

No trials reported the following outcomes: the number of runners who failed to return to running/previous level of running; adverse events; number of runners requiring hospital admission, surgery or both for musculoskeletal injury or adverse event; economic or resource outcomes.

Potential conflicts of interest

Five studies reported potential conflicts of interest. Four studies received trial funding from running shoe manufacturers (Decathlon and Nike) (Malisoux 2016a; Malisoux 2016b; Ryan 2011; Ryan 2014, and one study author received funding from ASICS to undertake a separate study (Fuller 2017a). Furthermore, in three studies one

author was an employee of the same running shoe company that funded the trial (Malisoux 2016a; Malisoux 2016b; Ryan 2011).

Excluded studies

We excluded 38 studies that did not meet the review selection criteria (see Excluded studies and Characteristics of excluded studies) for the following reasons.

Twenty-two studies were not RCTs or quasi-RCTs (Archer 2019; Andréasson 1986; Attwells 2000; Atukorala 2017; Begizew 2019; Bejjani 1987; Brund 2017; Conrad 1975; Grier 2016; Hamill 2017; Hein 2011; Johnson 1995; Kirby 2019; Korsgaard Brund 2019; Marti 1989; NCT03636425; NCT03867890; Nielsen 2014; Powell 2011; Robinson 1991 Stubbs 2006; Taunton 2003). In 10 studies the intervention was not a running shoe (Bendix 1985; Finestone 1992; Kemler 2018; Milgrom 1992; NCT03311490; NCT02987517; NCT02567123; NCT04363476; CTRI/2019/08/020567; NCT01332110). The participants in four studies did not include runners (Bishop 2018; Frecklington 2019; NCT03760380; Ryan 2019b).

Ongoing studies

One trial is ongoing (ACTRN12613000612718) and is detailed in the Characteristics of ongoing studies section. This trial plans to compare motion control running shoe with a minimalist running shoe. Outcomes will include running injuries and shoe comfort. It is unclear when this trial is due to be completed; however, correspondence with the principal investigator confirmed this trial is ongoing.

Studies awaiting classification

One trial is awaiting classification (Ryan 2019a) and is detailed in the Characteristics of studies awaiting classification section. This trial has been reported as an incomplete abstract this far. There are differences between the trial registration document, which plans a four-armed trial, and the data reported in the abstract, a three-armed trial. We contacted the investigators of this study reported only as a conference abstract to obtain further details, and it was confirmed a full report was not yet available. Therefore, this trial awaits classification when the full report does become available.

Risk of bias in included studies

Full details of the risk of bias judgements are in the risk of bias section at the end of each Characteristics of included studies table. A summary of the risk of bias of all included studies are in Figure 2 and Figure 3. Three independent review authors (NR, RA and SS) independently assessed the risk of bias for each of the included studies and reached agreement.

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

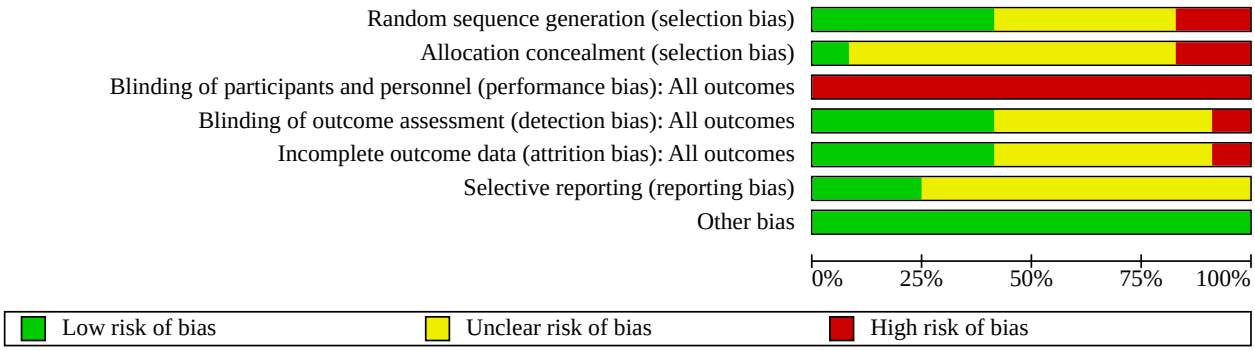
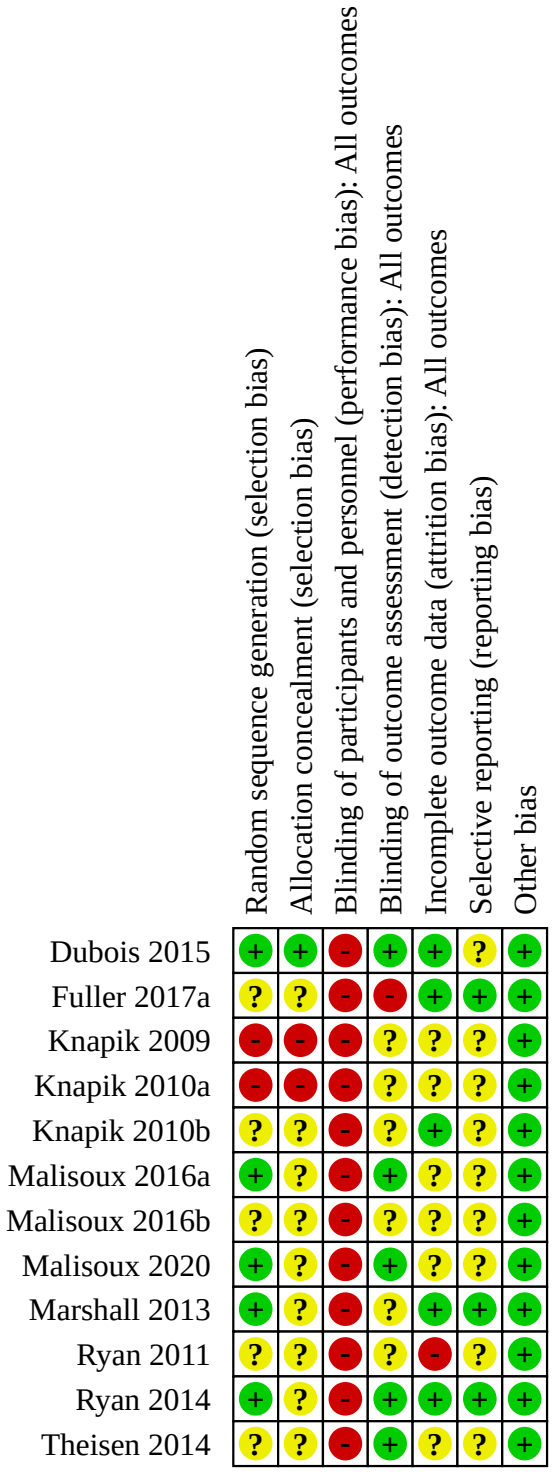


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Random sequence generation

We judged five studies to be at low risk of bias for random sequence generation as they described random number generator (Dubois 2015), prepared by a statistician (Malisoux 2020), coin toss (Marshall 2013) computer generated (Ryan 2014) and process of minimisation (Malisoux 2016a). Methods used to generate the randomisation sequence were judged as unclear in four trials Fuller 2017a; Malisoux 2016b; Ryan 2011; Theisen 2014. We judged the risk of this selection bias to be high in the two remaining trials as sequence generation was described as sequential order of study entry (Knapik 2009; Knapik 2010a).

The randomisation of participants has resulted in an unclear risk of bias regarding baseline characteristics in two studies (Knapik 2010b; Ryan 2011). Although we noted that Knapik 2010b used an appropriate method to generate randomisation sequences, we judged Knapik 2010b to be at unclear risk of selection bias for sequence generation because we noted that there were more men in the intervention group with prior lower-limb injuries than the control group; previous injury is a strong predictor of a new injury (Fulton 2014), and this difference may therefore influence the intervention effect. Additionally, there were significant differences in weight, body mass index (BMI) and running experience at baseline in Ryan 2011. Again, these factors are thought to influence the risk of injury in runners and hence was deemed a potential risk of bias (Van Gent 2007).

Allocation concealment

We judged the methods of concealing the allocation of participants to study groups as low risk of bias in one trial that used sealed numbered envelopes (Dubois 2015). Allocation concealment was unclear in nine trials (Fuller 2017a; Knapik 2010b; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013; Ryan 2011; Ryan 2014; Theisen 2014). Methods of concealment allocation were deemed high in the two quasi-RCTs as allocation may be predictable (Knapik 2009; Knapik 2010a). However, it should be noted that four trials stated that allocation of running shoe was completed by someone not involved in data collection (Fuller 2017a; Malisoux 2016a; Malisoux 2020; Theisen 2014).

Blinding

Blinding of participants and personnel (performance bias)

All 12 trials were judged at high risk of performance bias as participants were not blinded to the running shoe interventions, though we acknowledge that blinding was not possible. We also acknowledge that four trials attempted to blind runners to their allocated running shoe by concealing the brand of the shoe (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014). However, as the effectiveness of this concealment was not directly reported in these four studies, we still judged these studies as high risk of bias.

Blinding of outcome assessment (detection bias)

We judged the risk of detection bias to be low in five trials (Dubois 2015; Malisoux 2016a; Malisoux 2020; Ryan 2014; Theisen 2014) as outcome assessors were blinded to group allocation. However in six trials (Knapik 2009; Knapik 2010a; Knapik 2010b; Malisoux 2016b; Marshall 2013; Ryan 2011;) this risk was unclear as insufficient detail was provided in the methods to determine outcome assessor blinding. Blinding of outcome assessment was not completed in one study (Fuller 2017a) and hence this was judged to be high risk.

Incomplete outcome data

Five trials were judged to be at low risk of attrition bias (Dubois 2015; Fuller 2017a; Knapik 2010b; Marshall 2013; Ryan 2014) as these trials reported the reasons for dropout and these were not related to the allocated running shoe. In six trials the risk of attrition bias was unclear (Knapik 2009; Knapik 2010a; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014), as it was not possible to ascertain whether study dropout was related to the running shoe. One trial stated that two runners dropped out of the trial as the running shoes were uncomfortable or poor fitting and these runners were not included in the final analysis, it was unclear which running shoes these runners had been allocated (Ryan 2011). A further eight runners withdrew from the allocated running shoes (four from the neutral/cushioned shoes, two from the stability shoes and two from the motion control shoes), and continued in the trial with their own running shoes, although further reasons and analyses were not provided (Ryan 2011). Hence this trial was deemed at high risk of attrition bias.

Selective reporting

Three trials were judged to be at low risk of reporting bias as prospective study protocols (Fuller 2017a) or trial registrations (Marshall 2013; Ryan 2014) were available and all outcomes were reported as pre-specified. In one trial (Malisoux 2020), a trial protocol was available, and all injury outcomes are reported. However, biomechanical measures stated in the protocol are missing from published trial and so we deemed this risk to be unclear. In the remaining trials the risk of reporting bias was unclear (Dubois 2015; Knapik 2009; Knapik 2010a; Knapik 2010b; Malisoux 2016a; Malisoux 2016b; Ryan 2011; Theisen 2014) as trial protocols were unavailable.

Other potential sources of bias

We identified no other sources of bias in any of the included studies.

Effects of interventions

See: **Summary of findings 1** Neutral / cushioned versus minimalist running shoes for preventing lower-limb running injuries in adults; **Summary of findings 2** Motion control versus neutral / cushioned running shoes for preventing lower-limb running injuries in adults; **Summary of findings 3** Soft versus hard running shoes for preventing lower-limb running injuries in adults; **Summary of findings 4** Running shoes recommended and selected on foot posture versus running shoes not recommended and selected on foot posture for preventing lower-limb running injuries in adults

Here we present data for different comparisons. In order to provide more information to the reader, we report the direction of effect with each effect estimate (e.g. favours neutral/cushioned shoe). However, describing the direction of effect is not intended to infer that one shoe type is statistically better than another.

Running shoes versus non-running shoes.

We did not find any trials that compared running shoes with non-running shoes.

Different types of running shoes

Nine trials compared one type of running shoe with another type of running shoe (Dubois 2015;Fuller 2017a; Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Marshall 2013; Ryan 2011; Ryan 2014; Theisen 2014). There was a total of five shoe comparisons. For these comparisons, we nominated the control group as the shoe with the least features thought to influence lower-limb function (see Table 1 and Table 2). One trial appears in three comparisons (Ryan 2011). See Summary of findings 1; Summary of findings 2; Summary of findings 3.

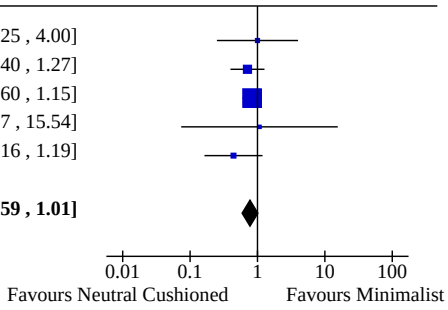
Neutral/cushioned running shoes versus minimalist running shoes

Five trials, with a total of 766 participants, compared neutral / cushioned running shoes (intervention) with minimalist running shoes (control) and were included in a meta-analysis (Dubois 2015; Fuller 2017a; Malisoux 2016b; Marshall 2013; Ryan 2014). Two trials included two different types of minimalist running shoe and the data for these shoe types was combined in analysis for the minimalist shoe group (Malisoux 2016a; Ryan 2014). Pooled data showed no significant difference in the number of runners sustaining lower-limb running injuries between the two comparison groups (risk ratio (RR) 0.77, 95% confidence interval (CI) 0.59 to 1.01; favours neutral/cushioned shoe; P = 0.06; I^2 = 0%; Analysis 1.1; Figure 4). The certainty of the evidence was rated as low for this comparison due to serious risk of bias and the wide confidence interval crossing the line of no effect.

Figure 4. Forest plot of comparison: 1 Neutral / cushioned versus minimalist, outcome: 1.1 Number of runners injured.

Study or Subgroup	Neutral Cushioned Events	Neutral Cushioned Total	Minimalist Events	Minimalist Total	Weight	Risk Ratio IV, Random, 95% CI
Dubois 2015	3	12	3	12	3.8%	1.00 [0.25 , 4.00]
Fuller 2017a	11	30	16	31	21.4%	0.71 [0.40 , 1.27]
Malisoux 2016a (1)	38	176	98	377	66.6%	0.83 [0.60 , 1.15]
Marshall 2013	1	14	1	15	1.0%	1.07 [0.07 , 15.54]
Ryan 2014 (2)	4	32	19	67	7.3%	0.44 [0.16 , 1.19]
Total (95% CI)		**264**		**502**	**100.0%**	**0.77 [0.59 , 1.01]**
Total events:	57		137			

Heterogeneity: Tau² = 0.00; Chi² = 1.68, df = 4 (P = 0.79); I² = 0%
Test for overall effect: Z = 1.87 (P = 0.06)
Test for subgroup differences: Not applicable



Footnotes

(1) 1 Malisoux 2016a had two minimalist (control) groups, and one neutral/cushioned (intervention) group. The data for the two minimalist (control) groups l
(2) 2 Ryan 2014 had two minimalist (control) groups, and one neutral/cushioned (intervention) group. The data for the two minimalist (control) groups has be

The details of the reported injuries, where available, are provided in Table 3. To note, only three studies reported the location of the injury. Six of the included injuries were reported in the lower back/ pelvis region. Only one study reported the type of injury, with 90% of 136 injuries in this paper being overuse (defined as "progressive" in Malisoux 2016a). The first reported injuries were counted in the studies. There was inconsistency in the definition of a running-related injury. In Dubois 2015, the definition was unclear; however, if runners reported pain, this was followed up by a sports medicine physician blinded to the assigned group. Fuller 2017a, defined this as quote: "any musculoskeletal problem severe enough to cause a visit to a health professional, use of medication, or reduced weekly training". Malisoux 2016a's, definition was quote: "any physical pain located at the lower limbs or lower-back region, sustained during or as a result of running practice and impeding planned running activity for at least 1 day (time loss definition)". Marshall 2013, defined this as quote: "any reported muscle, joint or bone problem/ injury of lower limb resulting from running training that required the runner to miss at least one training day or a training session". Ryan 2014, defined this as quote: "three consecutive missed run work-outs secondary to running-related pain". The variation in injury definitions between studies may have resulted in injuries to parts of the body other than the lower limb being included within the analysis.

No trials reported number of lower-limb injuries. The number of runners who failed to return to their previous level of running was not reported. Adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

Running shoe satisfaction was reported by two trials. Dubois 2015, reported 67% (8/12) and 92% (11/12) of runners were satisfied with their neutral/cushioned or minimalist running shoes, respectively using a dichotomous question. However, there were no significant differences in the number of runners who were satisfied with their running shoe between the two groups (RR 0.73, 95% CI 0.47 to 1.12; P = 0.15, 1 study, 24 participants; low-certainty evidence; Analysis 1.2). Marshall 2013, reported mean satisfaction scores from 1 (very dissatisfied) to 5 (very satisfied) at 0, 4, 8 and 12 weeks. Average scores ranged from 4.0 to 4.3 in the neutral/cushioned group and 3.6 to 3.9 in the minimalist running shoe group and these were reported in the trial as not statistically significantly different (P > 0.05; exact values not reported by study authors). The certainty of the evidence was rated as low for this comparison due to serious

risk of bias (lack of blinding) and imprecision due to small number of runners.

Motion control running shoes versus neutral / cushioned running shoes

Pooled data from two studies (Malisoux 2016b; Ryan 2011) reported no significant reduction in the number of runners sustaining lower-limb running injuries when comparing motion control running shoes (intervention) with neutral/cushioned running shoes (control) (RR 0.92, 95% CI 0.30 to 2.81; favours motion control shoe; P = 0.89, I^2 = 88%; 2 studies, 421 participants; Analysis 2.1). The certainty of the evidence was rated as very low for this comparison due to serious risk of bias, wide confidence interval crossing the line of no effect and imprecision due to the injury definition used within one trial providing an indirect assessment of injury (Ryan 2011). We also downgraded the certainty of the evidence because there was a high level of heterogeneity that is likely explained by the differences in injury definitions and specific footwear assessed between the two trials; there were too few trials to test this using subgroup analysis.

The details of the reported injuries, where available, are provided in Table 3. To note, the majority of injuries were lower-limb injuries. Two of the included injuries were in the lower back/pelvis region. One study reported 72 injuries as overuse (defined as "progressive" in Malisoux 2016b) injuries. The first reported injury were counted in the studies. Malisoux 2016b defined an injury as quote: "any physical pain located at the lower limbs or lower-back region, sustained during or as a result of running practice, and impeding planned running activity for at least 1 day (time-loss definition)". The other trial Ryan 2011 defined a running-related injury (RRI) as quote: "a missed training day due to running-related pain". Again, the injury definitions open the possibility that some of the reported injuries were in locations other than the lower limb.

Neither trial reported total number of lower-limb injuries. The number of runners who failed to return to their previous level of running was not reported. However, Malisoux 2016b reported that 21 injuries, or 18% of all injuries in this analysis, required more than 28 days away from running. Running shoe satisfaction, adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

Soft running shoes versus hard running shoes

Two trials, with a total of 1095 participants, compared soft running shoes which had more compliant midsoles (intervention) with hard running shoes with stiffer midsoles (control) (Malisoux 2020; Theisen 2014). Pooled data showed no significant difference in the number of runners sustaining lower-limb running injuries between the two comparison groups (RR 0.82, 95% CI 0.61 to 1.10; favours soft midsole shoe; P = 0.18; I^2 = 27%, Analysis 3.1). The certainty of the evidence was rated as low for this comparison due to serious risk of bias and the wide confidence interval crossing the line of no effect.

The details of the reported injuries, where available, are provided in Table 3. However, to note, The majority of injuries (94.4% of 197) were lower-limb injuries and overuse (defined as "progressive" in Malisoux 2020) injuries (79%). One included injury was in the shoulder/collarbone, one in the head/ neck, seven in the trunk and two in the lower back region. Thus, not all included injuries were to the lower limbs. The first reported injury was counted in the studies. However, Malisoux 2020 defined this as quote: "running-related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least seven days or three consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional first injury only". The other trial, Theisen 2014, defined a running-related injury (RRI) as quote: "physical pain or a complaint sustained during or as a result of running practice and impeding normal running activity for at least 1 day (time-loss definition)".

No trials reported total number of lower-limb injuries. The number of runners who failed to return to their previous level of running was not reported; however, of note is that 69 (35% of 197) of injuries were severe enough to require taking over 28 days off from running. Running shoe satisfaction, adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

Stability running shoes versus neutral/cushioned running shoes

Data from one study, which included 57 participants, compared the influence of stability running shoes (intervention) to neutral/ cushioned running shoes (control) (Ryan 2011). No significant difference in the number of runners injured were reported between conditions (RR 0.49, 95% CI 0.18 to 1.31; favours stability; P = 0.36; Analysis 4.1). The certainty of the evidence was rated as very low for this comparison due to serious risk of bias and the limited number of studies within this comparison.

No details of the injures were provided. The first reported injury was counted in this study. Ryan 2011, did not report total number of lower-limb injuries. The number of runners who failed to return to their previous level of running, running shoe satisfaction, adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

Motion control running shoes versus stability running shoes

Data from one study, which included 56 participants, compared the influence of motion control running shoes (intervention) to stability running shoes (control) (Ryan 2011). A significant reduction in the number of runners injured in the stability running shoe was reported (RR 3.47, 95% CI 1.43 to 8.40; favours stability; P = 0.006; Analysis 5.1). The certainty of the evidence was rated as very low for this comparison due to serious risk of bias and the limited number of studies within this comparison.

No details of the injuries or total number of injuries were reported (Ryan 2011) . The number of runners who failed to return to their previous level of running, running shoe satisfaction, adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

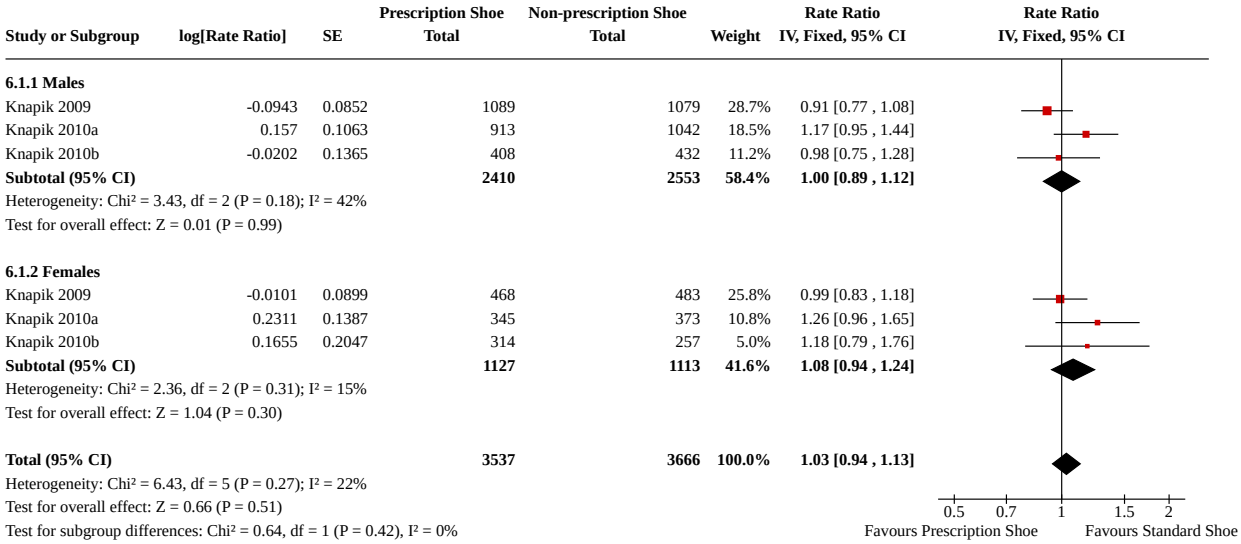
Prescribed running shoes based on foot posture versus non-prescribed running shoes.

Three trials compared prescribed running shoes based on foot posture (intervention) versus non-prescribed running shoes (control) using injury incidence rates (Knapik 2009; Knapik 2010a; Knapik 2010b). These trials included 7203 military personal. Injury incidence rates were presented as person-time injury incidence rates (injured subjects per 1000 person-days) and calculated as

(subjects with ≥1 injury) / (total time in Basic Combat Training x 1000). See Summary of findings 4 for an overview of the findings.

These trials reported female and male injury data separately. These analyses found no significant differences in injury rates for males (rate ratio 1.00, 95% CI 0.89 to 1.12; P = 0.99, I^2 = 42%; Analysis 6.1, Figure 5). This finding was repeated in females (rate ratio 1.08, 95% CI 0.94 to 1.24; P = 0.30; I^2 = 15%). Pooled data from males and females, with a total of 7203 participants, again revealed no significant reduction in risk of a lower-limb running injury comparing prescription to non-prescription running shoes (rate ratio 1.03, 95% CI 0.94 to 1.13; favours non-prescribed shoe; P = 0.51, I^2 = 22%). The certainty of the evidence was rated as moderate for this comparison due to serious risk of bias.

Figure 5. Forest plot of comparison: 6 Prescribed Running Shoes versus Non-prescribed running shoes, outcome: 6.1 Rate Ratios of Injuries.



The first four diagnoses of an injury were considered for inclusion in the data, although the authors state that "a single visit usually included only one diagnosis". Injury details were provided in one trial only (Knapik 2010b). The 10 most common ICD-9-CM codes in men were enthesopathy of the knee, other sprains/strains, sprains/strains of ankle and foot, sprains/strains of knee and leg, internal derangement of knee, superficial injury of other, multiple and unspecified sites, sprains/strains of unspecified back sites, pain in lower leg, sprains/strains of shoulder/upper arm and sprains/strains of hip/thigh. In women, the top 10 were pain in limb, superficial injury of other, multiple and unspecified sites, pain in lower leg, pain in pelvic region and thigh, superficial injury of other, sprains/strains of ankle and foot, pain in ankle and foot, pain in shoulder region, sprains/strains in unspecified sites, superficial injury of other, multiple and unspecified sites, plantar fascial fibromatosis. The ICD-9-CM codes highlight again that not all injuries reported and included were within the lower limbs.

No trials reported total number of lower-limb injuries as an absolute figure. The number of runners who failed to return to their previous level of running, running shoe satisfaction, adverse events, hospital admissions and economic and resource outcomes were also not reported in this comparison.

Subgroup analysis

Due to the limited number of studies in each comparison (maximum of five) we did not perform subgroup analyses. However, some trials did report subgroup data, which we report under the appropriate comparison.

Neutral/cushioned running shoes versus minimalist running shoes

Malisoux 2016a reported occasional runners (< 6 months of regular practice over the previous 12 months) using minimalist shoes had a lower rate of injuries (hazard ratio (HR) 0.48, 95% CI, 0.23 to 0.98) than regular runners (≥ 6 months of regular practice over the previous 12 months) (HR 1.67, 95% CI, 1.07 to 2.62) in the same shoes. Fuller 2017a considered weekly training distance and body mass subgroups. Training distance did not effect injury in the shoe groups (HR 1.05, 95% CI 0.99 to 1.11). However, a body mass of greater than 71.4 kg and less than 71.4 kg increased the risk and decreased the risk of injury in runners wearing minimalist shoes, respectively (HR = 0 at this body mass). Ryan 2014 compared pain location subgroups for each type of shoe, out of five pain locations, only one at the shin/calf was significantly greater in the full minimalist shoe compared with the partial minimalist and neutral/cushioned shoes (P < 0.01).

Motion control running shoes versus neutral/cushioned running shoes

Malisoux 2016b compared foot types in subgroup analysis. Runners with pronated feet who had been allocated motion control shoes (which follows traditional shoe prescription advice) had lower injury rates than those with neutral feet who has been allocated neutral / cushioned shoes (HR 0.34, 95% CI, 0.13 to 0.84). Furthermore, in the group allocated neutral / cushioned shoes, runners with pronated feet had a higher injury rate than runners with neutral feet (HR 1.80, 95% CI, 1.01 to 3.22). This supports the allocation of pronated feet to motion control shoes. Ryan 2011 also

compared foot types in subgroup analysis but using pain scores as the outcome. Runners with neutral foot types allocated motion control shoes (not following tradition shoe prescription advice) reported significantly greater pain scores than runners with neutral feet allocated stability or neutral / cushioned shoes (P<0.05). Contradictory to Malisoux 2016b, Ryan 2011 also reported runners with pronated foot types allocated motion control shoes had significantly greater pain than runners wearing neutral / cushioned or stability shoes (P < 0.05). However, there were no significant main effects for runners with highly pronated foot type (Ryan 2011) (P > 0.05).

Soft midsole running shoes versus hard midsole running shoes

Malisoux 2020 also compared body mass in subgroup analyses and reported that injury risk was higher in "light" runners (less than the median body mass) using the hard midsole shoes compared with soft midsole shoes (SHR 1,80, 95% CI 1.09 to 2.98). There were no significant differences in the "heavy" runners (greater than the median body mass) (SH 1.23, 95% CI, 0.75 to 2.03). However, Theisen 2014 did not find any subgroup effects for body mass when comparing soft midsole with hard midsole shoes (HR 0.94, 95% CI, 0.35 to 2.50).

Prescribed running shoes based on foot posture versus non-prescribed running shoes.

The test for subgroup differences between male and females showed no significant differences (Chi^2 = 0.64, df = 1 (P = 0.42), I^2 = 0%). The three trials also included subgroup analysis of foot type. Knapik 2009 reported men with high arches prescribed neutral/ cushioned shoes had a higher risk of injury than men with normal arches prescribed stability shoes (HR 1.34, 955 CI, 1.04 to 1.72), but no other effects for foot type were found. Knapik 2010a also reported no significant subgroup effects for foot type and shoe allocation except for men with low arches who were prescribed motion control shoes compared with normal arch foot types wearing stability shoes (HR 1.39, 95% CI, 1.02 to 1.43). Similarly, Knapik 2010b did not find any effects of foot type and shoe on injury in their subgroup analyses.

Sensitivity analysis

Sensitivity analysis was limited by the number of studies in each shoe comparison. Specifically, we were unable to perform any of the listed sensitivity analysis in analyses Analysis 1.2, Analysis 2.1, Analysis 3.1, Analysis 4.1, Analysis 5.1 and Analysis 6.1 due to each containing only one or two trials each. Furthermore, we felt that data that were missing were adequately explained in each of the included studies. For example, three papers used an intention-to-treat analysis (Dubois 2015; Fuller 2017a; Ryan 2014), four studies censored runners who stopped reporting for reasons other than running-related injuries (Malisoux 2016a; Malisoux 2016b; Malisoux 2020; Theisen 2014) and other trials had very few runners lost to follow up (Marshall 2013; Ryan 2011). However, we did conduct four sensitivity analyses in the neutral / cushioned versus minimalist running shoe comparison.

Neutral / cushioned running shoes versus minimalist running shoes

We did consider the influence of including studies that did not include an intention to treat analysis in comparison neutral / cushioned versus minimalist shoes Analysis 1.1. Two of the five included trials did not use a true intention to treat analysis as not all runners who were randomised were included in the final analysis (Malisoux 2016a; Marshall 2013). One these two studies were removed from the analysis, the effect of the intervention remained the same, that is not significant (RR 0.67, 95% CI 0.42 to 1.07; P = 0.09, 184 participants, 3 studies, I^2 = 0%). In the same comparison we also considered the influence of included a trial that did not provide a clear injury definition (Dubois 2015). Once removed from Analysis 1.1, the effect of the intervention again remained unchanged (RR 0.77, 95% CI 0.58 to 1.01; P=0.06, 742 participants, 4 studies, I^2 = 0%). One study was at a high risk of performance and detection bias, and an unclear risk of selection bias but was included in the final analysis (Fuller 2017a; Analysis 1.1). Again, removing this trial did not change the effect of the intervention (RR 0.79, 95% CI 0.59 to 1.07; P = 0.13, 705 participants, 4 studies, I^2 = 0%). Finally, we explored the influence of using a fixed-effect model rather than a random-effects model but the heterogeneity (I^2 = 0%) and main effects reported remained consistent (RR 0.77, 95% CI 0.59 to 1.01; P = 0.06).

DISCUSSION

Summary of main results

A total of 12 trials exploring the influence of type of running shoes on frequency of running injuries were included in the review. We had planned to focus on lower-limb running-related injuries. However, all comparisons included within the review include some studies with injury definitions broad enough to have resulted in injuries or pain to other locations (back or upper limbs) to be included within the data sets analysed. Participants were either non-professional (defined as leisure, recreational, distance or endurance) runners (2761 participants across nine studies), or military personnel (7203 participants across three studies). The trials included motion control, stability, neutral/ cushioned and minimalist running shoes (or variants of minimalist shoes). Non-conventional prototype running shoes were also included, comparing soft and hard midsole running shoes. We included the following comparisons between conventional types of running shoes; neutral / cushioned vs. minimalist, motion control vs. neutral/ cushioned, motion control versus stability, stability versus neutral/cushioned and bespoke soft versus hard midsole running shoes. We also included comparisons of running shoes recommended based upon foot posture or not, and varying footwear depending upon the type of workout being undertaken or not. The main findings related to each comparison are detailed below. We had initially aimed to compare running shoes with non-running shoes, but no evidence was available for this planned comparison. Furthermore, the original aim was to compare only lower-limb running-related injuries.

Different types of running shoes

We found low-certainty evidence from five studies, on non-professional runners, that there is little to no difference in the number of runners developing lower-limb running-related injuries when comparing neutral/cushioned and minimalist running shoes (Summary of findings 1). Low-certainty evidence was provided from a single study which suggested no difference in running shoe satisfaction when comparing between neutral/cushioned and minimalist running shoes (Summary of findings 1).

We found very low-certainty evidence which suggested no difference in the number of non-professional runners who developed lower-limb related running injuries when comparing motion control and neutral/cushioned running shoes across two studies (Summary of findings 2).

We found low-certainty evidence which suggested no difference in the number of non-professional runners who developed lower-limb related running injuries when comparing hard and soft midsole running shoes across two studies (Summary of findings 3).

A single study reported very low-certainty evidence of no difference in the number of non-professional runners developing running-related pain when comparing stability and neutral/cushioned running shoes (Ryan 2011).

The same study also reported very low-certainty evidence that motion control running shoes reduce the number of runners developing running-related pain compared to stability running shoes (Ryan 2011). It is important to note that this study utilised training sessions lost due to pain as a measure of injury, had a relatively small sample size and utilised a single shoe within each category assessed.

Prescribed running shoes based on foot posture versus non-prescribed running shoes

We found moderate-certainty evidence from three studies within military populations that running injury incidence rates did not differ when running shoes were prescribed based upon foot posture or not (Summary of findings 4; Figure 5). These group level findings were supported by subgroup analysis exploring the influence of prescribed and non-prescribed footwear based upon sex.

Overall completeness and applicability of evidence

The findings of this review need to be interpreted in light of the limitations in the available evidence and variations primarily in the participant cohorts and footwear interventions assessed.

The number of trials included within each comparison is typically low (one to three trials), with the exception of the comparison of neutral/cushioned and minimalistic running shoes (five trials) (Summary of findings 1). Furthermore, a number of the studies (Dubois 2015; Fuller 2017a; Marshall 2013; Ryan 2014), appear to lack sufficiently large sample sizes to achieve the desired level of statistical power based upon the power calculations reported in Malisoux 2020. These factors combined result in a lack of data for most comparisons, which in turn reduces the confidence we can have in the evidence presented within the review. Additionally, our findings are limited to the shoe classifications used in the included studies that do not, for example, include the more recently developed maximalist running shoe (opposite of minimalist [see Hoka running shoes for examples]). Future work exploring the influence of more conventional types of commercially available running shoes (motion control, stability, neutral/cushioned and potentially maximalist running shoes), which utilise sufficiently large sample sizes are therefore required.

The participants in included studies were limited to either recreational runners or military personnel. Extrapolation of findings between these two populations is limited by the different characteristics of basic military training (such as increased cross-training and load carriage) compared with recreational runners that would impact footwear wear, musculoskeletal loading and injury risk. Furthermore, military personnel complete running as part of their vocational training and may be reluctant to report injury for fear of jeopardising completion. Recent work has demonstrated that high- and low-mileage runners, and competitive and recreational runners, have different running patterns (joint kinematics), and these factors may influence response to specific footwear and consequently the likelihood of injury (Clermont 2017; Clermont 2019).

In relation to the footwear interventions assessed, three key factors that need to be considered when interpreting the findings of this review: lack of consensus regarding design features or classification for motion control, stability and neutral/cushioned groupings; differences in footwear characteristics between manufacturers; and the method by which footwear was prescribed between studies.

Inconsistent reporting of types of running shoes may increase heterogeneity between studies (Marchena-Rodriguez 2020; Knapik 2009). However, where there are clearer differences in design features between the two types of footwear, such as between conventional and minimalist running shoes, our review shows that heterogeneity is negligible. Studies comparing subgroups of more conventional running shoes (motion control, stability and neutral/cushioned) where the variation in design features are less distinct, may be more influenced by inconsistent classification and our review showed significant heterogeneity (Analysis 2.1). The lack of consensus definitions for these different types of running shoes may therefore help in part, to explain the contradictory findings when comparing injury rates between neutral/cushioned and motion control running shoes (Malisoux 2016b; Ryan 2011). It is beyond the scope of this review to provide a comprehensive definition for these sub-classifications of conventional running shoes, however, Table 1 offers a proposed classification that could be explored in future research.

The plethora of footwear manufacturers and brands further compounds the difficulties of classification, but studies in the review represent a relatively small proportion of these (see Table 2) . Design philosophies differ between manufacturers leading to variation in included features, materials and geometries. Pooling of different brands of running shoes may therefore result in a masking effect, with beneficial (reduced injury rates) effects of certain shoe models or brands being masked by negative effects (increased injury rates) of others within the same classification. However, these effects are unlikely to be a factor in our review as only two studies used different brands of shoe within the same classification. Additionally, the findings across studies, even where varying running shoe brands have been assessed, again appear relatively consistent, at least in relation to the direction if not the magnitude of effect.

Finally, there is some disparity between studies comparing injury rates between shoe types matched to foot type (prescribed) with shoes not matched to foot type (non-prescribed) (Knapik 2009; Knapik 2010a; Knapik 2010b). Firstly, injury rates between prescribed and non-prescribed groups, rather than by type of shoe, are reported within these studies (Knapik 2009; Knapik 2010a; Knapik 2010b). As such these trials, may have missed the beneficial effect of motion control running shoes on those with a pronated foot type reported in a subgroup analysis included in Malisoux 2016b. Additionally, the means of classifying foot type and thus

prescribing running shoes differs between the studies. Visual assessments of wet footprints were used in three studies (Knapik 2009; Knapik 2010a; Knapik 2010b), which is a method that lacks validity (Cobey 1981; Hawes 1992). In contrast, one study used the validated Foot Posture Index (Malisoux 2016b). The extent to which static foot assessments can predict dynamic foot motion has been challenged and moves towards dynamic foot classification have been advocated (Langley 2015; Nachbauer 1992). Furthermore, research indicates that clinicians may lack valid assessment tools to support clinical judgements when prescribing footwear to runners (Ramsey 2020), and there is no consensus on important shoe design features (Honert 2020).

Unsurprisingly we did not find any studies that compared running shoes with non-running shoes. We found no evidence that considered the number of runners who failed to return to running or their previous level of running as an outcome measure, though this may be partly due to the limited duration of follow-up in the included studies. Similarly, studies did not measure our other review outcomes, adverse events, hospital admissions, economic or resource use. These outcomes can be used as a measure of impact of the injury and hence should be included in future trials. Future research might also consider collection of economic and resource outcomes.

Quality of the evidence

Our overall confidence in the evidence included in the review ranged from very low to moderate certainty based on the GRADE criteria. We downgraded our certainty in the evidence for four reasons: risk of bias, imprecision, inconsistency and indirectness. We did not downgrade for publication bias.

Different types of running shoes

Our certainty in the evidence for each of the outcomes is in Summary of findings 1; Summary of findings 2; Summary of findings 3. We downgraded all evidence in these comparisons to low or very low certainty, because of risk of bias due to lack of blinding and uncertainty in the ascertainment of injury, indeed only one study used a professional to confirm the running injury (Dubois 2015). Furthermore, the evidence was downgraded for imprecision as sample sizes and number of events were low and confidence intervals were wide. The certainty of evidence from one outcome was further downgraded due to indirectness as the outcome data used in this study was pain, rather than injury (Ryan 2011), and for inconsistency owing to the high levels of statistical heterogeneity in this result.

Prescribed running shoes based on foot posture versus non-prescribed running shoes

Our certainty in the evidence for each of the outcomes is in Summary of findings 4. Certainty in the evidence was downgraded for this comparison due to the lack of blinding to the intervention and lack of appropriate random sequence generation and hence risk of bias. We have moderate-certainty evidence for this comparison.

Potential biases in the review process

Potential biases in the review processes have been considered for the search strategy, trial selection and data and analysis process.

Search strategy

The search strategy was comprehensive including multiple databases and clinical trials registries. We also handsearched the reference lists of all primary studies and relevant manufacturers websites. Further, we searched conference abstracts and the journal "Footwear Science" as these were not indexed in the included databases. We acknowledge the possibility of publication bias in this review that could either overestimate or underestimate effects of the intervention. Trials reporting negative or neutral outcomes are less likely to be offered or accepted for publication resulting in a potentially biased set of included data. However, our searches included trials registries, manufacturers websites and an unpublished study. Nevertheless, as we included only a few studies, we were unable to formally test for publication bias.

Trial selection

It is possible that some papers may have been misclassified as ineligible for the review. However, two review authors independently assessed all studies and selection was verified by a third review author, so we are confident that our consistent approach minimised the risk of selection bias. We adopted a similar rigorous approach to minimise the risk of data extraction errors.

Data and analyses

Owing to the small number of included studies, we were unable to conduct all planned sensitivity and subgroup analyses.

Two review authors discussed and allocated footwear to either the control or intervention group in each trial. The intervention shoe was determined by the number of features considered to influence lower-limb function compared with the control shoe (see Table 1 for more details). Therefore, we acknowledge that this may represent a source of review author bias. Where two types of the same running shoe were included within the same study, data were pooled. The choice to combine neutral and cushioned running shoes under the umbrella term neutral/cushioned within the review may also be another source of review author bias. Our decision to pool these shoes types together was pragmatic, with the terms often used interchangeably within clinical practice and research studies. Additionally, while the original intention was to explore changes over a range of time periods, due to a lack of available data, injury rates were pooled across reported time periods. These two decisions may be viewed as potential sources of review author bias. Furthermore, we were unable to conduct sensitivity analysis due to the small number of trials included in the review. Two review authors also discussed pooling trials that had used differing definitions of injury and agreed that these were similar enough to synthesise and were careful to analyse heterogeneity values for each comparison. Review authors also agreed to include a small percentage of non-lower-limb injuries.

Agreements and disagreements with other studies or reviews

Most of the research in the area of running shoes for preventing lower-limb injuries focuses on injury risk factors, such as lower-limb biomechanics and does not collect occurrence of injury as an outcome measure (Hoitz 2020). Therefore, we were unable to compare our review with this work. However, a previous Cochrane Review included running shoes as a subsection (Yeung 2011). The authors concluded that there was no evidence of reduction in

running injuries associated with prescribing running shoes based upon footprint measures, based on military populations using two trials from the current review (Knapik 2009, Knapik 2010a). Similar populations in our review concur with findings, providing further evidence of little discernible benefit.

AUTHORS' CONCLUSIONS

Implications for practice

- There is no evidence available comparing a running shoe with a non-running shoe.

- Neutral/cushioned running shoes compared with minimalist style running shoes may make little or no difference to running injuries in recreational runners (low-certainty evidence).

- We are uncertain whether motion control running shoes compared with neutral/cushioned running shoes reduces running injuries in recreational runners as the certainty of the evidence has been assessed as very low.

- Soft midsole running shoes compared with hard midsole running shoes may make little or no difference to running injuries (low-certainty evidence).

- We are uncertain whether stability running shoes compared with motion control running shoes reduces running injuries in recreational runners as the certainty of the evidence has been assessed as very low.

- We are uncertain whether stability running shoes compared with neutral/cushioned running shoes reduces running injuries in recreational runners as the certainty of the evidence has been assessed as very low.

- Recommendation of different types of running shoes based upon footprint and/or Foot Posture Index measures may make little or no difference to running injuries in recreational runners (moderate-certainty evidence).

Implications for research

The findings of this review and limitations of the existing evidence pose a number of challenges for the research community. Development of consensus definitions for shoe design features associated with motion control, stability and neutral/cushioned running shoes would help to standardise the classification of footwear to aid comparisons and pooling of interventions across studies. A consensus definition for minimalist running shoes has been developed (Esculier 2015) and future work could use a similar approach to better standardise the features used to categorise running shoes into motion control, stability and neutral/cushioned categories. Future trials also need to include all running shoe designs, including, for example, the maximalist running shoe not investigated in any of our included trials.

Future randomised controlled trials exploring the influence of prescribed and non-prescribed running shoes upon running-related injuries is warranted based upon the variation in foot posture measurements of Knapik 2009; Knapik 2010a; Knapik 2010b;and Ryan 2011. In these studies authors should look to report the influence of each type of prescribed shoe upon running-related injuries while also providing a range of interventions to facilitate a more comprehensive analysis of the interaction between running shoes type and injuries in runners with neutral, pronated and supinated feet. This would allow the influence of each type of shoe upon each type of foot to be explored rather than pooled comparisons of prescribed and non-prescribed. Additionally, future work should consider alternative means of prescribing footwear other than just static foot type.

Furthermore, consistency is required when reporting running injuries. If self-report measures are used, these should be followed up by a practitioner as in Dubois 2015, rather than relying on self-reported injuries only. Also, more frequent use of footwear satisfaction measures is required. Adverse events and hospital admissions were not reported and researchers should look to include these in future trials. No trial included economics and resource outcomes, and so again, this should be considered in future work. Future research should include longer follow-up times that would allow collection of outcomes that assess the number of runners who were unable to return to running following their injury.

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Editorial and peer-reviewer contributions

Cochrane BJMT supported the authors in the development of this review.

The following people conducted the editorial process for this article.

- Sign-off Editor (final editorial decision): Xavier Griffin, Co-ordinating Editor, Cochrane Bone, Joint and Muscle Trauma Group
- Editor (advised on methodology and review content, edited the article): Sharon Lewis, Deputy Co-ordinating Editor, Cochrane Bone, Joint and Muscle Trauma Group
- Managing Editor (selected peer reviewers, collated peer-reviewer comments, provided editorial guidance to authors, edited the article): Joanne Elliott, Managing Editor, Cochrane Bone, Joint and Muscle Trauma Group
- Information Specilaist (developed search strategy, advised on search methods): Maria Clarke, Information Specialist, Cochrane Bone, Joint and Muscle Trauma Group
- Copy Editor (copy-editing and production): TBC
- Peer-reviewer (provided comments and recommended an editorial decision): Codi Ramsey (clinical reviewer)

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CHARACTERISTICS OF STUDIES

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

References to other published versions of this review

Relph 2019

Relph N, Greaves H, Armstrong R, Gichuru P, Prior TD, Griffiths IB, et al. Running shoes for preventing lower limb running injuries in adults. *Cochrane Database of Systematic Reviews* 2019, Issue 7. Art. No: CD013368. [DOI: 10.1002/14651858.CD013368]

* Indicates the major publication for the study

Dubois 2015

Study characteristics	
Methods	**Aim:** to gather feasibility data and determine sample size needed for a larger study comparing the effects of traditional running shoe (neutral/cushioned) and minimalist running shoe on the incidence of overuse injuries in recreational runners. **Design:** parallel group, pilot RCT. **Duration:** 16 weeks. **Centres and locations:** unclear. **Method of recruitment:** via posters in specialised running stores. **Start/End dates:** March 2012 to August 2012. **ITT:** ITT analysis at 16 weeks, with consideration of training sessions completed prior to drop out (no further detail provided).
Participants	**Number:** 24. **Inclusion criteria:** 18 to 55 years and able to run for 20 minutes continuously. **Exclusion criteria:** presence of an underlying lower-limb degenerative pathology; past medical history of lower-limb surgery; use of orthotics within the last 6 months; history of lower limb. **Age:** traditional running shoe mean 33.7 ± SD 7.8 years, minimalist running shoe mean 29.8 ± SD 8.7 years. **Gender:** 7 male, 17 female. **Baseline imbalances:** no significant differences at baseline (age, BMI, running experience, step frequency, VO_2 max, foot strike pattern, shoes prior to study, muscle strength). **Withdrawals:** 1 (8%); TS, 3 (25%) MS.
Interventions	**Neutral / cushioned shoes (intervention)** (N = 12): ASICS Cumulus, Landreth, Nimbus, Brooks Defyancew, Ghost, Ravenna, Mizuno Wave, Inspire, Wave Rider. **Minimalist shoes (control)** (N = 12): Inov8 F-Lite 195, Bare X-Lite 150, Road X-Lite 155, Mizuno Wave Universe; Saucony A5. An experienced shoe retailer helped participants select "properly fitted" shoes, without comment on the shoe type.

Dubois 2015 *(Continued)*

	Schedule: both groups completed a standardised 16-week training programme towards the completion of a half marathon.
Outcomes	**Primary:** total recruitment, rate of adherence; drop out rate at 16 weeks. **Secondary:** total number of runners with running-related injuries; injury incidence; injury diagnosis (e.g. stress fracture); missed training days; shoe satisfaction at 16 weeks. **Injury defined as:** not defined. However, a sports physician and physical therapist completed a standardised evaluation sheet to establish a diagnosis.
Notes	**Study funder and contribution:** study supported by funding from the Canadian Academy of Sport and Exercise Medicine research programme. **Conflicts of interest:** None reported by the authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "*A random number generator was used to define the sequence of shoe assignments*".
Allocation concealment (selection bias)	Low risk	Sealed numbered envelopes were opened by the shoe retailer. Only the shoe retailer and one named study researcher were aware of shoe assignment. Quote: "S*ealed numbered envelopes subsequently assigned participants to a choice of MS or TS models. An experienced specialised shoe retailer, who was instructed not to comment on shoe type, helped select properly fitted shoes within the assigned group. Sealed envelopes were opened by the retailer, and only the shoe retailer and one member of the research team were aware of the shoe assignment".*
Blinding of participants and personnel (performance bias) All outcomes	High risk	Some personnel were blinded and it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinicians assessing injuries were blinded to shoe assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study withdrawal reported with reasons unrelated to intervention.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Fuller 2017a

Study characteristics

Methods	**Aim**: to compare running-related pain and injury between conventional (neutral / cushioned) and minimalist shoes in trained runners.

Fuller 2017a *(Continued)*

	Design: parallel group, RCT. 5 km time trials used as the minimisation variable for 1:1 allocation ratio. Method of randomisation not stated. **Duration**: 26 weeks. **Centres and locations**: University of South Australia. **Method of recruitment**: via public advertisement at local running clubs, fitness centres and running events. Participants received AUD $100 voucher for running shoes. **Start/End dates**: study enrolment: 10 July 2013 to 9 October 2014. **ITT**: per-protocol analysis at 6 weeks; ITT analysis at 26 weeks.
Participants	**Number**: 61. **Inclusion criteria**: 18 to 40 years, running ≥ 15 km per week, habitual rearfoot footfall, able to run a 5 km time trial in 23 minutes. **Exclusion criteria**: prior experience with minimalist shoes, use of orthotics, having a current or recent (< 3 months) musculoskeletal injury or history of recent (< 12 months) invasive surgery that affected running. **Age**: mean 27 ± SD 7 years. **Gender**: male. **Baseline imbalances**: baseline characteristics not reported. **Withdrawals**: 9 (14.7%); neutral / cushioned 5 (16.6%); minimalist 4 (13.3%).
Interventions	**Neutral / cushioned shoes (intervention)** N = 30: Asics Gel Cumulus - 14, 15 or 16; mass 324 g/shoe; heel drop 9 mm. Shoe type scored 12% on the minimalist index. **Minimalist shoes (control)** N = 31: Asics Piranha SP4; mass 125 g/shoe; heel drop 5 mm. Shoe type scored 72% on the minimalist index for classification of shoes (0 = least minimalist, 100 = most minimalist). **Schedule**: in both groups, in week 1 participants wore allocated shoes for 5% of daily running, then incrementally increased use of allocated shoe by 5% weekly until worn for 100% of running at week 20. From weeks 20 to 26 all running performed in allocated shoe condition. Participants followed their usual running habits, including surface and time of day.
Outcomes	**Primary**: 5 km time trial performance at 6 weeks. **Secondary**: at 6 months; Injury incidence, 5 km time trial performance, running economy, running biomechanics, triceps surae strength, bone mineral density (also at 6 weeks), pain (10cm VAS). **Injury defined as:** any musculoskeletal problem severe enough to cause a visit to a health professional, use of medication, or reduced weekly training. Injured participants independently assessed and treated by medical professionals.
Notes	**Study funder and contribution**: ASICS Oceania (ASICS Oceania Pty Ltd, Eastern Creek, NSW, Australia) donated 20 pairs of Asics Gel Cumulus-16 running shoes. No other sources of industry support were reported. Study supported by funds awarded to JTF by University of South Australia Vice Chancellor and President's Scholarship (AUD $10,000). **Conflicts of interest**: DT received funding from ASICS Oceania to undertake separate research. **Correspondence:** The author confirmed the abstract found in our search was that of the full paper included as Fuller 2017a.
Risk of bias	

Fuller 2017a *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation unclear, however, used 1:1 randomisation based on time trial performance. Quote: "*Participants were randomized to shoe group (conventional or minimalist) via a process of minimization, with time trial performance used as the minimization variable.*"
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated but participants allocated by one researcher not involved in data collection. Quote: "*Allocation of participants was performed by 1 investigator who was not involved in data collection.*"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel were not blinded and it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data collection was not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study withdrawal reported with reasons unrelated to intervention.
Selective reporting (reporting bias)	Low risk	All outcomes in pre-published protocol are reported in results.
Other bias	Low risk	We identified no other sources of bias.

Knapik 2009

Study characteristics	
Methods	**Aim:** to determine whether injury risk can be reduced by selecting running shoes based on plantar type. **Design:** parallel group, quasi-RCT. Randomisation, to either a running shoe based on plantar shape or control group, was based on sequential ordering upon arrival for testing. No further detail provided. **Duration:** 9 weeks. **Centres and locations:** Fort Jackson, S.C, USA. **Method of recruitment:** US army recruits participating in Basic Combat training were enrolled on the study. **Start/End dates:** March to July 2007. **ITT:** no ITT analysis.
Participants	**Number:** 3952. **Inclusion criteria:** enrolled in Basic Combat training.

Knapik 2009 *(Continued)*

	Exclusion criteria: did not or could not obtain the prescribed shoe. Did not wear the prescribed shoe for all of the Basic Combat Training. **Age:** mean male 23 ± SD 5 years, female 23 ± SD 6 years. **Gender:** male 2689, female 1263. **Baseline imbalances:** baseline characteristics not reported. **Withdrawals:** 264: 257 (19%), male intervention, (20%); male control; 165 (26%); female intervention, 147 (23%); female control.
Interventions	**Running shoe based on plantar shape** (low arch was provided with motion control shoes, high arch was provided with cushion type shoes and normal arch was provided with stability shoes)**(intervention)** N = 1979. **Stability Shoes (control)** N = 1973. Details of footwear are provided in Table 2. **Schedule:** basic Combat Training is described in US Army Training Doctrine and Command Regulation. Physical training sessions were performed from 1 to 1.5 hours, 4 to 6 days per week. Sessions alternated between cardiorespiratory and muscle strength days. Cardiorespiratory days involved distance running 0.5 to 3 miles and/or sprinting some push-ups and sit-ups. Four running ability groups were formed in each company based upon the distribution of run scores on the first fitness test. Muscle strength days involved a variety of push-ups and sit-ups in addition to other army training drills. No effort was made to restrict the wearing of running shoes to physical training and no mechanism was in place to record how long subjects wore their running shoes during discretionary time.
Outcomes	**Primary:** five injury indices; Installation Injury Index, Modified Installation Injury Index, Overuse Injury Index, Training Injury Index, Comprehensive Injury Index (CII). All are injury incidences (injuries/1000 person-day) based on the ICD-9-CM. **Secondary:** none. **Injury defined as:** no definition provided. However, all indices include specific ICD-9-CM codes.
Notes	**Study funder and contribution:** no financial disclosures were reported. **Conflicts of interest:** none reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method of sequence generation was in sequential order of arrival for testing. Quote: "*Subjects were randomized into a control (C) or experimental (E) group in sequential order (alternatively in order of arrival for testing).*"
Allocation concealment (selection bias)	High risk	Method of allocation concealment not stated but participants allocated by a researcher. Quote: "*A member of the study team assured that each person selected the prescribed shoe type and was fitted with the proper shoe.*"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel were not blinded and it was impossible to blind runners to the footwear.

Knapik 2009 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal reported with reasons. Some participants withdrew because of shoe discomfort but numbers are unclear.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Knapik 2010a

Study characteristics	
Methods	**Aim:** to determine whether injury risk can be reduced in basic military training by selecting running shoes based on plantar type and to examine risk factors for injury in basic military training. **Design:** parallel group, quasi-RCT. Randomisation, to either a running shoe based on plantar shape or control group, was based on sequential ordering upon arrival for testing. No further detail provided. **Duration:** 4 months. **Centres and locations:** Lackland Air Force Base, Texas, USA. **Method of recruitment:** US air force recruits participating in Basic Military Training were enrolled on the study. **Start/End dates:** March to July 2007. **ITT:** no ITT analysis.
Participants	**Number:** 3021. **Inclusion criteria:** enrolled in Basic Military Training. **Exclusion criteria:** did not enter Basic Military Training for administrative or medical reasons or did not complete the Basic Military Training. **Age:** not provided but split into 18 to 19, 20 to 24 and ≥ 25 years for Hazard Ratio analysis. **Gender:** male 2167, female 854. **Baseline imbalances:** no significant differences between experimental and control groups for weight, BMI, push-ups, crunches and 1.5 mile run. For the variable race, the experimental group men had more black recruits than the control group men. **Withdrawals:** 319 (11%) of the initial sample. Of the remaining 2702, 8.9% in the intervention group and 8.2% in the control group of males and 16.0% of the intervention group and 11.3% of the control group of females withdrew from training.
Interventions	**Running shoe based on plantar shape** (low arch was provided with motion control shoes, high arch was provided with cushion type shoes and normal arch was provided with stability shoes) **(intervention)** N = 1258. **Stability shoe (control)** N = 1415. Details of footwear are provided in Table 2.

Knapik 2010a *(Continued)*

	Schedule: basic military training.
Outcomes	**Primary:** five injury indices; The Installation Injury Index, The Modified Installation Injury Index, The Overuse Injury Index, The Training Injury Index, The Comprehensive Injury Index (CII). All are injury incidences (injuries /1000 person-day) based on the ICD-9-CM. **Secondary:** none. **Injury defined as:** no definition provided. However, all indices include specific ICD-9-CM codes.
Notes	**Study funder and contribution:** no financial disclosures were reported. **Conflicts of interest:** none reported. **Correspondance:** The author confirmed the sample sizes of male and female participants.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method of sequence generation was in sequential order of arrival for testing. Quote: "*Study participants were randomly assigned to either an experimental (E) or a control (C) group, based on order of arrival for testing*."
Allocation concealment (selection bias)	High risk	Method of allocation concealment not stated. However, seem predictable and is not blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear if personnel were blinded and it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal numbers reported but unclear on reasons.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Knapik 2010b

Study characteristics

Methods	**Aim:** to determine whether injury risk can be reduced in Marine Corps basic military training by assigning running shoes based on static weightbearing plantar foot shape. **Design:** parallel group. RCT. Assignment order randomly generated by a statistical software programme. **Duration:** 12 weeks.

Knapik 2010b *(Continued)*

	Centres and locations: Marine Corps Recruit Depot, San Diego, California and Parris Island, South Carolina, USA. **Method of recruitment:** US Marine Corps recruits participating in Basic Training were enrolled on the study. **Start/End dates:** not reported. **ITT:** no ITT analysis.
Participants	**Number:** 1611. **Inclusion criteria:** enrolled in United States Basic Marines Corps Training. **Exclusion criteria:** none reported. **Age:** unclear. **Gender:** male 917, female 694 **Baseline imbalances:** male intervention group; significantly more participants had a prior lower-limb injury compared with the male control group. **Withdrawals:** 20 (4%); male intervention, 45 (15%); male control; 57 (15%); female intervention; 24 (6%); female control.
Interventions	**Running shoe based on plantar shape** (low arch was provided with motion control shoes, high arch was provided with cushion type shoes and normal arch was provided with stability shoes)**(intervention)** N = 803. **Stability Shoes (control)** N = 751. Details of footwear are provided in Table 2. **Schedule:** basic military training.
Outcomes	**Primary:** five injury indices; The Installation Injury Index, The Modified Installation Injury Index, The Overuse Injury Index, The Training Injury Index, The Comprehensive Injury Index (CII). All are injury incidences (injuries /1000 person-day) based on the ICD-9-CM. **Secondary:** none. **Injury defined as:** no definition provided. However, all indices include specific ICD-9-CM codes.
Notes	**Study funder and contribution:** no financial disclosures were reported. **Conflicts of interest:** none reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation was generated using statistical software. Quote: "*Following all foot measurements, participating recruits were randomized into 1 of 2 groups using an assignment order that was randomly generated by a statistical software program.*" However, baseline differences in previous injury existed between groups and previous injury is a strong predictor of increased injury risk.
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment unclear.

Knapik 2010b *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear if personnel were blinded and it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study withdrawal reported with reasons unrelated to intervention.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Malisoux 2016a

Study characteristics	
Methods	**Aim:** to determine whether the drop of standard cushioned running shoes influences running injury risk. **Design:** parallel groups, RCT. Experience with minimalist running shoes (drop < 10 mm) used to stratify participants for randomisation. Block randomised (block size = 60). **Duration:** 6 months. **Centres and locations:** Sports Medicine research Laboratory, Luxembourg Institute of Health. Recruitment from Luxembourg, France, Belgium and Germany. **Method of recruitment:** via public advertisement in local newspapers. **Start/End dates:** study enrolment: September to December 2014. **ITT:** ITT analysis after 6 months.
Participants	**Number:** 577; D10 Group 190; D6 Group 194; D0 Group 193. **Inclusion criteria:** good health, 18 to 65 years old, no use of minimalist shoes (< 4 mm drop) in previous 12 months, no contraindications to running, no surgery to the lower limbs or lower back in the last 12 months, and not using orthopaedic insoles when running. **Exclusion criteria:** not stated. **Age:** D10 Group 38.3 ± SD 9.7 years; D6 Group 38.0 ± SD 9.6 years; D0 Group 38.6 ± SD 9.9 years. **Gender:** D10 Group 106 males, 70 females; D6 Group 11 males, 79 females; D0 Group 124 males, 63 females. **Baseline imbalances:** small variation in gender distribution. **Withdrawals:** D10 Group 14 (7%); D6 Group 4 (2%); D0 Group 6 (3%).
Interventions	**Neutral / cushioned shoes (intervention)** D10 group, custom running shoe with 10 mm drop between rearfoot and forefoot.

Malisoux 2016a *(Continued)*

	Minimalist shoes (control) D6 groups, custom running shoes with 6 mm drop between rearfoot and forefoot. **Minimalist shoes (control)** D0 group, custom running shoes with 0 mm drop between rearfoot and forefoot. **Schedule:** sports participant and adverse events (injuries, pain and illness) collected throughout the intervention period (6 months) using an online platform. Addition information on training sessions collected, including information on type of activity, duration, perceived intensity (0 to 10), distance covered, running surface, shoes used and pain during activity.
Outcomes	**Primary:** number of runners who sustained a running-related injury, characteristics of injuries (location, type, severity, recurrence, category). **Secondary:** none. **Injury defined as:** physical pain located in the lower limbs or lower back, sustained during or as a result of running practice and impeding planned running activity for at least one day (time-loss definition).
Notes	**Study funder and contribution:** the study was cofunded by Decathlon, who also provided footwear for the study. **Conflicts of interest:** one or more of the authors declared potential conflict of interest or source due to the funding source. The study was cofunded by the Movement Sciences Department, Decathlon, Villeneuve d'Ascq, France. One author is employed at Decathlon.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Two pre-established randomisation lists were used (block size 60) based on previous experience of low-drop running shoe. Quote: "*Participants who presented a pair of shoes with a drop less than 10 mm were classified as participants with previous experience with low-drop running shoes.*" Quote: "*Previous experience with low-drop running shoes (low-drop experience) was suggested to be a confounding factor for injury risk.3 Therefore, at the moment of recruitment, eligible participants were stratified according to their low-drop experience (\10 mm). Two pre-established randomization lists (block size = 60) were thus used to allocate the 3 shoe versions randomly to the participants*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated but shoes were coded by one researcher not involved in data collection. Quote: "*Each shoe pair was coded by a coworker not involved in the study before the distribution*."
Blinding of participants and personnel (performance bias) All outcomes	High risk	There is an attempt to blind runners to the type of shoe they were given by de-identifying the brand of shoe. However the authors later acknowledge that runners could reasonably work out if they had received a different shoe drop to their normal shoe.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors of outcome assessment were blinded to shoe allocation.

Malisoux 2016a *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal reported with reasons that may be related to intervention, for example participants did not use study shoes, participants suffered from blisters caused by the shoe. But unclear how many were from the intervention and control groups.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Malisoux 2016b

Study characteristics	
Methods	**Aim:** to determine whether motion control running shoes modify running injury risk and whether the influence of these running shoes is dependent upon foot type. **Design:** parallel group, RCT. Group allocation based upon stratification by age, BMI and foot type. **Duration:** 6 months. **Centres and locations:** Sports Medicine Research Laboratory, Luxembourg Institute of Health. Recruitment from Luxembourg, France, Belgium and Germany. **Method of recruitment:** via public advertisement in local newspapers. **Start/End dates:** study enrolment: March to April 2014. Intervention period: June to December 2014. **ITT:** ITT analysis after six months.
Participants	**Number:** 423; Motion control 211; Neutral / cushioned 212. **Inclusion criteria:** good health, 18 to 65 years old, no use of minimalist shoes (< 4 mm drop) in previous 12 months, no contraindications to running, running at least once a week in the 6 months preceding the study, no surgery to the lower limbs or lower back in the last 12 months, and not using orthopaedic insoles when running. **Exclusion criteria:** not stated. **Age:** Motion control 39.9 ± SD 9.7 years; Neutral / cushioned 41.0 ± SD 11.2 years. **Gender:** motion control: male 11, female 76; Neutral / cushioned: male 113; female 72. **Baseline imbalances:** none. **Withdrawals:** motion control 4 (2%); Neutral / cushioned 10 (5%)
Interventions	**Motion control (intervention)** commercially available motion control running shoe featuring 10 mm heel-to-toe drop, thermoplastic polyurethane structure within the midfoot and dual density EVA midsole. **Neutral / cushioned (control)** commercially available neutral / cushioned running shoe featuring 10 mm heel-to-toe drop, identical to motion control shoe besides features detailed above. **Schedule:** sports participant and adverse events (injuries, pain and illness) collected throughout the intervention period (6 months) using an online platform. Addition information on training sessions collected, including information on type of activity, duration, perceived intensity (0 – 10), distance covered, running surface, shoes used and pain during activity.

Malisoux 2016b *(Continued)*

Outcomes	**Primary:** number of runners who sustained a running-related injury, characteristics of injuries (location, type, severity, recurrence, category). **Secondary:** none. **Injury defined as:** physical pain located in the lower limbs or lower back, sustained during or as a result of running practice and impeding planned running activity for at least one day (time-loss definition).
Notes	**Study funder and contribution:** the study was cofunded by Decathlon, who also provided footwear for the study. **Conflicts of interest:** one or more of the authors declared potential conflict of interest or source due to the funding source. The study was cofunded by the Movement Sciences Department, Decathlon, Villeneuve d'Ascq, France. three authors were employed at Decathlon. **Correspondence:** the author confirmed the abstract found in our search was that of the full paper included as Malisoux 2016b.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not stated but used stratification by confounders (age, BMI and foot morphology). Quote: "*Participants were randomly allocated to one of the two shoe models in accordance with stratification by potential confounders (age and body mass index (BMI); cut-off values are medians) and foot morphology*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated. But it was stated that shoe distributors were blinded. Quote: "*Participants and assessors involved in the shoe distribution and participant follow-up were both blinded regarding the shoe allocation*."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear if personnel were blinded. It was impossible to blind runners to the footwear. However there was an attempt to blind runners to the type of shoe they were given by de-identifying the brand of the shoe.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal reported with reasons but unclear if related to shoe allocation (e.g. did not use shoe for more than two sessions).
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol, however all outcomes in method were reported.
Other bias	Low risk	We identified no other sources of bias.

Malisoux 2020

Study characteristics

Malisoux 2020 *(Continued)*

Methods	**Aim:** to investigate if shoe cushioning and body mass are associated with running injury risk in recreational runners, and whether there is an association between shoe cushioning and injury risk is influenced by body mass. **Design:** parallel group, RCT. Group allocation based upon stratification by gender (block stratified in blocks of 40). **Duration:** six months. **Centres and locations:** Sports Medicine Research Laboratory, Luxembourg Institute of Health. Recruitment from Luxembourg, France, Belgium and Germany. **Method of recruitment:** via public advertisement in local newspapers. **Start/End dates:** study enrolment: September 2017 to January 2018. **ITT:** ITT analysis after six months.
Participants	**Number:** 874; Soft 438, Hard 436. **Inclusion criteria:** good health, 18 to 65 years old and capable of running for 15 minutes consecutively. **Exclusion criteria:** contraindications to running, lower limb or back surgery in the last 12 months, use of orthopaedic insoles when running or running-related injury in the month before enrolment. **Age:** Soft 40.4 ± SD 10.2 years; Hard 40.5 ± SD 9.8 years. **Gender:** Soft: male 259; female 169; Hard: male 260, female 160. **Baseline imbalances:** none. **Withdrawals:** Soft 10 (2%); Hard 16 (4%).
Interventions	**Soft shoes (intervention)** soft sole with a stiffness of 61.3 ± 2.7 N/mm, identical to hard running shoe in all other areas. **Hard shoes (control)** hard sole with a stiffness of 94.9 ± 5.9 N/mm, 337 ± 17 g mass, heel-to-toe drop 10 mm, stack height at the heel 34 mm. **Schedule:** Sports participant and adverse events (injuries, pain and illness) collected throughout the intervention period (6 months) using an online platform. Addition information on training sessions collected, including information on type of activity, duration, perceived intensity (0 to 10), distance covered, running surface, shoes used and pain during activity.
Outcomes	**Primary:** number of runners who sustained a running-related injury, characteristics of injuries (location, type, severity, recurrence, category). **Secondary:** none. **Injury defined as:** running-related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least seven days or three consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional.
Notes	**Study funder and contribution:** none reported. **Conflicts of interest:** none reported.

Risk of bias

Bias	Authors' judgement	Support for judgement

Malisoux 2020 *(Continued)*

Random sequence generation (selection bias)	Low risk	Two pre-established randomisation lists (for male and female runners, block size: n = 40) prepared by a statistician not involved in the study. Runners were stratified according to sex. Quote: "*The participants were stratified according to their sex, as it influences body mass and other anthropometric characteristics. Thus, 2 pre-established randomization lists (for male and female participants; block size: n = 40) were prepared by a statistician not involved in any other part of the study and used to allocate 1 of the 2 shoe versions to each participant.*"
Allocation concealment (selection bias)	Unclear risk	The shoes were coded by a non-involved co-worker before distribution. But allocation concealment is unclear. Quote: "*Each shoe pair was coded by a noninvolved coworker before distribution*."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear if personnel were blinded. It was impossible to blind runners to the footwear. However there was an attempt to blind runners to the type of shoe they were given by de-identifying the brand of the shoe.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The shoe code was broken after the completion of data collection. Therefore data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal reported with reasons unrelated to intervention. However, large proportion of data analysed was right censored without explanation.
Selective reporting (reporting bias)	Unclear risk	All injury outcomes are reported. However, biomechanical measures stated in the protocol are missing from published trial.
Other bias	Low risk	We identified no other sources of bias.

Marshall 2013

Study characteristics	
Methods	**Aim:** to determine if the gradual transition from conventional (neutral / cushioned) running shoes to minimalist running shoes increased the risk of lower-limb pain or injury and improved lower-limb muscle function in experienced distance runners. **Design:** parallel group, RCT. Participants were stratified by running experience and age. Group allocation was determined by coin toss (heads intervention; tails control). **Duration:** 12 weeks. **Centres and locations:** Port Elizabeth, South Africa. **Method of recruitment:** participants were then recruited for the study. Participants were recruited through word-of-mouth and advertisements on Facebook, at running clubs and at the Nelson Mandela Metropolitan University in Port Elizabeth. **Start/End dates:** unclear. **ITT:** 31 participants randomised, only 29 in the final analysis, no ITT.
Participants	**Number:** 29.

Marshall 2013 *(Continued)*

	Inclusion criteria: healthy males, 18 to 50 years, ran in neutral / cushioned running shoes, running 40 to 60 km per week in the 6 months prior to the study, running experience ≥ 2 years. **Exclusion criteria:** participants who reported any relevant medical or surgical history, including a history of lower-limb or lumbar-spine injury or pathology within the last three months prior to the study. Participants that were already running in minimalist running shoes. Increased Q-angles (more than 14 °) and a leg length discrepancy (discrepancy of more than 15 mm). Participants who took part in any races over 21.1 km during the study period. **Age:** neutral / cushioned shoes mean 33.3 ± SD 8.3 years; minimalist shoes mean 32.9 ± SD 7.5 years. **Gender:** male. **Baseline imbalances:** no significant differences at baseline. **Withdrawals:** neutral / cushioned 2 (12.5%); 2 (6.5%); minimalist 0
Interventions	**Neutral / cushioned shoes (intervention)** N = 16; no detail provided. **Minimalist shoes (control)** N= 15; Inov8. **Schedule:** participants in both groups performed calf muscle training (hopping) for four weeks. Participants in the experimental group also underwent a gradually progressive running four-week training programme that was designed to facilitate adaptation to running in minimalist shoes. The control group continued with their usual individual running training. In both groups, participants continued with their usual individual running training after the four-week training programme.
Outcomes	**Primary:** number of running-related injuries after 12 weeks. **Secondary:** location of injury, shoe satisfaction. **Injury defined as:** as any reported muscle, joint or bone problem/injury of lower limb (i.e. buttock, hip, thigh, knee, shin, calf, ankle, foot) resulting from running training that required the runner to miss at least one training day or a training session.
Notes	**Study funder and contribution:** none stated. **Conflicts of interest:** none stated. **Correspondence:** the author confirmed the thesis had not been published in a peer-reviewed journal.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Method of sequence generation was coin tossing for the first allocation, then alternate groups from there. Quote: "*A coin was then flipped to determine which group received the first participant. 'Heads' indicated that the experimental group received the first participant. 'Tails' indicated that the control group received the first participant*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated but an independent auditor was present to conduct and observe the procedure of allocation. Quote: "*An independent auditor was present to conduct and observe the procedure*."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of runners was not completed. Runners in experimental group picked up shoes from a store whereas runners in the control group continued to use their own shoes. Personnel were not blinded.

Marshall 2013 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study withdrawal reported with reasons unrelated to intervention.
Selective reporting (reporting bias)	Low risk	All outcomes in a prospective trial registration document are reported in results.
Other bias	Low risk	We identified no other sources of bias.

Ryan 2011

Study characteristics	
Methods	**Aim:** to compare missed training days and running-related pain levels between neutral, stability and motion control shoes assigned by foot posture in female runners. **Design:** parallel groups, RCT. Using FPI runners were first stratified to either a neutral, pronated or highly pronated foot posture group. The, subjects in each foot posture group were randomly assigned via a block randomisation scheme—block size 8. Random sequence generation and group allocation method unclear. **Duration:** 13 weeks. **Centres and locations:** University of British Columbia, Vancouver, Canada. **Method of recruitment:** via newspaper advertisement and word of mouth. **Start/End dates:** unclear. **ITT:** the authors stated an ITT analysis was used for comparisons for shoe type. A last value carried forward strategy was used for missing data (due to withdrawals resulting from injury and/or forgoing wearing assigned footwear) in the cases where participants had reported a minimum of two weeks of outcome scores. However, subjects who reported fewer than two follow-up data points were considered dropouts, and their data were omitted for the purpose of analysis.Therefore, not a true ITT analysis.
Participants	**Number:** 81 **Inclusion criteria:** 18 to 50 years, could run continuously for 60 minutes, had no history of running injuries or foot orthosis usage within the preceding 6 months. **Exclusion criteria:** history of surgery to the lower extremity that would have the potential to impact their running gait and if there were any known, or suspected, degenerative conditions such as osteoarthritis or chondromalacia. **Age:** Neutral / cushioned shoes (N=25): mean 37 ± SD 9 years (neutral feet), mean 35 ± SD 7 years (pronated feet), mean 27 ± SD 3 years (highly pronated feet). Stability shoes (N=32): mean 35 ± SD 5 years (neutral feet), mean 35 ± SD 9 years (pronated feet), mean 26 ± SD 2 years (highly pronated feet). Motion Control shoes (24): mean 38 ± SD 3 years (neutral feet), mean 34 ± SD 4 years (pronated feet), mean 29 ± SD 6 years (highly pronated feet). **Gender:** female. **Baseline imbalances:** significant difference across shoe categories at baseline for weight, BMI and running experience.

Ryan 2011 *(Continued)*

	Withdrawals: 24 (23%) withdrew after enrolment, 2 (8%) of these were due to immediate discomfort or poor fit of running shoes. Of the remaining 81 participants, 9 (11%) elected to withdraw from wearing their assigned shoe and return to their original running footwear; (neutral / cushioned shoes × 4 (1 × neutral feet; 2 × pronated feet; 1 × highly pronated feet); stability shoe × 2 (2 × neutral feet); motion control shoe × 2 (2 × highly pronated feet)), and three subjects chose to withdraw due to running-related pain (motion control shoe × 2 (2 × highly pronated feet); neutral / cushioned shoe × 1 (neutral feet)).
Interventions	**Neutral / cushioned shoes:** N = 25 Nike Pegasus **Stability shoes:** N = 32 Nike Structure Triax (note: 12 randomised but 13 followed-up in the pronated foot group) **Motion control shoes:** N = 24 Nike Nucleus **Schedule:** All participants were given one week to gradually break in the shoes for use with running. Then runners underwent a 13-week training programme targeting a half-marathon event. The weekly volume started at approximately 20 km and increased to 40 to 45 km at the peak of the programme.
Outcomes	**Primary:** number of missed assigned workouts due to running-related pain and VAS items for pain at rest (VASRest), during activities of daily living (VASADL) and during or immediately following running (VASRun) via attendance at weekly group runs and using an online questionnaire. **Injury defined as:** missed a training day due to running-related pain.
Notes	**Study funder and contribution:** Nike Global, One Bowerman Drive, Beaverton, Oregon, USA. Nike Canada donated clothing to clinic leaders and Nike Global provided footwear. **Conflicts of interest:** A research partnership grant from Nike Global was awarded to MBR, JET and KM to conduct this investigation. GAV is employed at Nike Global.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not stated. However, subjects in each foot posture category were randomly assigned (via a block randomisation scheme—block size 8) to one of three footwear conditions. Quote: "*Subjects in each foot posture category were then randomly assigned (via a block randomisation scheme—block size 8) to one of three footwear conditions*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated. Additionally, differences in weight, BMI and running experience at baseline between groups, with all factors linked to increased risk of injury.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear if personnel were blinded and it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Study withdrawal reported with reasons and some were related to the footwear allocation.

Ryan 2011 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	No pre-published protocol available.
Other bias	Low risk	We identified no other sources of bias.

Ryan 2014

Study characteristics	
Methods	**Aim:** to prospectively determine the effect of two different minimalist footwear models, and one conventional (neutral / cushioned) model, on injury incidence and pain in a population of recreational runners. **Design:** parallel groups, three arms, prospective RCT. For concealed group allocation, participants were randomly assigned by a researcher (via a computer-generated block randomisation scheme—block size 8). **Duration:** 13 weeks. **Centres and locations:** Vancouver, Canada. **Method of recruitment:** via a newspaper advertisement and word of mouth. **Start/End dates:** November 2011 for 12 weeks. **ITT:** ITT analysis used. A last value carried forward strategy was used for missing data (due to withdrawals resulting from injury and/or for going wearing assigned footwear) in the cases where participants had reported a minimum of one follow-up outcome score. Participants who reported fewer than one follow-up data point were considered drop-outs and their data were omitted for the purpose of analysis.
Participants	**Number:** 99. **Inclusion criteria:** 19 to 50 years, regardless of the running fitness level, could run continuously for 60 minutes, minimum of five years' running experience, running on a regular basis (minimum once per week over past 6 months), could tolerate 20 to 40 km/week training programme, had no running-related injuries requiring a stoppage of training for two weeks or more in the past six months, feet categorised as "neutral", "supinated" or "pronated". **Exclusion criteria:** surgery to their plantar fascia or achilles tendon, diagnosis of osteoarthritis or other degenerative musculoskeletal disorder affecting the lower extremity, currently taking analgesic medication, already using minimalist running footwear, foot postures at the extremes listed as "highly pronated" or "highly supinated". **Age:** Neutral / cushioned; 34 ± SD 8 years, Partial Minimalist; 31 ± SD 7 years, Full Minimalist; 33 ± SD 8 years. **Gender:** 39 male, 60 female. **Baseline imbalances:** No baseline imbalances although P values are not provided. **Withdrawals:** 13 (13%) (4 dropped out after baseline assessment, 2 after the 2 week follow-up, 2 after the 4-week follow-up and 5 after the 8-week follow-up).
Interventions	**Neutral / cushioned shoe (intervention):** N = 32: Nike Pegasus+ 28 (neutral / cushioned), stack height in mm (rearfoot/ forefoot): 33/21, weight (men's size 10): 12.2g. **Partial minimalist shoe (control):** N = 32: Nike free 3.0 V2, stack height in mm (rearfoot/ forefoot): 17/13, weight (men's size 10): 7 g.

Ryan 2014 *(Continued)*

	Full minimalist shoe (control): N = 35: Vibram 5-Fingers Bikila, stack height in mm (rearfoot/ forefoot): 4/4, weight (men's size 10): 6 g. **Schedule:** Following a 1-week break-in period to their assigned footwear, participants began a 12-week run training programme targeting a 10 km run. The programme followed a gradual increase in total running minutes from 160 minutes the first week to a peak of 215 minutes in week 10 before a 2-week taper. Participants did not always run in their assigned footwear, rather had a gradual increase in exposure as a percentage of their total weekly running time starting at 10 minutes (19% of volume) in week 1 to 115 minutes (58%) in Week 12. Estimated weekly volume approximately 15 km increasing to 30 to 40 km at the peak of the programme.
Outcomes	**Primary:** number of injury events at baseline, 2 weeks, 4 weeks, 8 weeks and 12 weeks, injury incidence, absolute risk reduction, relative risk, FADI, 100 mm VAS items for pain associated with running (regions: overall pain; foot/ ankle pain; shin/ calf pain; knee pain; pelvis/ groin pain; lower back pain). **Secondary:** anatomical location specific 100 mm VAS pain associated with running at the foot, lower leg, knee, groin/pelvis and lower back. With a weekly online survey, compliance, footwear compliance. **Injury defined as**: three consecutive missed run workouts secondary to running-related pain.
Notes	**Study funder and contribution:** this study was funded through an industry partnership grant with Nike Inc. Jack Taunton received funding to his institution to support the research reported in this manuscript. Michael Ryan and Maha Elashi received consulting payments for work to carry out this research. **Conflicts of interest:** none stated. **Correspondence:** the author confirmed the abstract found in our search was that of the full paper included as Ryan 2014.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Method of sequence generation was a computer generated block randomisation scheme (block size n = 8). Quote: "*For concealed group allocation, participants were then randomly assigned by a different author (ME) (via a computer-generated block randomisation scheme—block size 8) to one of the three footwear conditions*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Some personnel were blinded but it was impossible to blind runners to the footwear.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study withdrawal reported with reasons unrelated to intervention.
Selective reporting (reporting bias)	Low risk	All outcomes in a prospective trial registration document are reported in results.

Ryan 2014 *(Continued)*

Other bias	Low risk	We identified no other sources of bias.

Theisen 2014

Study characteristics	
Methods	**Aim:** to investigate whether the mid-sole hardness of running shoes influences running-related injuries. A secondary aim was to determine other modifiable and non-modifiable risk factors for running-related injuries. **Design:** double-blind RCT with two parallel groups. Stratified random allocation into one of two running shoe groups was performed based on the age, sex, BMI and recent regular running practice. **Duration:** 5-month follow-up period (22 weeks). **Centres and locations:** recruitment from Luxembourg, France, Belgium and Germany. **Method of recruitment:** via advertisements in local newspapers and on specialised Internet sites. **Start/End dates:** no information given. **ITT:** per protocol analysis at 22 weeks.
Participants	**Number:** 299. **Inclusion criteria:** healthy (uninjured) volunteers above 18 years were eligible for the study, regardless of the running fitness level. **Exclusion criteria:** runners who were currently injured. **Age:** runners with soft shoes mean: 41.8 ± SD 10.4 years; runners with hard shoes mean: 41.8 ± SD 10.1 years, **Gender:** runners with soft shoes; male: 79 (59%), female: 55 (41%); runners with hard shoes; male: 57 (50.4%), female: 56 (49.6%). **Baseline imbalances:** significantly more running experience in hard shoe runners than soft shoe runners. No imbalances for BMI, previous injury, regular runner and sport participation patterns. **Withdrawals:** total: 5 (1.7%); soft shoe group 2 (1.3%); hard shoe group 3 (2%). 47 (15.7%) were excluded because the study shoes were not produced; soft shoe group 14, hard shoe group 33.
Interventions	**Soft shoes (intervention)** N = 136: a more compliant midsole. **Hard shoes (control)** N = 116; a stiffer midsole. A Quote: "renowned sport equipment manufacturer", anonymised the study shoes, both had a heel-to-toe-drop of 12 mm, the shoes in both groups were strictly identical. However, the Asker C values showed that the midsole hardness was higher (13.1%, P < 0.001) for the hard shoe compared with the soft shoe. Also the standard impact test showed that the hard shoe had a greater overall stiffness (14.9%, P < 0.001). **Schedule:** Participants were required to train on average at least once a week, to report systematically training data pertaining to running and all other sports at least once a week, to report systematically any injury sustained during the follow-up period, to use the provided study shoes for the majority of running sessions but not for the other sporting activities, not to replace the shoe insole with another (orthopaedic) insole.

Theisen 2014 *(Continued)*

Outcomes	**Primary:** running-related injuries in total number and %; the incidence was calculated as the number of RRIs/1000 hours of running activity. **Secondary:** modifiable and non-modifiable risk factors. **Injury defined as:** physical pain or a complaint sustained during or as a result of running practice and impeding normal running activity for at least 1 day (time-loss definition). Injuries were recorded in accordance with published recommendations for sports injury surveillance studies, considering the runner as the unit of analysis. A new injury could be declared either via the sport practice session interface or a dedicated injury declaration page.
Notes	**Study funder and contribution** The study was financially supported by the National Research Fund, Luxembourg (AFR Laurent Malisoux: ref.1189878), and by Oxylane Research, France. **Conflicts of interest:** None stated.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not stated but stratified random allocation into one of two running shoe groups based on age, sex, body mass and regular running practice. Quote: "*Stratified random allocation into one of two running shoe groups was performed based on the age, sex, body mass index (BMI) and recent regular running practice. The latter was evaluated with reference to the 12 months prior to the study, based on regular training (at least once a week) for more than 50% of the time. Thus, the participants with more than six cumulated months of regular running training were defined as regular runners*."
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not stated but each pair of shoes were coded by a co-worker not involved in the study. Quote: "*Each shoe pair was coded by a coworker not involved in the study, such that neither the participants nor the researchers in charge of the trial knew what shoe version a particular runner was using.*"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel were blinded but it was impossible to blind runners to the footwear. However there is an attempt to blind type of shoe by anonymity of shoe and the fact they differed only by stiffness of midsole.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collection was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study withdrawal reported, unclear if reasons were related to intervention. Authors stated some participants did not use their allocated study shoe, but did not provide further information.
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol.
Other bias	Low risk	We identified no other sources of bias.

AUD: Australian dollars ;**BMI:** body mass index; **FADI:** foot and ankle disability index; **FPI:** foot posture index; **ICD-9-CM:** Classification of Disease, Ninth Revision, Clinical Modification; **ITT:** intention-to-treat; **N:** number; **RCT:** randomised controlled trial;**SD:** standard deviation; **VAS:** visual analogue scale.

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

Study	Reason for exclusion
Andréasson 1986	A modelling paper on shoe and surface characteristic. Excluded as the study design was not a RCT or quasi-RCT.
Archer 2019	An opinion article. Excluded as the study design was not a RCT or quasi-RCT.
Attwells 2000	An observational study of foot motion during walking and running. Excluded as the study design was not a RCT or quasi-RCT.
Atukorala 2017	A case cross-over study to identify risk factors for knee osteoarthritis pain flares. Excluded as the study design was not a RCT or quasi-RCT.
Begizew 2019	An observational prospective study of injuries among Ethiopian long-distance runners. Excluded as the study design was not a RCT or quasi-RCT.
Bejjani 1987	A book chapter on the comparative biomechanics of athletes and dancers. Excluded as the study design was not a RCT or quasi-RCT as was not primary research.
Bendix 1985	A study describing the effects of soft shoes and clogs on foot swelling. Excluded as the intervention was not running shoes.
Bishop 2018	A RCT including patients with unilateral plantar fasciopathy who were randomly allocated to either a control or insoles group. Excluded as the study did not include runners as participants.
Brund 2017	A cohort study on medial shoe-group pressure on specific running injuries. Excluded as the study design was not a RCT or quasi-RCT.
Conrad 1975	A cross-sectional survey study collating responses on foot problems in runners. Excluded as the study design was not a RCT or quasi-RCT.
CTRI/2019/08/020567	A trial registration for a RCT comparing barefoot running to shod running. Excluded as incorrect intervention.
CTRI/2020/11/029412	A trial registration for a cross-sectional observational study. Excluded as the study design was not a RCT or quasi-RCT.
Finestone 1992	A prospective RCT of military recruits. Excluded as the intervention was not running shoes.
Frecklington 2019	A RCT including patients with gout who were randomly allocated to either a control or footwear group. Excluded as the study did not include runners as participants.
Grier 2016	A case series study design comparing physical characteristics, fitness performance, and injury risks associated with soldiers wearing minimalist running shoes and those wearing traditional running shoes. Excluded as the study design was not a RCT or quasi-RCT.
Hamill 2017	An abstract of a lecture presenting an overview of parameters used to evaluate footwear. Excluded as the study design was not a RCT or quasi-RCT.
Hein 2011	A prospective cohort study following runners over one year. Excluded as the study design was not a RCT or quasi-RCT.

Study	Reason for exclusion
Johnson 1995	A book chapter on the design of running shoes. Excluded as the study design was not a RCT or quasi-RCT.
Kemler 2018	A protocol for a RCT comparing an injury prevention application to a control group. Excluded as the intervention was not running shoes.
Kirby 2019	A comparison study of a performance shoe to a traditional shoe. Excluded as the study design was not a RCT or quasi-RCT.
Korsgaard Brund 2019	A prospective cohort study following runners over one year. Excluded as the study design was not a RCT or quasi-RCT.
Marti 1989	A cross-sectional observational study that collected injury data from participants of a 16 km run. Excluded as the study design was not a RCT or quasi-RCT.
Milgrom 1992	A randomised prospective study comparing the effects of basketball shoes to standard infantry boots on injury. Excluded as the intervention was not running shoes.
NCT01332110	A RCT registration document for a study comparing the effects of footwear in patellofemoral patients on knee moments and knee pain. Excluded as the intervention was not running shoes.
NCT02567123	A RCT registration document for a study comparing interventions which include switching runners from a rearfoot strike pattern to a forefoot strike pattern. Excluded as the intervention was not running shoes.
NCT02987517	A RCT registration document for a study comparing interventions which include a strength programme and gait re-training aimed at reducing running injuries. Excluded as the intervention was not running shoes.
NCT03311490	A RCT registration document for a study comparing an intervention, shoe tape aimed at reducing running injuries to a control group. Excluded as the intervention was not running shoes.
NCT03636425	A registration document for a cross-sectional study collecting injury information from mountain runners. Excluded as the study design was not a RCT or quasi-RCT.
NCT03760380	A RCT registration document for a study comparing different sole designs on patients with knee arthritis. Excluded as the population was not runners.
NCT03867890	A registration document for a prospective cohort study collecting injury data on leisure-time walkers and runners. Excluded as the study design was not a RCT or quasi-RCT.
NCT04363476	A RCT registration document for a combined exercise and education intervention with osteoarthritis patients. Excluded as the intervention does not include footwear.
Nielsen 2014	A prospective cohort study collecting injury data in novice runners wearing a neutral shoe. Excluded as the study design was not a RCT or quasi-RCT.
Powell 2011	A commentary on Knapik 2010b. Excluded as the study design was not a RCT or quasi-RCT.
Robinson 1991	A preliminary observational study design measuring biomechanical characteristics of seven running shoes. Excluded as the study design was not a RCT or quasi-RCT.
Ryan 2019b	A case series for a physiotherapy regimen directed at improving the pain levels in individuals experiencing plantar fasciitis in two types of footwear. Excluded study as the population was not runners.

Study	Reason for exclusion
Stubbs 2006	A retrospective cohort study to compare runners who had footwear recommended and selected on foot posture to those that had not. Excluded as the study design was not a RCT or quasi-RCT.
Taunton 2003	A prospective survey study collecting injury information from runners involved in a 13-week running programme. Excluded as the study design was not a RCT or quasi-RCT.
Willems 2021	A secondary analysis of Malisoux 2016b. Excluded as the study design was not a RCT or quasi-RCT.

RCT: randomised controlled trial

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

Ryan 2019a

Methods	**Aim:** to investigate the effect of variable training-session and alternating running shoe type on the risk of injuries and onset of running-related pain. **Design:** parallel groups, randomised controlled trial. Method of randomisation not stated. **Duration:** 12 weeks. **Centres and locations:** Vancouver, Canada. **Method of recruitment:** unclear. **Start/End dates:** unclear. **ITT:** unclear.
Participants	**Number:** 264. **Inclusion criteria:** unclear. **Exclusion criteria:** unclear. **Age**: unclear. **Gender:** unclear. **Baseline imbalances:** baseline characteristics not reported. **Withdrawals:** unclear.
Interventions	**Alternating footwear (intervention)** N = unclear: Nike models: Pegasus 33, LunarEpic, Free RunDistance, Streak. **Alternating workout type (intervention)** N = unclear. Footwear model unclear. **Constant workout type in same footwear (control)** N = unclear: Nike model: Pegasus 33. **Schedule:** progressive 12-week half-marathon training programme.
Outcomes	**Primary:** number of injury events, numerical rating of worst pain with running at the foot, ankle, lower leg, knee, upper leg, groin/ pelvis, and lower back. **Injury defined as**: three consecutive missed run workouts secondary to running-related pain.
Notes	**Study funder and contribution:** unclear. **Conflicts of interest:** unclear.

Ryan 2019a *(Continued)*	This is an abstract.

ITT: intention-to-treat

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

ACTRN12613000612718

Study name	The effect of running shoe design on comfort and injury rates in recreational runners
Methods	Randomised controlled trial
Participants	**Inclusion** i. Aged greater than or equal to 18 years ii. Recreational runners male or female with Foot Posture Index indicating a normal foot type (this category includes neutral to slightly flat) iii. Must run regularly (2 sessions or more per week). **Exclusion** i. The current use of foot orthoses ii. Any systemic disease affecting the musculoskeletal system iii. A history of major lower back and leg injury and/or surgery iv. A current acute injury that prevents running
Interventions	Arm 1: Participants will receive a pair of dual density running shoes. The ASICS (Registered Trademark) GEL-1100 (Trademark) series shoe provided is a motion control shoe that provides cushioning and stability. Arm 2: Participants will receive a pair of barefoot running shoes. The Vibram FiveFingers (Registered Trademark) Sprint model provided has a polyamide fabric upper and performance rubber sole.
Outcomes	1. Running injuries survey specifically written for this study that includes details on footwear worn, type and distance of training, practitioner and self-diagnosed injuries. 2. Running shoe comfort survey specifically written for this study with questions concerning shoe comfort measured using a 100mm Visual Analogue Scale (VAS) Timepoint: baseline and 1, 3 and 6 months after intervention commencement
Starting date	28 May 2013
Contact information	Vivienne.Chuter@newcastle.edu.au
Notes	**Correspondence:** Correspondence with the principal investigator on 28th April 2020 confirmed this trial was ongoing.

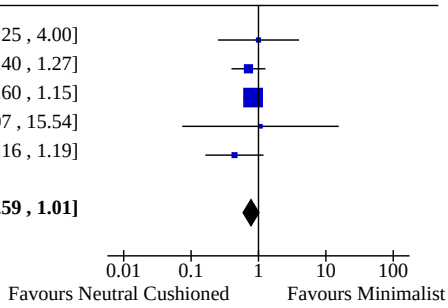
DATA AND ANALYSES

Comparison 1. Neutral / cushioned versus minimalist

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Number of runners injured	5	766	Risk Ratio (IV, Random, 95% CI)	0.77 [0.59, 1.01]
1.2 Running shoe satisfaction	1	24	Risk Ratio (IV, Fixed, 95% CI)	0.73 [0.47, 1.12]

Analysis 1.1. Comparison 1: Neutral / cushioned versus minimalist, Outcome 1: Number of runners injured

	Neutral Cushioned		Minimalist			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Dubois 2015	3	12	3	12	3.8%	1.00 [0.25 , 4.00]	
Fuller 2017a	11	30	16	31	21.4%	0.71 [0.40 , 1.27]	
Malisoux 2016a (1)	38	176	98	377	66.6%	0.83 [0.60 , 1.15]	
Marshall 2013	1	14	1	15	1.0%	1.07 [0.07 , 15.54]	
Ryan 2014 (2)	4	32	19	67	7.3%	0.44 [0.16 , 1.19]	
Total (95% CI)		**264**		**502**	**100.0%**	**0.77 [0.59 , 1.01]**	
Total events:	57		137				

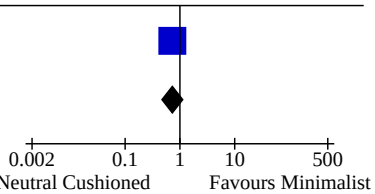


Heterogeneity: Tau² = 0.00; Chi² = 1.68, df = 4 (P = 0.79); I² = 0%
Test for overall effect: Z = 1.87 (P = 0.06)
Test for subgroup differences: Not applicable

Footnotes
(1) 1 Malisoux 2016a had two minimalist (control) groups, and one neutral/cushioned (intervention) group. The data for the two minimalist (control) groups l
(2) 2 Ryan 2014 had two minimalist (control) groups, and one neutral/cushioned (intervention) group. The data for the two minimalist (control) groups has be

Analysis 1.2. Comparison 1: Neutral / cushioned versus minimalist, Outcome 2: Running shoe satisfaction

	Neutral Cushioned		Minimalist			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Dubois 2015	8	12	11	12	100.0%	0.73 [0.47 , 1.12]	
Total (95% CI)		**12**		**12**	**100.0%**	**0.73 [0.47 , 1.12]**	
Total events:	8		11				



Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)
Test for subgroup differences: Not applicable

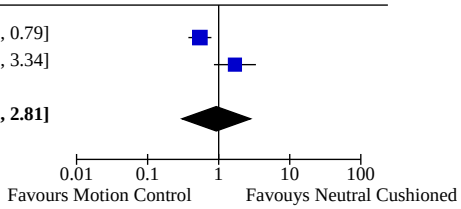
Comparison 2. Motion control versus neutral / cushioned

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Number of runners injured	2	421	Risk Ratio (IV, Random, 95% CI)	0.92 [0.30, 2.81]

Analysis 2.1. Comparison 2: Motion control versus neutral / cushioned, Outcome 1: Number of runners injured

Study or Subgroup	Motion Control Events	Motion Control Total	Neutral Cushioned Events	Neutral Cushioned Total	Weight	Risk Ratio IV, Random, 95% CI
Malisoux 2016b	33	187	60	185	53.3%	0.54 [0.37 , 0.79]
Ryan 2011	13	24	8	25	46.7%	1.69 [0.86 , 3.34]
Total (95% CI)		**211**		**210**	**100.0%**	**0.92 [0.30 , 2.81]**
Total events:	46		68			

Heterogeneity: Tau² = 0.57; Chi² = 8.23, df = 1 (P = 0.004); I² = 88%
Test for overall effect: Z = 0.14 (P = 0.89)
Test for subgroup differences: Not applicable



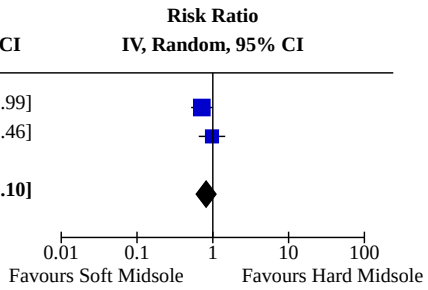
Comparison 3. Soft midsole versus hard midsole

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Number of runners injured	2	1095	Risk Ratio (IV, Random, 95% CI)	0.82 [0.61, 1.10]

Analysis 3.1. Comparison 3: Soft midsole versus hard midsole, Outcome 1: Number of runners injured

Study or Subgroup	Soft Midsole Events	Soft Midsole Total	Hard Midsole Events	Hard Midsole Total	Weight	Risk Ratio IV, Random, 95% CI
Malisoux 2020	54	428	74	420	57.7%	0.72 [0.52 , 0.99]
Theisen 2014	37	134	32	113	42.3%	0.98 [0.65 , 1.46]
Total (95% CI)		**562**		**533**	**100.0%**	**0.82 [0.61 , 1.10]**
Total events:	91		106			

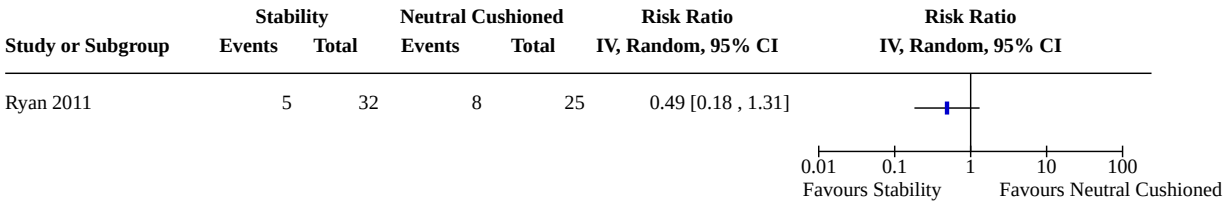
Heterogeneity: Tau² = 0.01; Chi² = 1.38, df = 1 (P = 0.24); I² = 27%
Test for overall effect: Z = 1.33 (P = 0.18)
Test for subgroup differences: Not applicable



Comparison 4. Stability versus neutral / cushioned

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Number of runners injured	1		Risk Ratio (IV, Random, 95% CI)	Totals not selected

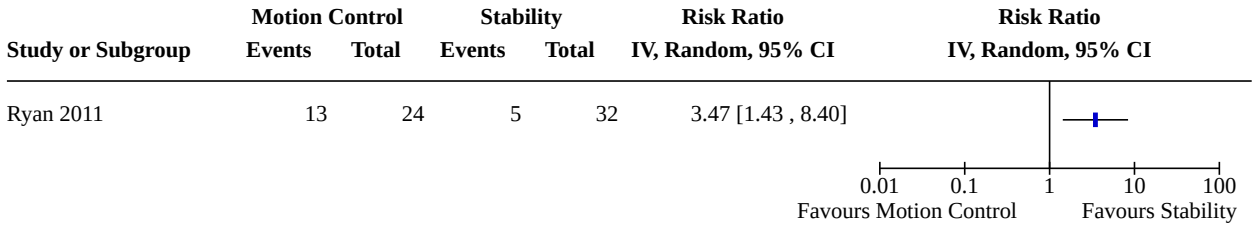
Analysis 4.1. Comparison 4: Stability versus neutral / cushioned, Outcome 1: Number of runners injured



Comparison 5. Motion control versus stability

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Number of runners injured	1		Risk Ratio (IV, Random, 95% CI)	Totals not selected

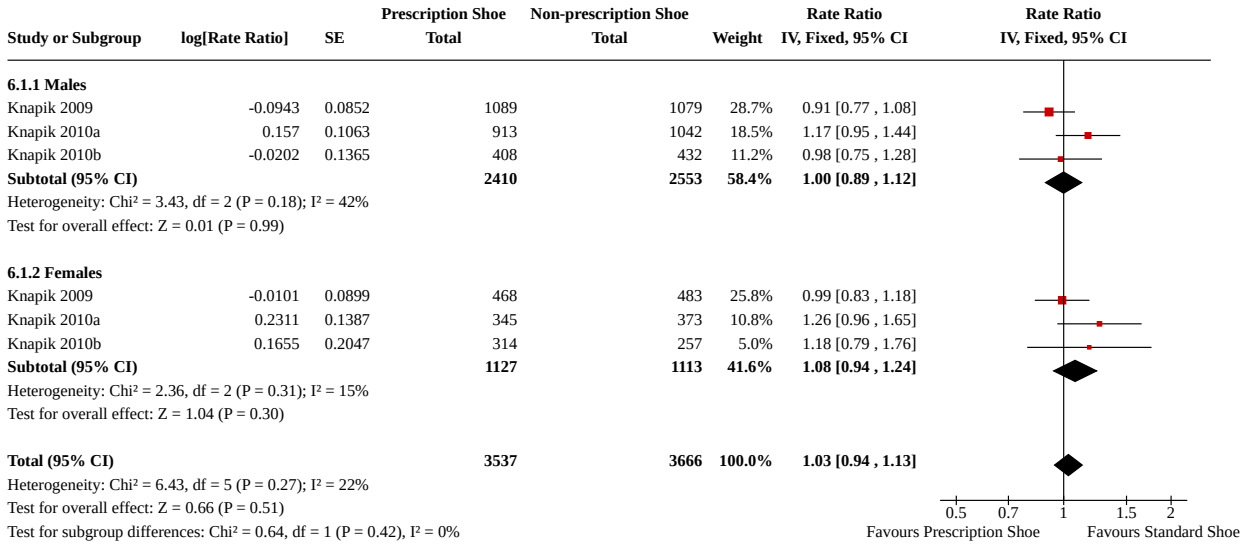
Analysis 5.1. Comparison 5: Motion control versus stability, Outcome 1: Number of runners injured



Comparison 6. Prescribed versus non-prescribed

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Rate Ratios of Injuries	3	7203	Rate Ratio (IV, Fixed, 95% CI)	1.03 [0.94, 1.13]
6.1.1 Males	3	4963	Rate Ratio (IV, Fixed, 95% CI)	1.00 [0.89, 1.12]
6.1.2 Females	3	2240	Rate Ratio (IV, Fixed, 95% CI)	1.08 [0.94, 1.24]

Analysis 6.1. Comparison 6: Prescribed versus non-prescribed, Outcome 1: Rate Ratios of Injuries



ADDITIONAL TABLES

Table 1. Common design features of motion control, stability, neutral/cushioned and minimalist running shoes

Design feature	Motion control	Stability	Neutral/cushioned	Minimalistic
Flexibility (bending stiffness)	Rigid	Rigid rearfoot Flexible forefoot	Flexible	Flexible
Midsole	Firm Multi-density (firmer on medial aspect)	Intermediate Multi-density (firmer on medial aspect)	Soft Multi-density (firmer on medial aspect)	Soft
Heel counter	Rigid Reinforced	Rigid	Varies	No
Medial posting	Yes	Yes	Varies	No
Torsion control system (midfoot trussic)	Yes (reinforced)	Yes	Varies	No
Heel height (mm)	22–30	22–30	22–30	2-8
Forefoot height (mm)	12–24	12-24	12–20	2–8
Heel-toe drop (mm)	10-12	5-12	8-10	0–6
Weight (grams)	290-416	290-330	200-310	120–212

The design features detailed in the table provide a guide as to common features of each type of running shoe and as such are not exhaustive and differences between manufacturers and models of shoe are common.

Table 2. Running shoe type and manufacturer of included studies

Study	Running Shoe Type	Brand and Model
Different Types of Running Shoes		
Dubois 2015	Neutral / Cushioned (intervention)	ASICS Cumulus, Landreth, Nimbus; Brooks Defyance,Ghost, Ravenna; Mizuno Wave Inspire, Wave Rider
	Minimalist (control)	Inov8 F-Lite 195, Bare X-Lite 150, Road X-Lite 155; Mizuno Wave Universe; Saucony A5
Fuller 2017a	Neutral / Cushioned (intervention)	Asics Gel Cumulus
	Minimalist (control)	Asics Piranha SP4
Malisoux 2016a	Neutral / Cushioned (10 mm drop) (intervention)	Decathlon
	Minimalist (6 mm drop) (control)	
	Minimalist (0 mm drop) (control)	
Ryan 2014	Neutral/ Cushioned (intervention)	Nike
	Minimalist (control)	Nike
	Minimalist (control)	Vibram
Malisoux 2016b	Motion Control (intervention)	Decathlon
	Neutral / Cushioned (control)	
Malisoux 2020	Soft (intervention)	Not Reported.
	Hard (control)	Not Reported.
Marshall 2013	Neutral / Cushioned (intervention)	Runners own shoes
	Minimalist (control)	Inov8
Theisen 2014	Soft (intervention)	Not Reported
	Hard (control)	Not Reported
Running shoes recommended and selected on foot posture versus running shoes not recommended and selected on foot posture		
Knapik 2009	Footwear based on foot posture (intervention)	Asics Gel Foundation 7
	Motion Control	Brooks Addiction 7
	Stability	Saucony Grid Stabil 6
	Neutral / Cushioned	New Balance 767ST

Table 2. Running shoe type and manufacturer of included studies *(Continued)*

		New Balance 857 Asics Gel 120 Asics Gel 2120 Brooks Adrenaline GTS6 Brooks Adrenaline GTS7 Nike Structure Triax Saucony Grid Omni 5 New Balance 717G4 Nike Air Max Moto New Balance 755 Asics gel Cumulus Brooks Radius 6 Nike Air Pegasus Saucony Grid Trigon 4 New Balance 644
	Stability (control)	New Balance 767ST
Knapik 2010a	Footwear based on foot posture (intervention) Motion Control Stability Neutral/Cushioned	New Balance 587 New Balance 498 New Balance 755
	Stability (control)	New Balance 498
Knapik 2010b	Footwear based on foot posture (intervention) Motion Control, Stability, Neutral / Cushioned	New Balance
	Stability (control)	New Balance
Ryan 2011	Motion Control (intervention)	Nike Nucleus
	Stability (control)	Nike Structure Triax
	Neutral/Cushioned (control)	Nike Pegasus

Table 3. Injury Details

Study	Location of injury intervention (number of injuries)	Location of control (number of injuries)	Injury type intervention	Injury type control	Injury severity intervention	Injury severity control

Table 3. Injury Details *(Continued)*

			(number of injuries)	(number of injuries)	(number of injuries)	(number of injuries)
Comparison: neutral / cushioned shoes versus minimalist shoes						
Malisoux 2016a	Lower back region/pelvis 2 Hip/groin 1 Thigh 0 Knee 9 Lower leg 13 Ankle 10 Foot 2 Toe 1	Lower back region/pelvis 4 Hip/groin 1 Thigh 6 Knee 22 Lower leg 28 Ankle 16 Foot 19 Toe 0	Tendon 19 Muscle 11 Capsules and ligaments 5 Bone structures 2 Other joint structures 1	Tendon 53 Muscle 31 Capsule and ligaments 6 Bone structures 4 Other joint structures 4	Slight (0-3 days) 9 Minor (4-7 days) 6 Moderate (8-28 days) 11 Major (>28 days) 12	Slight (0-3 days) 17 Minor (4-7 days) 18 Moderate (8-28 days) 29 Major (>28 days) 34
Dubois 2015	Lower back region 1 Lower leg 2	Foot 2 Thigh 1	Non-specific low back pain 1 Medial tibial stress syndromes 2	Metatarsal stress fracture 1 Iliotibial band syndrome 1 Plantar fasciitis 1	Not specified	Not specified
Fuller 2017	Thigh 0 Knee 5 Calf 4 Shin 1 Ankle 0 Foot 1	Thigh 1 Knee 5 Calf 4 Shin 3 Ankle 2 Foot 1	Not specified	Not specified	Not specified	Not specified
Marshall 2013	Calf 1	Calf 1	Not specified	Not specified	Not specified	Not specified
Comparison: motion control shoes versus neutral / cushioned shoes						
Malisoux 2016b	Lower back region/pelvis 0 Hip/groin 1 Thigh 4 Knee 7 Lower leg 7 Ankle 10 Foot 4 Toe 0	Lower back region/pelvis 2 Hip/groin 5 Thigh 5 Knee 10 Lower leg 16 Ankle 13 Foot 8 Toe 1	Tendon 17 Muscle 9 Capsule and ligaments 5 Bone structures 1 Other joint structures 1 Other 0	Tendon 25 Muscle 18 Capsules and ligaments 8 Bone structures 5 Other joint structures 2 Other 2	Slight (0-3 days) 7 Minor (4-7 days) 8 Moderate (8-28 days) 12 Major (>28 days) 6	Slight (0-3 days) 16 Minor (4-7 days) 4 Moderate (8-28 days) 25 Major (>28 days) 15

Table 3. Injury Details *(Continued)*

Comparison: soft shoes versus hard shoes

Malisoux 2020	Lower back region 0 Buttock/pelvis 3 Hip/groin 3 Thigh 5 Knee 12 Lower leg 9 Ankle 13 Foot 9	Lower back region 2 Buttock/pelvis 3 Hip/groin 1 Thigh 5 Knee 16 Lower leg 15 Ankle 21 Foot 11	Tendon 25 Muscle 11 Capsule and ligaments 5 Bone structures 2 Other joint structures 5 Other 6	Tendon 37 Muscle 14 Capsule and ligaments 10 Bone structures 1 Other joint structures 3 Other 9	Moderate (8-28 days) 29 Major (>28 days) 25	Moderate (8-28 days) 51 Major (>28 days) 23

APPENDICES

Appendix 1. Search strategies

The searches were run in three stages: the first search was run in July 2019, top-up searches were run in July 2020 and May/June 2021.

CENTRAL (CRS Web)

Search 1

1. MESH DESCRIPTOR Running EXPLODE ALL AND CENTRAL:TARGET (1713)
2. MESH DESCRIPTOR Sports AND CENTRAL:TARGET (801)
3. MESH DESCRIPTOR Track and Field AND CENTRAL:TARGET (46)
4. MESH DESCRIPTOR Athletes AND CENTRAL:TARGET (585)
5. MESH DESCRIPTOR Athletic Injuries AND CENTRAL:TARGET (548)
6. MESH DESCRIPTOR Military Personnel AND CENTRAL:TARGET (772)
7. MESH DESCRIPTOR Naval Medicine AND CENTRAL:TARGET (51)
8. MESH DESCRIPTOR Military Medicine AND CENTRAL:TARGET (164)
9. (runn* or jog* or sprint* or athlet* or overuse*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET (14727)
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 (15954)
11. MESH DESCRIPTOR shoes AND CENTRAL:TARGET (357)
12. (footwear or shoe* or footgear or shod):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET (1441)
13. #11 OR #12 (1441)
14. #13 AND #10 (272)

Search 2 (top-up search)

15. 22/07/2019_TO_03/07/2020:CRSCREATED AND CENTRAL:TARGET (165667)
16. #15 AND #14 (57)

Search 3 (top-up search)

#15 03/07/2020_TO_28/05/2021:CRSCREATED AND CENTRAL:TARGET (121819)
#16 #14 AND #15 (38)

MEDLINE (Ovid)

Search 1

1 exp Running/ or Sports/ or "Track and Field"/ or Athletes/ or Athletic Injuries/ (76435)
2 Military Personnel/ or Naval Medicine/ or Military Medicine/ (63512)
3 (runn* or jog* or sprint* or athlet* or overuse*).tw. (104022)

4 1 or 2 or 3 (202334)
5 shoes/ (6022)
6 (footwear or shoe* or footgear or shod).tw. (9190)
7 5 or 6 (11204)
8 randomized controlled trial.pt. (485119)
9 controlled clinical trial.pt. (93135)
10 randomized.ab. (388095)
11 placebo.ab. (180756)
12 drug therapy.fs. (2122506)
13 randomly.ab. (268562)
14 trial.ab. (403787)
15 groups.ab. (1667186)
16 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 (4121235)
17 exp animals/ not humans.sh. (4598182)
18 16 not 17 (3517983)
19 4 and 7 and 18 (318)

Lines 8 to 18 are the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised studies (Lefebvre 2011).

Search 2 (top-up search)

20 (201907* or 201908* or 201909* or 201910* or 201911* or 201912* or 2020*).ed,dt. (2013500)
21 19 and 20 (37)

Search 3 (top-up search)

20 (202007* or 202008* or 202009* or 202010* or 202011* or 202012* or 2021*).ed,dt. (2023531)
21 19 and 20 (33)

Embase (Ovid)

Search 1

1 Sport/ or Jogging/ or Running/ or Triathlon/ or Athlete/ (105249)
2 Sport injury/ or leg injury/ (33229)
3 Soldier/ or Navy/ or Military Medicine/ or Military Service/ (44253)
4 (runn* or jog* or sprint* or athlet* or overuse*).tw. (152021)
5 1 or 2 or 3 or 4 (257767)
6 Shoe/ (8693)
7 (footwear or shoe* or footgear or shod).tw. (13316)
8 6 or 7 (15744)
9 5 and 8 (2521)
10 Randomized controlled trial/ (555816)
11 Controlled clinical study/ (464063)
12 Random*.ti,ab. (1419065)
13 randomization/ (83099)
14 intermethod comparison/ (251247)
15 placebo.ti,ab. (285079)
16 (compare or compared or comparison).ti. (464352)
17 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. (1940474)
18 (open adj label).ti,ab. (72252)
19 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. (213566)
20 double blind procedure/ (159939)
21 parallel group*1.ti,ab. (23727)
22 (crossover or cross over).ti,ab. (96566)
23 ((assign* or match or matched or allocation) adj5 (alternate or group*1 or intervention*1 or patient*1 or subject*1 or participant*1)).ti,ab. (305787)
24 (assigned or allocated).ti,ab. (359382)
25 (controlled adj7 (study or design or trial)).ti,ab. (320569)
26 (volunteer or volunteers).ti,ab. (229799)
27 trial.ti. (269090)
28 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 (4307139)
29 (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.) (5758605)

30 28 not 29 (3715989)
31 9 and 30 (590)

The RCT filter (lines 10 to 30) is an adapted version of the Cochrane Centralised Search Project filter for identifying RCTs in Embase Ovid (see https://www.cochranelibrary.com/central/central-creation for information).

Search 2 (top-up search)

32 (2019* or 2020*).dc,yr. (3007823)
33 31 and 32 (68)

Search 3 (top-up search)

32 (2020* or 2021*).dc,yr. (3000965)
33 31 and 32 (78)

AMED (Allied and Complementary Medicine) (Ovid)

Search 1

1 exp running/ (2088)
2 Athletic injuries/ or Sports/ (6179)
3 athletics/ or jogging/ (333)
4 Military Personnel/ or military medicine/ (509)
5 (runn* or jog* or sprint* or athlet* or overuse*).tw. (10593)
6 1 or 2 or 3 or 4 or 5 (12380)
7 shoes/ (1092)
8 (footwear or shoe* or footgear or shod).tw. (1977)
9 7 or 8 (1977)
10 6 and 9 (488)
11 Randomized controlled trial.pt. (4614)
12 Controlled clinical trial.pt. (70)
13 Randomized Controlled Trials/ (2210)
14 Random Allocation/ (322)
15 Double-Blind Method/ (717)
16 clinical trial.pt. (1228)
17 exp Clinical trials/ (4067)
18 (clinic* adj25 trial*).tw. (7453)
19 ((singl* or doubl* or trebl* or trip*) adj (mask* or blind*)).tw. (3065)
20 Placebos/ (625)
21 placebo*.tw. (3350)
22 random*.tw. (19263)
23 exp Research design/ (19810)
24 (latin adj square).tw. (25)
25 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (38315)
26 exp Animals/ not Humans/ (11555)
27 25 not 26 (37371)
28 10 and 27 (64)

Search 2 (top-up search)

29 (2019* or 2020*).up,yr. (18209)
30 28 and 29 (6)

Search 3 (top-up search)

29 (2020* or 2021*).up,yr. (25007)
30 28 and 29 (8)

CINAHL Plus (EBSCO)

Search 1

S1 MH running+ (11,764)
S2 MH jogging (219)

S3 MH athletes (10,224)
S4 MH athletic injuries (16,398)
S5 MH sports (7,903)
S6 TX runn* or jog* or sprint* or athlet* or overuse* (84,051)
S7 MH military personnel OR MH servicemembers OR MH armed forces (14,009)
S8 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 (101,826)
S9 MH shoes OR MH athletic shoes (5,259)
S10 TX footwear OR TX shoe* OR TX footgear OR TX shod (10,511)
S11 S9 OR S10 (10,511)
S12 S8 AND S11 (2,692)
S13 MH randomized controlled trials (84,278)
S14 MH double-blind studies (41,671)
S15 MH single-blind studies (12,644)
S16 MH random assignment (55,758)
S17 MH pretest-posttest design (38,935)
S18 MH cluster sample (3,830)
S19 TI (randomised OR randomized) (91,157)
S20 AB (random*)(260,066)
S21 TI (trial)(93,149)
S22 MH (sample size) AND AB (assigned OR allocated OR control) (3,672)
S23 MH (placebos) (11,370)
S24 PT (randomized controlled trial) (87,065)
S25 AB (control W5 group) (92,013)
S26 MH (crossover design) OR MH (comparative studies) (216,835)
S27 AB (cluster W3 RCT) (289)
S28 MH (animals+) (83,353)
S29 MH (animal studies) (104,335)
S30 TI (animal model*) (2,742)
S31 S28 OR S29 OR S30 (180,050)
S32 MH (human)(1,950,372)
S33 S31 NOT S32 (159,382)
S34 S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27(599,893)
S35 S34 NOT S33 (574,433)
S36 S12 AND S35 (455)

Lines S13 to S35 are a validated filter to identify reports of controlled clinical trials within CINAHL Plus (Glanville 2019).

Search 2 (top-up search)

S37 EM 2019 OR EM 2020 (558,233)
S38 S36 AND S37 (35)

Search 3 (top-up search)

S37 EM 2020 OR EM 2021 (473,780)
S38 S36 AND S37 (25)

SPORTDiscus (EBSCO)

Search 1

S1 DE "RUNNING injuries" or DE "jogging injuries" or DE "OVERUSE injuries" (4,057)
S2 DE "SPORTS injuries" or DE "SPORTS injury prevention" (10,500)
S3 ((DE "RUNNING") OR (DE "JOGGING")) OR (DE "TRACK & field") (38,353)
S4 TX (runn* or jog* or sprint* or overuse* or athlet*) (444,503)
S5 S1 OR S2 OR S3 OR S4 (451,956)
S6 (DE "SHOES") OR (DE "RUNNING shoes") (3,707)
S7 TX footwear OR TX shoe* OR TX footgear OR TX shod (17,289)
S8 S6 OR S7 (17,289)
S9 S5 AND S8 (10,284)
S10 TX ((clinic* N3 trial) or (controlled N3 trial) or (comparative N3 trial) or (placebo N3 trial) or (prospective N3 trial) or (randomi?ed N3 trial)) or TX ((clinic* N3 study) or (controlled N3 study) or (comparative N3 study) or (placebo N3 study) or (prospective N3 study) or (randomi?ed N3 study)) (90,823)
S11 (random* N7 allot*) or (random* N7 assign*) or (random* N7 basis*) or (random* N7 divid*) or (random* N7 order*) (12,779)

S12 TX ((singl* N7 blind*) or (doubl* N7 blind*) or (trebl* N7 blind*) or (tripl* N7 blind*)) or TX ((singl* N7 mask*) or (doubl* N7 mask*) or (trebl* N7 mask*) or (tripl* N7 mask*)) (7,679)
S13 TX (cross#over*) or TX (cross N1 over*) (6,546)
S14 TX randomi?ed control* trial* (18,276)
S15 TX ((allocat* N3 condition*) or (allocat* N3 experiment*) or (allocat* N3 intervention*) or (allocat* N3 treatment*) or (allocat* N3 therap*) or (allocat* N3 control*) or (allocat* N3 group*)) or TX ((allot* N3 condition*) or (allot* N3 experiment*) or (allot* N3 intervention*) or (allot* N3 treatment*) or (allot* N3 therap*) or (allot* N3 control*) or (allot* N3 group*)) or TX ((assign* N3 condition*) or (assign* N3 experiment*) or (assign* N3 intervention*) or (assign* N3 treatment*) or (assign* N3 therap*) or (assign* N3 control*) or (assign* N3 group*)) or TX ((divid* N3 condition*) or (divid* N3 experiment*) or (divid* N3 intervention*) or (divid* N3 treatment*) or (divid* N3 therap*) or (divid* N3 control*) or (divid* N3 group*)) (14,222)
S16 TX placebo* (10,802)
S17 S10 or S11 OR S12 OR S13 OR S14 OR S15 OR S16 (111,768)
S18 S09 AND S17 (523)

Search 2 (top-up search)

S19 S09 AND S17: Published date: 20190101-20201231 (38)

Search 3 (top-up search)

S19 S09 AND S17: Published date: 20200101-20211231 (25)

WHO International Clinical Trials Registry Platform

1. Runn* and shoe* or sport* and shoe* or jog* and shoe* or athlet* and shoe* or sprint* and shoe* or overuse and shoe* (50)
2. Runn* and footwear or sport* and footwear or jog* and footwear or athlet* and footwear or sprint* and footwear or overuse and footwear (16)
3. Search using 'Advanced Search'(runn* OR jog* OR athlet* OR sport*) Title field AND (shoe* OR footwear) Intervention field (31)
Combined total 97

ClinicalTrials.gov

(running OR runners OR jogging OR athletic OR athlete OR sport) AND (shoe OR footwear OR shod OR footgear) (162)

HISTORY

Protocol first published: Issue 7, 2019

CONTRIBUTIONS OF AUTHORS

NR: wrote and contributed to all sections, and acts as guarantor
HG: reviewed all sections; screened the search results, and data extraction,
RA: reviewed all sections; risk of bias; contributed to the writing of the background and discussion
TP: reviewed all sections; contributed to the writing of the background and discussion
IG: reviewed all sections; contributed to the writing of the background
SS: reviewed and contributed to all sections; data extraction, risk of bias and data analysis
PD: reviewed and contributed to all sections
BL: reviewed all sections; screened the search results and full texts, selected the included studies, contributed to the writing of all sections

All authors contributed to, and approved, the final version of the review.

DECLARATIONS OF INTEREST

NR: none
HG: none
RA: none
TP: Contributer to a think tank for a sports equipment manufacturing company (expenses only)
IG: none
SS: none
PD: none
BL: Dr Ben Langley has previously undertaken research funded by Anima Sana in Corpore Sano (ASICS). However, the nature of Dr Langley's previous work and the proposed work would not be eligible for inclusion within the review and focuses more on how running shoe modification or types of running shoes influence potential markers of injury risk or performance rather than injury occurrence.

SOURCES OF SUPPORT

Internal sources

- Edge Hill University, Other

  Internal support

External sources

- None, UK

  None

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following changes were made from the original protocol; we merged data across all time points reported in studies within the analysis because we found that there was limited information in the study reports about the time points of assessment; where two types of the same running shoe type were included within a study, the data were combined to provide a single injury rate/risk for that specific type of running shoe; a narrative description of subgroup analysis was provided due to a lack of data sets to facilitate meta-analysis on a subgroup level; we added body mass index (BMI) as a subgroup analysis as it was included as a risk factor in three included trials and hence we thought it was an important finding to report; we undertook sensitivity analysis exploring the influence of including studies which did not undertake true intention-to-treat analysis and where definitions of injury were unclear.

INDEX TERMS

Medical Subject Headings (MeSH)

Europe; *Lower Extremity; *Shoes

MeSH check words

Adult; Female; Humans; Male