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Effectiveness of foot orthoses for the prevention of lower limb overuse injuries in naval recruits: a randomised controlled trial

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ABSTRACT

Objectives To evaluate the effectiveness of prefabricated foot orthoses for the prevention of lower limb overuse injuries in naval recruits.

Methods This study was a participant-blinded and assessor-blinded, parallel-group randomised controlled trial. Three-hundred and six participants aged 17–50 years who undertook 11 weeks of initial defence training at the Royal Australian Navy Recruit School (Cerberus, Australia) were randomised to a control group (flat insoles, n=153) or an intervention group (contoured, prefabricated foot orthoses, n=153). The combined incidence of medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain during the 11-week training period were compared using incidence rate ratios (IRR). Data were analysed using the intention-to-treat principle.

Results Sixty-seven injuries (21.9%) were recorded. The control and intervention group sustained 40 (26.1%) and 27 (17.6%) injuries, respectively (IRR 0.66, 95% CI 0.39 to 1.11, p=0.098). This corresponds to a 34% reduction in risk of developing medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy or plantar fasciitis/plantar heel for the intervention group compared with the control group. Participants in the prefabricated orthoses group were more likely to report at least one adverse event (20.3% vs 12.4%; relative risk (RR) 1.63, 95% CI 0.96 to 2.76; p=0.068; number needed to harm 13, 95% CI 6 to 253). The most common adverse events were foot blisters (n=20, 6.6%), arch pain (n=10, 3.3%) and shin pain (n=8, 2.6%).

Conclusion Prefabricated foot orthoses may be beneficial for reducing the incidence of lower limb injury in naval recruits undertaking defence training.

Trial registration number Australian New Zealand Clinical Trials Registry: ACTRN12615000024549.

BACKGROUND

Regular physical activity provides many health and social benefits, yet activity-related lower limb overuse injuries are common.[1–3] The incidence of these injuries among long-distance runners and physically active defence personnel has been reported to range from 19% to 79%[1] and 20% to 50%,[2] respectively. The most common activity-related injuries include medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain.[1–3] These injuries can result in lost training time, adversely affect an individual's physical and mental health and incur financial costs, all of which can increase the risk of ceasing physical activity.[2 4]

Given the high incidence and detrimental effects of lower limb overuse injuries, interventions that are effective at preventing injuries would be beneficial for physically active individuals. Foot orthoses are commonly used for the prevention of overuse injuries.[5] A recent systematic review that included 11 clinical trials found that foot orthoses decrease the incidence of lower limb stress fractures and shin splints during defence training by 41% and 73% respectively, but there was no evidence for the prevention of any other lower limb soft-tissue injuries.[5] Although promising, caution is required when interpreting these findings as the clinical trials on this topic are generally of low to moderate quality, and as such, they may have overestimated the treatment effect.[5]

Given the lack of high-quality evidence supporting the use of foot orthoses to prevent lower limb injuries, this trial aimed to evaluate the effectiveness of prefabricated foot orthoses in naval recruits.

METHODS

Design

The Australian Navy Cerberus Orthotic Research (ANCOR) trial was a participant-blinded and assessor-blinded, parallel-group randomised controlled trial, comparing flat insoles (control) to prefabricated foot orthoses (intervention). The location of the trial was the Royal Australian Navy Recruit School, Cerberus, Australia. Ethical approval was provided by the Australian Defence Human Research Ethics Committee (764-14) and the La Trobe University Faculty Human Ethics Committee (FHEC 14/250). All participants provided written informed consent prior to enrolment. The full trial protocol has been published previously,[6] with some of the methods reproduced below.

Sample size

An *a priori* sample size calculation estimated that 306 participants (ie, 153 per group) were required to provide 80% power to detect a 50% reduction in injury in the intervention group (alpha set at 5%).[6] The sample size for the study was calculated assuming a combined incidence of injury of 30% and a drop-out of 20%.

Participants

Participants were naval recruits from the Australian Defence Force undertaking 11 weeks of initial defence training. Prior to attending initial defence training, naval recruits were required to pass a

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pre-entry fitness assessment (see online supplementary file 1). All naval recruits were invited to participate. Participants were excluded if they already used foot orthoses or had a lower limb injury (worst pain at least 30 mm on a 100 mm visual analogue scale (VAS)[7 8]) at the time of recruitment.

Interventions

Practising podiatrists registered with the Podiatry Board of Australia provided all interventions. Participants were randomised to one of two groups: (i) a control group (3 mm flat insoles) or (ii) an intervention group (Formthotics prefabricated foot orthoses) (figure 1). Both interventions were manufactured by the same company (Foot Science International, Christchurch, New Zealand) and were full-length insoles made from the same material (140 kg/m^3 single-density, closed-cell polyethylene foam) and had identical branding. The prefabricated foot orthoses are commercially available, while the flat insoles were made specifically for this trial. To maintain blinding, participants were advised that they were receiving one of two types of 'shoe insoles' during the study. The allocated shoe insoles were fitted to each participant's athletic footwear and Defence-issued boots (Oliver Footwear Pty Ltd Structural Fire Fighter Boot, Model Number 20292). All participants received a handout explaining how to wear in, and care for, their shoe inserts.

Randomisation

To ensure allocation concealment, permuted block randomisation with random block sizes, stratified by sex, were undertaken using an interactive telephone service provided by the NHMRC Clinical Trials Centre (University of Sydney, New South Wales, Australia).

Data collection sessions

Participants attended three data collection sessions: sessions 1–3.

Session 1 (baseline): an initial eligibility assessment was performed. Participants completed the Recent Physical Activity Questionnaire to determine their physical activity in the 4 weeks prior to commencing training,[9] and injury history, general demographic data, physical assessments and anthropometric measures were collected.[6] Participants' fitness information (eg, 2.4 km time trial results) was obtained. Participants were then randomly allocated to one of the two groups. The allocated shoe insoles were placed in the participant's footwear and heated. The participants were then required to stand in their footwear with the heated insoles to enable the insoles to mould to their feet and footwear. Participants rated the comfort of their shoes and insoles after wearing the allocated shoe insoles for several minutes using a 100 mm VAS. Following this, participants rated the insole's credibility using The Treatment Credibility Scale (scored out of 240 mm).[10]

Participants were then provided with self-report diaries that consisted of body[11] and foot[12] pain drawings. Each week, participants were required to indicate the presence of pain on the pain drawings. If pain was reported, participants were required to indicate the usual and worst pain experienced during the previous week on two separate 100 mm VASs. In addition, participants were required to report any adverse events in their weekly self-report diaries. An adverse event was defined as any harmful or unpleasant outcome that may or may not be related to the intervention that did not result in lost training days, require a medical appointment or develop into a subsequent injury. Participants were required to describe each adverse event in their own words, record how long it lasted and rate the severity as either mild, moderate or severe.

Session 2 (week 2): if participants reported that their allocated insoles were uncomfortable, the insoles were inspected and modified (eg, remoulded, spot-heated or ground down) until comfort was achieved.

Session 3 (week 11): an exit interview was conducted with a blinded assessor. If lower limb pain was reported by the participants, the assessor determined the presence of medial tibial stress syndrome,[13] patellofemoral pain,[14] Achilles tendinopathy[15] and plantar fasciitis/plantar heel pain.[16] The self-report diaries were collected and to verify the information contained in the diaries, defence medical records were audited for injury data.

Definition of injury

Injury was defined by the presence of pain that scored at least 30 mm on a 100 mm VAS when at its worst.[7 8] The diagnosis of medial tibial stress syndrome,[13] patellofemoral pain,[14] Achilles tendinopathy[15] and plantar fasciitis/plantar heel pain[16] was determined using standardised clinical assessments (see online supplementary file 2).

Outcome measures

The primary outcome measure was the combined incidence of participants with medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain as determined at medical appointments throughout the 11 weeks of training and by assessors at the exit interview (week 11).

Secondary outcomes were: (i) the overall incidence of participants with a lower limb injury; (ii) the severity of lower limb pain; (iii) days to lower limb injury; (iv) days to drop-out from injury; (v) the type, frequency and severity of self-reported adverse events; (vi) lost training days; (vii) shoe comfort and (viii) health status (see online supplementary file 3).

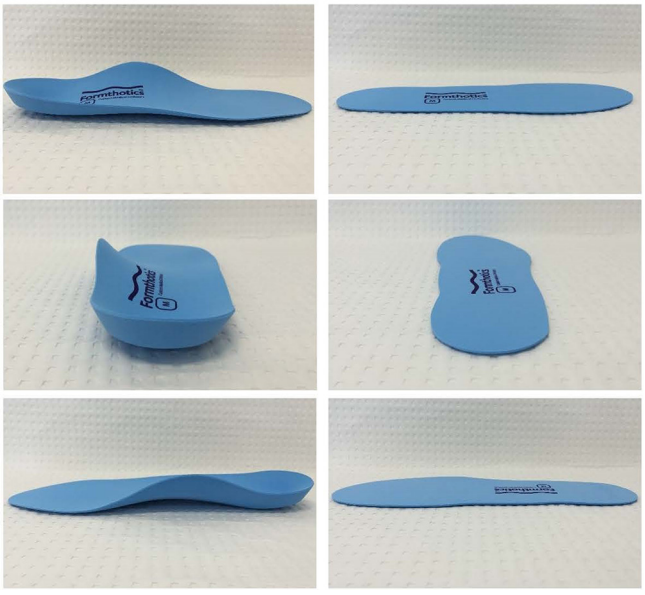

Figure 1 The prefabricated foot orthosis (left) and flat insole (right) prior to being heat moulded to a participant's foot. Top panels show lateral view, middle panels show posterior view and lower panels show medial view.

Data handling and analysis

Statistical analysis was performed using SPSS V.24.0 (IBM Corporation, New York, USA) and Stata SE V.14 (Stata Corporation, Texas, USA) using the intention-to-treat principle for all randomised participants.[17] The endpoint was the completion of the 11 weeks of training for each participant. Multiple imputation was used to replace any missing data using five iterations, with age, and group allocation as predictors.[18] The exception was for adverse events where no data substitution was applied.

The differences between groups for the primary outcome of lower limb injury and the secondary outcome measure of the incidence of lower limb injury were compared using incidence rate ratios (IRRs). Number needed to treat (NNT) and number needed to harm (NNH) were calculated based on the primary outcome and adverse event data, respectively. Differences between groups for continuous outcome measures were analysed using independent *t*-tests. Time to lower limb injury and drop-out were compared using Cox proportional HRs. The difference between groups for health status was compared using analysis of covariance (ANCOVA) with baseline scores and intervention group entered as independent variables (to account for baseline differences).

RESULTS

Participants

Figure 2 shows the flow of participants through the study. The sample consisted of 306 participants (65 women and 241 men) aged 17–50 years, mean age 22.2±4.8 years. One-hundred and fifty-three participants were allocated to each group. Baseline characteristics of the two groups were similar (table 1).

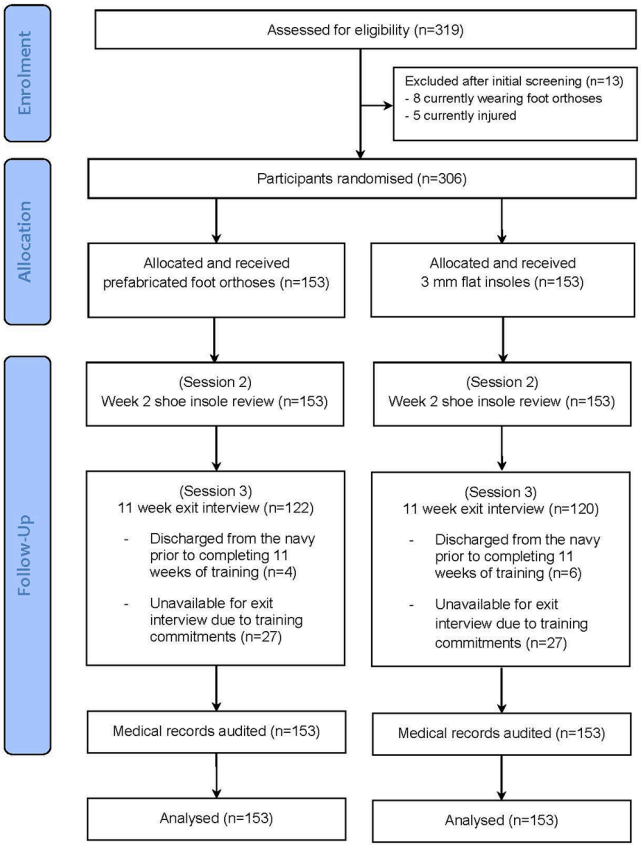

Figure 2 Flow of participants through the trial.

Participant retention and intervention adherence and credibility

The trial commenced in January 2015 and was completed in August 2015. Participants in the flat insole and prefabricated orthosis groups reported wearing their shoe inserts for a similar number of mean hours per day during the trial (10.5±3.6 vs 10.2±5.2 hours; p=0.695). There were no differences between the flat insole and prefabricated orthosis groups for insole credibility at baseline (177.5±34.0 vs 181.5±31.2 mm; p=0.287).

Primary outcome

Sixty-seven participants (21.9%) developed a lower limb injury during the 11-week training period, with the flat insole and prefabricated orthosis groups sustaining 40 (26.1%) and 27 (17.6%) of these injuries, respectively. This corresponds to a 34% relative reduction in risk of lower limb injury in the prefabricated orthosis group (IRR 0.66, 95% CI 0.39 to 1.11, p=0.098), an absolute risk reduction of 8.5% and NNT of 12 (95% CI 139 harm to ∞ to benefit 6) (table 2).

Secondary outcomes

One hundred and forty-eight participants (48.4%) developed lower limb injuries during the 11-week training period, with the flat insole and prefabricated orthosis groups sustaining 81 (52.9%) and 67 (43.8%) of these injuries, respectively. This

Table 1 Baseline characteristics of participants

Variable	Prefabricated foot orthosis (n=153)	Flat insole (n=153)
Age (years)	22.2 (5.2)	22.3 (4.3)
Sex, n (%) man	121 (79)	120 (78)
Height (cm)	175.4 (8.7)	175.9 (8.2)
Weight (kg)	77.8 (13.7)	78.8 (13.8)
Body mass index (kg/m^2)	25.3 (3.5)	25.4 (3.6)
Waist circumference (cm)	87.3 (9.9)	87.3 (10.5)
Hip circumference (cm)	102.7 (7.3)	102.2 (8.0)
Waist to hip circumference ratio	0.85 (0.06)	0.85 (0.06)
Foot posture * †	2.6 (2.8)	3.1 (7.8)
Supinated, n (%)	10 (6.5)	13 (8.5)
Normal, n (%)	102 (66.7)	108 (70.6)
Pronated, n (%)	41 (26.8)	32 (20.9)
Navicular drop (mm) ↺	5.6 (4.6)	7.4 (5.8)
Ankle dorsiflexion, knee extended (degrees) ↺	42.1 (6.5)	40.9 (6.0)
Ankle dorsiflexion, knee flexed (degrees) ↺	45.8 (6.5)	44.7 (6.3)
Education (total years)	13.1 (1.97)	13.1 (1.8)
Total PAEE (kJ/kg/day) ‡	188.5 (46.4)	185.6 (47.2)
PAEE at home (kJ/kg/day)	4.7 (3.9)	5.3 (4.5)
PAEE at work (kJ/kg/day)	0.6 (0.4)	0.5 (0.4)
PAEE for recreation (kJ/kg/day)	181.6 (46.3)	178.7 (48.3)
PAEE for travel (kJ/kg/day)	1.6 (6.1)	1.1 (5.4)
Multistage fitness test	7.8 (1.8)	8.1 (1.8)
2.4 km time trial (mins)	11.4 (1.7)	11.2 (1.7)

Values are mean (SD) unless stated.
*Data presented for right foot.
†Foot posture was determined using the FPI, which scores between −12 (supinated characteristics) and +12 (pronated characteristics).[29] Foot posture classified as supinated (FPI <0), normal (FPI 0–5) or pronated (FPI >5).[30]
‡PAEE was determined using the Recent Physical Activity Questionnaire.[9]
FPI, Foot Posture Index; PAEE, physical activity energy expenditure

Table 2 Number of participants with medial tibial stress syndrome, patellofemoral pain, Achilles tendinopath and plantar fasciitis/plantar heel pain

Injury	Prefabricated foot orthosis (n=153)	Flat insole (n=153)
Combined lower limb injuries*	27	40
Medial tibial stress syndrome	11	14
Patellofemoral pain	7	14
Achilles tendinopathy	2	0
Plantar fasciitis/plantar heel pain	7	12

*Includes combined cases of medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain (primary outcome).

corresponds to an 18% reduction in risk in developing lower limb pain for the prefabricated orthosis group (IRR 0.82, 95% CI 0.59 to 1.15, p=0.121). Physical health status (SF-12v2, physical component) slightly reduced in the prefabricated orthosis group relative to the flat insole group (ANCOVA-adjusted mean difference of −1.8 points; 95% CI −3.3 to −0.3; p=0.019).

There were no differences between the flat insole and prefabricated orthosis groups for shoe comfort at baseline (69.9±13.2 vs 70.8±14.7 mm; p=0.581) and week 11 (62.9±23.2 vs 63.0±22.2 mm; p=0.995), usual (25.6±17.3 vs 26.3±22.5 mm; p=0.890) and worst lower limb pain (32.0±21.4 vs 35.3±26.2 mm; p=0.612), usual (22.9±17.7 vs 17.7±18.7 mm; p=0.348) and worst (28.4±22.5 vs 25.3±26.1 mm; p=0.679) foot pain, time to lower limb injury (29.1±23.6 vs 26.7±22.7 days; p=0.530; HR 1.14, 95% CI 0.83 to 1.58, p=0.425), time to drop-out from injury (34.5±24.3 vs 35.6±14.2 days; p=0.931; HR 1.33, 95% CI 0.22 to 8.06, p=0.756), lost training days (1.6±4.2 vs 1.0±2.7 days; p=0.206) and mental health status (SF-12v2, mental component) (ANCOVA-adjusted mean difference of 1.6 points; 95% CI −0.1 to 3.3; p=0.065).

Adverse events

Participants in the prefabricated orthosis group were more likely to report at least one adverse event (20.3% vs 12.4%; RR 1.63, 95% CI 0.96 to 2.76; p=0.068; NNH 13, 95% CI 6 to 253). The most commonly reported adverse events were arch pain (n=10, 3.3%), shin pain (n=8, 2.6%) and blisters of the arch (n=8, 2.6%), posterior heel (n=7, 2.3%) and plantar heel (n=5, 1.6%). The majority of adverse events were reported by the participants as mild (46.7%) or moderate (39.3%) in severity and mostly occurred in the first 2 weeks of the trial (77.1%).

DISCUSSION

This study is the first participant-blinded and assessor-blinded, parallel-group randomised controlled trial to investigate the effectiveness of foot orthoses for the prevention of lower limb overuse injuries. Prefabricated orthoses, compared with flat insoles, reduced the combined incidence of medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain by 34% in naval recruits undertaking 11 weeks of initial defence training.

Although this reduction in injury incidence is clinically relevant, the probability of occurring by chance was slightly greater (p=0.098) than the conventional p value threshold of 0.05 to be considered statistically significant. It must be noted that the *a priori* sample size was calculated assuming a 50% reduction in injury with the prefabricated orthoses compared with the flat insoles. Given the findings of our trial, it is clear that the forecast reduction in injury incidence in the prefabricated orthoses group was overly optimistic. As such, a larger sample would have been required in order for the reduction in injury rate to achieve statistical significance. However, it is important to note that because the p value is borderline with what is commonly accepted as statistically significant, the true effect is most likely be around the point estimate.[19 20] Accordingly, the findings of this trial (IRR 0.66, 95% CI 0.39 to 1.11) indicate that it is likely that prefabricated orthoses are beneficial for reducing the incidence of common lower limb injuries in naval recruits undertaking initial defence training.

Regarding the secondary outcomes, the prefabricated orthoses reduced the incidence of overall lower limb pain by 18% when compared with the flat insoles, although similar to our primary outcome, it was not statistically significant (p=0.121). There were no differences between groups for time to lower limb injury, severity of lower limb pain, time to drop-out from injury, lost training days and mental health status (SF-12v2, mental component). Adherence to the flat insoles and prefabricated orthoses was similar, with an average wear time of 10 hours per day for both groups. The excellent intervention adherence for both groups may, in part, be explained by the finding that the flat insoles and prefabricated orthoses were both perceived to be equally comfortable and credible by the participants. Of interest, and somewhat in contrast to the primary outcome, the flat insole group reported a greater physical health status (12-Item Short Form Health Survey (SF-12) version 2, physical component) compared with the prefabricated orthoses group. The minimal clinically important difference (MCID) of the physical component of the SF-12 is not known in this population, so it is unclear whether a difference of <2 points (out of 100 points) is clinically meaningful, particularly when the MCID for patients who have undergone major back[21] and knee[22] surgery is 3 and 5 points, respectively.

The prefabricated orthosis group reported a greater number of adverse events (20.3% vs 12.4%). The trial data (NNH) indicate that 13 participants needed to receive prefabricated orthoses for 1 participant to experience at least one adverse event, compared with the flat insole group. Importantly, the adverse events were generally minor (eg, arch irritation and arch blisters) and in most cases are transitory. These findings are not surprising as foot orthoses have been shown to increase pressure in the medial arch, whereas flat insoles have been shown to provide a relatively small mechanical effect in this region.[23]

Choice of interventions used in this trial

Prefabricated orthoses were selected for this trial as they are more practical than custom-made orthoses as they can be issued to participants immediately. Additionally, prefabricated orthoses are relatively inexpensive compared with custom-made orthoses, which is likely to be a factor when deciding whether they become a standard issue for defence force recruits. It is also worth noting that a recent systematic review found that prefabricated orthoses and custom-made orthoses provided a similar risk reduction for preventing overall injuries, although the reduced risk provided by custom-made orthoses did not reach statistical significance.[5]

A distinguishing feature of this trial compared with previous trials was the use of a flat insole as a control intervention that was perceived to be credible. Ten of the 11 previous randomised trials used either a flat insole (not intended to appear as a credible intervention) or standard military-issued footwear (shoe alone) as the comparator. The control insole we used minimises non-intervention effects that may confound or bias the findings,

such as placebo effects, resentful demoralisation and ascertainment bias.[24] Although the influence of these factors are difficult to measure, the flat insole used in this trial was perceived by participants to be equally credible and likely to provide the same benefits as the prefabricated foot orthosis. Finally, it is worth noting that the flat insole used in this study is best considered as a 'sham' rather than a true placebo, as it is likely to have some mechanical effect on the foot (eg, redistribution of plantar pressure), as shown by similar 'sham' insoles in previous studies.[23 25]

Strengths and limitations of this trial

This trial was designed to optimise scientific rigour with some key features including the use of allocation concealment, appropriate participant randomisation, participant-blinding and assessor-blinding, blinded data entry, adhering to the intention-to-treat principle to analyse data and the use of a control intervention. Further, this is the first trial on this topic to calculate injury based on days of exposure, thereby accounting for participants who completed less days of training over the 11-week period. However, our findings need to be interpreted in the context of several limitations. First, the participants were predominantly healthy young men enrolled in a standardised training programme and this is unlikely to be representative of the general population. Second, participants used defence-issued footwear (including boots), the biomechanics of which differ compared with standard athletic footwear.[26–28] Third, it is unknown if the flat insole provides any therapeutic effects, so the inclusion of the control insoles could potentially mask some of the treatment effects of the contoured foot orthoses. Finally, our trial focused on a selection of four common overuse injuries, which were combined during analysis. Future investigators will need to consider whether they report overall injury or specific injuries, with this decision needing to be made in the context of the population under investigation.

Clinical implications

In the absence of evidence-based guidelines for the prescription of foot orthoses, an unmodified prefabricated orthosis was used in this study. Although the results of this study may not be generalisable to different orthotic prescriptions, the orthosis selected in our trial is commercially available and widely used in clinical practice. The primary outcome of our study is consistent with 11 previous trials that evaluated a large variety of foot orthoses for the prevention of injury.[5] When data from 11 of the 12 trials are pooled (one trial is unable to be included), the overall effect (RR 0.71, 95% CI 0.56 to 0.91) is similar to the estimates from our study (RR 0.68, 95% CI 0.44 to 1.04).[5]

Knowing the number of recruits requiring foot orthoses to prevent an injury (relative to the flat insole group) provides a clinically useful measure of relative benefit (ie, NNT). The data from this trial indicate that 12 naval recruits need to receive foot orthoses to prevent one episode of medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy or plantar fasciitis/plantar heel pain (relative to the recruit receiving a flat insole). This information needs to be contextualised with the knowledge that the foot orthoses used in this study have a relatively low supply cost ($AUD 35), while the cost of an injury should also be considered when determining costs and benefits associated with their use.

CONCLUSIONS

This randomised controlled trial found that prefabricated foot orthoses, when compared with flat insoles provide a clinically relevant reduction in the combined incidence of medial tibial stress syndrome, patellofemoral pain, Achilles tendinopathy and plantar fasciitis/plantar heel pain in naval recruits undertaking 11 weeks of initial defence training.

What are the new findings?

- The incidence of common lower limb injuries in naval recruits undertaking initial defence training can be reduced by using prefabricated foot orthoses.
- This is the first participant-blinded and assessor-blinded, parallel-group randomised controlled trial to find whether contoured, prefabricated foot orthoses can prevent lower limb overuse injuries.
- This trial provides new evidence that foot orthoses may be beneficial for reducing the incidence of common lower limb soft-tissue injuries by one-third.

How might it impact on clinical practice in the near future?

- Foot orthoses may be used for the prevention of common lower limb injuries in defence personnel.
- A reduction in common lower limb injuries can provide benefits for physically active individuals.
- Prefabricated foot orthoses provide individuals and employers with a relatively cost effective intervention for the prevention of injury.

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Contributors DRB and GSM: responsible for acquisition of data and can take responsibility for the integrity of the data. DRB and HBM: involved in statistical analysis and interpretation of data. DRB: responsible for the preparation of the manuscript with all other authors involved in its review prior to submission for publication. All authors: were involved in study concept and design; read and approved the final manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Australian Defence Human Research Ethics Committee (764-14) and the La Trobe University Faculty Human Ethics Committee (FHEC 14/250).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Unpublished data are available upon request subject to ethical approval.

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