Reviewer's report

Title: Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial

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Reviewer: Trevor D Prior

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'Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial'

This study protocol is well written and presented and appears suitably designed to test the hypotheses.

There are sufficient details to allow replication although some clarification of terminology is required which I have detailed below.

Major compulsory revisions

1. The paper evaluates the ‘use of foot orthoses’. However, the variability in design / materials and prescription protocols is so wide it is important that the orthoses being evaluated are accurately described. The authors have sufficiently explained the choice of device utilised based on ease, cost effectiveness etc. and should accurately describe the device, particularly in the title. Whatever results they obtain will be relevant to this specific device.

It would be of benefit if there were commonly used descriptions of differing devices but a description such as ‘personalised / modified / heat moulded preformed EVA orthoses would be a more accurate description. Alternatively, they could state the product in the title.

2. Similarly, the authors also provide a good reasoning regarding the choice of the control intervention which can be a contentious issue. I believe they have justified the device utilised but some confusion could remain.

In their justification, they quote a paper that evaluates a small range of sham orthoses (reference 50). However, in this reference, the 3 sham orthoses were described as:

1. Contoured polyethylene sham foot orthosis
2. Contoured ethylene vinyl acetate (EVA) sham foot orthosis
3. Flat ethylene vinyl acetate (EVA) sham foot orthosis

In the paper being reviewed, the flat insole is to be moulded to the subject’s foot within the shoe and thus most closely resembles the contoured EVA device rather than the flat device. Given that they have used the above paper as
justification for their choice, they should be consistent with the terminology. It will also remove the possibility of confusion or misunderstanding and enhance the ability to replicate the study.

3. The authors acknowledge the difficulty in predicting which individuals will benefit from the prophylactic use of foot orthoses using characteristics such as foot posture. However, they also report that they will be collecting data on foot posture, ankle joint dorsiflexion and lumbopelvic stability. This would suggest that they would be able to evaluate the effect of these factors on outcomes yet have not indicated that these will be incorporated in the analysis. This leaves some conclusions / possibilities:

a. The authors omitted this and it should be included.
b. The authors intend to analyse this and report in a separate paper. If this is the case, then these aspects of data collection should either be
   i. removed as they have no relevance to this paper as it stands or
   ii. acknowledge that this will be reviewed in a separate paper so that both papers can identify that they were evaluating the same group of subjects. In my opinion, this has great value when comparing results.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I have a business relationship with a company that produce preformed orthoses but do not feel this is a competing interest.