Reviewer's report

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

Version: 1 Date: 14 July 2015

Reviewer: Michelle Spruce

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1. Is the question posed original, important and well defined?
The area is of importance but initially is limited to the specific sample group under investigation, namely naval recruits. Therefore, any potential extrapolation should be treated cautiously but it appears this is recognised in the submitted article. Further detail is required as to the definition of the proposed orthotic intervention as there does not appear to be a prescriptive/functional element to separate it from that of a simple insole. Consequently, the proposed question would not match the study design.

2. Are the data sound and well controlled?
Some justification as to why a cross over design would be not beneficial as it would appear that participants will be able to identify the difference in intervention, thus querying the claim of a “blind” RCT. This statement is underpinned by the fact that the participants will be living and working in close proximity and the visual difference between the control and intervention device maybe apparent.

Moreover, the reviewer was unsure from the manuscript if the flat insoles were also to be heat moulded (see text on pp 8 of the article). Therefore, clarification of this point would be essential to differentiate between the validity of a control and intervention. Namely, is the difference due to a presence or absence of a medial arch support as the material and density appear to be identical? The reviewer would also like to know if the protocol allowed for data to be captured any potential participant visits to the medical officer or physio during the trial period.

3. Is the interpretation (discussion and conclusion) well balanced and supported by the data?
The proposed study outline suggests that a robust strategy is being employed. However, consideration must be given to the aspect that any benefit from the moulded device maybe due to increased surface area contact over pressure rather, thus accommodative rather than altering functionality of the foot during gait/activity. This point is relevant given the normal definition of orthoses versus insoles.

4. Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?
Given the assessors are “blinded” further detail should be provided as to how this is being undertaken. Given the variety of Formthotics models (the website suggests >20) the paper should specify which device has been selected and the underpinning rationale, thus allowing future replication.

5. What are the strengths and weaknesses of the methods?

See previous comment re extrapolation of data. In addition, further information regarding boot construction (it is assumed that new boots are issued at the same point for all recruits) and lacing styles are both standardised.

6. Can the writing, organization, tables and figures be improved?

Identification of insole/orthoses models and confirmation of boot style for naval recruits.

7. When revisions are requested.

The paper appears to be of interest, pertinent and displays a sound rationale. However, the above mentioned points should be clarified to support study design, data and potential conclusions.

8. Are there any ethical or competing interests issues you would like to raise?

The study appears to address all ethical issues and details them very clearly. It may be beneficial to state if the devices were supplied by Formthotics free for the purpose of the study and who retains the right to publish data. This is particularly relevant given the company concerned uses previous papers on their website.