

Reviewer's report

Title: Calcaneal apophysitis: a randomised control trial of clinical treatment options.

Version: 2 Date: 28 September 2009

Reviewer: Anthony Redmond

Reviewer's report:

This is an interesting trial protocol detailing a study that certainly has merit and would be expected to add to the body of knowledge. The authors are to be commended for putting together a study which should address such a relevant and important research question. Nevertheless there are several issues that must be addressed. This is especially the case as this is a trial that has not been funded through a competitive national funding mechanisms and so is based on a protocol that has been subject to minimal peer review.

I note also that the study has already been submitted for ethical review and the authors may have to reconcile recommendations made in the final published version of this manuscript with the trial protocol ratified by their local IRB.

Overall this is a potentially valuable study and the authors are to be complimented for their attempt to put together a solid clinical trial protocol on what is clearly a minimal budget. I am sure that all of my comments can be addressed directly or the limitations discussed.

MAJOR COMPULSORY REVISIONS

1. The authors need to be very careful with their use of the term calcaneal apophysitis. I fully appreciate that this is a term that is widely used in clinical practice but in this context the authors are applying the name to a clinical presentation that is not being verified as an inflammation of the apophysis. I would be perfectly happy for the authors to draw a link in the background section, between the pathology of apophysitis and the clinical presentation but the definitive badging of the pathology as an apophysitis without imaging verification is a step too far.

In the absence of confirmatory imaging or histology would strongly advise the use of a more justifiable clinical label such as posterior heel pain.

2. An extension of this point is improving the definition of the method of case ascertainment. The authors are attempting to investigate a series of therapeutic approaches which purport to address what is presented as a single disease entity underpinned by inflammation of the apophysis (see introduction line 8). It is essential that in the absence of confirmatory imaging or histology, the team adopts a strict protocol for including only participants with the tightest conformity to a single clinical syndrome. Should the term posterior heel pain be adopted instead then this criticism becomes redundant of course.

3. All participants receive a standard minimum care program of icing and stretching. What is the rescue protocol for patients failing one of the subsequent randomised treatment protocols – especially group three who receive no treatment other than the initial ice/stretching?

4. The study relies heavily on two patient reported outcomes, supported by a simple lunge test as the only clinical investigation. I appreciate that without external funding the authors are making the best of what resources are available, but the subjectivity of the outcome set must be addressed in the discussion and conclusions. They should highlight the potential lack of equipoise in the trial design as the perceptions of patients in group 3 (and other groups) may be influenced by the lack of provision of new footwear or 'sophisticated' insoles.

5. The randomisation method is less than gold-standard. In the absence of external funding this is understandable but potential confounding must be discussed.

MINOR ESSENTIAL REVISIONS

1. Please use page numbering to aid in reviewer feedback.

2. Abstract, participants section. See general comments re use of the term calcaneal apophysitis – applies throughout..

3. Introduction, Line 7. The authors note the association of calcaneal apophysitis with histological changes. These should be described in more detail.

4. Introduction (paras after the five bullet points). This section is over-referenced. Rather than list nine or so references to a single concept, it would help the reader to stick with either first-order clinical/scientific studies or landmark reviews.

5. Interventions, para 1. Check spelling gastrocnemus c/f gastrocnemious

6. Methods, factor 1. In the absence of any scientific underpinning for the reduction in gastroc tension produced (or not!) by the EVA heel raise, this is a hypothesised or proposed mode of action rather than a specific intention.

7. Procedure, para 3. The authors should specify the degree of tolerance that will be applied to the timeframe for follow up appointments (eg +/- 2 weeks).

8. Analysis. The authors correctly indicate that an ITT analysis is the best primary strategy. Will there also be a follow-up per protocol analysis to account for dropouts/ins.

9. Justification is given for the specified sample size. This is acceptable although the authors will need to be very careful in the application of any secondary or exploratory analyses. n=108 is only barely adequate for a four group comparison. Any subgroup analyses should be undertaken very judiciously.

10. Conclusion, 2nd para. The authors note the potential for confounding through the lack of clinician blind. The same applies also to the absence of patient blinding, especially in groups who may feel that optimal treatments are being 'withheld'. This should also be discussed.

11. Figures. All three figures were not of adequate quality. Better reproduction is required.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests