Reviewer’s report

Title: Efficacy of customised functional foot orthoses in the treatment of Achilles tendinopathy: study protocol for a randomised trial

Version: 1 Date: 18 August 2009

Reviewer: Julia Potter

Reviewer’s report:

This is a well written protocol with great attention to detail.

Major compulsory revisions

1. Although eccentric muscle exercise has been cited as being an emerging treatment intervention, the background does not go into any detail of the frequency or duration of these exercises. Therefore later in the protocol there seems to be little evidence of why 3 sets of 15 repetitions twice a day was optimum. This needs to be expanded upon either in the background or in the exercise section.

2. The explanation of how orthoses might help Achilles tendonopathy centres around reducing pronation, but Donoghue et al (2008) found this not to be the case in their case-series study. Some explanation may be needed to justify why the proposed study is using orthoses targeted at reducing pronation as a treatment. How did they establish foot position during gait?

3. Statistical analysis

It is stated that if there is a ‘significantly larger number of participant drop out’ etc. You need to be specific about what constitutes ‘significant’.

Minor essential revisions

1. I feel it would be beneficial to the reader to include a brief overview of ‘sham orthoses’ in the abstract rather than just leaving it to the later, detailed section.

2. Is the Victorian Institute of Sport – Achilles questionnaire the only disease-specific scale?

3. Inclusion criterium (ii) states ‘have symptoms in the Achilles tendon of one lower limb only for at least 3 months duration’, which render the exclusion criterium (i) redundant.

4. It needs to be acknowledged that a proportion of the data being collected relies upon participants being vigilant in completing daily diaries; they may complete the exercises but forget to complete the diary, or may make it up!

Discretionary revisions

Assessments

Although you have started with the project it would have been worth considering collecting dominant limb data too as this may provide more understanding of the
development of Achilles tendinopathy. You may want to address this in the discussion.

Baseline assessments and outcome measures
It is not until this late stage that it emerges that data collection will be via postal questionnaires at the 3, 6 and 12 month follow-up. While this is probably appropriate (both for the type of data collected and on cost basis) for the 3 and 6 months, it may not be wise for the final data collection. Although you have built in a 10% drop out, without direct contact with the research centre, participants may be more inclined to drop out of the study. This change would increase the cost of the project, but may be worthy of consideration before you get to this stage of data collection, or acknowledge it in the discussion.

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