Author’s response to reviews

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

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Author’s response to reviews: see over
Reviewer 1: Julia Potter

Reviewer's report:
Major compulsory revision:

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.

   Point taken. We have provided additional information regarding the use of 3 sets of 15 repetitions (twice per day) in the Introduction section of the revised manuscript. We have included the results from a recently published systematic review by Meyer et. (2009).

   ... Although the mechanism of action [1] and optimum dosage (speed of contractions, duration and frequency) for rehabilitation using eccentric calf muscle exercises has yet to be clearly established, up to three sets of fifteen repetitions, performed twice daily for at least eleven weeks of a twelve week period has been shown to be effective in high quality studies [2].

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 targetted at reducing pronation as a treatment. How did they establish foot position during gait?

   The mechanism of action of foot orthoses for Achilles tendinopathy is not fully known. We have modified the introduction (paragraph 4) of the revised manuscript to make this more explicit (and avoid centering around correction of pronation as evidence [3-5] suggests that pronation is not a strong risk factor for Achilles tendinopathy).

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’.

   We have modified the manuscript. This statement now reads:

   Missing data will be replaced with the last score carried forward; although the authors reserve the right to review this if a significantly larger number
of participants drop out of one group (15% difference between groups) [6] as this technique may falsely affect the results [7].

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.

We have modified the abstract to include this information. The abstract now reads:
... One hundred and forty community-dwelling men and women aged 18 to 55 years with Achilles tendinopathy (who satisfy inclusion and exclusion criteria) will be recruited. Participants will be randomised, using a computer-generated random number sequence, to either a control group (sham foot orthoses made from compressible ethylene vinyl acetate foam) or an experimental group (customised foot orthoses made from semi-rigid polypropylene)...

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

Yes. It has been validated and shown to be reliable for measurement of the clinical severity of Achilles tendinopathy by one of the co-authors (JLC) of this manuscript.

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

Point taken. Exclusion criterion (i) has been deleted.

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!

Point taken. However, as both study groups will be instructed to perform the exercises, there is an equal chance of having non-compliant participants in each study group. We are measuring compliance as best as we can and will report this for each study group in the results of this study. We are measuring compliance in the same manner as previous work which showed that compliance was ‘good’ (defined as performing at least 75% of the recommended exercises) for 90%, 80% and 50% of participants at weeks 1, 2-7, and 13 respectively [8].

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.

We have included assessment of the dominant leg (determined as the preferred leg of participants for kicking a ball) in our initial assessment. However, we would prefer not to report this as we cannot find any evidence that shows this to be a risk factor of Achilles tendinopathy, or a predictor variable in response to a clinical response following an intervention.

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.

Following careful consideration to the above comments, we have decided to change the three month assessment to be direct contact between the research centre and participant. We would prefer to make the three month assessment a direct contact, rather than the twelve month assessment, as it may improve participant compliance with the eccentric exercise program (and is still within our cost projections for the study). We believe that conducting the final twelve month review via a postal questionnaire may reduce participant drop-out as it is more convenient for participants to provide data.

The relevant text of the revised manuscript has been altered to reflect the above changes.

Reviewer: Joshua Burns
Reviewer’s report:
The study protocol is very well-written.

Major Compulsory Revisions
1. It is unclear how the authors expect custom foot orthoses to help Achilles tendinopathy. The literature is sparse and in some cases contradictory. The rationale for prescribing a custom device in light of contradictory evidence as to their mechanism of action needs expansion. For instance, if custom foot orthoses reduce pronation and realign the calcaneus, how are they expected to help
people with ‘normal’ feet and ‘supinated’ feet which may not need realignment or mechanical support and who may end up being the majority of participants.

Similarly, the modification of the device for the supinated foot type according to Burns et al. (2006) was originally designed to reduce and redistribute plantar pressure. It is unclear how these properties will assist Achilles tendinopathy. Allocating the most commonly prescribed device is pragmatic and understandable but the authors need to provide a rationale of how they expect it to help people with Achilles tendinopathy. If the mechanism of action is unclear and not mechanical, then simply prescribing footwear or a prefabricated intervention may be suitable.

It would be helpful to understand, at least in the authors’ experience, which of the design features of the custom device are expected to act on the complaint.

Our expectation that the foot orthoses may help Achilles tendinopathy is based on recommendations commonly found within the literature for the treatment of this condition [9, 10-12]. However, given that these clinical trials had a number of methodological limitations, we wish to test if their positive effects are indeed real.

There is currently a lack of high quality evidence that describes the mechanism of action of foot orthoses for Achilles tendinopathy. This is confounded by the equivocal findings regarding the role of foot biomechanics in the development of Achilles tendinopathy [3-5, 13]. There are a number of theories regarding the mechanism of action of foot orthoses (see paragraph 4 of the Background section of the revised manuscript), but the evidence for each one is not strong. Therefore, we cannot speculate on which design features will assist in the complaint. We have revised paragraph 4 of the Background section of the revised manuscript to state more clearly that the mechanism of action is unknown.

We agree that because the mechanism of action is not known, one could argue that prescribing footwear or pre-fabricated foot orthoses may also be suitable. However, as custom foot orthoses are advocated for this condition, we are testing the hypothesis that custom foot orthoses are effective in those with Achilles tendinopathy. Future studies could be aimed at evaluating other interventions for Achilles tendinopathy.

The orthosis prescription protocol described in this manuscript was based on the need to, (i) use the only evidence currently available regarding prescription habits of Australian and New Zealand podiatrists, and (ii) satisfy the criticism that a large proportion of existing research investigating custom foot orthoses effects fails to customize the prescription beyond contouring the plantar surface of the foot.
In our opinion, most podiatrists would consider their client’s body mass as well as foot posture when prescribing a foot orthosis for musculoskeletal injury. We have therefore chosen to use this pragmatic approach to determine the custom foot orthosis prescription.

We chose to use a laterally posted orthosis for the pes cavus foot type as this prescription variable was reported in the literature [14, 15]. We have included Hertel et al.[15] to support our orthosis prescription. We have acknowledged that the prescription protocol was different to Burns et al. [14] as it does not have a padded top-cover.

2. Did the authors consider controlling footwear? Treatment effect may relate to differences in footwear choices rather than differences in the device. For instance, the custom device requires deeper footwear and in many cases a fastening device for comfortable wear, but the sham can be worn in a wider variety of footwear due its highly compressible nature. Even though an inclusion criteria is accommodating footwear, the transient nature of footwear choices will depend on the device allocated for the 12-months study duration, especially for non-athletes.

We agree that controlling footwear would allow for a more precise assessment of the effects of the foot orthoses. However, it would not be feasible to control the participants’ footwear given the study duration (12 months) and multiple styles of footwear participants are likely to wear for different activities. Nevertheless, we have included questions to measure the number of participants who have modified their footwear that they normally wear to accommodate their ‘shoe inserts’ (at 1, 3, 6 and 12 months). Participants will be asked: “Since your last appointment, have you changed your footwear that you normally wear to accommodate your shoe inserts?” Participants who answer “yes”, will then complete questions to document if the change was for footwear for ‘everyday activities’ and/or ‘sporting/exercise’ activities.

We have included these changes (page 23 of the revised manuscript) in the revised manuscript:

Participants will also questioned to determine if they have changed their footwear they normally wear (worn for everyday or sporting activities) to accommodate their foot orthoses.

3. Please clearly state which time-point and domain(s) of the VISA-A constitute the primary outcome. As it stands, there seems to be the potential for 16 comparisons as the primary endpoint (VISA-A Pain, Function, Activity or Total at 1, 3, 6, 12 months). Once selected, please justify the domain and time-point the
authors are most interested in improving in the context of natural history data of Achilles tendinopathy.

The primary outcome will measure will be the total VISA-A score (out of 100). We will not be performing sub-analysis for each domain of the VISA-A questionnaire. Therefore, there are 4 comparisons. We have modified the description of the VISA-A questionnaire in the revised manuscript to include the following:

“The primary outcome measure will be the total score of the Victorian Institute of Sport – Achilles (VISA-A) questionnaire”.

“Scores are summated to give a total score out of 100”.

“The sample size for the study has been pre-specified using an a priori power analysis using the primary outcome measure of the total score of the VISA-A questionnaire”.

We believe the primary time-point for outcome assessment will be 3 months given the financial costs associated with using custom foot orthoses. We have included the following statement in the statistical analysis section of the revised manuscript:

“...the primary efficacy end-point will be change in the total score of the VISA-A questionnaire at 3 months”.

4. Did the authors consider stratification (or minimisation) for foot type and body mass to help balance the groups in case a particular foot type or weight category is prognostic of a treatment response?

At present, the evidence that a particular foot type is associated with Achilles tendinopathy [3-5, 13] is equivocal. Also, height, body mass or BMI do not appear to predict the development of Achilles tendinopathy [5].

There is not currently any evidence that a particular foot type or weight category will predict treatment response to the foot orthoses intervention in those with Achilles tendinopathy. Once the study is complete, we will perform analyses to determine if there are any clinical prediction rules for the success of the foot orthoses intervention.

Minor Essential Revisions
1. Reference no. 1 is not an epidemiological study as referred to in the opening sentence of the introduction (‘6-18%....). Please amend with the original source.

   Point taken. We have inserted more appropriate references in the revised manuscript.

2. How will the custom orthoses be obtained: purchased, discounted, donated?
The custom foot orthoses will be donated. We have added this detail to the revised manuscript.

Discretionary Revisions

1. The word ‘functional’ in the title is meaningless, especially in light of our lack of understanding of how an orthosis produces its ‘function’.

Point taken. This word has been deleted from the title in the revised manuscript.