

Friday 13<sup>th</sup> May 2022

Dear reviewers,

Thank you for providing your reviews of our manuscript **“Does the Use of Orthotics Improve Comfort, Speed and Injury Rate During Running? – A Randomised Control Trial”**, which now has the updated title: **“Does Orthotics Use Improve Comfort, Speed and Injury Rate During Running? – Preliminary analysis of a Randomised Control Trial”**.

Please see the attached revised manuscript which we would like to submit for your consideration for publication.

We have provided details below of our responses to your reviews, including the revisions we have made to the manuscript:

Review #1:

- We appreciate your concerns about the conflict of interest present. We are aware of this and can assure you that this conflict of interest did not impact the collection or analysis of the data. Additionally, the analysis and write up was performed by Alice Fortune who has no conflict of interest.
- We have conducted a sample size calculation. This is mentioned in the ‘data collection’ section of the manuscript. The final study report will include the full sample of 106 participants.
- Our inclusion and exclusion criteria were selected designed with the intention of our study recruiting the ‘average’ amateur runner. The aim of our study is largely to assist amateur runners in improving their comfort and speed and reducing their running related injury (RRI) rates. This is important as amateur runners display higher rates of RRIs than elite runners. If we had designed stricter inclusion and exclusion criteria, ensuring that no participant had any lower limb pathologies at all, this would have excluded many amateur runners from our study, and so would have produced a sample that poorly represents the amateur runner population.
- Recruitment of study participants via virtual methods (telephone or voice call) is a valid and frequently used method. This study was also conducted during the COVID-19 pandemic, when social distancing restrictions were in place, meaning that recruitment via virtual methods was a safer and more practical option.
- Thank you for your suggestion regarding blinding of participants and researchers. Unfortunately, we do not believe that effective blinding of participants in this study was possible. Knowledge of the appearance and function of orthotics amongst the general public is widespread. We believe that a sham orthotic (i.e. a flat innersole) would not have been sufficiently convincing to act as an effective placebo. Regarding blinding of researchers: this would not have changed the way that data was collected or analysed. Therefore, we do not believe that researcher blinding would significantly improve this study.
- Numerous studies have shown that orthotics can improve comfort and decrease incidence of certain lower limb injuries. Some studies show conflicting or

insignificant evidence; therefore, our study was performed to add to the current evidence on orthotics.

- Thank you for highlighting the two types of runners (minimalist and maximalist). We appreciate that our study does not provide any relevant evidence for barefoot (minimalist) runners. It is our understanding that on the whole, the 'average' amateur runner, for whom this study was aimed at, runs in trainers rather than barefoot. Therefore, whilst our study into orthotics use cannot be relevant to every runner, it is relevant to most amateur runners.
- The variables studied in this piece of research gained approval by the Wales Research Committee 5 (reference number: 21/WA/0098) and are the same as variables studied in other published work.
- We have modified the first reference and removed it from the abstract and core tip.

#### Review #2:

- We encouraged participants to record running time and distance data by smartphone to ensure this data was accurate. We are aware that the majority of participants did this.
- We have adjusted the manuscript title to state that it is a preliminary analysis.

#### Review #3:

- We have explained in the discussion and conclusion sections that our findings suggest that orthotics may have a cost benefit, and that a full cost analysis will be provided in the final study report.

#### Review #4:

- We have explained what is meant by "one participant withdrew from the study due to injury, however they were assigned to the control group" within the revised manuscript.
- We have explained the working principle of the Orthotics in the discussion of the revised manuscript.
- We have added an image of the Orthotics and diagrams illustrating how they work, to help readers understand their usefulness.

#### Science editor's report:

- Please see our comments above, in the responses to reviewer #1, regarding conflict of interest and blinding of participants and researchers.
- We performed a power calculation to calculate the appropriate number of participants to recruit for our study. This is described in the manuscript on page 7.
- Thank you for your suggestion to correct analyses for participant factors such as gender, age and injury tendency. Unfortunately, we feel that the sample size is too small to do such an analysis. The groups as analysed by gender, age etc. would be too small to provide appropriate results. However, we will consider this in future studies.
- We have modified the first reference and removed it from the abstract and core tip.

#### Company editor-in-chief's report:

- We have checked that the authors names and institutions meet the requirements of the journal.
- We have checked that the manuscript information is correct.
- We have provided a running title, given on page 1 of the revised manuscript.
- We have added author contributions, given on page 1 of the revised manuscript.
- We have added the article highlights, given on page 12-13 of the revised manuscript.
- We have followed the BGP guidelines and requirements for manuscript revision for randomised control trials.
- We have followed the BPG format for manuscript revision.
- We have reviewed the common issues in revised manuscript and made necessary amendments.
- We have provided all figures in a separate PowerPoint file titled “76189-Figures.pptx”. Figures 2, 3 and 4 are original and so we have added the copyright. Figure 1 was provided by Aetrex, and we have been given permission to use it.
- We have provided all tables in a separate Word document titled “76189-Tables.docx”.

We hope you find these revisions are satisfactory, and we look forward to hearing your response.

Yours sincerely,

Alice Fortune, George Ampat, Jonathan Sims and Samantha Rhodes