

03 August 2023

Dear reviewers,

Thank you for providing your reviews of our manuscript **“Title: Use of Orthotics with Orthotic Sandals Versus the Sole Use of Orthotics for Plantar Fasciitis: Randomised Controlled 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. We have provided it in a tabular format. In the column on the left are the comments made by the reviewer and in the column on the right is our response.

Review #1:

Comments by reviewer	Our response
Scientific Quality: Grade C (Good) Language Quality: Grade B (Minor language polishing) Conclusion: Minor revision	We are grateful for these comments.
This research is well-conducted, with clear, defined methods and well-thought-out statistical analysis. However, like any research, it has strengths and weaknesses that need to be considered when interpreting the results.	We are grateful for these comments.
Strengths: 1: The researchers adhered to CONSORT guidelines for RCT design, which enhances the quality and transparency of the study. This approach strengthens the internal validity of the results. The use of well-established and validated measures (NRS, FHSQ, GROG) increases the reliability of the results.	We are grateful for these comments.
2: Randomization and having a control group allow for a more robust comparison of interventions. This design is critical in ruling out other potential influencing factors. A variety of statistical tests were used to compare within-group and between-group changes over time, improving the robustness of the findings.	We are grateful for these comments.
Weaknesses: 1: Lack of blinding could introduce bias. Even though it's acknowledged that blinding was impossible	We acknowledge this weakness. As stated by the reviewer we have discussed this weakness in our submission. We have gone

in this particular study, it is a limitation since knowing the group assignment can influence the perception of pain and improvement.	to explain how blinding for a physical product like an orthotic can be farcical. In a medicinal trial, a tablet can be produced which looks similar to the test medication, however, when performing research on Orthotics, producing a "Control Orthotic" which looks like the real but which will not function as the real is difficult. It will either have bulk and provide support like the real. Or in contrast if a "Control Orthotic" is produced which is not bulky, then the participants can easily recognise that this is not the real one by searching on the internet and looking at basic designs of Orthotics.
2: The diagnosis was made remotely, which may not be as accurate as a clinical examination. This situation may have resulted in potential misdiagnosis or under diagnosis.	We acknowledge this weakness and thank the reviewer for bringing this to our notice. We have added a few lines in the second paragraph of the discussion to address this weakness.
3: The use of social media for recruitment could introduce bias since it may not represent the overall population affected by plantar fasciitis.	We acknowledge this weakness and thank the reviewer for bringing this to our notice. We have added a few lines in the second paragraph of the discussion to address this weakness.
4: The dropout rate, although accounted for in sample size calculations, could introduce bias if the dropout was not random.	We acknowledge this weakness. While performing sample size calculation we accommodated for a dropout rate of 20%. In the intervention group 2 (4%) participants dropped out and in the control group 4 (8%) participants dropped out. One in the control group had naturally passed away. Taking this into account we do not believe the dropout was not random and was nearly equal in both groups. The strength lies in that the dropout was much less than what was accommodated for.
5: The study does not discuss the potential confounding factors which may influence the outcome, such as lifestyle, physical activity level, or concurrent treatments (e.g., physiotherapy, exercises).	We acknowledge this weakness and as stated by the reviewer, we have discussed this weakness in our submission. However, we had not stated about concurrent treatments and have suggested that they should be considered in future trials.
Overall, the study provides valuable insights into the comparative effectiveness of two interventions for managing plantar fasciitis. It suggests that the combined use of orthotics and orthotic sandals may offer	We are grateful for these comments. However, the main purpose of the study was to empower patients to choose a non-invasive and over-the-counter treatment to address plantar fasciitis or plantar heel pain

additional benefits over the use of orthotics alone in terms of pain reduction. However, given the limitations mentioned, the findings should be interpreted with caution. Future research could benefit from blinded assessments, more diverse recruitment strategies, and consideration of potential confounding factors.	without the need to seek professional help and thereby reduce the burden on the health care system. We have added some comments to the manuscript to address this.
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Specific Comments to Authors: Comments to the authors:

Reviewer #2:

Specific Comments to Authors: Abstract: Manuscript

Scientific Quality: Grade C (Good) Language Quality: Grade A (Priority publishing) Conclusion: Major revision	We are grateful for these comments.
Dear Authors Thanks a lot for the opportunity you have offered me to revise the fascinating manuscript " Use of Orthotics with Orthotic Sandals Versus the Sole Use of Orthotics for Plantar Fasciitis: Randomised Controlled Trial". I thank the authors for their effort in producing this exciting manuscript. From the editing point of view, I recommend the authors to fully respect the editing requirements imposed by this scientific journal and clearly indicated in the template. More specifically, I mean: the number of words in the abstract and manuscript, the number of keywords and the way to indicate the bibliographic sources.	We are grateful for these comments. We wish to reiterate that we respect and have complied with all editing requirements.
As a significant strength, this proposal is a novelty in the field and adds information to the existing evidence in the literature produced in the field.	We are grateful for these comments.
As a major weakness, the manuscript sometimes lacks details and clarity concerning methodological steps that would help improve the understanding of the manuscript. Therefore, I have suggested some strategies to improve authors' reporting and increase the quality of their work (e.g., rationale/background, methods and discussion of the manuscript).	We are grateful for these comments. We have addressed them as stated below.
Overall, my peer-review is a major revision: I	We are grateful for these comments. We

suggest revising the manuscript to improve the pitfalls presented. The final goal is to improve the overall clarity of the message to help the reader understand this fundamental topic.	have made edits to improve the clarity of the message.
Keywords: use MeSH keywords	We have changed the keywords to MeSH keywords
1. Mention the study design, study duration and study setting.	We have addressed that in the revised manuscript.
2. Mention the character of the study participants.	We have addressed that in the revised manuscript.
3. Mention the statistical tests used for the study.	The statistical tests used in the study has already been enumerated under statistical analysis.
4. Mention the reports with 95% CI with upper and lower limits and its p score.	We have addressed that in the revised manuscript.
5. The conclusion should be drawn on the basis of the study reports, not on an assumption.	We have addressed that in the revised manuscript.
6. Remove the sub-titles in the introduction part.	We have addressed that in the revised manuscript.
7. Mention in detail about the orthotic sole, its role, merits and demerits in PF.	We have addressed that in the revised manuscript.
8. Mention the gaps monitored by the researcher in the previous studies.	In the revised manuscript we have stated that the recent systematic review and meta-analysis suggest that the current conclusions on this topic are based on low-quality studies and suggest the need for high-quality trials.
9. Include the study aim and objectives.	We have addressed that in the revised manuscript.
10. Include the clinical significance of this study over clinicians, patients, and researchers after the study hypothesis.	We have addressed that in the revised manuscript.
11. Mention the diagnostic criteria for PF and its ICD classification.	We have addressed that in the revised manuscript.
12. Mention the ethical approval number and clinical trial registration.	We have addressed that in the revised manuscript.
13. Present the study as per the CONSORT guidelines format.	The study has been presented as per the CONSORT guidelines. The CONSORT checklist has been populated
14. Mention in detail the character of study participants.	This is a repeat. See point 2 above which has been addressed.
15. Mention who has diagnosed the participants and their qualification and experience.	We have addressed that in the revised manuscript.
16. Mention the outcome measures	The primary and secondary outcome

measured in the study its reliability and validity and its interpretation.	measures and the details have already been addressed on Page 10, 11 and 12
17. Mention the blinding procedures in detail.	The study was not blinded.
18. The sample size calculation was not apt to this study, please revise it with reference.	The sample size was based on detecting a 1 point difference in change between groups. We understand that using repeated measures ANOVA could have caused confusion and have hence removed that statistic.
19. Mention the demographic details of the study participants.	We have addressed that in the revised manuscript.
20. Present the reports with 95%CI with upper and lower limits for all outcome variables.	This is a repeat. See point 4 above and has been addressed.
21. Describe the results in detail and clearer.	We have addressed that in the revised manuscript.
22. Include the treatment compliance rate, adverse effects and number of drop outs.	We have addressed that in the revised manuscript.
23. Mention the MCID and effect size of each variable.	We have addressed that in the revised manuscript.
24. The discussion is not presented in a logical manner.	We have addressed that in the revised manuscript.
25. Mention in detail how the intervention changes the outcome variables in these participants?	We have addressed that in the revised manuscript.
26. The conclusion should be more concise and self-explanatory and drawn on the basis of study reports.	We have addressed that in the revised manuscript.
I look forward to reading the revised version of the manuscript. Thanks again, and good luck with researching in this challenging time.	Thank you

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

Yours sincerely,

Portia Amoako-Tawiah, Holly Love , Jaida Madathilethu-Chacko , Jessica LaCourse, Alice Fortune , Jonathan M G Sims, George Ampat