Author’s response to reviews

Title: Effectiveness of therapeutic footwear for children: A systematic review

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Response to reviewer reports

The authors appreciate the time it has taken to review our manuscript and thank the reviewers for their insightful comments. A clean untracked version is presented for ease of reviewing. All changes made to the document (inclusive of additions and deletions) are highlighted in a tracked change version located at the end of the clean submission.

In addition, the authors would like to inform the reviewers and editors that minor corrections have been made to Tables 3, 4 and 5 and additional file 3; these corrections have not affected the findings of this study.

Reviewer reports:

Reviewer #1:

The authors have addressed my previous comments well. A few minor concerns with some adjustments are noted below.

· Thank you for your thoughtful comments please find our amendments and response to these below.

Line 1060 - The number 13 needs to be spelled out as it is at the beginning of a sentence.
Line 1063 - additional requires capitalisation to be consistent with previous uses.
Line 1128 - why is participants in quotation marks?

· The text has been modified to address these comments.

The discussion section has much improved with the reduction in length. The first section though is still focused on data management and results. For example, Sentences beginning line 1263 and ending 1271 should be in early results. Lines 1271 to 1282 could then be summarised as 'Study quality was negatively affected in most studies by the reporting strategy, with a lack of descriptions of basic participant anthropometrics and inadequate blinding of participants and assessors impacting generalisability, internal and external validity'. the sentence starting line 1283 could be removed completely. Otherwise it reads well.
The text has been modified to address these comments.

Table 1 - change 'sex' for 'gender'

Table 1 has been modified to address this comment.

Table 3, 4 & 5 - I am unsure why you are describing the statistical analysis in the final column. This is not normally required for a SR and adds bulk to an already bulked result section. Bolding or indicating statistically significant results with an * should be sufficient.

Table 5 has been modified with the removal of the last column and annotation that no statistical testing for significance was performed. However, the authors consider the inclusion of the specific statistical analysis given in Tables 3 and 4 aids the reader to interpret unambiguously, within-group, between group and post hoc statistical findings without altering the overall size of the table.

Reviewer #2:

Thank you for asking me to review the further draft of this manuscript. The paper is improved by the alterations made to it.

My comments are mainly corrections that have identified typos / grammatical errors and a few points for clarification.

Abstract

Line 55 - "When using" - not "whilst using"

Line 56 - remove the colon

Line 66-67 - "and that too...." needs to be change for example, "and only in..."

The text has been modified to address these comments.

Background

No further changes needed

Methodology

Line 178 - this refers to the eligibility criteria identified in the scoping review. As mentioned by the other reviewer previously, this SR should be able to stand alone and there is still too much referencing back to the scoping review. A reader will not wish to be having to continually access that paper to follow all the procedures so they do need to be stated in this review.

Line 178 - "Abstracts which met the definition of children's therapeutic footwear from the scoping review were screened by two reviewers" - this should not be required as the search strategy for the SR
should have picked up these reviews anyway. It would certainly be a useful way to check that your strategy was appropriate, to make sure it picked up papers you already knew, but you shouldn't have had to screen the scoping review papers separately from the SR papers.

Now that I have re-read this, I wonder if you mean that the "definition of children's footwear" was from the scoping review as opposed to the "abstract" screening? - needs clarification either way. Please consider the rest of the paper for over-emphasis on the scoping review.

· The authors note this potential ambiguity. This has been addressed in the text to establish the systematic review followed on from the scoping review (which met PRISMA-ScR extension guidelines), whereby the abstracts that were identified as considering footwear from a therapeutic perspective were assessed against the systematic review criteria. All relevant points from the scoping review are now provided for the reader in the current paper, including descriptors of the therapeutic footwear groupings and the search strategy employed.

Line 194 - "2nd" needs to be changed to "second"

· The text has been modified to address this comment.

Results

Line 222 - change "13" to "Thirteen" - should not start a sentence with a number. Odd rule but the number just looks wrong!

· The text has been modified to address this comment.

Line 232 - numeral "2" needs to be changed to "two".

· This was modified to a numeral in reference to reviewer one’s previous suggested formatting correction.
  “If you are using a number over 10 it can be numerical. If you have a sentence with a number under 10 and a number over 10, convention allows you use the numerical form for both”

Line 232 - there defined footwear groups are still in bold and I am still not sure why this is, particularly as only two of the three groups are in bold. I am not convinced these groups need the defining feature.

Line 267/8 - remove comma after 4 in (Table 4,)

· The text has been modified to address these comments.

Line 283 - why are there inverted commas around "participants"?

· The text has been modified to address these comments.

Line 286 - you describe the "wearing in" period here. Is that relevant? I am not sure that you come back to the point in the discussion. If it is relevant then it needs discussion later as this may be potentially influencing the results of these studies compared to others. If it is not discussed later then please remove the comment.

· This has now been addressed in the discussion alongside the point you have raised in line 470.

Line 357 - remove the full stop before the reference .[41]
Line 374 - "However, two of the dynamic balance outcomes were seen to improve statistically" - does this mean the outcomes were statistically significant? Just saying "statistically" does not provide any information beyond the numbers showed a change.

· The text has been modified to address these comments.

Discussion

Line 465 - again the bold font is present.

· The text has been modified to address this comment.

Line 456 to 479 - these paragraphs tends to report the results and are not discussing the findings. I could perhaps be written to discuss how the quality of the study influence the results - what does it mean for the reader in terms of their practice, should they be using these treatments or not.

· This section has been edited to be clearer on how the design and quality of the studies may potentially inform on clinical practice or where the current evidence is unable to provide informed clinical guidance.

Line 470 - refers to the blinding of subjects in the functional footwear group but the problem of lack of blinding would apply to all the footwear groups, so maybe this needs to be in a general section discussing how the study biases may have influenced results - this could pick up on other issues such as the wearing in period that was noted in the methods section.

· The issue with blinding and its effects on internal validity has now been moved to the general discussion of issues with the footwear studies. The potential effects of an inadequate wearing in period in before-after studies have been included alongside that of a training effect to repeated test conditions.

Line 494 - "Poor quality evidence indicated that instability footwear..." Needs re-wording such as "The evidence indicated that.......but this evidence was of poor quality" - and again it needs a discussion of how the results might have been changed by that poor quality rather than the statement of fact that it was.

· The text has been modified to reflect the bias of participant drop out and the heterogeneity of the participants on the validity of the central trend analysis generated in the study.

Line 533 refers to sexual dymorpism. This needs further explanation as to why this needs to be considered in further studies. What do we know about male / female feet that might make them respond differently to the footwear? The same explanation may be required for height / weight.

· Reference to previous studies that have demonstrated how, gender, height and weight can impact on foot function and skeletal geometry have been included here to support this statement.

Overall, I would like to see much more application of the findings to clinical practice in the discussion.

· Additions to the text have been added to make it clearer what the current evidence base may support. However, the current evidence is limited for any of the therapeutic footwear groupings, not only in the
number of studies but also by the quality and design of these studies. This precludes anything other than tentative clinical recommendations. This has also been found in earlier reviews for other children’s assistive aids such as foot orthoses and symptomatic flexible pes planus (MacKenzie, Rome and Evans, 2012; Dars et al., 2018) The review highlights potential limitations of the included studies and provides suggestions for improving the evidence base.

Limitations

Given my initial concerns over the vague outcome criteria chosen, the limitations have expanded with a single sentence to mention the lack of broad range of outcome measure precluding analysis. Perhaps it warrants a little more than this to consider the lack of validated outcome criteria or consistently defined outcome criteria used in footwear studies which therefore limited the ability to define specific outcome criteria in the SR that could be used for meta-analysis with the review. In the authors reply to my comments they mention the Standard Outcome Sets (ICHOM Standard Sets) so maybe that could be included in the limitations section as it very much confirms the point above.

· The text has been modified to address this comment.
