Reviewer’s report

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

Version: 0  Date: 05 Feb 2020

Reviewer: Jill Ferrari

Reviewer's report:

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

In providing this peer review, I recognise the considerable amount of work that has been undertaken by its authors to form this systematic review. The SR has collated studies on a very useful area of practice that is relevant to the many health professionals involved in the prescription of this footwear. The review is very important is driving the quality of future studies in this field. I feel that this SR does warrant publication and the aim of my comments below are to improve the presentation and clarity of the information to the reader so that the extensive data presented can be better understood. With the complexity of the information provided by a SR it is never easy to present such information is an easy-read format.

The first section of my comments are minor corrections that have identified typos / grammatical errors and a few points for clarification. The second section is suggesting a more detailed consideration of the results section and how the outcome criteria are included.

1. Background

Line 82 - This doesn't read very well - I would suggest "The World Health Organisation International Classification of Function (…) recognises that mobility impairment affects the body structure and function of a child and it may lead……."

Line 89 - "Footwear has been.." change to "footwear is...."

Line 91 - no comma after including,
Small p for pes planus
Line 92 - no comma after cerebral palsy and,
Line 93 - remove comma after professional,
Line 97 - remove comma after effects,

Line 100 - "highlighting that children's (add in "conventional") footwear research has grown rapidly"

Line 102 - "was represented in (add in "just") a small population…"

Line 105 onwards - why are certain words in bold? - this is not necessary.

Line 107 - add comma "further to this, "


Methodology

Line 146 - remove comma after randomised,
Line 147 - "case studies and case report studies (remove comma) were not….."
Line 151 - remove comma between children, and…..

Line 164-167 - need to state what adverse effects were being looked for specifically and state whether these were in the primary or secondary outcomes.

Line 180 - remove comma from between developed, and …..

Results

Line 229 remove comma "These three studies, focused on….."
Also change semi-colon after alignment to a colon

Line 231Start a new sentence for "….all randomised controlled (level 2 evidence). Two were …"

Line 231 - two of the three studies had a fair QI and one had a poor QI.

Line 235 - "The sample size of two of the studies gave sufficient power to detect a moderate change". This needs further defining - what is meant by a moderate change?

Line 249 - "in the development of asymptomatic pediatric pes planus" - does this mean " in the correction of developmental asymptomatic pes planus"? or "in the development of asymptomatic pes planus"? It is unclear if this study would be eligible if it was looking at the development of the condition since the criteria for the review is footwear for correction rather than influencing normal development.

Line 250-256 - please be consistent whether splint is capitalised or not.

Line 262 - add "with an" between studies (with an) age range….
Line 263 - participants needs an apostrophe "participants' "
Line 264 - add "the" - "that (the) small sample size…"
Line 265 "amongst" ???
Line 281 - "medial" or "medical"?
Line 282 - be consistent in Downs or Down's syndrome
Line 284 "three of the four studies [….]" needs a space before bracket and full stop after.

Line 295 - could you clarify in the text whether the "no difference were noted between the stabilising footwear and taping comparator…" is referring to the Down's study or to a different study?

Line 299 remove the semi-colon between study and however

Line 298-300 - there is a contradiction here "No SD was found in the step symmetry however the regular shoe and orthotic demonstrate a significant increase in step symmetry…"

Line 301 please define "meaningful effects"
Discussion

Analysis and synthesis

There are no adverse effects reported in the results, is that because no study included them? Maybe reiterate this important point is that was the case and discuss relevance.

The quality of the studies is reported in the discussion. It would be more useful here to summarise the quality points and then discuss the relevance. - it would benefit the review if the overall result was summarised here and discussed.

Line 484 - as in the comment above for again quality of studies, the results of the pain outcome should summarised and then discussed here.

2.

Outcome criteria
One of my main concerns with this systematic review is the lack of very specific, pre-determined outcome criteria. The selection of important outcomes is a feature that sets a SR apart from a literature review and the prospective planning of the outcome criteria reduces any bias from the authors. Without detailed prospective planning in a review it is unclear if authors are consistent in extracting data or are choosing new outcomes as they start the data extraction and new ideas develop. Whilst I appreciate that the general outcome criteria stated in this SR were considered prospectively, they are not specific in detail and the presence / absence of all the selected criteria is not made clear for each study in this review. By not having strictly specified outcomes in this review, the authors have provided a mixture of outcomes in an overall summary of each paper and therefore there is no consistent representation of outcomes between the studies (this is particularly noted for the secondary outcomes, for example, number of falls, pain or adverse effects). In this situation, the piece of work has a systematic literature search but is not a systematic presentation of results.

The primary outcomes are stated as "biomechanical and skeletal geometric measures". These ideally needed to be considered in smaller outcome groups. The authors needed to identify what are the most important biomechanical outcomes they would be looking for - for example, measures of pronation, and they should state what measures of pronation they would include, for example, foot posture index, navicular drop, arch index. The same would apply for skeletal geometric measures - this needs to be reduced to outcome measures such as transmalleolar axis, metatarsus adductus angle, MLA angles, other recognised X-ray measures. Whilst I appreciate that these might be numerous, the authors needed to identify prospectively, which ones are useful to include, for example only valid measures.

I note in the discussion section (Line 437) that five studies considered velocity as an outcome. If the authors had chosen velocity as a predetermined outcome in the "biomechanical" outcomes, then they might have been able to apply meta-analysis to this outcome or at least presented the data on a forest plot to identify a trend across the studies.

The secondary outcomes are expanded a little more: quality of life, physical activity, social participation, self-esteem, pain. Line 440 in the discussion also states that compliance was a secondary outcome but it does not appear in the listing of the secondary outcomes in the method section, creating the possibility that it was chosen as an outcome at the point of data extraction and not pre-determined in the protocol.

In the results section, the authors have given an overview of the outcome measures of interest when they have been included by each study, but they have not clearly stated when outcomes of interest were not included in the studies. In the therapeutic footwear section, it is clearly stated at the end of the first paragraph that no study considered adverse effects. In the corrective footwear subgroup, it would also be important to state that none of those studies considered any of the secondary outcomes. In that way the reader will know that those outcomes were not considered by the study as opposed to the authors not including the data for other (possibly biased) reasons.

I appreciate that it is not possible now to go back and be specific about the breakdown of outcome criteria considered, unless it was done at the time of protocol planning - but I am thinking it was not as the protocol is also general in the description of the chosen outcomes, but I think the results section could be tightened up little by making sure that all the outcomes of interest have a statement against them if the study did not include any of the pre-selected outcomes. And perhaps the lack of systematic presentation of outcomes needs a comment in the limitations section.

**Level of interest**

Please indicate how interesting you found the manuscript:
An article of importance in its field

**Quality of written English**
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

'I declare that I have no competing interests'

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license ([http://creativecommons.org/licenses/by/4.0/](http://creativecommons.org/licenses/by/4.0/)). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal