Reviewer’s report

Title: A randomised controlled trial and cost-consequence analysis of traditional and digital foot orthoses supply chains in a National Health Service setting: application to feet at risk of diabetic plantar ulceration.

Version: 0 Date: 04 Sep 2018

Reviewer: Gordon Hendry

Reviewer’s report:

JFAR-D-18-00117

Thank you for the opportunity to review this interesting manuscript. I have provided point by point suggestions for revision below.

Major revisions

1. Methods section. Please use recommended headings and subheadings as outlined in CONSORT recommendations for reporting of trials, pragmatic trials and non-pharm intervention trials.

2. Methods, p5, line 45. Discussion around the clinical significance of this is required. The margin of 11.29% seems high and this needs to be explained in terms of the clinical significance/impact of this choice. I note that the studies cited yielding an orthotic effect of 14.5% are all dated. Perhaps there were more suitable PP figures from meta-analyses available?

3. Methods p5 line 56. This is not an effect size as presented. Also should it read 11.29 (typo)? If the mean diff is 11.9 and the SD is 15.2 then the effect size is 0.78 which is very large and unsurprising that this was not achieved.

4. Methods p6, line 1. What software was used for calculation of sample size and how was randomisation generated and administered i.e. software, sealed envelopes?

5. Methods p6 line 20. "Study comprised three visits". This would be better summarised in a SPIRIT table/diagram for trial procedures.

6. Inclusion/exclusion criteria. Confusion as to whether or not absent pulses were included or excluded. Please clarify.

7. Methods p6, line 53. JFAR readership will not be aware of EQ5D and ICECAP - please provide further details including measurement properties.
8. Methods p6 and 7 lines 59-2 (over page). The authors have undertaken a per protocol analysis which is unusual for an RCT. Usually I would expect an intention to treat analysis supplemented with per protocol and/or CACE analyses. Can the authors provide justification for this course of action?

9. Methods p8 line 24. Methods and results for resource use and costs should be reported separately.

10. Stats analysis p9 lines 9-12. Can the authors clarify in greater detail how they have determined the clinical meaningfulness of the NIM?

11. Results, p9, line 55-58. The digital supply chain cannot be both non-inferior and superior, it has to be one or the other. Please see Piaggio et al JAMA 2012(24):2594-2604 figure 1.

12. Results p10 line 2. "...both traditional and digital supply chains was inferior to the NIM" - This isn't quite correct. The error bars should be constructed with mean difference and 95% CI for scores between the two intervention arms. The control and experimental arms should not both be compared to the NIM. Therefore, both interventions cannot be inferior to the NIM.

13. Cost analysis p10 line 43-53. Did they authors not consider the costs of training, equipment or software for the digital supply chain. This seems like a major omission from the costings model.

14. Discussion p11 line 11-13. "largely comparable" - this seems contradictory to the abstract which states a stat sig difference between supply chains in PP at time point 1.

15. A conclusion paragraph is missing from the manuscript.

16. Legend for figure 2 needs to be revised. For figure 2, please see Piaggio et al, 2012 to see how to construct the proper error bar diagrams for non-inferiority.

17. Figures 3 and 4 are not visible for appraisal in their current form.

Minor revisions

1. Title and abstract: please state "cost-consequence analysis" in the title and abstract.

2. Background, line 4. "close clinical management" - needs re-wording.

3. Background, line 11. "reducing pressures <200kPa" needs re-wording.

4. Background, lines 11-12. "Foot orthoses are the result…” needs re-wording.

5. Background, line 23. "In a traditional…” please remove unnecessary commas.
6. Background line 26. "processes" please remove unnecessary "s".

7. Background lines 29-31. Use of "successfully optimised" and "to optimise" suggest these researchers have solved the problem. My understanding is that these look promising pieces of work which have improved pressure reduction, but that further research is required. Please re-word with sufficient caution in the language.

8. Background line 43 "digital" add capital D.

9. Background line 43. "involve fewer human decisions" please clarify.

10. Background line 50-51 "or any lesser efficacy…" please re-word.

11. Methods,p5 line 30. "pragmatic parallel group…" please add "non-inferiority" and "cost-consequence analysis"

12. Methods p5 line 51. How were these figures obtained from the 3 studies? Pooled? Clarity required.

13. Methods p7 line 13-17. "At this stage…." Please cut and paste to results section.

14. Methods p7 line 22. "Orthotic devices", please change to "Interventions"

15. Stats analysis, p8 lines 56-61. This paragraph is confusing and perhaps could be framed as primary analyses and secondary analyses? Some re-wording for clarity required.

16. health economic data and outcomes, p9, lines 23-24. Please explain to the JFAR readership about the significance of the "NHS perspective" as opposed to "societal perspective".

17. Results, HRQoL, line 40. "(preventing cost per QALY analysis)" - if the original intention was to conduct a cost consequence analysis over a cost utility analysis, then this is not relevant and can be deleted.

18. Limitations line 40. Did they authors consider reducing efficacy of FOs due to material compression?

19. Figure 1. Please check totals for exclusions which don't appear to add up correctly.

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