Reviewer's report

Title: Study Protocol for a Randomized Controlled Trial on the Effect of the Diabetic Foot Guidance System (SOPeD) for Prevention and Treatment of Foot Musculoskeletal Dysfunctions in People with Diabetic Neuropathy: FOotCAre (FOCA) Trial I

Version: 0 Date: 15 Dec 2019

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment.

This is a well written comprehensive protocol on the Effect of the Diabetic Foot Guidance System (SOPeD) for Prevention and Treatment of Foot Musculoskeletal Dysfunctions in People with Diabetic Neuropathy: FOotCAre (FOCA) Trial I.

1. I had a few comments and have mainly used the SPIRIT checklist to structure my questions. It has, however, been difficult to check items in the SPIRIT checklist as the page numbers do not correspond to the manuscript, one item was page 1923. I believe you may have used the original protocol submitted to the funder for your SPIRIT checklist but please use the protocol submitted to Trials when completing. The protocol document you may be referring to is too large to submit as a supplementary document so please select the relevant information for your Trials protocol manuscript.

2. I am unclear why Trial 1? It suggests there is a Trial 2 etc. If that is the case I would suggest you insert a sentence saying this is part of a series of proposed trials OR one of two trials etc. Sorry if I have missed information regarding this.

3. There seems to be duplication with page 15 "Intervention" and page 5 "Intervention Group".

4. Figures 2, 3 and 4 are unclear - please check when zoom in details can be read by the reader.

* SPIRIT checklist - It is not acceptable for Trials journal for the authors leave any items blank or with N/A in the SPIRIT checklist. Further information is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

Item 2b: All items from the World Health Organization Trial Registration Data Set. Please state: Please refer to Item 2a and registration in the ClinicalTrials.gov Identifier: NCT04011267

Item 3: Date and version identifier cannot be N/A eg Version 2.0. Date.
Item 5b: this item cannot be N/A. Please give the contact details for the sponsor.

Item 5c: role of sponsors etc information needs to be inserted into the protocol. An example of what has been written is: "The sponsor played no part in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication"

Item 5d: This cannot be N/A. Perhaps you could give information on the composition, roles and responsibilities of the coordinating centre and trial steering committee and all groups providing day to day support for the trial. We also need information on who is responsible for all aspects of local organisation including identifying potential recruits and taking consent. Who is supervising the trial and how often they will meet, plus information on the Trial Steering Committee (TSC), and how often they will meet over the course of the trial to oversee conduct and progress. Plus, information and how often the Stakeholder and Public Involvement Group (SPIG) if there is one, and their specific role.

Item 17b: N/A is not acceptable please answer the question and state why N/A for instance write in the SPIRIT checklist "the design is open label with only outcome assessors being blinded so unblinding will not occur".

Item 19: N/A is not acceptable. Please give details for data entry, coding, security, and storage, including any related processes to promote data quality (e.g. double data entry, range checks for data values). Reference to where data management procedures can be found, if not in the protocol. For instance, will paper based and electronic data entry will be used. Who will collect data? And who will enter the data into the database for screening and randomisation purposes? If paper forms used, will you ensure that the paper-based Case Report Form (CRF) data are delivered securely to the Trial Office for data entry?

Item 20b: please complete methods for any subgroup analysis, if not please state this.

Item 21-23 Monitoring cannot be N/A please insert this information and edit the SPIRIT checklist.

Item 21a requires information inserted into the SPIRIT checklist on Data Monitoring committee referring to page X stating that additional information is in the Appendix.

Item 21b please state why N/A re interim analyses and why there is not anticipated to be no formal stopping rules for the trial.

Item 22: Please insert information on reporting of Adverse events (AEs) or Serious Adverse Events (SAEs) and harms from the intervention. It may be that evidence suggests that SAEs are not anticipated so please state this and indicate what potential minor AEs may be anticipated. And that they will be reported to the DMEC and relevant regulatory bodies as required indicating expectedness, serious-ness, severity, and causality. For instance, page 16 Foot ulcer.
Item 23: Frequency and plans for auditing trial conduct - needs information, this cannot be N/A. For instance, how often Project Management Group meet to review trial conduct. The Trial Steering Group and the independent Data Monitoring and Ethics Committee meet to review conduct throughout the trial period.

Item 25: protocol amendments - please details plans for notifying of any changes to the protocol i.e. notifying sponsor and funder first then the PI will notify the centres and that a copy of the revised protocol will be sent to the PI to add to the Investigator Site File. You may also want to state that any deviations from the Protocol will be fully documented using a breach report form. You can also include you will update the protocol in the clinical trial registry.

Item 26b: Can suggest something like this "On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data with people from the Universities taking part in the research or from regulatory authorities, where relevant. This trial does not involve collecting biological specimens for storage."

Item 30: Provisions for post-trial care - you could state "There is no anticipated harm and compensation for trial participation" and it would be helpful to know if there will be any provision for post-trial care.

Item 31a: This item is blank in the SPIRIT checklist and there does not appear to be information in the manuscript. Please document dissemination in the protocol and in the checklist. Perhaps you could state how results will be communicated to X and X and other relevant groups via publications, reporting results in databases, data sharing arrangements, twitter - social media or through the sponsor etc

Item 31b: page x you state the author contributions please insert page number into checklist or you could also state "All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication." Or All authors have contributed to writing the manuscript as detailed pX, no professional writers have been involved.

Item 31c: Access to data cannot be left blank - it is really important so complete information. Consider stating "The datasets analysed during the current study are available from the corresponding author on reasonable request."

Item 33: See above 26b there will be no biological specimens collected OR if applicable "For this SPIRIT item, please add information on plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trials and for future use in ancillary studies."

**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:

Acceptable

Quality of figures
All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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?

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Were you mentored through this peer review?

No