Author’s response to reviews

Title: Lower limb biomechanical characteristics of patients with neuropathic diabetic foot ulcers: The diabetes foot ulcer study protocol

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Version: 1 Date: 18 Sep 2015

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15th September 2015

Dr Tim Shipley
BMC Endocrine Disorders

Dear Dr. Shipley

Re: Manuscript BEND-D-15-00019. Lower limb biomechanical characteristics of patients with neuropathic diabetic foot ulcers: Diabetes foot ulcer study protocol Please find attached below a response to each of the points that were raised regarding the ethics approval, funding and ongoing status of our study.
1) Requesting ethics and funding proofs

- As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins. Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

a. Ethical and Funding Approval Documentation

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

The ethics approval and extensions of ethics approval for this study have been attached to an email.

b. Funding

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

As we have stated in our funding disclosure on the manuscript and during submission, this work is primarily supported by funding from the Department of Health, Queensland Government, through the Health Practitioner Research Grant Scheme (2013-2014). I have attached the relevant letters of approval of funding in the email.

c. Study status

The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.
This study is ongoing. We have collected our baseline data and are in the process of analysing this data.

d. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

We have not published any results from our study described in the protocol. However, a reproducibility study manuscript investigating the gait methods to be utilised in this longitudinal study is currently under peer-review with the Journal of Foot and Ankle Research; reference; ‘The variability of three dimensional gait analysis and plantar pressure measurement methods using established protocols in participants with and without type 2 diabetes and foot ulcers: a cross-sectional analysis’. If you recall, our initial submission to BMC Endocrinology contained data regarding reproducibility of methods which was suggested to be removed from the protocol. Therefore we incorporated this into a separate manuscript for publication. While the data collected as a part of the reproducibility study came under the same ethics approval, this does not report on any of the outcomes from the planned study and instead focuses on the reproducibility of methods.

Thank you.

Yours Sincerely,

Malindu Fernando
(Corresponding Author)