Reviewer’s report

Title: Lower leg muscle strengthening does not redistribute plantar load in diabetic polyneuropathy. A randomized controlled trial.

Version: 1 Date: 16 January 2013

Reviewer: Joanne S Paton

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Lower leg muscle strengthening does not redistribute plantar load in diabetic polyneuropathy. A randomised controlled trial.

Major Revisions

1. Data should be converted to kPa, the accepted System International unit of pressure.

2. It would be useful for more detail to be provided with regard to exclusion criteria. For example was the diagnosis of severe cardiac disease etc patient reported or from hospital notes? What was the definition of severe cardiac disease/osteoarthritis. How did the researchers define foot deformities and did this include toe deformities? Did they include participants with a history of foot ulceration? How did they assess risk of falling.

3. Authors should consider and describe how using merged data from two different pressure analysis systems could affect the validity of the results and specifically how they overcame this problem. For example it would be helpful if they could present data from a pilot study to confirm that the two systems are comparable or alternatively discuss with reference to their findings that the pressure values did not differ between sites.

4. Authors should adjust p values to correct for multiple testing (Using for example the Bonferroni method). It would also help readers if the authors could expand on the implications of multiple testing and the risk of finding a significant outcome by chance.

5. Authors should be encouraged to include and comply with the CONSORT statement checklist for reporting RCT.

6. I apologise that I am unfamiliar with the statistical tests used but I am confused by the results. I wonder if it would be helpful to clarify a couple of points. Whilst the results section explains that the intervention had no effect on peak pressure, table 2 Group (IG vs CG) suggests the difference between groups was significant. Does this actually mean that groups were not comparable for PP at baseline?

7. I am not clear if the analysis actually compares PP before and after intervention between groups? Is that not your primary outcome given that you have undertaken a RCT? If it is rather to build a model to determine the association of a number of predictor variables on plantar pressure then why use
an RCT design when a observational cohort study with an appropriate sample size would be more appropriate. It is normal practice to use intention to treat analysis when applying an RCT. I have serious concerns given the high attrition rate that this approach was not adhered particularly given that the sample size calculation was not based on the primary outcome measure but do not have the expertise on how to give advice on how to proceed.

In summary my primary concern is that the research question and analysis is not a comparison of intervention effectiveness and therefore not aligned to the RCT research design.

Minor Essential Revisions

1. Abstract results section: 3rd line change the word increased with to increased by.

2. Authors need to acknowledge within the design overview section the limitations and implications of using a sample size calculation based upon an un-reported primary outcome measure.

3. It would be useful to have more details on the recruitment settings. For example how many recruitment centres were participants enrolled from and if they community or hospital based.

4. Typo page 7. Should gnostic read diagnostic?

5. In the same sentence I don’t really understand the word ‘sensibility’ may be better to rephrase or define.

6. When describing the randomisation procedure. Details about how the randomisation allocation sequence was generated and whether it was stratified to centre should be included. Also confirmation about when the group allocation occurred could be mentioned for improved clarity. It appears from Fig 1 that it was after baseline data collection?

7. Whilst authors describe a high dropout rate in terms of attendance to exercise training sessions there is no mention of home exercise compliance rates. Did authors record home compliance to the exercise programme? This would be important additional information.

8. When describing the data collection procedure it would be useful to know how long the test track was at each site and if the test surface was the same length at both centres.

9. Authors should give more detail with regard to the data collection protocol. For example which foot was chosen for pressure analysis, how the decision was made and was it consistent within individuals across time.

10. Also was the peak pressure region selected consistent across time or did the site of peak pressure change?

11. It is not until the discussion section that it becomes clear that patients preferred velocity was inconsistent over time. This should be detailed in the methods. Also the method of determining gait velocity should be described.

12. Page 11. The phrase ‘more on that later’ should be revised to sound less
chatty.

13. Table 1. Length is more commonly referred to as height.

14. There should be a section entitled ‘Blinding’ to describe and define for the reader who was blind to the treatment allocation and when.

15. The results text does not seem to accurately describe table 2. When tabulating the effect of time on plantar loading, it would improve clarity for readers to add that negative values represent an increase in peak pressure and positive a decrease (as this seems counter intuitive). 1) Change in PP at the heel over 52 weeks using the imposed walking velocity was not significant if the table is correct. 2) Likewise change in PTI at the heel over 52 weeks using the imposed walking velocity was not significant if the table is correct.

16. Discussion section. Stating that the exercise program did not affect plantar pressure patterns does not from your results appear to mean you did not observe a difference between intervention group’s pre and post intervention which is what you claim in the opening of the discussion (although the figures seem to suggest that is likely to be the case). I am unable to locate significance test data comparing the two intervention groups before and after intervention. Given that this should be the primary outcome of the RCT described it is important for the reader to see this presented statistically.

17. The requirement to standardise gait velocity when evaluating an intervention over time using pressure analysis, whilst important, is not a new finding as implied and would be better discussed within study limitations.

18. The discussion appears unbalanced. Little attention or depth is given to addressing the main aim of the study. Instead much discussion is centred on 1) method limitations and 2) the natural PP progression of DPN. I am unclear from the current manuscript what it is within these two topic areas that the authors are suggesting is new information.

19. Conclusion section. The conclusion appears to focus on the finding that PP increases over time in patients with PDN. This is not a new finding or the primary research question being addressed. The conclusion should therefore be revised.

Discretionary Revisions
1. Abstract Background
2. 3rd line It would be advisable for authors to reduce the strength of supposition by replacing the words responsible for to associated with.
3. Table 1. The new IFCC measurement unit for HbA1C is mmols/mol. It would be preferable to convert from %.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable
**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests