Reviewer’s report

Title: Rheumatoid Arthritis Foot Trial (RheumAFooT): a pilot for a randomised controlled trial of podiatry care

Version: 1 Date: 8 August 2007

Reviewer: Karl Landorf

Reviewer's report:

General

Thankyou for the opportunity to review this manuscript, which presents the findings from a pilot project that was set up to inform a larger randomised trial. This project aimed to evaluate the effectiveness of podiatry care and investigate a number of issues relating to a trial of this sort prior to implementing a larger randomised trial. The manuscript is generally very well written and the information, while limited in its conclusions, may be helpful for researchers contemplating similar larger randomised trials. I’m uncertain about whether a manuscript like this will receive many citations, however the experiences of the team presented in this paper will be useful for other researchers contemplating similar research.

Most of the information included in the manuscript is appropriate for a publication such as this, however I’m not convinced by the addition of the correlation between the change in scores from the Leeds Foot Impact Scale and the Foot Function Index. I understand one paper has already been published relating to the validation of the Leeds Foot Impact Scale, perhaps another is needed that includes further validation techniques. As it stands at the moment, inclusion of this information in the manuscript under review does not really sit that comfortably with the main thrust of the paper and is not included in the aims/focus of the study (page 4) – something for the authors to consider.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. Page 6, ‘Interventions’: Can the authors explain how the “podiatry staff were blinded to the allocation”? I’m uncertain that this could occur if they provided treatment? Do the authors mean that the allocation was ‘concealed’ from the podiatry staff prior to the allocation being revealed? ‘Blinding’ and ‘allocation concealment’ are really two different concepts; blinding indicating that the podiatry staff did not know what group the participants were in for the duration of the trial.

2. Page 12, 2nd paragraph: this finding may require further discussion in relation to the concept of ‘response shift’, which has not been mentioned by the authors.
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Page 2, Abstract, line 8 of ‘Results’: is it important to present that some participants were ‘casted’ for orthoses? Wouldn’t the more important issue be if they had ‘received’ orthoses.

2. Page 3, last line of 1st paragraph: add a hyphen between ‘health’ and ‘related’, so it reads “health-related quality of life”.

3. Page 3, sixth line of the 2nd paragraph: the word ‘correcting’ is used (i.e. “…correcting biomechanical problems…”). Suggest using the word ‘treating’, rather than ‘correcting’ as an orthosis will not ‘correct’ biomechanical problems per se; orthoses can be used to treat or possibly prevent worsening biomechanical problems.

4. Page 4, main paragraph, last sentence: this sentence is very long with a number of distinct design features listed. I suggest adding a colon after the words “in particular” to highlight that all the points (i.e. design features) after the colon relate to the first part of the sentence. All of these design features are separated by semi-colons, so I think a colon prior to listing these design features makes sense from a sentence structure point of view. The sentence would now read, “This study focused on establishing the key design features required for a full scale trial, in particular:…”.

5. Page 7, 2nd line: I suggest rewording the phrase “sensitively detected change” as it sounds awkward. I assume the authors mean that the instrument has been found to be sufficiently sensitive to detect clinically meaningful change?

6. Page 7, lines 6 and 7: add brackets around “a quantitative measure of global function”, so this section reads, “…and walking (a quantitative measure of global function).”

7. Page 9, 2nd sentence of the section ‘Primary outcome’: this is an awkward sentence - I suggest rewording it or even breaking it into two sentences.

8. Page 9, section ‘LFIS and FFI outcomes’: as previously covered in my general comments, I suggest removing this material.

9. Page 10, ‘Discussion’: there is a major limitation regarding the lack of control in this study. The authors have attempted to discuss this but it may need more prominence - something for the authors to consider.

10. Page 12, third last line of 1st paragraph: change ‘scores’ to score’, so it reads, “The LFIS score does not correlate with the HAQ score…”.

11. Page 13, 2nd paragraph, third sentence: add a comma after ‘However’, so it reads, “However, additional visits to clinic….”.
12. Page 13, 2nd paragraph, second last sentence: the authors mention “resentful demoralisation”. I’m unfamiliar with this term, so perhaps a short explanation may be warranted?

13. Page 14, 3rd line: sentence beginning “For example…” – this sentence needs revisiting, there are mistakes in it.

14. Page 14, 1st paragraph, last sentence: remove the word ‘with’ (i.e. “…with between…”, so it reads “Alternatively the interaction between pharmacological…”

Table 1: add more details regarding the ‘Key’ to the table. For example, that the results are means (SDs) unless otherwise stated – there are quite a few medians and ranges presented (I think) for example. In addition, the FFI sub-scale ‘Functional Limitation’ should be ‘Activity Limitation’ as presented in the original FFI article by Budiman-Mak et al (this is also how the sub-scale is named in the actual questionnaire developed and distributed by Budiman-Mak and colleagues).

Table 2: Include a ‘Key’ so readers understand what ‘BL-12M’ is, as well as all of the other abbreviations.

Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions

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

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests