Reviewer's report

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

Version: 1 Date: 12 July 2007

Reviewer: fay crawford

Reviewer's report:

General

-----------------------------------------------------------------------------------

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

Thank you for inviting me to review this interesting paper, I was already aware of the pilot study and was glad to have an opportunity to read the report. The authors have produced some useful information for trialists. I have made some comments below and I hope the authors find them helpful.

There are really 2 original and good questions being asked simultaneously but the report does not distinguish them well and misses the opportunity to write about the methodological aspects, which in my view are the most important conclusions for the study to make.

The 2 questions are;

Question 1; What are the key methodological features required for a randomised controlled trial to evaluate the effectiveness of 12 months of podiatry-led foot care in RA patients with foot problems?

Question 2; How effective is podiatry-led foot care in RA patients with foot problems?

For a methodological assessment I have referred to the CONSORT statement to help me think about the report and the authors have clearly been influenced by parts of CONSORT as they provide a flow diagram and describe certain items e.g. the randomisation procedure and blind outcomes in some detail. The report might further benefit if their results section strictly adhered to the CONSORT checklist and reported the success or failure of each of the various methodological parts evaluated during the pilot study. For example the authors already do this in discussing the short comings of having such strict trial inclusion criteria and also in suggesting ways in which recruitment might be improved [patient preference trial].

The authors do make useful suggestions about some aspects of study design but they should review all items listed by CONSORT, for example, where the outcomes are presented the authors need to discuss the possibility that this pilot
study is not adequately powered for all the outcomes. Discussing the effect of the between group variance for each of these outcomes and the consequences for adequate trial sample size would be informative.

Another example of reporting the methodological findings rather than concentrating on the clinical findings [which are probably affected by a type II error for most outcomes] would be to discuss the randomised process: In the pilot, the groups were different according to disease duration, age, and lower disease activity but this was not statistically significant. The authors can therefore state that the remote randomisation worked and is feasible for a trial of this kind. They might too wish to consider using a randomisation schedule that is unequal, i.e. 2:1 randomisation would allow 2/3 of the patients to be allocated treatment and this improved chance might also improve recruitment.

It is possible to present an ITT analysis which includes everyone randomised for the methodological results but not for the clinical findings. It is potentially confusing at the moment to present baseline data for 34 people in an ITT analysis and then conduct significance testing on 24 according to a per protocol analysis. I agree that it is important for the authors to publish these clinical efficacy data however in order to make them available for future systematic reviews and meta analyses.

The discussion is not properly focused; the authors suggest 3 main reasons for why no statistically significant difference was identified between the groups, but none of these reasons is a lack of statistical power. This pilot study is small and it is surprising that a statistically significant effect was even detected. What are the implications of this for an adequately powered trial?

The title and abstract and report would be more appealing as: “Methodological considerations for a randomised controlled trial of podiatry care: lessons from a pilot study”.

The report is well written.

I found the inclusion of details about the role of podiatrists in the UK distracting and unhelpful. The trial is not designed to answer a question about professional training or differences in professionals effectiveness and it is confusing to have it creep into the report [page 3 paragraph 2 line 13, page 14 paragraph 3, first three sentences and the whole of the conclusion] I would edit these out as they are unnecessary and detract from the report.

Incidentally people might be happier to participate if the intervention phase was shorter, and they only had to endure the no treatment arm for 6 instead of 12 months.

-----------------------------------------------

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Discretionary Revisions (which the author can choose to ignore)

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

**Level of interest:** An article of importance in its field

**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