Reviewer’s report

Title: Identifying the primary outcome for a randomised controlled trial in rheumatoid arthritis: the role of a discrete choice experiment

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Reviewer: Gordon Hendry

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Thank you to the authors for the opportunity to review this manuscript. I have provided itemised suggestions for major and minor revisions below and have provided an annotated PDF to assist the authors with their resubmission.

MAJOR SUGGESTED REVISIONS:

General comment. Should the authors refer to "outcome domains" as opposed to "outcomes" in isolation?

P3. Line 61-62. Primary outcome selection for RCTs should be based on a relationship between intervention components and the outcome and supported theories concerning mode-of-action of the intervention. The choice of primary outcome should be influenced by patients and key stakeholders where appropriate, but they should not have the casting vote without other due diligence. Perhaps the DCE is more appropriate where there are several outcomes which may improve as a result of an intervention (demonstrated by previous studies). Some re-wording required here to outline that the DCE may be of use for primary outcome selection once clinically relevant outcomes have been identified and mechanisms of change are known/understood.

P4 line 72-73. Should there be more discussion around other methods for selection of primary outcome domains for RCTs and why DCEs are advantageous for this purpose?

P4 line 95-96. How was this decision made concerning selection of attributes? Why 5? Much more detail required here. There are recommendations as to how DCE attributes should be selected which should be referred to/adhered to.

P5 line 98-99. It's interesting that pain has been selected as an attribute. Is there any evidence to suggest that a gait rehabilitation intervention can reduce foot pain? This seems surprising and may threaten the relevance-validity of the results. Realistically any outcome i.e. blood pressure may be of importance to patients but the outcome choices presented need to be relevant to the
intervention in question. Far more explanation concerning the relationship between pain and gait rehabilitation intervention components is required. Similarly for "choice of footwear" p6 line 135. How would gait rehabilitation have any impact on "choice of footwear" as an outcome domain?

P7. Line 160-167. The placing of this paragraph is confusing. It should maybe be placed after the first paragraph of the methods section. Also, far more detail required concerning the nature of the qualitative methods and consensus techniques employed to yield the results as well as approach to qualitative analyses, use of transcription etc.

Results. General comment. The results section includes some detail which should be in the methods and some detail which should be in the discussion. The results should focus more on the quantitative outputs as opposed to how they should be interpreted (please see PDF). This section needs to be revised to read more like a traditional results section.

Discussion. General comment. The discussion is too brief and does not go into enough detail about the relevance of the study. Other important work not cited. There is some unnecessary repetition from previous sections throughout.

P15. Line 315. Main limitation to me appears to surround the selection of the outcome domains. This is not discussed in sufficient detail. Far more emphasis should be placed on the modelling phase for RCTs where underlying mechanisms by which interventions will influence outcomes are discussed. 2 of the 5 outcome domains selected in this study would be unlikely to improve directly as a result of gait rehabilitation. This threatens the validity/relevance of the study results.

Conclusions. There needs to be a more detailed paragraph on the significance of this work. Far more discussion with reference to the literature on outcomes in gait rehab and physical interventions in RA is necessary. This read too much like a technical paper that might be better suited to a health economics journal. I wonder if some general re-wording is required to acknowledge that while the outcomes selected by patients via this DCE robustly indicate their perceived importance, the results do not necessarily support their selection as primary outcomes for an RCT of gait rehab because there is a lack of evidence to support the mechanism of action of gait rehab on RA-related foot pain.
MINOR SUGGESTED REVISIONS:

P2. Abstract, background. Given focus on foot problems, please expand the sentence to include "where the population of interest was people with RA-related foot problems".

P3. Line 40. Please remove "adults having the condition in 2006" (superfluous).

P3. Line 42-43. Please provide details here as to why the focus on disease related foot problems in RA. It might not be immediately obvious to the reader why the focus on the feet when the intervention of interest is a health and fitness/gait rehabilitation intervention. Perhaps the authors could provide a bit of background as to why gait rehab might be a promising intervention for foot and ankle problems in RA with reference to relevant evidence from the literature. That might help to set the scene.

P3. Line 44-45. Please cite the study which has demonstrated RA related foot problems impact on HRQoL.

P3. Line 49-50. Please provide further explanation to the comment re. no treatment to maintain or improve walking ability. I would argue that yes perhaps not directly but there are other exercise-based interventions which would most likely indirectly result in improvements in walking ability such as muscle strengthening/endurance exercises from a physiotherapist.

P3. Line 53-54. For consistency please choose either "health and fitness" intervention or "gait rehabilitation" and use one term throughout.

P3. Line 54-55. Please remove final sentence of this paragraph (superfluous).

P3. Line 58. Replace "right" with "most appropriate".

P3. Line 60. Clarity required re statement concerning "with clinical advice".

P3 lines 65-69. This sentence is too long and hard to understand. Can this be re-written as 2 separate sentences.

P4. Lines 85-87. Please present the study objective as the final sentence of the background section.

P4. Lines 87-91. The final 2 sentences of this paragraph should be in the methods and discussion section respectively.

P5. Line 115-116. Is gait the same as mobility? Gait would be considered to be a component of the mobility domain, but these are not necessarily interchangeable. Also, why would gait rehabilitation for people with RA related foot problems result in improvement in upper limb mobility?


P14. Table 5. Mobility_1 more important than Mobility_2 in conditional logit model. This seems counter-intuitive but is not discussed anywhere in the discussion section.

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An article of limited interest

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