Reviewer's report

Title: A pilot randomised clinical trial of physiotherapy (manual therapy, exercise and education) for early-onset hip osteoarthritis post-hip arthroscopy

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Reviewer: Gregory Parkin-Smith

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Title: A pilot randomised clinical trial of physiotherapy (manual therapy, exercise and education) for early-onset hip osteoarthritis post-hip arthroscopy.

Submitted to: Pilot and Feasibility Studies

Review

Abstract

Page 3 Line 47: The authors refer to the main outcomes of adherence and follow-up, both of which are important. However, a pilot study should also provide some insight and recommendations regarding the research process, management of the study, the research environment, sample size estimation and the experience of the researchers. Insight into these aspects of a study facilitates the implementation and collection of good-quality data in a definitive, larger trial. Therefore, outcomes should extend beyond the adherence and follow-up of participants, but include aspects of the research process with a view to provide recommendations for a future, larger trial. An example and discussion in this area is offered in Lancaster et al., Campbell et al and Amorin-Woods et al. (Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: recommendations for good practice. Journal of evaluation in clinical practice, 10(2), 307-312; Campbell, M., Fitzpatrick, R., Haines, A., & Kinmonth, A. L. (2000). Framework for design and evaluation of complex interventions to improve health. British medical journal, 321(7262), 694; Amorin-Woods, L. G., Parkin-Smith, G. F., Nedkoff, L., & Fisher, C. (2016). Critique of a practice-based pilot study in chiropractic practices in Western Australia. Chiropractic & Manual Therapies, 24(1), 38.) With an critique of the research process for this pilot study in mind, the authors could expand on the
sections on Page 5 line 85-90, where the primary aims could be increased to cover relevant aspects of the study process evaluation. Similarly the section on Pages 8-9 lines 152-155 could be expanded, and also within the Discussion section page 11 lines 211-218.

The Results section in the Abstract (page 3 lines 46-50) include the results of statistical analysis and confidence intervals, suggesting that there was no difference between the two intervention groups, implying that the addition of a physiotherapy treatment group did not add to outcomes - if this may be the case, then why bother with a fully-powered larger study? The statement of the results in this paper detracts from the "feasibility" of a future, larger study, but suggesting that the physiotherapy care will not have any benefit over a standard care approach. Also, only two primary outcomes are included in this pilot study or "adherence" and "follow-up" and I feel more than this is required to be convincing of feasibility. To improve on this section, and the other relevant parts of the paper, expand on the primary outcomes, as suggested above, and use your data/results to make sample size estimated (calculations) for future study. Also, emphasise that the statistical analysis and results of this pilot study are meant to offer insights into possible outcomes and certainly are not conclusive.

In the Abstract conclusion section (page 4 lines 52), the authors state that a full trial will need adequate Power. It is not partly the purpose of a pilot trial to calculate or estimate the needs/requirements of a fully-powered trial? I suggest expanding on the requirements and recommendations for a fully-powered trial in the future, in the Discussion section, alongside sample size estimates to achieve the required Power.

Background

On page 5 lines 85-88, this section requires expansion to includes aspects of the research process to be evaluates as part of the primary objectives, as suggested in the first paragraph above.

Setting & Participants

This section is good and well written. The patient characteristics are clearly set out, which, interestingly, indicates that patients were relatively young adults around 32 years old and of a
good body weight/BMI of around 25.6. These data/results should be discussed in the Discussion section with a view to optimise the research design and recruitment of patients where there is a representation of a broader population, particularly including those patients that are older and overweight - this population group known to have more problems with joint degeneration. The authors should offer a brief account of the confounding effect of the patient characteristics of this pilot study results and how this may influence the design and sample size of a larger, definitive study. Would an older population who are overweight have a better or worse outcome with treatment? How would this affect sample size needed for a definitive trial? Would patient characteristics influence the number and duration of treatment proposed?

Randomisation and Interventions

This section is well written and clearly describes the interventions.

Outcomes & Follow-up

Again, I feel the section on primary outcomes should be expanded to include aspects of process/design evaluation, thus the argument for feasibility would be much stronger (lines 154-155).

Statistical Analysis

Well written and clearly described. This section, and the relevant sections before it, could be strengthened by offering a clear rationale and reason(s) for doing the data analysis and the secondary outcomes. Pilot studies are not intended to offer definitive results - pilot studies by their nature cannot do this because of poor/low power - so why offer results at all? Indeed, results of low-power pilot trials increase the change of Type II error and may proving an incorrect result or conclusion. Rather, statistical analysis and results of a pilot study should, at most, offer insights into outcome only, and the data should be used for sample size estimated for a fully-powered study and to provide a critique on the appropriateness of the outcome measures used. The Discussion section should also be improved by considering the points made in this paragraph.
Discussion

Page 11 lines 211-214. I agree that a definitive, future study does seem feasible, but the authors tend to jump to the conclusion of "feasibility" without offering enough of an argument and rationale. Relying just on adherence and follow-up is not quite good enough, particularly if applying for a large grant to fund a fully-powered study. The Discussion should be expanded to include the items mentioned in the paragraphs above.

Conclusion

A bit hasty on confirming "feasibility" but otherwise a good section.

Overall, a good, well-written paper that would be of interest to a broad readership and worthwhile publishing, if the support for the feasibility of the study and an expansion on the analysis of the research process is offered in a revised paper.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

An article of importance in its field

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Acceptable
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