Author’s response to reviews

Title: The effectiveness of the McKenzie method in addition to first-line care for acute low back pain: A randomized controlled trial

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Author’s response to reviews: see over
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Mick Aulakh, M.Sc.
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London

Re: Revised MS 1650966647295700 “The effectiveness of the McKenzie method in addition to first-line care for acute low back pain: A randomized controlled trial”

Dear Mr. Aulakh,

We have addressed the residual comments from the referees in the revised manuscript. We have also edited the section ‘Acknowledgements’ and inserted the new sections ‘Competing interests’ and ‘Authors’ contributions’ as requested. Changes to the previous version are highlighted in light grey. Responses to the referees’ comments are listed below.

Responses to Dr Julie Fritz

I do not completely agree with the authors’ response to the request to consider expressing the results as a proportion of patients achieving a threshold level of improvement on the primary outcome as well as mean between-group changes. This is an approach that is advocated by many and can be considered an aspect of "best practice" in reporting the results of clinical trials because it improves the interpretability of the results, which should be an important consideration in reporting. The authors’ concern about the differing results based on different thresholds speaks to the need to pre-define a valid threshold, it does not speak to the usefulness of the approach per se. Although I disagree with the authors on this issue, I understand the published protocol did not include this approach to the analysis.

A new paragraph has been inserted in the Discussion (page 15) to address this concern:

“Some trials provide a description of the results by computing the proportion of subjects who improve with each treatment. We chose not to follow this approach in the current trial because statistical power is reduced when continuous outcomes are dichotomized and because the choice of cut-offs for improvement can influence the results. As an illustration for pain improvement at 1 week with a cut-off of 2 points or less for improvement the McKenzie Group had more participants improved (54.4% versus 45.6%), when the cut-off for improvement was raised to 3 or 4 points the First-line Care Group had more participants improved (53.7% versus 46.5%), and for a cut-off of 5 or 6 points there was a similar number of participants improved in both groups (50%). This pattern demonstrates the limitations of this approach.”
I also have some disagreement with the authors' contention that a sensitivity analysis evaluating patients who were adherent to the exercise protocol is not an aspect of "best practice". The CONSORT statement indicates that in instances where compliance is an issue, this type of analysis in addition to the intention-to-treat analysis can be informative. Unfortunately the degree of missing information on subject adherence in this trial would make this sort of analysis difficult.

We thank the reviewer for the comment but we believe these types of analyses potentially introduce confounding and are not 'good practice' as the reviewer suggests. We could not find a section of the CONSORT statement advocating that this type of analysis be undertaken. On the other hand what the CONSORT statement does is to recommend the report of ancillary analyses if there are any.

Responses to Reviewer Teresa Liu-Ambrose

In a RCT sample size justification, you are expected to hypothesize what is your primary statistical analysis -- such that you do need to specify at what time frame you expect to see a between-group difference in your primary outcome measure. Otherwise, when you have a trial with multiple measurement sessions, multiple comparisons becomes an issue.

We have inserted a brief discussion addressing the reviewer’s concern on page 17:

"We acknowledge that it would have been preferable to select only one primary outcome measure to minimize the potential for a type I error; i.e., when we registered the trial we specified 4 primary outcome measures. However, this would be a concern if we were claiming that the statistically significant pain outcomes were clinically important, whereas our view is that these effects are trivially small."