Author's response to reviews

Title: Osteopathic intervention in chronic non-specific low back pain: a systematic review

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Osteopathic intervention in chronic non-specific low back pain: a systematic review

Responses to second Peer Review (in bold/italics after peer comments)

Thanks to Reviewer 2 for these constructive points, we agree it makes a much tighter and clearer paper. Please find below our comments and actions in relation to the points made.

Major Compulsory Revisions:
1. Inclusion/Exclusion Criteria:
   - The trial with pain as a secondary outcome should not be excluded on that grounds alone.
   - The menopause trial has been excluded also because it did not define the pain as chronic, and the technique does not fit the definition of osteopathic technique. This has been made clear in the manuscript.
   - A trial should not be excluded on the basis of quality alone. This was not an exclusion criterion. The absence of information on randomization should do it.
   - Many of the 12 studies reviewed do not meet the inclusion criteria in Figure 1 outright. Studies with mixed acute/chronic populations are not studies of chronic low back pain, so can be excluded outright unless you can get the data from the authors on the chronic patients. Studies without nonspecific low back pain can be excluded outright. The UK BEAM trial was not limited to osteopaths or chronic patients. If randomization is questioned and cannot be confirmed, the study can be excluded on that ground.

   The manuscript and table been adjusted to reflect this point. The Systematic Review now is presented as a one-step exclusion process. We have described some detail of why we excluded trials that were included in the most recent systematic review in 2003, in order for readers to understand the difference in conclusions, and the issues regarding methodology.

   - Tables 1, 2, and 3 can be simplified. Methods – Results of Individual Studies should be revised.

   Tables and figures have been revised and simplified:
   - Figure one now reflects the selection and review process more simply.
   - Study characteristics and Risk of Bias assessment results are now included in one table (Table 2)

2. Abstract - Results
   - Limit the selection reporting and concentrate on the results in this section. Compare OMT regimens to specific controls for the studies included in the evidence. Mobilization appears here but the physical therapy and exercise do not.

   The results in the abstract have been re-written to give detail on the two included
papers and to make the results sections more consistent.

- The language “no better than” can be deceptive, implying that OMT has to be better than a comparison group. Consider language such as “similar in effect” unless the effect size is slightly in favor of mobilization.

The language used has been made consistent with this advice in both the abstract and manuscript.

3. Abstract - Conclusion:
- The conclusion should contain general statements comparing OMT to control(s).

The conclusions have been re-written to reflect the advice – “suggests similarity” is a more appropriate phrasing in view of the findings.

- Conclusion about physical therapy and exercise are out of place here without addressing them in the results.

Full results are now explicit in Table 2, and described in the manuscript.

- The first sentence on paucity of evidence is ambiguous. Do you mean lack of supporting evidence for efficacy, lack of RCT’s, or lack of quality RCT’s?

The wording has been changed to be more specific: “…there is a paucity of quality clinical trials testing osteopathic intervention in adult patients with chronic non-specific low back pain, and more data is required”.

4. Methods - Synthesis of Results: The criteria for pooling in a meta-analysis are presented. However, the criteria for synthesis and inference from non-pooled data are not included. State the a priori criteria for determining the superiority, inferiority, and equivalence of OMT. For example, were there effect size, statistical significance, or comparison type considerations?

The a priori criteria are now explained in the manuscript (page 8).

5. Results – Results of Individual Studies
- Include the pain outcomes and group differences with SD’s and confidence intervals and/or p-values in the text (Inclusion in Table 2 would be helpful). This is the most important information for supporting the conclusions of the review.

The details requested are now in Table 2

- Describe the OMT regimen for the included trials.

The details requested are now in Table 2

- Some studies are not trials on chronic low back pain. See Comment 1 above.

As mentioned, the exclusion process has been made clear, and no excluded trials are discussed (beyond the comparison with the 2003 review).

- Table 2 and 4 should be simplified to the included trials.

The details requested are now in the simplified Table 2.

6. Risk of Bias:
There is no discussion of the risk of bias for the studies. Which studies have high/low risk of bias? How does this impact inference?
The Risk of Bias assessment results for the 2 included studies is described in Table 2. This includes the score and the criteria that each failed, and the manuscript also reports on this detail with a discussion of the implications of the weaknesses in methodology.

7. Comparison to previous review:
Contrast the reviews and identify why the conclusion may be different. For example, the previous review included more studies, presumably not limited to chronic, nonspecific low back pain.

A further explanation and discussion of the differences between the 2003 review and the current one has been added.

8. Conclusion:
- This is not supported. The outcomes data are not included to show the relative merits of treatment and controls.

As mentioned, the reporting of the results in the abstract and manuscript has been made more clear, and the language used in the conclusion has been changed.

- The similarity between mobilization and exercise and physiotherapy should be a separate sentence.

Amended

We hope this covers the reviewer’s queries

Yours sincerely

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