Author's response to reviews

Title: Osteopathic Manipulative Treatment for Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Author's response to reviews: see over
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Elizabeth C. Moylan, Ph.D.
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Dear Dr. Moylan:

We have completed the third round of revisions to our manuscript (MS: 6646212565097155) entitled, "Osteopathic Manipulative Treatment for Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials." The point-by-point responses to the reviewer comments are summarized below.

Reviewer 1: Dan Cherkin

Major Compulsory Revisions
None requested.

Minor Essential Revisions
None requested.

Discretionary Revisions
None requested.
Reviewer 2: Dave Baxter

Major Compulsory Revisions

None requested.

Minor Essential Revisions

None requested.

Discretionary Revisions

None requested.

Reviewer 3: Elmer Villanueva

Major Compulsory Revisions

None requested.

Minor Essential Revisions

Reviewer Comment (1): I do not accept that the issue of (non) head-to-head comparisons between OMT and NSAIDs has been clarified. The authors persist in using the Discussion section as an editorial base from which to launch statements that have very little supportive evidence precisely because no head-to-head comparisons have been conducted...

My original advice was simple: in the absence of information from a head-to-head comparison, cease making comparative claims...

Authors' response: We understand the reviewer's concern with respect to the lack of a direct head-to-head comparison of OMT and NSAIDs in our study. Thus, we have removed all indirect comparisons from the manuscript, including in the abstract, discussion section, and conclusion. This reduced the manuscript length by about 200 words and resulted in the elimination of two references.

Reviewer Comment (2): I accept that the authors may not need to back-transform effect size estimates into their original scales. However, the
authors make an extraordinary claim the implication of which I am unsure whether they fully realise. This relates to their belief that pain measures, at least as used in the source studies, are not “readily interpretable from a clinical perspective” (Response to Reviewers, p8). I am certain experts in the arena of pain management will have views about this. My concern, however, is more basic. First, if they claim that these measures are not readily interpretable, why use them (as they have done in Ref 46) in place of more patient-relevant measures such as the number of days of pain free or ability to perform activities of daily living? Second, if these measures are not readily interpretable, then their summary is even more so. Thus, what is the utility of a meta-analysis of outcomes with little clinical meaning?

Authors' response: As our comments noted above were made in the Response to Reviewers, rather than in the manuscript narrative, we will continue to respond herein in our present Response to Reviewers.

We should have more properly stated that, “Changes in either of these measures are not readily interpretable from a clinician’s perspective.” This is because the effect size in our meta-analysis addressed changes in low back pain with OMT. Thus, we agree that most clinicians would recognize “90 mm” on a 100-mm visual analogue scale for pain as indicative of severe pain. However, we are uncertain as to how clinicians would interpret a “10 mm” reduction in pain. Further, would a reduction in pain from 90 mm to 80 mm represent the same clinical effect as a reduction from 20 mm to 10 mm? We believe that practicing clinicians think of pain reduction in more tangible terms, such as the amount of pain reduction that patients typically report with a prescription of 400 mg of ibuprofen three times daily.

The visual analogue scale for pain was used (Ref 46) because it is a standard measure in research studies of low back pain. We also used the SF-36 bodily pain subscale, which is a recommended outcome measure. (Ref 59 in the present revision). The number of days pain free is rarely used in research studies of low back pain; therefore, any study that uses this outcome would have no useful frame of reference for comparison. The ability to perform activities of daily living is not a direct measure of pain. It is a measure of back-specific function, which is a different outcome domain in research on low back pain (Ref 59).

In performing meta-analysis, we were constrained by the measures that were commonly used and reported in the literature. Hence, our current reliance on the visual analogue scale for pain. Thus, the utility of our meta-analysis is that it reflects a commonly used and reported outcome measure in low back pain research. Had other measures, possibly with greater clinical relevance, commonly been used and reported, then our meta-analysis would have reflected such measures.
Discretionary Revisions

None requested.
Again, we thank the reviewers for their comments and suggestions.

Sincerely,

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On behalf of all the authors