Reviewer's report

Title: The long-term effects of naprapathic manual therapy on back and neck pain. Results from a pragmatic randomized controlled trial

Version: 2 Date: 30 October 2009

Reviewer: Mitchell Haas

Reviewer's report:

General:

This pragmatic RCT compared a combination of manual therapy and exercise was compared to a physician advice on staying active and coping with pain (included booklet with general information and exercises). The manuscript is interesting and well written. It will make an important contribution to the literature. Find below revisions that will enhance the quality of the paper and decrease the risk of bias in this report.

Major Compulsory Revisions:

1. The paper has multiple primary outcomes. A corrected significance test should be used to account for the 4 outcomes. The confidence interval should either be corrected or a p-value included with statistical significance set at .05/4.
2. Specify that the dichotomized improvement variables are the primary analysis. State if this was planned in advance or not. State if the cut points used to dichotomize the variables were pre-planned or not.
3. GEE: Why were generalized estimating equations used for dichotomized but not the continuous variables in the analysis? This would seem more appropriate than t-tests. The same reasoning for longitudinal analysis would apply to both types of data. Clarify whether the confidence intervals for group comparisons are based on the GEE analysis or not.
4. GEE: Why was GEE for the entire study reported in the results section, when the purpose of the report is long-term outcomes? You should include p-values for the 26- and 52-week time points in the text.
   Also, the GEE analysis in the text appears to be for the entire sample, but Figure 2 showing the longitudinal data separates out neck pain and back pain. Why show these data separately but present a combined analysis? The lack of consistency can be confusing to the reader.
5. Was an intention-to-treat analysis performed? State in the text.
6. Missing data analysis: There is nontrivial missing data at follow-up. A sensitivity analysis using imputed data should be performed. A brief description explaining missing data at follow-up would be helpful.
7. 12-week data: Remove from text and tables. 1. This is a short-term outcome
covered in a previous publication and is not consistent with the purpose of the paper (long-term outcomes). 2. The text and tables are inconsistent, sometimes including and sometimes excluding 12 weeks.

Minor Essential Revisions:

1. Background: It is true that the Cochrane review (ref. 8) concluded that SMT was no more effective than other treatments. However, the language is misleading, implying that SMT has to be more effective to be recommended as a treatment option. Cherkin et al (ref. 12) concluded that SMT was as effective as other treatment options. Bronfort et al (ref. 7) found quality evidence of similarity and superiority of SMT to other treatment approaches. They concluded that the evidence supports SMT as an option for chronic low back pain. This alternative interpretation should be included. It should be noted that the Cochrane review used meta-regression, while Bronfort et al used a best-evidence synthesis approach.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.