Reviewer's report

Title: A structural equation model for the effects of the doctor-patient encounter and expectancy in an open-label randomized trial of spinal manipulation for the care of low back pain

Version: 2
Date: 22 November 2013

Reviewer: Theresa Munyombwe

Reviewer's report:

The study aimed at confirming the ability to balance the DPE over treatment groups and to present a path analysis modelling the effects of ongoing expectation of success and DPE on chronic low back pain outcomes using a larger randomised trial. The authors have shown that DPE can have relatively important effects on low back pain in open-randomised trials of treatment efficacy. They also demonstrated that DPE and patient baseline expectations can be successfully balanced across treatment groups. The paper is well-written and clearly structured, the authors adhered to the CONSORT guidelines for reporting randomised clinical trials, the methods are sound and the rationale is clearly described. The topic is of interest for a scientific perspective. I am not an expert of spinal manipulation and my review will concentrate mostly on the statistical analysis. I have minor suggestions for improvement of the manuscript as follows:

Specific Comment and Recommendations for Revisions:

Title
Discretionary Revisions:

The title implies that the authors conducted structural equation modelling but this is not the case as the authors only did a path analysis, I therefore suggest that the title be rephrased to accurately convey what has been done: could rephrase to “A path analysis of the effects of the doctor-patient encounter and expectancy in an open-label randomised trial of spinal manipulation for the care of low back pain”

Discretionary Revisions:

Abstract
I suggest that in the abstract the authors simply state that: A path analysis was conducted to determine the effects of dose rather than saying: Structural equation modelling was used in a path analysis.

Introduction
The scientific background and rationale of the study was reported. However, almost the same introduction was used by the authors in their earlier article (ref 14)
Method
The study design, protocol, participants, interventions and study variables were well described. The primary outcome of the study, low back pain was assessed using a scale that has been shown to be reliable, valid and responsive and the rationale for choosing this scale was provided.

Discretionary Revisions:
The authors could also provide evidence for the reliability and validity of the measure used to assess DPE.

The use of path analysis was appropriate as the authors aimed to study the interrelationships between the various variables that were stated in the hypothesized model. Appropriate multiple measures of model fit were used. The authors have indicated that the final model was satisfactory according to all indices though the fit indices were not reported.

Discretionary Revisions
The authors could include the fit indices for their final model

Discretionary Revisions
The key weakness of this study was to use an average of four questions to assess DPE. A greater effect of DPE may be shown if a measurement model was included rather than using an average of four items. I suggest that the authors consider including a measurement model for DPE with the four questions used to assess DPE as the indicators of a latent construct.

Discretionary Revisions: The authors could comment on how they evaluated the assumptions of multivariate normality and checked for multi collinearity.

Discretionary Revisions. The methods used to handle missing data were reported but the authors could also do a sensitivity analysis using appropriate values to test what happens if a patient drops out for example due to low DPE or high pain

Results
Results are well presented in form of tables and a graphical display of the final path model. A participant flow diagram showing number of participants at each time point was provided as required by the CONSORT guidelines. Adequate statistics are given in tables (means, standard deviations, standardised coefficients and 95% CI). Direct, indirect and total effects were well presented and a detailed interpretation of these was provided. However they is a typo error in Figure 2, PPE 12 weeks should be DPE 12 weeks. (Minor Essential Revisions)

Discussion
The findings of the study were clearly summarised in relation to the aims of the
study. The interpretation of findings was consistent with the results and the authors have also discussed their findings in the context of other relevant evidence. The discussions and conclusions are adequately supported by the data and the study limitations were reported.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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