Reviewer’s report

Title: Does different information disclosure on placebo control affect blinding and trial outcomes? A case study of participant information leaflets of randomized placebo-controlled trials of acupuncture

Version: 0 Date: 16 Oct 2017

Reviewer: Valerie Durkalski-Mauldin

Reviewer's report:

The authors present interesting research on an important topic, particularly for studies that require a sham procedure such as placebo acupuncture. The presented approach is informative however there are aspects of the research methods that need attention and/or clarification, and are listed below.

1. The authors should consider different terminology than 'deceitful disclosure'; it should not be implied that investigators intended to be 'deceitful' in the PIL.

2. Page 10, line 26: You should explain to the audience why Scenario 5 in table 1 is an 'ideal' blinding situation even though the acupuncture group was 'unblinded'.

3. Page 10, line 43: It appears that Figure 2 illustrates the calculated BIs for each included trial. Is the quoted 42% AND 41% in the text, the overall BIs for each group? Or is this simply the proportion of correct guesses. This should be clarified to the reader.

4. Page 13, line 4: Of these half, how many were the older studies that were included from the previous review? If you are trying to show a change over time, it would be helpful to know this piece of information.

5. Page 13, line 38-50 and Page 14, line 4-9: I would be hesitant to make this assumption. It is not a given that if you sampled more studies, that you would see a link between the PIL information and direction of blinding. Your results did not support this based on the confidence intervals of the proportions (16% vs 21%).

6. Page 14; line 35: The term 'investigator bias' should be expanding for the setting of acupuncture studies; I am assuming the investigator is unblinded in this setting (they know if the patient is receiving placebo or real acupuncture?). If that is the case, do the authors know if the outcomes were completed by a blinded assessor? That would be important to know to help explain the level of investigator bias.

7. Page 14, line 26: Commenting on the expectation is helpful for the discussion but the study as designed does not appear to measure expectation of treatment. This should be made more clear in the discussion.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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