Reviewer's report

Title: Reactions to treatment unmasking among the participants of a placebo controlled trial

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Reviewer: Elina Hemminki

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General
This paper deals with many aspects of using placebo in trials. In my mind the most important, and new, aspect is: what impact (harm) revealing the exposure to placebo may have on trial participants. They also have an empirical material which, even though small, could shed some light on the issue. For the methodological problems of the own data collection very little can be made in this stage. But the analysis of the data and writing the report is only half done.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1. Study aims are not focused. On p. 7 four aims are given and on p.15 three aims. Two are joint (guessing and reactions to unmasking). Making the aims clearer might help to focus the results, too.
2. Methods (p. 9) starts with the description how the contact to the study subjects was made. This is a central part of the Methods, because it explains the time lag, the low response rate, and may be related to the way how people responded. In its current form it is difficult to follow. Please, give the different steps in a chronological order, and refer to Figure 1 already in this stage. Some methods are given only in results (p. 11). Transfer here.
3. The description of the interview (p. 9) needs more explanation: Tape-recording? Who was the person interviewing? How the study was presented? Were all questions open? Were the results of the study presented first or the group the patient was in?
4. Analysis of the survey (p. 9) needs more details. How the coding was made? Any computer program used? Which data was structured, which open, etc.?
5. Currently there is no real analysis of the qualitative data, just citations and overall impression. The data could be analyzed in two ways: making it numerical (x% were surprised, y% were angry etc.), or in a standard qualitative way searching for themes etc. From the quantitative results, there is only the table of the desire and ability to guess the treatment. Otherwise the figures are in the text or no figures are given. Various quantitative results (such as % expecting improvement, wishing for this and that, happiness with debriefing) could be collected to one table.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
6. An important claim, and relevant to the current paper, is that "participants are often kept in the dark about their allocation once the experiment is over". It is supported with one reference only (their own previous work). More studies should be searched to find if this is really so (seems odd), and if no such studies exist, make the claim softer.
7. The term "debriefing" is a central concept, but not explained what do the authors mean with it in this context. Please, explain (or use longer expression). Likewise, please define, "expectations about treatment".
8. Because the numbers of patients are so few, presenting all results by responders & non-responders (4 groups) only, is not easy for the reader. Give also the totals by group.
9. The last (important?) sentence of the 1st paragraph of "Treatment Debriefing" (p. 13) is unclear.
Discretionary Revisions (which the author can choose to ignore)

10. Abstract could be made more informative by adding more details into Methods & Results. For unclear points, see my comments above (are repeated in Abstract). Conclusions are many, and not all come from the present study.

11. Introduction could be notably abbreviated and focused: what are the problems of using placebo at the end of the trials (informing participants). Because there is a huge literature on placebo as such, but very little on patient information aspects in regard to placebo, it would be more useful to concentrate to the latter and try to do a comprehensive review on that. Now it is not clear on which criteria the cited literature has been chosen.

12. The description of the local anaesthetic as an "active" placebo (p. 7) is messy. Why not simply say that the comparison was an active drug, but assumed to be ineffective for plantar heel pain, i.e. worked as a placebo.

13. Discussion would benefit from rewriting. The first 1.5 pages are mainly Results (could be integrated there). The discussion of expectations (p. 16) is a side issue in terms of this paper, and does not cover the literature on this topic. Delete? "Limitations of the study" contains information which would better suit into Methods.

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No

**Declaration of competing interests:**

I have no competing interests