Author's response to reviews

Title: Cognitive Interviews Guide Design of a New CAM Patient Expectations Questionnaire

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Author's response to reviews: see over
We appreciate the opportunity to submit a revised version of our manuscript, “Cognitive Interviews Guide Design of a New CAM Patient Expectations Questionnaire”. We have now revised the manuscript in response to the comments by the reviewers.

As we mentioned in the original cover letter to Dr. Rowles, our manuscript describes the use of cognitive interviews to guide the design of a questionnaire. As a result, it is both long and technical and includes a number of lengthy tables as well as some supplementary appendices. We think this level of detail is important for three groups of researchers: those interested in understanding how we did this; those who might wish to incorporate cognitive interviews into their own work on questionnaire development; and those who use expectation questionnaires currently and want to understand the strengths and pitfalls of current tools.

We recognize that some readers might be interested in a more superficial treatment of this topic, but this manuscript was not designed for that purpose, although we have made a few changes to assist the more casual reader. It is important to keep our goal in mind when reading our responses to the reviewers, which we present below in detail.

Because the reviews are concise and in some cases, the suggestions are contradictory, we have organized our responses by section of the manuscript. This way, we can highlight the areas of disagreement among reviewers and explain our revisions and their rationale.

Overall:
**Reviewer 1**: This was an interesting paper to review. It is not often that you come across a study that so carefully reports on the development of a new measure.

**Reviewer 2**: The manuscript reports a very rigorous attempt to develop a questionnaire to grasp and measure patient expectations… I have almost no comments. I wondered why there has to be so much focus on back pain.

**Reviewer 3**: This is an important study to produce a standardized questionnaire to assess treatment expectations in patients with back pain… A real strength of the study is the bottom-up approach which aimed to capture areas of important to participants as well as the specific means to accurately evaluate these expectations.

We thank the reviewers for their interest in our manuscript, which is consistent with our belief that the manuscript would be of interest to readers of BMC CAM. In response to Reviewer 2’s comment about the focus on back pain, our funding was awarded for us to develop a questionnaire related to expectations of back pain. However, we have now added a sentence on page 5 (1st paragraph, 1st full sentence), that we think our questionnaire could be used for other pain conditions with minor changes.

**Background:**
**Reviewer 1**: Thought this section was commendably brief
Reviewer 3: Thought the ‘background’ was very brief – “although it provided a clear rationale for the study, I would like to see some reference to previous approaches to measuring expectations to provide greater context for the current study.”

We have attempted to keep the background brief since this was appreciated by one reviewer. We have added a paragraph (2nd paragraph on page 4) that refers to previous approaches to measuring expectations to provide some additional context.

Methods:
Reviewer 1: Thought that this section was clearly outlined.

Reviewer 2: Recommended we shorten the methods section and put details considered necessary in a supplemental file.

Reviewer 3: Thought that most of the methods were clearly described. Reviewer 3 did want us to describe the literature search for published questionnaires (p5) “rather than just describe the list of researchers contacted in Appendix 1. These authors/studies are also referred to in Table 1 so there is unnecessary repetition. Table 1 would be better placed as an appendix with authors listed numerically (as elsewhere).”

We agree with Reviewers 1 and 3 that the methods were clearly described. For Reviewer 2, we have now shortened the methods section slightly by removing superfluous language wherever possible. We think that the use of headings and the logical presentation will help readers interested in a more superficial view of this topic than we intended for this manuscript to select which sections they choose to read.

Reviewer 3’s comments suggested that we were not clear about the process we used for obtaining expectancy questionnaires used in previous studies of CAM therapies for back pain. On page 5, 1st paragraph under methods, line 4 to 8, we have clarified that we used two mechanisms to collect extant questions related to expectations. In addition, we have revised table and appendix headings to add clarity. Appendix A provides a list of the researchers we contacted to obtain their expectancy questions (as well as some representative publications, the CAM modality and the types of items or questionnaires they used in their study). Table 1 is not redundant with Appendix A. Rather, it is a comprehensive list of the specific terms we tested in the seven rounds of cognitive interviewing. It includes the sources of each of these terms. In some cases, those terms came from qualitative interviews we have described in a manuscript currently under review, while in other cases, they came from published questionnaires or questionnaires we obtained from CAM researchers.

Results:
Reviewer 1: Thought the results were very comprehensive.

Reviewer 2: Thought the results were long, too, but would not shorten them. Recommended we consider preparing a few relatively short tables with key issues/findings, while keeping additional information in supplemental file for interested readers.
Reviewer 3: Thought the paper was clearly written, but felt that the length of the results and excessive use of lengthy tables (as well as appendices) detracted from the core content of the findings. “I would therefore suggest additional editing of the paper to make it more accessible to the general interested reader. Thus, careful consideration needs to be given as to how best represent the data.”

We agree with Reviewers 1 and 2 that the results are comprehensive and though long, appropriate. We have, however, attempted to shorten the tables by deleting excess quotations and removing the original Table 5. The tables are now roughly half the original size. Because our primary aim in writing this paper was to provide the level of detail for readers interested in actually incorporating cognitive interviews in their work, we think that focusing our paper layout for that audience is most appropriate. While we agree that the general reader might find this paper a bit long, we have made it somewhat more accessible by adding a little more detail to the abstract, making liberal use of headings and sub-headings within the results section, and making sure that more general points are summarized at the beginning of each section of the results.

Discussion and Conclusions:
None of the reviewers recommended revision to these sections.

Minor specific revisions:
We have made all the minor revisions (e.g., key to table 2, removal of citation to manuscript under revision, definition of FDA)

Informed Consent:
The editorial staff noted correctly that our IRB’s (ethics committees) waived the requirement for formal approval because the study was deemed “not Human Subjects research”. They asked that we clarify whether informed consent was required and include that in the manuscript.

On page 10 (1st paragraph, lines 3 to 6) we now state that formal informed consent was not required. However, we did provide a description of the study and information about privacy and protection of the data collected.

Thank you for your interest in our work. We hope we have addressed the comments made by the reviewers and editorial board. Please do not hesitate to contact me if you need additional information.

Sincerely,

Karen J. Sherman, Ph.D.
Senior Scientific Investigator