

Author's response to reviews

Title: Researching complementary and alternative treatments - the gatekeepers are not at home.

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Author's response to reviews:

Dear editor of BMC Medicine

Thank you for letting us resubmit our manuscript. We will accept your suggestion of moving it to BMC Medical Research Methodology.

We have addressed every comment of the two reviewers point by point:

Reviewer #1:

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. This manuscript lacks a detailed discussion of the most important methodological tools: randomization and blinding. The authors do not distinguish between the purposes of the two tools, nor do they address them. In order to propose a valid new research paradigm for CAM, one needs a thorough understanding of methodologic issues involved. This does not seem to be the case. Here the authors make the same mistake as they "accuse" conventional researcher of who enter the field of CAM research: they seem not to have a good understanding of "context, paradigms, and philosophical understanding" of conventional research methodology.

Our response: All of the authors of this manuscript have been either responsible for or involved in randomized, double-blind clinical trials both in the CAM field and/or in conventional medicine. The first author is currently a co-investigator of two large randomized clinical trials, one double-blind and placebo-controlled, the other a pragmatic trial. The second author is head of the RCT unit at the Regional Health Authority of North-Norway, and an additional example: Professor Cheryl Ritenbaugh was clinical site principal investigator for Women's Health Initiative (the largest clinical trial to date) at two different sites - the University of Arizona in Tucson, Kaiser Permanente's Center for Health Research in Portland - and has served on that trials's Executive Committee and Publications & Presentations Committee. We thus have broad expertise in, and respect for the concepts of randomization and blinding. We think these issues are crucial when research is done to determine efficacy of pharmaceutical drugs or other treatment approaches that are to be delivered likewise.

We are sorry if this manuscript has led the reviewer to the impression that we in any way discredit the randomized, double-blind clinical trial methodology. We do not think the manuscript will benefit from a detailed discussion of blinding and randomization. The point of the manuscript is not to discredit this approach, but we intend to argue for giving it the appropriate role in the clinical research of CAM. We think it is well suited for testing of component efficacy. It is, however, unsuitable for other aspects of clinical research. We have made some adjustments in our wording to ensure that we are not seen as discrediting randomization and blinding in clinical trials.

2. How do they foresee the evaluation of safety of CAM interventions?

Our response: As now included in the manuscript, we suggest a research approach similar to the one used

to determine drug side effects, and that has been successfully utilized to determine the scope and incidence of side effects in acupuncture.

3. What methodology will be involved in effectiveness research. Merely observational research will not give valid estimates of effectiveness. The proposed strategy is not very useful if they do not provide critical methodological suggestions for research design.

Our response: In the manuscript we have indicated that "pragmatic trials" are needed in effectiveness research. Pragmatic trials are widely used in conventional medicine in areas where blinding and/or placebo control is not possible, for example in dietary intervention studies such as the Women's Health Initiative. We would suggest that we do not enter into a detailed discussion of this methodology. It will probably be familiar to the readers of BMC Medical Research Methodology. If the editor wishes, however, we will of course be happy to cover the topic in more detail.

Reviewer #2:

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Page 6 3rd para, 2nd sentence: "To study only the specific effect....." The authors address the problem of a specific effect by using two examples one from homeopathy and another from acupuncture. The presentation of these examples seems to short and the content might be difficult to understand for less involved people.

Our response: We have expanded the sentence somewhat to help the reader understand that acupuncture and homeopathic treatments involve several additional factors intended to have a therapeutic potential.

2. Page 6 3rd para, 3rd sentence: Do the authors really mean that all researchers who do research on CAM must have a thorough contextual and philosophical understanding of the investigated CAM method? It might be also acceptable that one researcher of the main project team has this knowledge.

Our response: We have changed the wording from researchers to research teams. That implies that not every single person of the team needs the same level of thorough understanding.

3. Figure 1 looks like a chronological sequence of the phases although the authors state in the text that the phases have a non chronological approach. A figure which represents more the framework idea of these phases might be more adequate.

Our response: We have made the arrows dotted in the right side of the figure to illustrate a weaker chronology.

Discretionary Revisions (which the author can choose to ignore)

4. The manuscript is well written and sound. However, for some of the researchers it would be very helpful to get more practical information about study designs for each phase.

Our response: See our #2 and #3 comments to reviewer 1.