Author’s response to reviews

Title: Intervention development for integration of conventional tobacco cessation interventions into routine CAM practice

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Author’s response to reviews: see over
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Tom Rowles, PhD
Senior Executive Editor
BMC Complementary and Alternative Medicine

Dear Dr. Rowles,

We are pleased to submit to you our revised manuscript (MS: 2069806034124542) entitled “Intervention development for integration of conventional tobacco cessation interventions into routine CAM practice” for your consideration.

We appreciate the thoughtful comments and recommendations of the reviewers and believe that the resulting revisions have strengthened the manuscript. The specific responses to reviewer comments are detailed in *italics in the attached document*.

Thank you for your time and consideration.

Sincere regards,

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Response to Reviewers

We thank the reviewers for their insightful and thought-provoking comments. Upon careful reflection, we understand how our use of the term “model validity” in the context of this paper was a source of confusion for the reader and did not accurately convey the concept we are trying to communicate. We believe that a better description of the goal of our development process is context validity of the intervention with real world CAM practice. This term encompasses both the acceptability of the intervention in actual practice and consistency of the intervention with practitioner scope of practice, practice patterns and client/patient flow. It also encompasses the need to maintain the integrity of PHS Guideline recommended practices that we are attempting to integrate, while also adapting how they are implemented in the different context of CAM practitioners/practices. We have defined what we mean by “context validity” as we use it in this paper and have replaced the term “model validity” with “context validity” throughout the manuscript to reflect this conceptual shift.

Integration of an evidence based health care and/or behavior change interventions widely employed in conventional medical and behavioral health into the CAM practice context in ways that ensure validity within the specific context of a CAM practice, and maintain validity of the evidence-based intervention.

Reviewer: Andrew Long

“Throughout the authors are recommended to ensure that the terms used are appropriate for an international readership. Particular examples, which may not be understood outside of the USA, are the term ‘provider-based CAM’ and ‘quitting’ (vs. stopping/ giving up smoking).”

We have defined the term ‘provider-based CAM” for the reader. We have also defined “quitting” as equivalent to “permanently stopping/giving up tobacco use”

Major Compulsory Revisions:
1. “Greater insight/detail is needed into how model validity is assure and integrated into the programme. And, on p6, is model validity an ‘aspect’, or rather a core principle underlying CAMR – and thus, how is it followed through?”

   See explanation above regarding replacing “model validity” with “context validity”

2. “Be explicit in the Methods about the aim of each step. Given the data sought in Step 2, make clear how this contributes to the development of the CAMR programme. In Step 3, give more detail on how feasibility and acceptability was explored.”

   In the Methods section, we have added more details on the aims and methodology for each step of the CAMR intervention development process. We added text specifically addressing how feasibility and acceptability were explored in Step 3. In the Results section, we added more detail on how the results of each Step were used to shape the intervention in the next development step.
In the Results section:

3. “Remind the reader of the aim of each step.”

   We have added a reminder of the aim for each step.

4. “Integrate the quotes into the surrounding text more effectively, in particular those on p17. Add commentary on Tables where appropriate in the text – e.g. for Step 1 – indeed maybe the table is better situated a little earlier in the text.”

   We have integrated the relevant quotes closer to the referring text and also added three additional quotes. We have also moved Table 1 up to the beginning of the results for Step 1.

5. Add a key to Table 2 (LAcS are …)

   A key was added to the bottom of Table 2.

4. “The Discussion section needs to be extended. Areas to cover include:
   “Issues relating to model validity – for example, in relation to aspects of the findings such as observed ‘hesitancy’ in introducing talk about tobacco (Step 1) and how does CAMR address or reconcile this….. This is a critical issue for wider use of the programme and also in relation to adherence/assurance of CAM model validity, or needed compromises or remaining tensions on this (or might the introduction of tobacco consumption and cessation be raised only where appropriate – in relation to wider lifestyle and linkage of this back to the client’s reasons for seeking CAM treatment; or only for those who are coming for health maintenance?). Consideration needs also to be given to this as a potential barrier to wider implementation and implications for the client-practitioner relationship (building and maintaining).”

   See above explanation regarding overall revision of paper by eliminating use of “model validity” in favor of “context validity” – which we have defined, and which we believe more accurately fits the concept we are trying to communicate. We have expanded the discussion section to describe how the CAMR intervention addresses the hesitancy of CAM Practitioners to talk to patients about tobacco use. We also discuss how the four steps of the structured helping conversation are at once both attentive to the context of the patient-practitioner relationship and facilitative of the need for building and maintaining patient rapport.

5. “Limitations of the study (sample related issues e.g. typicality, working with persons expressing interest vs. other CAM practitioners; response rate to Step 2; transferability of findings …);”

   We have expanded the discussion to include a section of limitations specifically addressing the response rate in Step 2, and that the results of this study conducted in the US may not be transferable or generalizable to CAM Practitioners in other countries.

6. “Indication of value and need for further research and evaluation (before wider adoption – or what?).

   We have added the end of the discussion text about the potential of the CAMR intervention for the three CAM disciplines in the study and for CAM Practitioner interprofessional
education and practice, noting that the CAMR research study currently underway intends to test the efficacy of the CAMR intervention to change practice behavior. We also posed what we feel is an important related research question about whether the foundational principles of patient-centered care and role of the practitioner in the patient-practitioner relationship might also be a way to bring together conventional and CAM Practitioners in collaborative efforts to help patients give up tobacco, and called for more research to address this question.

**Minor Essential Revisions**

7. “P7, first sentence: It would be useful to add in some examples to illustrate this.”
   
   We decided this sentence did not contribute to the paper and deleted it.

8. “It would be valuable to provide a little more detail of the CAM practitioners who participated in the research, in particular, in relation to their style of practice (this relates to a judgement by a reader about the issue of transferability and use of the findings).”

   *We added more detail describing the practice styles of practitioners participating in Step 1, and noted that practice styles of practitioner participants for Steps 3 and 6 were similar to those of the key informants in Step 1.*

9. “P12 – questionnaire mailed to all? Or is it a sample – assumed former, but make explicit”
   
   *We added text to clarify the survey sample to methods for Step 2.*

**Response to reviewer 2: SP**

**Major Compulsory Revisions**

1. “Research Question. I was not totally certain of the specific question this research is addressing. Was it how behaviour change interventions can be integrated into CAM practice in ways that do not detract from the CAM practice or ways that do not compromise the model validity of the smoking cessation programme or both of these? Was the purpose of the paper to describe the iterative process of the development of the programme? I was not convinced that the authors’ use of the question of model validity was entirely appropriate. This maybe because I did not understand the overall research question, or it may have been because it was not the right question for the methods, and/or that there was not enough data to convincingly answer the question. It might also have been that this is a large body of work to report in one research article. In pursing the interest in model validity for three different CAMS, there was sparse detail on what the model validity for these three practices were, and assumptions may have been made, as a consequence, about what these practices had in common to make it appropriate to introduce a new practice (tobacco cessation programme) without compromise of model validity. This is especially relevant when there was a very poor response rate to the survey, and overall, a very small number of participants were involved at the different stages.”

   Upon reflection, we realize why this paper appeared so unclear to the reviewer. In fact the paper was originally written as an intervention development protocol paper, with the intention of describing the iterative process of developing a contextually valid intervention protocol. It was not originally written as a research study paper. BMC CAM requested that the paper be resubmitted as a research paper, but we neglected to fully revise the paper in a
way that would be more appropriate and understandable in a research paper context. Note that the title has been changed to better reflect this developmental focus.

The reviewers’ questions also prompted us to reconsider our use of the term “model validity” and ultimately replace it with “context validity” as we have explained above. We have defined what we mean by context validity in this study and our iterative process of developing an intervention protocol to have context validity for three different CAM disciplines in their real world practice contexts.

We have expanded the discussion to note limitations of the study and its findings with respect to the response rate in Step 2, and the transferability and generalizability of the formative research findings and final CAMR intervention protocol due to the study’s conduct in the U.S. and the limited numbers of practitioners participating in some of the development steps.

2. “Tobacco cessation and CAM Practitioners 3rd paragraph. The NIHS data on the high proportion of smokers that seek CAM may be a specific characteristic of the US.”

We have revised the text to emphasize that this is based on a US population, and noted that published reports (in English) of similar data from other counties are sparse. We have also included two studies on non-US populations of CAM use that also reported tobacco use status.

3. “Methods: The idea of a six stage iterative process is worthy for the development of model validity, but the links between some of these stages were not made explicit. For instance, in what way did the first stage (interviews) inform the second stage (the survey) – this is a ‘results’ question but the description of the process by which the findings of the first stage would inform the survey is missing from the methods section. There is sparse information on the analysis of the interviews and the data generally. How the survey was developed is not made explicit or how the survey information was going to inform the further stages.”

We have revised the text to more clearly indicate the relationship of the results from each step to inform the next step. We also added more detail to the methods for each step to describe participant recruitment, survey development, and data analysis.

4. “Recruitment – it is not clear what the process for recruiting the participants at some of the different stages was, or what numbers were required or achieved (for instance the demonstration stage).”

We added descriptions of participant recruitment to the methods for each step, and noted that the sample size recruited was based on practical considerations and likely saturation of feedback themes from a qualitative sample.

5. “Regarding the demonstration stage (step 3) – there is too much information given on the ‘helpers’ programme, this could be given as a brief outline with a reference.”

This section was revised and cut down as recommended.

6. “Feedback stage: it is not clear which stage of this process the practitioners’ feedback is originating from.”
We added text to clarify that feedback in Step 3 was from the practitioner’s experience of the demonstration Helpers training.

7. “Pilot: what was the purpose of this pilot, was it an exploration or a test of the program and how was the data collected and analyzed? Without a clearer focus of what the pilot was for, it is difficult to make judgments about the methods or findings.”

*In Methods, we added a description of the purpose and aim of the Step 3 pilot study, and a description of the data collection and analysis process.*

8. “Results: This section is problematic because of the weaknesses in the methods. Survey: there was limited information on the survey, the questions, how they were developed and what the main purpose was. The response rate was very low 23% which brings uncertainty on the strength of any findings. For instance the authors write that ‘two-thirds of practitioners’ were interested in receiving cessation training, which should read ‘of those that responded’.”

*We have substantially revised the Methods to include more detail of the methods employed for each step. We also revised the results section to remind the reader of the aim for each step. As a consequence we believe the results section is now clearer. We also revised the wording in Step 2 to reflect that results are based on those responding. The low response rate is discussed as a limitation in the Discussion section.*

9. “Discussion This study involved a very small number of CAM practitioners from three arguably, very different disciplines, the survey had a very low response rate and little data was provided on the pilot study, or how the participants were recruited – is it possible to say that this is representative of the professions and what do the authors mean by model validity? Is the question really about whether the new intervention is acceptable to CAM practitioners and can be incorporated into practice - acceptability and model validity are different.”

*We have expanded the discussion to address these limitations and their implications for generalizability. And we have attempted to more clearly emphasize that this intervention model development is only in aid of further testing in a larger intervention study. Results from this study will provide additional insight regarding broader acceptability, efficacy for behavior change, and relevance to practitioner experience.*

10. In discussing ‘step five results’ or step six results – it would be helpful to remind the reader what these steps were and what questions were being answered by the results.

*In the Results section, we have added reminders about the name of each developmental step and its aims in the developmental process.*

11. “What were the three guiding principles of the CAMr intervention, it might be helpful for the reader to be reminded of them at this stage? Little comment was made on how the three CAM practices responded differently with the acupuncturists much more interested in the programme than the massage therapists from the survey response rate.”

*We have added text to remind the reader of the three guiding principles of the CAMR intervention. We have also added a comment to the discussion as to possible reasons for the differential response to the survey by the different practitioner types.*
12. The writing style in this section needs to be addressed, for instance: discussion section second para – this is a useful comment, but words like ‘surprise’ and ‘unexpected’ do not add to the discussion, but rather detract from it. If these words are used, then comments need to be made about the expectations of the researchers and whether they used a reflexive approach.

We have revised this section to eliminate the words the reviewer finds objectionable. The work reported in this paper is preliminary work, in that it describes a formative and iterative process of intervention development. It was not intended to be hypothesis-driven research, but intervention development with results from each step of development informing the next, and moving toward the creation of the final CAMR intervention protocol. In that sense, we have used a reflexive approach- utilizing the results of each step to reflexively inform the next step.

13. “Final paragraph of the discussion section: This point goes too far as until this programme is shown to be effective, it is not possible to comment on what dimensions of the programme are ‘working’ and useful. It is not clear how the authors have arrived at the conclusion that the therapeutic relationship could be a common touchstone to bring together CAM and conventional practitioners – these different modalities all contain different styles of relating to patients – this is a very complex subject and not one necessary to bring into this paper, and at this stage without further detail and referencing. The authors bring in dimensions of the therapeutic relationship at this discussion stage that have not been raised earlier and are not part of the findings of this work.”

Upon re-reading, we agree with the reviewer that the language in our conclusion is more definitive than is warranted, based on the developmental work presented in this paper. We have revised this section to comment on the CAMR intervention’s apparent context validity across three different types of CAM Practitioner practice – and note that this is a premise that is being tested in the full CAMR practice-based research study. We have also revised the text to more specifically indicate that we believe the results of this developmental work support a premise that the importance of the patient-practitioner relationship is a common theme across the three CAM disciplines – strongly endorsed by participating practitioners as well as external expert reviewers. Should the CAMR intervention prove effective in the full CAMR study, we believe this finding has potential implications for future CAM Practitioner interprofessional education and practice.

14. “No mention is made in the discussion section of the limitations of the study including the poor demonstration of the iterative process, the poor response rate and the questions over generalizability and whether all three CAM modalities are suitable to deliver tobacco cessation programmes given some of the comments from the interviews by the massage therapists and also the poor response from the massage therapists. The conclusions are much too definitive given the limitations of the methods, and analysis and discussion of the data and that this is preliminary work, developing a programme that has not yet been tested.”

We have expanded the discussion to note limitations of the work presented, including low response rate of survey, limited number of CAM Practitioners for some of the developmental steps, and the implications for potential limited generalizability/transferability of the developmental process results and the CAMR intervention protocol to other CAM Practitioner populations.
As we have explained above, the purpose of this paper is to describe preliminary, formative research work to develop the CAMR intervention protocol. It is not describing the actual full-scale practice-based, mixed methods CAMR study that is currently underway. Upon rereading our conclusion, we agree with the reviewer that we were more definitive in our conclusions than is warranted by the results of this formative intervention development work. We have revised the conclusions accordingly. We have also added text to clarify for the reader that the purpose of the full CAMR study is to test the efficacy of the final CAMR intervention protocol (development of which is described in this paper) to change practitioner clinical