Author's response to reviews

Title: Protocol for the development of a salutogenic intrapartum core outcome set (SIPCOS)

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Version: 1 **Date:** 14 Mar 2017

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BMRM-D-16-00509

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Response to Editor and Reviewers' comments

Dear Editor and Reviewers,

Thank you very much for your comments and suggestions for amendments on our manuscript. We have provided a point-by-point response to each of these as below, which we hope satisfactorily addresses these.

Kind Regards,

Valerie Smith

Editor Comments

Thank you very much for your submission to BMC Medical Research Methodology. Both reviewers were generally positive about your manuscript but have a number of points which should now be addressed in a revised version of the manuscript (see below for their reports). In addition, we would be grateful if you could carry out the following editorial revisions:

1. In the main manuscript file, please include a title page which should include the title of the manuscript as well as a list of all the authors including their institutional addresses and email addresses. Please also indicate the corresponding author.

Response: The title page, with a list of all authors, including their institutional and email addresses, is now added to the main manuscript file (page 1). The corresponding author is indicated by *

2. After the title page please also include the manuscript abstract.

Response: The abstract is now added after the title page (page 2)

3. At the end of the manuscript text (after the Discussion section) please include a full declarations section which should contain the following:

a. Ethics approval and consent to participate (currently missing)

b. Consent for publication (currently missing)

c. Availability of data and material (currently missing)

d. Competing interests

e. Funding

f. Authors' contributions

g. Acknowledgements (currently missing)

h. Authors' information (optional)

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Response: A complete Declarations section, containing all of ‘a’ to ‘h’ above is now included (pages 11 and 12).

4. In the authors' contributions section please ensure that the contributions of every author is listed. Currently there are a number of authors who are not mentioned in this section. At the end

of this section please also include a statement to confirm that all the authors read and approved the final version of the manuscript.

Response: The authors' contributions section has now been expanded to read (page 12);

"VS and DD conceived the idea. VS, DD, SD, ZA, MG and CB refined the study. VS, DDa, IL, TSE and DDe were involved in conducting phase one of the study. VS drafted the manuscript. DDa, IL, TSE, CB, MG, SD, ZA and DDe contributed important intellectual content to the paper. All authors read and approved the final version of the manuscript prior to submission."

Reviewer reports:

Julie Taylor (Reviewer 1)

Thank you for the opportunity to review this interesting protocol on developing a salutogenic intrapartum core outcomes set (SIPCOS). I am a great fan of salutogenic approaches and am delighted to see a shift in focus from the more usual pathogenic lenses. The protocol is well written, and whilst one may disagree with some of the proposed salutogenically focused outcomes, these will be further tested in the Delphi (for example, I am not convinced that maternal parenting confidence equates with maternal self-esteem, I think you could be a confident parent and have very low self-esteem at the same time).

Response: Thank you for this important comment. As acknowledged, we will test all outcomes in the survey. The outcomes will be listed separately for rating and participants will have the opportunity to add further outcomes, that they consider salutogenically-focused, if they so wish.

The key criticism I have of this paper though is 'why'? The case for offering salutogenically derived outcomes is not made, nor why this should be privileged over the existing core outcome set? Perhaps if the authors could offer a critique of the existing COS and make a strong case for why the SIPCOS is a. needed and b. superior, then this would be a much stronger paper. I believe this is worth doing. The case may already have been made in the previous paper by the authors, but reading this fresh here, I am left wondering why.

Response: The existing set of outcomes (Table 1) is a preliminary outcome set only, identified by the research team following a review of outcomes in published systematic reviews. This set of outcomes has not been through wider-stakeholder review, ranking, and consensus on which outcomes should be included in a final COS, as recommended by the COMET initiative when developing a COS. The list in Table 1 presents the first phase only of the SIPCOS development process. We have presented the case for a SIPCOS in much greater detail in our previous paper (Smith et al, 2014); however, we appreciate, in line with your comment, that others might be left wondering 'why'. To address your comment we have added the following text to the Background and Design sections;

- Background section, Lines 74-85

“While the case for identifying salutogenically-focused outcomes is presented comprehensively in the published review that informs this protocol [1], in brief, the central argument is predicated on a need to move away from existing risk-avoidance/harm prevention approaches, to maternity care which has health promotion at its core. The review authors further suggest that an emphasis on risk in maternity care has led to increased routine interventions including caesarean section. In capturing only pathological outcomes, or ‘satisfaction’, studies fail to capture the positive added benefits of specific interventions, or lack of interventions. Consequently, understanding the nature and effects of salutogenic outcomes in maternity care is limited. The systematic review of reviews identified 136 (8%) salutogenically-focused outcomes only, from a total of 1648 reported outcomes across 102 intrapartum systematic reviews [1], further adding to the rationale for this study.”

- Design section, Lines 140-145

“This initial list, as described, presents a preliminary set of outcomes proposed by the authors of the review that precedes the current study. There is a lack of multi-stakeholder involvement and agreement on whether these are the most important outcomes for including in a final SIPCOS. Phases two and three of the current proposed study, which include consensus methods, will develop an agreed SIPCOS that will be superior to an outcome set derived by a particular group of authors from a review of the literature alone.”

Edward R. Newton (Reviewer 2)

The manuscript describes an organized plan to develop a salutogenic intrapartum core outcome set (SIPCOS) to be used in addition to study outcomes in traditional trials of intrapartum management. The concept is similar to adding quality of life measures to chemotherapy trials for cancer treatment. This concept has been valuable in this realm for two or more decades. The development of an internationally nationally recognized, succinct, short list of questions eliciting the impact of intrapartum management changes on salutogenic variables is long overdue. The manuscript would be of high interest to BMC Medical Research Methodology.

I have two comments:

1. The quality of the final sample of surveyed individuals is critical to the final acceptance of the SIPCOS.

a. The "value" of each stakeholder group is different. Parous women with expertise and knowledge in obstetric care would have more valid opinions than a similar number of male anesthesiologists. Should the numbers in each group be weighted to reflect the relative "value" of the groups?

Response: Critical to the consensus process in COS development is representation from all relevant stakeholder groups, rather than a weighting of numbers across groups. We won’t know until the survey is complete how many participants will take part from each group, and it is likely there may be more from some groups taking part, compared to others. The analysis process, as

described on page 9 (Data analysis) accounts for this, whereby each representative groups' results are analysed separately and consensus on inclusion of an outcome is determined based on ≥ 70% of all members of at least three stakeholder groups, responding yes to the questions in round 3 as to whether an outcome should be included in the SIPCOS. Furthermore, we have placed greater value on ranking of outcomes by users of maternity care (women, partners of women, etc.) whereby we describe inclusion of an outcome based on ≥ 70% of all members of at least three stakeholder groups one of which must include users of maternity care, responding yes to the questions posed in round three (page 9, Lines 281-282).

b. How is that value determined?

Response: The decision to value the rankings of users of maternity care in this way was informed by another COS development process (in eczema) that involved users of healthcare and placed higher value on their ranking in determining which outcomes should be included in the COS and forwarded to the final consensus meeting. We have referenced this paper in our manuscript and added the following sentence (Lines 283-285) to highlight this; "Valuing maternity care users in this way was informed by a previous COS development process which placed greater emphasis on users of healthcare in deciding what outcomes should be included in the final COS [14]."

c. How was the sample size of phase 1 determined and what was the distribution of participants among the groups in regard to "value"?

Response: There is no sample size for phase 1 as this was a review of all systematic reviews of intrapartum interventions to identify salutogenically-focused outcomes for use in the survey. The full methods for the review of reviews are described in the referenced Smith et al, 2014 paper. Regarding the sample size for the survey, we have extended the sentence (page 6, Lines 187-191) to now read: "While there is no guidance that we are aware of on the optimum sample size for a Delphi consensus process, we propose to aim for a minimum of 30 participants from each stakeholder group to ensure adequate representation. These proposed numbers are based on a sample size achieved in a previous COS development process [14], although we anticipate our numbers will likely be much greater."

d. How did the sample size account for the cultural and economic differences in expectations of laboring women? A Swedish woman has different expectations than an African American woman in the American rural south.

Response: Thank you for this valuable comment. In line with COMET methodology and its mission, our aim is to achieve consensus on a minimum set of important outcomes that should be measured in all trials on a topic, irrespective of where the trial is being done. Individual researcher will add outcomes, alongside the core set that are specific/relevant in the context of their own trial (i.e. clinical, cultural, or other specific outcomes that are important for individuals and in different contexts). Furthermore, the international nature of the survey, and the consensus process (i.e. ranking of the importance of outcomes by individual participants), in addition to an opportunity for participants to add further outcomes, will allow for/enable cultural and economic variation input, whereby outcomes achieving a score of ≥ 70% of all members of at least three stakeholder groups, only, will be forwarded to round three for subsequent appraisal. The

demographic details section of round 1 of the survey will capture information on the country of origin of participants. Thus it will/should be possible to capture cultural variation in the ranking process and assess this by doing a sub-analysis of highly (very important) ranked outcomes by country, although this won't influence the final core set as ranked by participants overall in the survey. We capture this we have added the following to the Methods section (Lines 287-290); "Furthermore, the demographic details section of round 1 of the survey will capture information on the country of origin of participants. We therefore propose undertaking a sub-analysis of highly (very important) ranked outcomes by country to capture potential cultural variation in the ranking process"

2. There is very little detail of the Phase 1 survey results.

a. How many participants responded in each group of stakeholders?

b. How were the Phase 1 stakeholders selected?

c. Were the response rates similar across stakeholder groups?

Response: Perhaps there is a slight misunderstanding on the reviewer's part as the survey component of the study, which is phase two, has yet to be conducted. Phase one of the proposed study, which is complete, is a systematic review of reviews to identify salutogenically-focused outcomes already used in studies. The identified outcomes from the review (Table 1) will be used in the electronic Delphi survey. As the survey has yet to be administered (i.e. pending publication of this protocol), there are no 'participants' or 'response rates' to report on here (i.e. phase one involved published systematic reviews and counting of outcomes, only). We will report, in a separate/subsequent publication, the number of participants and stakeholder groups' response rates once the survey component of the proposed study is complete.

To address point b, the following sentence has been added (page 6, lines 185-186); "These groups were selected to ensure wide stakeholder inclusion and involvement of all potentially relevant and interested parties."