Author's response to reviews

Title: COS-STAR: A reporting guideline for studies developing core outcome sets (Protocol)

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Author's response to reviews: see over
Dear Editors,

Re: COS-STAR: A reporting guideline for studies developing core outcome sets (Protocol) [resubmission]

I would like to thank you for providing us with the opportunity to resubmit the above titled manuscript. In particular I would also like to thank the reviewer for their extremely helpful comments and suggestions, which I have thoroughly taken into account when revising the article. Responses to the reviewer’s concerns are included below.

In particular I have added in the extra methodological detail requested by the reviewer, particularly around Stage 3, the consensus meeting.

I would also like to request that Dr Sarah Gorst be added to the manuscript. Sarah has joined the group since the original submission, has contributed to the detail surrounding the number of participants in each stakeholder group in the protocol and will be managing the day-to-day activities surrounding this study.

I hope that with these revisions, you will seriously consider publishing this work in Trials. Many thanks again for taking the time to consider our work for publication in your journal.

Yours faithfully,

Dr Jamie Kirkham

University of Liverpool
Please find below our responses to the reviewer comments.

Reviewer's report

Title: COS-STAR: A reporting guideline for studies developing core outcome sets (Protocol)

Reviewer: George Tomlinson

Reviewer's report:

Since this is a protocol, there is little background on core outcomes sets and their use, and a focus principally on the methods of the planned project. The protocol lays out a straightforward plan of action, mainly without justification for the separate steps, and clearly defines the various participant groups and their interactions. It is clearly written and the authors are centrally involved in the COMET core outcomes initiative.

My first comment below assumes that the project is still amenable to change. The second and third comments are about the manuscript describing the protocol.

>> Individual responses have been provided for each reviewer comment below with full modification to the protocol text made where appropriate.

Major comments:

1. For the Delphi exercise, the plan is to approach approximately 200 COS developers, 220 journal editors, 8 members of the PoPPIE group and what looks like thousands of PIs from open phases III/IV trials on ClinicalTrials.gov. Presumably, there will be a much higher percentage of respondents from the first three groups

>>From a pragmatic perspective we have decided to take a random sample of 20% of the total number of potential chief investigators/co-investigators from the trials identified on ClinicalTrials.gov. We also plan to invite the COS developer contacts (i.e. corresponding author on the publication) to forward on the survey to all their co-investigators (this way we will also target COS methodologists). The PoPPIE group will also be extended to include patient facilitators of PPI workshops.

It is possible that some of the groups will have already engaged in COS work, and therefore response rates may be higher for these groups due to an invested interest in this current study. However, the contacts for the trialist group will be the most up-to-date (and potentially valid) list as contacts are taken from ongoing trials. Response rates and attrition will be reported in the findings.

but there is a possibility that the opinions of these three more informed groups will be washed out what could be a majority of 'trialists,' even if only 10-20% respond
In Round 2 of the Delphi, participants will be fed back the results to each stakeholder group and therefore will have an opportunity to re-score based on the opinions of each group. For each stakeholder group, feedback will consist of % summaries scoring 1 to 9 for each guideline item. Therefore it is the distribution of the proportion of participants from each stakeholder scoring each item (across scores 1-9) that is important rather than the total number scoring from each group.

Presumably this is why there will be a stage 3 review giving priority to the critical items from the Delphi exercise. This is the stage at which the steering committee, expert panel and a few other stakeholders will make a final decision on the items to be included in the reporting guidelines. If items are considered to have been missed or wrongly included at the threshold of 70% with a score of 7-9, the consensus meeting has the chance to make a correction. My comment is this - do you really need to approach all the PIs of eligible trials? A much smaller random sample or a stratified sample from a few different clinical areas could be more efficient and provide just as much useful information. A smaller sample might allow you to provide a little more inducement to participate (through personalised emails, for example) from this likely less-engaged group. A smaller sample of PIs also gives them a more appropriate weight in the ranking exercise and may leave the consensus panel with an easier job at the end.

Please see response above. Wherever possible personalised emails will be sent out to all participants using mail merging.

The manuscript might be strengthened by some justification of the choices of the various participants of the Delphi exercise and the numbers in each group.

Stakeholder groups were chosen to encompass all aspects of core outcome set development. Firstly those that develop core outcome sets (core outcome set developers), those that publish the core outcome set articles (Editors), users of core outcome sets (trialists, systematic reviewers and clinical guideline developers) and finally we felt it important to include patient facilitators to gain opinions from a PPI perspective.

Given the design, in which results from each stakeholder group will be summarised separately, we are taking the approach of trying to maximise the information, within practical limitations. As mentioned previously, for the core outcome set developer group we also plan to snowball by inviting contact authors to forward the survey onto their co-authors. Efforts will be taken to maximise the response rate across stakeholder groups.

The manuscript would be strengthened by a description of the methods whereby the consensus group will use the results of the Delphi exercise. The earlier stages are well-described but the process in stage 3 is somewhat vague. As it currently reads, a pragmatist might wonder about the value of the earlier stages when the final COS-STAR guidelines are decided by an expert panel and
a few additional stakeholders. I understand that some details will depend on the findings of the Delphi exercise, but I am curious about things like how much weight will be given to the results of that exercise in relation to the opinions of the consensus panel members, if there is a maximum size for the number of items in the reporting guidelines, or if there are previous examples of decisions at similar consensus meetings that could be used to give a sense of how the decisions will be made here.

>> We have provided more detail about the Stage 3 process in the protocol, following our experience in previous studies. Any protocol deviations will be documented in the final manuscript.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have