Author’s response to reviews

**Title:** Interventions to promote patients and families' involvement in adult intensive care settings: a protocol for a mixed-method systematic review.

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Author’s response to reviews:

Thank you for facilitating such a thorough peer-review for our mixed-method systematic review protocol. We have responded to the reviewers’ feedback below and noted all changes in the manuscript using red font. Given that it has now been a year since our first submission, and that the paper has already undergone two rounds of peer-review, we invite the Editor to consider our manuscript in its current revised form and we look forward to their decision.

Reviewer #1
#1.1: Thank you for consideration of previous comments made. Admittedly, overall, the revisions haven't made a great deal of impact re the clarity of the review project and how the authors intend to go about it.

#1.1 RESPONSE: We regret the Reviewer’s view. We note the paper has undergone extensive, rigorous peer review by two panels of experts as part of the UK National Institute for Health Research funding processes. The strength of our work lies beyond the narrow assessment of a single intervention, in a single setting, following a single research design -indeed, we pursue a mixed-method systematic review to avoid going down the path advocated by the reviewer. We note a precedence in Systematic Reviews
of publishing mixed method review protocols, e.g.: https://doi.org/10.1186/s13643-016-0372-8

#1.2: Re this: I appreciate some interventions have been named among the eligible interventions, however these could/should have been better tied into the introduction - to better support the rationale for the review and use of interventions.

#1.2 RESPONSE: We draw the Reviewer and Editor’s attention to our extensive background section, which provides both the context and rationale for the review. Here, we note our discussion in Page 4 where we draw from the wider literature, and a previously published scoping review on the topic, to give examples of the range of interventions considered. Interested readers can refer to the Olding paper, which we cite, for detail of the interventions - this is more appropriate in the context of a review protocol than repeating large parts of a previously published paper. Please see: https://doi.org/10.1111/hex.12402

#1.3: The authors are including multiple study designs in their analyses, (both randomised and non-randomised studies) have some predetermined outcomes named that appear to be both dichotomous and continuous. I think a well prepared protocol should be clear on the approach to statistics that will be pursued and how the effect estimates will be calculated and then used. On this latter point, where labels such as ‘suggestive’ or ‘firm’ evidence are used, these need clear criteria to distinguish them a priori based on size of effect and/or the quality or rigor of studies (at a minimum)

#1.3 RESPONSE: We appreciate the point made and indeed a clarification has been included in the manuscript, specifically regarding the ‘suggestive/ firm’ evidence distinction. Please see Page 9.

Reviewer #2

#2.1: Authors have addressed many of my comments. However, my comments # 3 and #6, were not fully addressed. Authors state that presenting 2 different sub-questions with a big overarching question would not be appropriate in a Mixed Methods Review and that would only be possible under 2 systematic reviews. I disagree. Conducting a Mixed methods synthesis, although requires integration of QUAL and QUAN research, does not prevent from clearly stating what are the QUAN and QUAL subquestions and what would be the approach to synthesize each stage. Furthermore, the only way to appropriately justify a Mixed Methods analysis, is after understanding what each component provides and how they complement or inform each other. Synthesizing QUAL and QUAN research without clear methods and clear questions for each one, will bring uncertainty to the Mixed methods approach.

#2.1 RESPONSE: We respect the Reviewer’s different perspective and interpretation of our mixed method review. We have provided detailed and clarity in our protocol regarding the objectives and method of our review, which we expect strengthens transparency and replicability of the work. At this time when mixed method systematic review methodology is developing, we invite the readers to gauge the relevance of our review to their practice.

#2.2: I suggest authors to clearly describe that as a MM SR, they have a big, overarching or general question that is in turn composed by at least two subquestions. In this case "What are the available interventions…" should be one of those sub-questions and "which are the most effective…” should be the second one. In general, I think authors need to rearrange the methods section to follow the approach I am suggesting above. I think each subquestion entails a different methodology and this should be explicitly described in the methodology, using subheadings if needed, and detailing each data analysis methods.
#2.2 RESPONSE: We refer the Editor and Reviewer to our previous response to this point. We maintain that two separate questions would demand two separate reviews. This becomes obvious when one develops two PICOS for each of the two questions, which in turn demands a slightly different approach to the search, data extraction, quality assessment, etc. Indeed, the reviewer is calling for separate method sections for each review question. In effect, this leads to two separate reviews. What the reviewer is advocating for is a multi-method, rather than a mixed-method review. This is not the approach we are taking, not the approach previous mixed-method reviews published in this Journal have taken, and not what our funders commissioned us to deliver. We have nevertheless updated our ‘analysis and synthesis’ section considerably to offer more detail and transparency to our approach. Please see Pages 8 and 9.