Author's response to reviews

Title: Examining health promotion interventions for patients with chronic conditions using a novel patient-centered complexity model: protocol for a systematic review and meta-analysis.

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

Thank you for your consideration of our manuscript, “Examining health promotion interventions for patients with chronic conditions using a novel patient-centered complexity model: protocol for a systematic review and meta-analysis”. The reviewer’s comments were very thoughtful, and we hope that by addressing each comment you will find our revised manuscript much improved and suitable for publication. Below we have included the reviewer’s comments; our responses are indented and italicized.

Reviewer’s comments:

1. (Major Revision) Details of how interventions will be coded according to the CCM are vague and the criteria used to make these assignments (increased, decreased and neutral effect on both workload and capacity) seem highly subjective; more details on the methods are needed.

   Thank you- we revised the manuscript on page 12, lines 3-16 to better define for the reader the CCM concepts and the methods for how they will be coded. Please note that we do plan to take several steps to reduce subjectivity (reviewers will code components independently followed by group consensus and will be blinded to the outcomes to reduce bias).

2. (Major Revision) Though the authors propose to measure interrater reliability for coding interventions according to the CCM model, the authors do not report any previous data regarding the reliability and validity of the strategy the authors propose to use. (For example, is there any relationship between a coder’s assessment of whether an intervention enhanced patient capacity and the patient’s assessment of capacity or self-efficacy?)

   At this time, we have no previous data on interrater reliability for the coding. As described on page 11, lines 21-23, this will be optimized by training and reported in the final paper. Regarding relationship between patient and coder assessments of capacity: patient-reported outcomes such as self-efficacy or functioning will included in the coding and analysis. If improvements are shown, then intervention outcomes will by definition be coded as having increased capacity according to the newly clarified definition (noted in our response to comment 1 and in the revised manuscript on page 12).

   We will be very transparent about our coding and report the reproducibility of our methods to ensure that readers can assess for themselves the validity of this work. The field is too young to have data about the agreement between patients and researchers regarding capacity. Other members of our team
are conducting qualitative research to best understand the fundamental patient perspective on this issue. This review will also contribute to build this understanding.

3. (Major Revision) The authors state they will assess intervention workload and capacity at 3 points in time (immediate, proximal, and distal), yet no definitions or specific time periods are provided and it is not clear how the analysis will address changes in workload and capacity across these time periods. As the authors point out the dynamic interplay of workload and capacity over time (for example, increase initial workload from an intervention that leads to enhanced capacity at some follow-up point) is key to understanding how an intervention impacts these factors;

   Thank you for this feedback. To improve the clarity of our methods and analysis, we have modified our analysis plan by eliminating the 3 time points (immediate, proximal, and distal) and instead we will code the impact on workload and capacity by both (a) the intervention components and (b) any reported outcomes related to the intervention (other than the final behavioral outcomes of interest).

4. (Major Revision) The authors will include interventions that aim to address single as well as multiple behaviors. Previous research indicates smaller effect sizes when multiple health behaviors are targeted by an intervention. It is not clear whether and how the authors will address the single vs. multiple behavior interventions in their analysis plan;

   We are aware that research suggests that multi-behavior interventions have smaller effects, and agree that to better test the model, we may benefit from narrowing our focus to “uptake” behaviors (physical activity and/or diet) instead of cessation behaviors (tobacco and alcohol use). You will find this change reflected throughout the manuscript. Additionally, we will add comparisons of single vs. multiple behavior interventions to our subgroup analysis (page 13, line 19).

5. (Major Revision) Similarly, the authors will include both provider facing and patient facing interventions in their review. It is not clear whether and how the authors will address patient facing vs provider facing interventions in their analysis plan;

   Thank you for this suggestion. We will include provider-facing vs. patient-facing interventions in the analysis plan as a subgroup comparison. This has been clarified in the manuscript on page 13, line 19.

6. (Major Revision) It is unclear how “presence of depression” will be operationalized in the coding process; might other mental health conditions also be considered, particularly since alcohol and tobacco are 2 of the 4 target behaviors;

   We will code presence of depression if it is a criterion for inclusion in a reviewed study. We clarified this in the manuscript on page 13, line 18.

Because of these concerns, particularly the limited detail provided regarding the methods to be used to rate and code interventions, I cannot be sure the study design will adequately test the proposed hypotheses. The authors might consider simplifying and limiting their review to interventions that address a single behavior (e.g., tobacco use), a specific intervention modality (e.g., patient-facing) to allow a more focused test of the CCM concepts of interest.

   We agree that by limiting our review to just physical activity and/or diet interventions we will be better able to test CCM concepts, and that the use of subgroup analyses to test for differences by modality and single versus multiple-behavior interventions are useful in clarifying the implications of our findings. You will see these revisions throughout the manuscript. We thank you for these helpful suggestions; we
have revised our study protocol accordingly and believe that these changes address the major revisions that were recommended.

We thank you again for your timely consideration of this manuscript.

Sincerely,

Amy E. Bodde