Author's response to reviews

Title: Brief cognitive behavioral therapy in primary care: A patient randomized hybrid effectiveness implementation design

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Author's response to reviews: see over
Dear Dr. Foy:

Thank you again for your thoughtful feedback and suggestions for improvement to our manuscript. We are excited to resubmit our work with the changes you requested. As this is my first implementation protocol paper, I found your feedback to be incredibly helpful and look forward to any other suggestions that you or your editorial office can provide to us.

In the manuscript, we have used a yellow highlight to indicate important changes to the manuscript to aid your review of our manuscript. Below are brief responses to your initial review.

Sincerely yours,

Jeffrey Cully, PhD
Michael E. DeBakey VAMC
Associate Professor, Baylor College of Medicine

Responses to Initial Review

1. You need to clarify what type of hybrid study you think this is. My current reading is that it is a type 2 because it involves dual testing of clinical and implementation interventions/strategies, using a nonrandomized or case study design to evaluate the implementation strategy in a largely formative manner.

Response: As indicated now in the title, we believe this trial can be best identified as a hybrid type 2 design with the acknowledgement that the implementation aspects of the trial are formative/developmental and do not involve the use of an implementation control group. This clarification was described throughout the manuscript.

2. You need to be explicit about the implementation element of this being a pilot study which aims to develop an implementation strategy which would then require further rigorous evaluation to determine its effectiveness. Any remarks about knowledge generated in dissemination need to be more tightly qualified than they presently are in the Discussion section.

Response: The Discussion section was revised with details added to discuss the general limitations of our implementation approach including our desire to use our formative data to build future implementation projects/studies.
3. There are a couple of related issues about the implementation strategy being evaluated within the context of a clinical trial – which can limit generalisability to non-trial contexts. Can you make a case as to how much the clinical effectiveness evaluation is likely to represent eventual practice in a ‘real world’ non-trial context? And if the clinical intervention being evaluated here actually turns out to be ineffective, what would the generalisable messages be that are potentially relevant to the wider implementation literature?

Response: We have now included information about the applicability of our effectiveness evaluation strategy and its current overlap with ongoing clinical efforts within VA. We also include a broader discussion of the importance of the implementation strategy that is independent of our effectiveness evaluation (see Discussion section).

4. The selection of the ‘implementation interventions’ is not grounded in any review of relevant implementation literature. Although you intend to develop and adapt the implementation strategy during the study, it would have been helpful to have seen an evidence-informed rationale for their selection.

Response: We have now more fully described the selection process of our implementation strategy which was founded on the relevant implementation literature. This section now includes a specific rationale and citations for these components. (see section on Implementation Strategy).

5. You do refer to PARIHS in the implementation strategy but it is not clear to me how PARIHS was specifically applied (beyond mentioning facilitation).

Response: We added information about how our implementation strategy maps onto the PARIHS framework (see section on Implementation Strategy).

6. The protocol for the evaluation of the clinical effectiveness of CBT currently omits important elements that should routinely be reported according to the CONSORT statement for individual RCTs – most notably a power calculation. You should also upload a copy of CONSORT specifying where each requirement of the statement is met in the manuscript as an additional file.

Response: We now include specific language about our sample size power calculations. We apologize in advance for the amount of detail in this paragraph. The trial involved complex power calculations that were not only influenced by expected outcomes but also by expected clinician involvement, use of multiple chronic disease groups, and use of two recruitment sites. We have also now included a copy of the CONSORT checklist indicating where and how our manuscripts conforms to the CONSORT statement.

7. The qualitative methods are under-specified, which is a rather critical issue for this formative evaluation. These need to be described in more detail.

Response: We have added details to the qualitative methods sections of the manuscript.