Author's response to reviews

Title: Behavioral Health Coaching for Rural-Living Older Adults with Diabetes and Depression: An Open Pilot of The HOPE Study

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Author's response to reviews: see over
Dear Drs. Crow and Neilan:

Thank you for the detailed response from reviewers for manuscript 1657285545629322: Innovations in Behavioral Health Coaching Using Goal-Setting Strategies: The HOPE Pilot Study Case Report. We have carefully addressed each of specific comments from both reviewers and your particular editorial points. We have made changes within the manuscript to reflect our responses to reviewers’ comments. We provide the location of these edits in our response to specific reviewers’ comments and have marked the changes in the revised manuscript with yellow highlight.

As you will note, much of the manuscript has been revised to address the reviewers’ helpful comments. The authors acknowledge that the manuscript is much improved after reflecting on reviewers’ comments and making appropriate modifications. We appreciate your assistance in this process and the opportunity for publication in BMC Geriatrics. Please see below for point by point responses to reviewers’ comments.

Response to Reviewers’ Comments

Editor: Emily Crow

Comment 1:
Could you please ensure that you outline the limitations of your study clearly.

Response to Editor Comment 1:
We have included a dedicated section on study limitations within the discussion section. This section presents a number of the limitations raised by reviewers and our own team.

Comment 2:
Please respond to the second point raised by Referee 2 regarding the need for a power calculation.
Response to Editor Comment 2:
We agree this is an important point, see our response to reviewer 2, comments 2 and 3. We believe our first submission of this manuscript did not clearly relate the open trial and preliminary nature of this intervention development project.

Comment 3:
Can you please also include a copy of the Abstract in your revised manuscript. This should appear after the Title Page.

Response to Editor Comment 3:
We have revised the abstract and placed it in the appropriate location within the manuscript (after the title page).

Reviewer 1: Colleen Doyle

Comment 1:
This is an interesting paper describing an intervention to treat depression in people with diabetes. The intervention is delivered by phone, by unqualified staff.

Response to Reviewer 1, Comment 1:
We appreciate Reviewer 1’s comment and the fact that we did not clearly describe the qualifications, training, and fidelity assessment of our intervention coaches. In response, we have cited additional evidence to support the role of paraprofessionals, community health workers and peers in the delivery of diabetes self-management interventions. We also provide details of our HOPE coaches and their training (see Description of HOPE Coaches (Providers), pgs. 8-9). We have provided additional details regarding weekly individual and group supervision conducted by the project’s dual primary investigators (PIs) with HOPE coaches (See Intervention Fidelity pgs. 10-11). The PIs combined expertise in diabetes care and mental health provided an appropriate venue that allowed coaches to address concerns around both physical and emotional health issues.

Comment 2:
While the paper is well written, the issue of delivery by non-experts is not addressed sufficiently. What safety measures are put in place to ensure that misleading or inaccurate information is not provided to the clients? What suicide risk procedures are followed?

Response to Reviewer 1, Comment 2:
We agree with Reviewer 1 regarding the need for more description about our intervention fidelity and safety procedures. In the revised manuscript, we have described our procedures for training and supervision of coaches including specific information for addressing clinical decompensation of
either condition within the Intervention Fidelity section on pages 10-11. In particular, this section addresses suicide risk procedures in addition to built-in safeguards to protect against the delivery of misleading or inaccurate information. In the discussion section on page 19, we also address how issues related to hypoglycemic symptoms were addressed.

**Comment 3:**
The liaison with attending health professionals is not described in detail.

**Response to Reviewer 1, Comment 3:**
Again, we acknowledge and appreciate Reviewer 1’s concern regarding our lack of detail. In accordance, we have added a paragraph on page 8 in the “HOPE Coach (Providers)” section to further describe the communication between coaches and primary care providers. This section includes a description of the electronic medical records system used by coaches to post weekly session notes accessible to providers. In the Limitations and Future Research section (pgs. 20-21) we have also acknowledged the difficulties inherent in interfacing with PCPs and suggestions for how this interface should be expanded in future research.

Overall, we feel that the new sections we have added to address Reviewer 1’s comments (i.e. comments 1-3 above) strengthen our manuscript and more adequately reflect the procedures employed in HOPE’s development and execution.

**Comment 4:**
The results for reduction in depression are impressive and in some ways slightly unbelievable, but that could be due to the very small numbers published.

**Response to Reviewer 1, Comment 4:**
We acknowledge Reviewer 1’s suggestion that the small sample size may have biased our results and we have included this as a limitation of our research (pgs. 20-21). Additionally, the lack of a control group (see comment 6 below) limits interpretation of effect sizes. Although our effect sizes for depressive symptoms (i.e. PHQ-9) and diabetes-related distress (i.e. PAID) using Cohen’s $d$ indicate clinically relevant, substantive changes, we agree with Reviewer 1 and have acknowledged these limitations. Given the small sample size, we understand that emphasizing clinically relevant changes is the extent of what we can reliably claim in contrast to statistically significant results.

**Comment 5:**
The paper would be better to be presented as a description of the intervention, and discussion of the pitfalls and advantages of using non-experts to deliver the coaching.

**Response to Reviewer 1, Comment 5:**
We appreciate and agree with Reviewer’s 1 comment. We have provided additional details in the methods, results, and discussion to focus more on the processes and challenge of conducting this type of intervention. In the revised limitations section, we describe these potential pitfalls in more depth and offer suggestions for refining the intervention to ensure greater safety and effectiveness for intervention participants.

Comment 6:
The lack of a clinical trial or control group comparison needs to be emphasized more.

Response to Reviewer 1, Comment 6:
To emphasize this limitation clearly, we have moved the sentence acknowledging the lack of a control group up in the Limitations section (pg. 20) so that it follows the first sentence (i.e. the limitation related to small sample size). Together we agree that these two limitations in particular limit generalizability and interpretation of effect sizes. We have also noted (pg. 21) that future work testing HOPE’s efficacy will include a control group to provide more meaningful comparisons and scientifically valid judgments of effectiveness.

Reviewer 2: Adrienne O’Neil

Comment 1:
The paper is well written and the intervention is an important one given the prevalence of the co-morbidity of diabetes and depression. However, there are several major issues associated with the conclusions drawn from the results that have been presented in this paper. They largely relate to the study design, data, and statistical analyses provided.

Response to Reviewer 2, Comment 1:
We appreciate Reviewer 2’s comment regarding the importance of HOPE; we also acknowledge and address this reviewer’s concerns related to study design, data and statistical analyses in the comments that follow.

Comment 2:
The small sample size on which these conclusions are based yield limited power from which to determine any potential intervention effects.

Response to Reviewer 2, Comment 2:
Given limited power to detect pre-post group differences, we also agree that the small sample size limits conclusions about HOPE’s efficacy (see response to reviewer 1, comment 4). The lack of a control group limits interpretation of effect sizes. We do provide calculations of Cohen’s $d$ to provide some quantitative estimate of differences between pre- and post-treatment scores divided by the pooled
pre- and post- standard deviations. This calculation does not rely on power and indicated clinically-important changes in outcome measures. That being said, we cannot state that the findings are statistically significant and the revised manuscript does not make this claim. In the revised limitations section, see pages 20-21, we do highlight the small sample size and lack of control group as major limitations.

**Comment 3:**
No information is provided describing sample size calculations which would be required to make a conclusion about “statistically meaningful improvements” of such a program. I understand that this is a feasibility trial which evaluates program acceptability, however without the power to detect changes in clinical outcomes (and in the absence of a comparator group) these conclusions cannot be drawn based on the existing data, methods and analysis presented.

**Response to Reviewer 2, Comment 3:**
We concur with Reviewer 2’s comment. We remove all mention of any language referring to statistically meaningful improvements in the revised manuscript. Our references to quantitative results are limited to calculations of Cohen’s $d$ and we now refer only to the potential for clinically relevant improvements that warrant a formal larger clinical trial.

We also concur with the reviewer that the primary purpose of the current manuscript is to describe the acceptability, feasibility, and procedures of the HOPE trial. We have revised the abstract, intro, methods, and discussion to consistently reflect this study objective.

**Comment 4:**
No comparator group is provided with which to compare participant outcomes, nor is there process evaluation to determine feasibility of implementation, despite the following conclusions being made, based on data from 7 completing participants: “The pilot cohort completion rate indicates feasibility for implementation and execution of HOPE in clinical practice.”

**Response to Reviewer 2, Comment 4:**
We acknowledge Reviewer 2’s concern and have modified our language. HOPE appears to have good acceptability and feasibility from the patient perspective as a potential clinical intervention but additional data are needed for understanding feasibility in routine clinical practice.

**Comment 5:**
In the statistical analyses, no adjustments are made for confounding factors. In the case of a randomized study design where between-group imbalances are negated by the process of randomization, this is acceptable, however with a non-randomized design, this is problematic.

**Response to Reviewer 2, Comment 5:**
Given the small sample size and limited power to detect pre-post outcome differences pointed out by both reviewers, we were unable to control for confounding factors. We agree that this also limits our conclusions as reflect on (pg. 21). As stated in our response to reviewer 2, comment 2; we now emphasize that the main purpose of this study is to evaluate acceptability and feasibility for a clinical trial and to describe intervention processes.

**Comment 6:**
Supplementing the quantitative data with qualitative is useful and provides a richer dataset, however, concluding that a program such as HOPE is feasible based on the limited number of enrolled and completing participants is problematic.

**Response to Reviewer 2, Comment 6:**
We agree that we overstated HOPE’s feasibility given the small number of participants who completed the program and the lack of a control group (please see response to comment 3 above).

**Comment 7:**
Although some of these limitations are discussed at the end of the manuscript, not all are acknowledged.

**Response to Reviewer 2, Comment 7:**
Based on both reviewers’ suggestions, we have added a new section entitled Limitations and Future Research (pgs. 20-21) to more fully address several limitations raised by reviewers and our own study team.

We thank you for your time and consideration of our manuscript.
Best Regards,

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