Author’s response to reviews

Title: Health literacy enhanced intervention for inner-city African Americans with uncontrolled diabetes: A pilot study

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Response to Reviewers’ Comments

We appreciate the thorough comments from the reviewers. Suggested changes have been made and highlighted in bold letters in the text. Our response to each comment is presented below.

Reviewer: 1

1. The aim of the manuscript was to describe the results of a pilot study on feasibility, acceptability and preliminary efficacy of a health literacy based intervention for African American with type 2 diabetes. The authors present interesting findings and the manuscript is well structured.

>>> Thank you.

2. The study presented in the manuscript is a pilot study. I would like to suggest to focus more on this study type and its specific aims and possibilities. I miss information on how this pilot study refers to a larger study. Is it planned to conduct a RCT, to perform a study with long-term
follow-ups, with larger sample size etc.? Will the decision for or against carrying out a larger study be informed by the results from the pilot study? What were your expectations/hypotheses? Were there any a-priori criteria for defining sufficient feasibility and acceptance, such as x% of participants completed the intervention etc.? What did you learn from the pilot study for the main study?..

>>> We modified the introduction section to address this concern. Specifically, we added more details about how the current study informs future research.

3. The description of patients who did not start the intervention is a crucial aspect of the feasibility of a study. I suggest to present sample characteristics (table 2) not only for the analytical sample but for all patients. Further, the description of non-participants and the comparison of participants with non-participants should be moved from the methods to the results section.

>>> Done. Specifically, we added sample characteristics for those who were not included in the analysis. We also moved the description of non-participants and the comparison of participants with non-participants to the results section.

4. The study assesses many outcomes. Which outcome was defined as the primary outcome? "Newest Vital Sign" is a measurement instrument which is very short and easy to administer. However, I am not sure whether it is suitable for repeated measurements and for assessing change over (a relatively short period of) time. Maybe the improvements that were found in HL were due to memory effects? Is there any literature on the use of the NVS as an outcome measure? Is there data on sensitivity to change of the instrument?

>>> Apologies for any confusion. We clarified this in the revised version by adding more details about the primary (feasibility and acceptability) and secondary (HbA1c, fasting glucose, and a number of psychosocial variables) outcomes. As for the Newest Vital Sign (NVS) as a study measure, we found several clinical trials [1-6] where NVS was included as a study measure but all used NVS as a control variable than as an outcome. We failed to identify research where NVS was measured over time as an outcome. Hence, our attempt to use health literacy as an intervention target is innovative. Given our targeted intervention activities involving health literacy training as part of our education, it is unlikely that the improvements in health literacy were due to memory effects.


Reviewer: 2

1. This pilot study is fascinating, even for the social aspect addressed. Authors do not focus specifically on this aspect, maybe they should explain why they choose such a specific population. The background, in my opinion, is fluent, the epidemiological data are reasonably up to date, but the supporting literature seems not so recent. >>> Thank you. The study population was chosen because of their profound health disparities in glycemic control. We added more recent references to address this concern.

2. Authors need to explain findings in previous health literacy intervention improvement better.

>>> Done.
3. The intervention itself is well described, but even this is a pilot, authors should inform about sample dimension they need to improve the next study. The first paragraph in the "Analysis section" should be put under "results".

>>> Thank you. We modified the manuscript according to this suggestion.

4. Authors declare that their intervention has been well accepted, citing participants answers, but nineteen of them dropped out, voluntary, and half of them immediately after the starting of the study. Do Authors check the reason why those patients never gone to meeting and visits?

>>> Given loss of contact, it was challenging to reaffirm the exact reasons for no shows. From our discussions with the study’s community advisory board, it might have had to do transportation among other things, as highlighted in our discussion.

5. Authors define the intervention effective; they should better describe what control, home visit, phone calls and counselling support their results.

>>> This information can be found in the results section.

6. Authors do not describe any assessment of patients self-care and self-efficacy ability; should these variables have an impact on their results? Authors need to explain this issue in the discussion section of the paper. In particular, the limits of the study should be better described.

>>> We added further details about the study limits to address this concern.

Reviewer: 3

1. The authors have presented findings for a pilot study that aimed to test the feasibility and preliminary efficacy of a health literacy-enhanced diabetes intervention in inner-city, low-income African Americans with uncontrolled diabetes. The content of the manuscript is very relevant and informative to researchers doing similar work. The manuscript explains the need for culturally-sensitive health education. However, the reasons for disparities among different racial groups could be explored more to further strengthen rationale for study focus.

>>> Thank you for the comment. Further details have been added. Please also see our response to comment #1 by reviewer #2.

Content of abstract is generally appropriate. However, in the abstract the authors state that "the purpose of this pilot study was to test the feasibility and preliminary efficacy" of the proposed intervention. Yet in the Background section, the aim is "to evaluate the feasibility, acceptability, and preliminary efficacy of the intervention. It is recommended that authors are consistent throughout the manuscript as these are distinct constructs in health research.

>>> Done. Now the study purpose is consistent throughout.

3. Background, Page 4. A community-engaged approach is mentioned but not clearly described. It is suggested that the authors provide a brief description of this approach as it was significant in the development of the proposed intervention.

>>> Done.

4. The aim of the pilot study is clear. However, the conceptual definitions of the constructs of acceptability, feasibility and efficacy would be useful to further clarify the study purpose.

>>> We modified our study purpose to address this concern.

5. Methods are generally well-described with pre-specified measurements to address each aspect of the pilot study objective. It's unclear if a definitive study will be conducted and as such there are no pre-specified criteria to determine whether, or how, to proceed with a future definitive trial. It is suggested that the authors state whether a definitive study will be conducted and if so they should indicate how pilot study findings will be used to inform the main study.

>>> A statement has been added to note how current study findings will be used to inform the next main trial.

6. Consent issues are not adequately addressed.

>>> We now have a separate section called “Ethical approval and consent” to address this concern.
7. Page 10, from line 20. The authors mention the importance of community stakeholders in developing the intervention components, improving the credibility and perhaps contextual relevance of the intervention. This is an important point as a thorough understanding of the context will not only strengthen the credibility but could also improve the uptake of intervention. It is suggested that this point be emphasized as part of the rationale for the study. Stakeholders' role/involvement should also be clearly described in Methods section.

>>> Thank you for acknowledging the importance of community stakeholders in relation to their role in developing the intervention components. As suggested, we have added a statement to discuss this both in the introduction and methods sections.

8. Transportation barriers are highlighted as a reason for the 58% retention rate. Other potential contributing factors should also be considered.

>>> We added more discussions (e.g., depression) to address this concern.

9. The paper is logically and clearly structured. Appropriate editorial care is taken.

>>> Thank you.