Author’s response to reviews

Title: Engaging Patients and Families to Create a Feasible Clinical Trial Integrating Palliative and Heart Failure Care: Results of the ENABLE CHF-PC Pilot Clinical Trial

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Author’s response to reviews:

Dr. Kirsten Wentlandt, PhD, MD

Editor
Dear Dr. Wentlandt:

Please find below our responses to the verbatim comments on our manuscript (PCAR-D-17-00051) entitled “Engaging Patients and Families to Create a Feasible Clinical Trial Integrating Palliative and Heart Failure Care: Results of the ENABLE CHF-PC Pilot Clinical Trial.” The authors would like to sincerely thank the two reviewers for their time and thoughtful critiques. We have found these suggestions extremely helpful and believe the modifications have greatly improved and strengthened this manuscript. We have addressed their suggestions point-by-point below and have made appropriate text modifications, which are indicated using “track changes” in the manuscript.

Thank you again for considering this revised and resubmitted manuscript.

Sincerely,

Marie A. Bakitas, DNSc
Corresponding Author

Reviewer Verbatim Comments
Author Responses

Reviewer 1

1. Overall
Please justify why you compared these two sites (probably in the background section?).
1. We have enhanced the clarity for the rationale of comparing the 2 sites. We have modified the introduction to identify that we were testing the intervention in a site that had a higher proportion of racially and culturally diverse samples as a part of our feasibility aim. We note that ours and other similar interventions have been tested in primarily a white, Catholic dominant population and it was important to see if participants responded differently to the intervention.

2. Methods

It is understandable, but all most important and interesting which answers the study aims came from outside of figures in a result section. I am not sure if the patient and caregiver feedback in this study should be treated as results. However, otherwise conclusions you made seem not to be drawn from the data.

2. We are a little uncertain about the meaning of the reviewers’ comment. We believe the reviewer raises the issue of whether the descriptive results (e.g. patient / caregiver acceptability feedback) should be reported within the results section. As the reviewer seems to then point out given the primary study aim is feasibility/acceptability we agree that it is appropriate to do so.

3. Setting and Sample

It is useful for readers if you could explain the background information of two study sites in 'Setting and Sample' section.

3. We have included brief background information about the populations served by the Dartmouth and UAB sites.
4. The ENALBLE CHF-PC Intervention

It is not clear if 'a comprehensive outpatient palliative care assessment' is the same as 'palliative care consultation' in abstract and 'protocol-driven palliative care consult' or 'outpatient palliative care consultations' in discussion?

4. We appreciate this comment and agree this was confusing. We have chosen to consistently use the term ‘outpatient palliative care consultation’ throughout the manuscript and have made edits to this effect.

5. The ENALBLE CHF-PC Intervention

Change a little comma after '[34]' in line 26/27 to the normal one.

5. Done.

6. The ENALBLE CHF-PC Intervention

Is reference [35] appropriate? It seems the title does not much the content of the description in a main text.

6. Yes, the life review component of the intervention was based on Steinhauser and colleagues Outlook intervention which is the paper that is cited. We have edited the text to make this clearer.
7. The ENALBLE CHF-PC Intervention

What is the 'interventionist script' in line 49 in 'The ENALBLE CHF-PC Intervention'? (Sorry this is my question but I could not get it.)

7. Interventionist scripts are conversational templates that research interventionists (nurse coaches) follow to guide the session content thus ensuring consistency (i.e., fidelity) of intervention delivery. This is standard practice when an intervention is delivered by more than one interventionist.

8. Data Collection and Measures

Please spell out 'SHFM' in line 11 as this is the first appearance.

8. Done.

9. Data Collection and Measures

I guess you are already aware, but I think it is not ideal the nurse coaches collected (?) for patient and caregiver feedback.

9. We agree that having the nurse coaches collect participant feedback might set-up a social validation bias whereby participants convey feedback that is overly positive and sensitive to “what the researchers want to hear.” Due to the limited resources of a pilot study and the fact that we used that strategy in a smaller published pilot study, and that patients/caregivers were instructed as part of their consent that we would be actively soliciting their “honest, truthful feedback” even if it was negative in order to improve the intervention, we attempted to overcome
this issue. We believe the feedback was quite candid and useful so we believe we were able to meet the goal.

10. Results

Sample Characteristics
Could you review the way you presented the overall characteristics of patients in line 13-26/27? I would not like to comment on English expressions, but this seems not grammatically accurate.

10. We have carefully reviewed the presentation of sample characteristics in the sections noted and believe it to be appropriate and consistent with the style of our past published work; however, we are happy to edit this section at the direction of the editor.

11. Results

Sample Characteristics
SHFM survival probabilities in line 38-40 are mean for all patients?

11. Yes and we have emended the text to note that this is a group average.

12. Feasibility/Acceptability: Intervention and Measure Completion
It is really good to have patient and caregiver feedback relative to the intervention - this seems, in my opinion, the most relevant information to the study aims.
12. Yes, we agree.

13. Resource Use

'ED' (and also 'ICU'?) should be spelled out

13. Done.

14. Overall results

Why did you compare outcomes between sites? They seem not that relevant to the study aims.

14. See response to #1 above.

15. Discussion

*Precisely speaking, you cannot discuss selection bias in this study

15. We have removed this term from the limitations paragraph.
16. Table 1

Not clear what figures in the brackets in Seattle Heart Failure Model and Charlson Comorbidity Index mean.

16. These are standard deviations and this has now been noted in the Table.

Reviewer 2

1. Firstly, it would be great to give a more comprehensive description of the intervention and its development.

1. In the Methods section, under the subheading, The ENABLE CHF-PC Intervention, we have provided some additional information however we refer readers to the first ENABLE CHF-PC pilot study that provides an in-depth overview of the historical development of the intervention. Due to space limitations, we weren’t able to provide a more in-depth summary.

2. Secondly, it would be great to give more insight in the experiences of the patients with the intervention, especially in light of the recruitment and its content.

2. Due to space limitations we chose to focus on the participants’ experiences that influenced intervention modifications and this information is presented in results and further commented upon in the discussion.

3. Thirdly, it is a bit risky to report differences in time in outcome measures due to the intervention, as the intervention and its supplementary data have been changed along the way of the feasibility trial. Furthermore, no control group is present and confounding is probably to be present. In a feasibility trail it would be better to report of the response rate, experiences with the outcome measures, etc.
3. We agree with this comment and have enhanced the limitations paragraph to further note the limitations of a pilot study which lacks a control group. We report measurement completion response rates in the Results section under the “Feasibility/Acceptability” subheading in the second paragraph.

4. Lastly, the discussion needs some attention, especially the paragraph re the experience of the PI is in my opinion redundant.

4. We agree that there were redundancies and have merged the paragraph’s non-redundant information in the appropriate sections (e.g. consolidated discussion so that all content pertaining to recruitment, etc.is together.)

5. Some minor comments:

Page 5, introduction

To further support the claim that the trajectory of a cardiac death is difficult to predict, it can be useful to read and cite the work of Lynn and Adamson, Living Well at the end of Life (white paper).

"However, given the difficulties in prognostication, the prevalence of sudden cardiac death, [23] and an erratic illness trajectory,[24] it is not clear when or how to integrate palliative care in HF."

5. Done.

6. Some minor comments

Page 6, setting and sample.
It would be helpful to further explain the criteria of eligibility of the patients. Patients with a diagnosis of NYHA Class III/IV and/or AHA Stage C/D HF were included. Why these two diagnosis? Are these patients in need of PC? We have clarified in the Background section that professional guidelines stipulate NYHA Class III/IV and AHA Stage C/D HF as appropriate for palliative care.