Author’s response to reviews

Title: Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience Among Surrogate Decision-Makers of ICU Patients (EMPOWER): Study protocol for a randomized controlled trial

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Author’s response to reviews:

5/22/19

Dear Mr. Murugappan and Dr. Calear,
Thank you very much for your comments and your consideration of our manuscript. We have addressed all comments as follows as tracked changes in the submitted documents:

Reviewer Comment 1. SPIRIT items 4 and 5c should be page 15. Please revise checklist.

Author Response: This has been revised in the checklist.

Reviewer Comment 2. SPIRIT item 11a: Please detail how long each module takes to complete on average and the length of the booster sessions.

Author Response: This information has been added on page 8. All new text is underlined.

It consists of six discrete modules that take approximately 15 to 20 minutes each to complete (for an approximate total of 1.5 to 2 hours) and can be delivered flexibly to accommodate the numerous interruptions and unexpected crises typical in an ICU setting... Booster sessions will focus on issues relevant to the surrogate, such as bereavement, and reviewing the skills taught in the original session to coping with new challenges. Each booster session will last approximately 45 to 60 minutes.

Reviewer Comment 3. SPIRIT item 11b: Please detail if under any circumstances the intervention would be stopped.

Author Response: This information has been added on page 13.

If a participant assigned to the EMPOWER intervention wishes to stop participating in the intervention for any reason, we will request that they inform the researchers, and, if willing and able, inform the research team of the reason for ceasing participation. If a participant appears to be at risk for harming him/herself or others during the course of the trial, the researchers will take immediate action to address this risk, and the participant would become ineligible for continuing with the study... If at any point during the study period, the study intervention is found to be associated with an undue risk for harm to subjects, the trial will be stopped, such as if the research team determines, in good faith, that the intervention appears to causing significant emotional distress or impairment for subjects beyond what would be expectable, or leading to increased risk for harm to self or others.

Reviewer Comment 4. SPIRIT item 11c: Please detail if you will use any strategies to encourage engagement/completion of the EMPOWER modules (e.g., reminders).

Author Response: This information has been added on page 9.

We will monitor progress of all participants and request their continued participation in the EMPOWER intervention. If a participant has not completed a part of the intervention, we will
contact that participant to remind and encourage them to continue up to three times, with an upper limit of contact in place to prevent bothering participants.

Reviewer Comment 5. Please refer to all Figures and Tables in the text (e.g., Figure 1 presents...).

Author Response: This information has been added as follows: Table 1 is referred to in the text on page 8, and Table 2 is referred to in the text on page 11. Figure 1 is referred to in the text on page 6, and Figure 2 is referred to in the text on page 11.

Reviewer Comment 6. SPIRIT item 18a: Please detail the number of items for each scale and internal consistency where possible.

Author Response: This information has been added to Figure 2.

Reviewer Comment 7. SPIRIT item 18b: Please detail if you will collect any data from participants who dropout of the study.

Author Comment: This information has been added on page 12.

If participants drop out of the study, the investigative team will attempt to ask them for their reasons for ceasing to participate, but no further data will be collected.

Reviewer Comment 8. SPIRIT items 29, 31b and 31c should be page 15. Please revise checklist.

Author Response: This has been revised in the checklist.

Reviewer Comment 9. SPIRIT item 31a: Please detail if/how results will be communicated to participants.

Author Response: This information has been added on page 16.

The final report will be published in a peer-reviewed journal to facilitate communication to healthcare professionals and the general public. Published results will be shared with study participants should they indicate an interest in receiving this information (e.g., publications of these data will be sent as a pdf to their email address).

In addition to responses to your comments, multiple citations have been reformatted in the references section of the main manuscript to reflect proper citation style, and new citations have been added. Citation #16 has been replaced to reflect the correct measure.
Since the time of submission, our protocol was amended at the main study site. This new amendment and proof of approval is uploaded in the same format as in the previous submission.

Lastly, in order for our manuscript to be as reflective as possible of our final operating protocol, we have made specific changes to the manuscript in anticipation of IRB approval. Once IRB approval of these changes has been provided at the main site, documentation of approval will be provided to Trials. The changes are as follows:

1. To provide greater flexibility for participants and reduce the risk of missing data for participants who may become bereaved during the course of the study, the one month and three month follow-up assessments will now be indexed to completion of the post-intervention assessment, rather than the baseline assessment.

2. An additional measure of anticipatory grief, to be administered only if the patient is alive, has been added to all 4 time points. This change has been reflected in the manuscript, Table 2, and Figure 2.

3. An additional measure of decision regret, to be administered at all 4 time points, has been added. This change has been reflected in the manuscript, Table 2, and Figure 2.

4. As noted above, in response to reviewer comment #9, we aim to share published results of the EMPOWER trial with all participants who express interest. To facilitate this, all sites will amend their informed consents to allow for contact of participants who indicate interest in seeing published data once they are no longer “on study.”

5. Physicians will no longer be surveyed for their opinions of the EMPOWER intervention during the RCT portion of the trial, as we feel we would not be able to provide an unbiased sample of clinicians.

Thank you,

Holly G. Prigerson