PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Mindfulness-based retreat for mothers of paediatric heart transplant recipients: protocol for a pilot intervention study
AUTHORS	Robertson, Taylor; Ahola Kohut, Sara; Telfer, Heather; Seifert-Hansen, Mirna; Mitchell, Joanna; Anthony, Samantha

VERSION 1 – REVIEW

REVIEWER	Krista Keilty Sick Kids Foundation
REVIEW RETURNED	23-Feb-2022

GENERAL COMMENTS	Overall- a very well written protocol, about a novel MBI to be pilot tested among family caregivers of children with heart transplant. Suggested revisions, questions of the authors: Article Summary Page 4, Line 17-18, it is unclear why the authors refer to the intervention as 'acute' Introduction: Effectively sets the context for the study. Page 5, Line 19- 20, consider the care regime also places physical strain on family systems. Some of these children require 24/7 vigilance pre & post transplant, and will require high skilled family caregiving (e.g. for home ventilation), physical effects on family includes sleep deprivation. (see: https://adc.bmj.com/content/103/2/137.abstract) which are typically responsive to MBI. Methods: Well described re: study design, intervention. Study dates are clear for start of study. Sample recruitment: Page 11, Line 12-13, there lacks justification for 20 participants. Respecting this is pilot work, and a sample size calculation was not completed, is there any other criteria informing this sample size? Is it related to # accommodations available? Preferred group size per facilitators? Other? Page 11, Line 28-29, will the sample include purposive variation for time since transplant? Length of hospitalization? Or other clinical indicators of health/complications? Line 35-36, It is anticipated approaching 46% will have PTSD (recent data re: prevalence in complex care population), so please address inclusion for 'coping well' as a limitation in study design

	Page 12, Line 8-9, how will baseline assessment of coping be achieved? Will this include objective/standardized measure or fully subjective. Page 13, Line 54-55, how will two groups be randomized to focus groups? In the methods section, it is unclear how fidelity to the intervention will be assessed. Qualitative interview guide is not included, thus not assessed. Data Analysis Quantitative & Qualitative- plans for descriptive statistics and thematic analysis are well described. Ethical Approval: authors confirm IRB in place Discussion How will the investigators evaluate for effect of social support alone vs effect of MBI in retreat like environment? Overall- a very strong protocol and pleasure to read. I've provided some feedback re: minor suggested changes. The largest critique is the lack of a clear plan for assessing fidelity to the intervention. Congratulations in designing a highly promising MBI intervention for the paediatric heart transplant - family caregiver population.

REVIEWER	Simone Cheli Guglielmo Marconi University
REVIEW RETURNED	16-Apr-2022

GENERAL COMMENTS	The protocol is well structured and addresses a new application area of mindfulness, carefully integrating quantitative and qualitative measures. I suggest only two possible revisions. First, the introductory part on mindfulness in a retreat format should be explored. The reader must be able to better understand the theoretical and practical bases that motivate the desired change. Second, I would specify the guiding questions to be used in the focus groups and which will therefore guide the elicitation phase of the narratives.

VERSION 1 – AUTHOR RESPONSE

Response to Reviewer 1: Dr. Krista Keilty, SickKids Foundation

1. **Comment**: Overall- a very well written protocol, about a novel MBI to be pilot tested among family caregivers of children with heart transplant.

   Response: Thank you for taking the time to review our protocol. We appreciate your positive overview and impression of this protocol.

2. **Comment**: Article Summary - Page 4, Line 17-18, it is unclear why the authors refer to the intervention as ‘acute’

Response: Thank you for your question about this word choice and highlighting that this might be unclear to readers. We have removed the word acute throughout the protocol.

3. **Comment:** Introduction –Effectively sets the context for the study. Page 5, Line 19- 20, consider the care regime also places physical strain on family systems. Some of these children require 24/7 vigilance pre & post-transplant, and will require high skilled family caregiving (e.g., for home ventilation), physical effects on family includes sleep deprivation. (see:https://urldefense.com/v3/__https://adc.bmj.com/content/103/2/137.abstract__;!!D0zGoin7BXfl!98m2HBNxwpOaAevynUcwhLuA_sCd6VVwW7jtn3AmeKLqPcoOTVRnRjS_18nnlkh2TtOXKc4HV-aKya0gTO1pT0YlrPIWSFsASIwj5Q$) which are typically responsive to MBI.

   Response: Thank you for your positive assessment of our introduction. We particularly appreciate your recognition to the demanding vigilance of caregivers for children post-transplant. We have reviewed your attached article and have included the reference in our introduction to highlight the additional impact on self-care and sleep deprivation for caregivers (Page 5, Line 8).

4. **Comment:** Methods—Well described re: study design, intervention. Study dates are clear for start of study.

   Response: Thank you for your review of the methods and your impression that our study design and intervention are *"well described."*

5. **Comment**: Sample recruitment—Page 11, Line 12-13, there lacks justification for 20 participants. Respecting this is pilot work, and a sample size calculation was not completed, is there any other criteria informing this sample size? Is it related to # accommodations available? Preferred group size per facilitators? Other?

   Response: Thank you for your question around sample size. Please refer to comment #6 from Editor's comments above on page 3-4 for detail on this methodological choice.

6. **Comment:** Page 11, Line 28-29, will the sample include purposive variation for time since transplant? Length of hospitalization? Or other clinical indicators of health/complications?

   Response: Thank you for your clarifying question around the sampling strategy. The sample will include purposive variation for the age of the heart transplant recipient at the time of retreat, as well as length of time post-transplant. This clarification appears on Page 11, Line 12-15.

7. **Comment:** Line 35-36, It is anticipated approaching 46% will have PTSD (recent data re: prevalence in complex care population), so please address inclusion for 'coping well' as a limitation in study design

   Response: Thank you for your insightful feedback. After review and discussion with the research team, we have decided to remove the inclusion criterion of "coping well." We believe that participation in this retreat will be beneficial to mothers at various stages of coping and hypothesize that each of the domains being assessed will see shifts regardless of their coping at baseline. As such, we have removed this criterion from the protocol. This revision can be seen on Page 11, Line 15-17.

8. **Comment:** Page 12, Line 8-9, how will baseline assessment of coping be achieved? Will this include objective/standardized measure or fully subjective.

   Response: Thank you for your question. As per our last response, the inclusion criterion of "coping well" has been removed from the protocol's participant eligibility review. These amendments are visible on Page 11, Line 15-17.

9. **Comment:** Page 13, Line 54-55, how will two groups be randomized to focus groups?

Response: Thank you for your question. To ensure maximum variation within the focus groups, purposive selection will be utilized to divide participants into two groups. This is reflected in the protocol on Page 14, Line 10-12.

10. **Comment:** In the methods section, it is unclear how fidelity to the intervention will be assessed.

    Response: Thank you for highlighting this. We have added a line on fidelity to the methods section to clarify how this intervention will be assessed. This is visible in the protocol on Page 9, Line 6-9. It has been included here for your review as well:

    "Fidelity of this intervention will be assessed through the components of treatment fidelity (facilitator factors include design, training, and delivery and participant factors include receipt and enactment) put forth by The Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium" (Ketcher et al., 2018).

11. **Comment:** Quantitative & Qualitative- plans for descriptive statistics and thematic analysis are well described. Ethical Approval: authors confirm IRB in place

    Response: Thank you for your feedback on our methods and ethics approval.

12. **Comment:** How will the investigators evaluate for effect of social support alone vs. effect of MBI in retreat like environment?

    Response: Thank you for your question. While isolation of a specific variable (e.g., social support) will be difficult given the intervention setting, the study has been designed to capture participant feedback at three time points to gather data for pre- and post-comparisons of these variables. Perceived social support is assessed at T1, T2, and T3 quantitatively, and at T2 and T3 qualitatively. Clarifying probes around participants' perceived social support and their experience of the retreat environment will be include in both the focus group and the individual interviews thereafter.

13. **Comment:** Overall- a very strong protocol and pleasure to read. I've provided some feedback re: minor suggested changes. The largest critique is the lack of a clear plan for assessing fidelity to the intervention. Congratulations in designing a highly promising MBI intervention for the paediatric heart transplant - family caregiver population.

    Response: Thank you for your review of our protocol and your positive feedback, particularly your assessment that this is a "*highly promising MBI intervention*" for our target population. We appreciate your feedback on our intervention fidelity assessment and have included a section in the protocol to provide clarity on fidelity assessment measures (Page 9, Line 6-9)

Response to Reviewer 2: Dr. Simone Cheli, Guglielmo Marconi University

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1. **Comment:** The protocol is well structured and addresses a new application area of mindfulness, carefully integrating quantitative and qualitative measures. I suggest only two possible revisions. First, the introductory part on mindfulness in a retreat format should be explored. The reader must be able to better understand the theoretical and practical bases that motivate the desired change.

    Response: Thank you for your positive review of our study protocol. We appreciated your feedback around the retreat format. Evidence suggests that when MBIs are delivered in a concentrated group format over a short period of time, such as in a retreat format, participants demonstrate better retention of the curriculum (Visted et al., 2014). Studies in other chronic disease populations cite increased feelings of social support that result from the shared experience of attending a retreat as an added benefit of this group format (Fjorback et al, 2011, Minor et al, 2006). These theoretical details are outlined in the protocol on Page 6 Line 22 – Page 7, Line 12.

We have added additional details on the practical components of derived benefits for participants attending a retreat-style intervention to the protocol to better articulate this intervention's purpose to the reader (Page 7, Line 12-15).

2. **Comment:** Second, I would specify the guiding questions to be used in the focus groups and which will therefore guide the elicitation phase of the narratives.

   Response: Thank you for your suggestion. A semi-structured focus group script will be developed by the study team based on existing literature, clinical and research experience, and feedback from our patient partner. Focus group guiding questions will probe several areas around implementation and efficacy of the MBR intervention, including but not limited to: i) decision-making around attending the retreat (e.g., hopes, expectations, worries), ii) experience and acceptability of participating in the retreat (e.g., impact on domains of well-being), iii) appropriateness of the retreat content (e.g., what components are useful and not useful), iv) feasibility (e.g., ease of participation), and v) post-retreat impressions (e.g., would the participant recommend the retreat to other mothers of heart transplant recipients?). While the questions are important, we plan to remain flexible in terms of probing (e.g., asking follow-up questions) based on participant answers and interactions. We have incorporated these additional details into the manuscript, as seen on Page 14, Line 14-22.

VERSION 2 – REVIEW

REVIEWER	Krista Keilty Sick Kids Foundation
REVIEW RETURNED	27-Jun-2022

GENERAL COMMENTS	I have reviewed and am satisfied that the authors have addressed all of the reviewers' feedback. I support this is ready for publication.

REVIEWER	Simone Cheli Guglielmo Marconi University
REVIEW RETURNED	31-May-2022

GENERAL COMMENTS	The authors acknowledged the revision requests and revised the paper accordingly. It is therefore suitable for publication.