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Mindfulness-based retreat for mothers of paediatric heart transplant recipients: A pilot intervention study protocol

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Abstract

Introduction: Mothers are often the primary caregivers for children requiring heart transplantation. Given that a mother's ability to successfully cope with the demands of her caregiving role may be predictive of positive familial psychosocial outcomes, it is critical that maternal coping is assessed and supported in paediatric health care. Mindfulness-based programs are proposed as one intervention that may enhance quality of life, improve distress tolerance and coping, and reduce social isolation in caregiving populations. This pilot study aims to investigate: (1) the implementation success of a mindfulness-based retreat (MBR), and (2) the effectiveness of the MBR at improving quality of life, distress tolerance, coping and perceived social support for mothers of paediatric heart transplant recipients.

Methods and Analysis: A convergent parallel, mixed method design is proposed for this pilot study. Quantitative data will be obtained using five standardized instruments completed at three time points: (T1) 24-hours prior to the intervention, (T2) immediately upon completion of the intervention, and (T3) three months post-intervention. Qualitative data will be collected from all participants both through semi-structured focus groups at T2 and individual telephone interviews at T3. Focus groups and individual interviews will be transcribed verbatim for thematic analysis. Quantitative and qualitative data will be merged and compared during interpretation to ensure that the intervention implementation and effectiveness of the MBR retreat are described with comprehensive accuracy.

Ethics and Dissemination: This research study received Institutional Research Ethics Board approval from The Hospital for Sick Children. Informed consent will be obtained prior to participants' study enrollment. This research addresses the quality of life and well-being of

mothers of paediatric heart transplant recipients and will inform a future randomized clinical trial to assess implementation outcomes and intervention effectiveness of MBRs within this population.

Article Summary – Strengths and Limitations

- This pilot study will be the first mindfulness intervention to specifically target the psychosocial needs of mothers of paediatric heart transplant recipients through an acute retreat-based mindfulness intervention.
- Results of this study will significantly increase the breadth of knowledge on interventions that may effectively support primary caregivers of paediatric heart transplant recipients and will inform a future randomized clinical trial.
- This is a single-centre study with a proposed small sample which may limit generalizability of findings.

Keywords: quality in health care, transplant medicine, mental health, paediatrics, paediatric transplant surgery, qualitative research

INTRODUCTION

From the time of diagnosis, caring for a child with a chronic illness is often a source of persistent stress for a family system.[1-4] Within paediatric heart transplantation, recipients face life-long medical follow-up that includes regular clinic visits, frequent, often invasive, medical tests and procedures, and immunosuppressive drug therapy with many accompanying side-effects (e.g., high blood pressure, kidney dysfunction, growth delay, infection risks, possible malignancies, and cosmetic effects).[5,6,7] This strict care regimen is disruptive to a family's daily life, and places chronic social, psychological, and financial strain on family systems.[3,7]

Maternal Caregiving Impact in Paediatric Heart Transplant

Mothers are most commonly the primary caregivers for paediatric heart transplant recipients.[5] As such, mothers' quality of life is impacted more than any other family member, by the mounting demands and parenting stressors associated with a child's illness.[5] Previous research on maternal coping in paediatric heart transplantation demonstrates clinically significant levels of psychosocial risk for poor mental health outcomes in 40% of respondents.[3] Additionally, the elevated psychosocial risk and significant emotional impact of transplantation on mothers appears to be enduring,[8,9] with high levels of caregiver burden reported several years post-transplantation.[8] Recent studies have cited the experience of paediatric transplantation as an ongoing source of trauma for parents.[7,10] In a study on parents of heart transplant recipients, (75% of which were mothers), 19% of participants were found to meet the Diagnostic and Statistical Manual – IV diagnostic criteria for post-traumatic stress disorder (PTSD), amounting to a prevalence rate that is two and half times higher than the general population.[7] Untreated symptoms of PTSD are commonly felt within the wider family

system as they directly impact parenting capacity, and consequently, child health and development, well-being, and adjustment.[11,12]

Increased clinical attention and accessible interventions to support the emotional coping and well-being of mothers may be efficacious to increase maternal coping and instrumental to support paediatric heart transplant recipients' health and well-being. The psychosocial needs of mothers of children with chronic illness are consistently underserved across healthcare settings.[1] Evidence-based interventions to support caregivers in paediatric healthcare are scarce and not prioritized,[13] and existing interventions (e.g., weekly support groups and individual counseling) are time-consuming which parents have cited as their primary barrier to participation in such health interventions.[1] To our knowledge this pilot study will be the first of its kind to specifically target the psychosocial needs of mothers of paediatric heart transplant recipients through an acute retreat-based mindfulness intervention.

Mindfulness-Based Interventions

There is empirical evidence that Mindfulness Based Interventions (MBI) significantly reduce psychological distress, anxiety, and depressive symptoms, and improve physical and mental health across many populations.[14,15] Mindfulness-Based Stress Reduction is currently the most widely recognized and utilized MBI for the treatment of PTSD and general stress management.[16-18] MBIs more broadly have been shown to improve mental and physical health in populations of caregivers for children with chronic illnesses.[19,20] MBIs are structured programs that incorporate tenets of mindful meditation and assume that the cultivation of compassionate and non-judgmental awareness will lead to a reduction in stress, suffering and symptoms of mental illness.[16-18] In MBIs, participants are guided through exercises that develop mindfulness skills through formal practice.[14,15] These supported

opportunities to build capacity practicing mindfulness skills increase the likelihood for post-intervention use of these skills as reliable coping tools to minimize distress in everyday life.[14,15]

This study proposes a novel, two-day mindfulness-based weekend retreat adapted for mothers of paediatric heart transplant recipients. It is recognized that an increased level of social support is derived from the shared experience of MBIs when offered in a retreat format.[14,19] This may provide benefit to the target population of this study as high prevalence of social isolation has been identified amongst mothers of heart transplant recipients, as well as their shared interest to connect with other mothers in similar positions.[5] MBIs facilitated through a mindfulness-based weekend retreat (MBR) increase the opportunity for social connection amongst participants because of environmental facilitators such as shared accommodations, meal times and free time. Mindfulness is ideally suited for this population to address the inherent stress they experience through their caregiving roles,[7] and group mindfulness practice has the ability to catalyze community building that is sustained beyond a research setting.[21] Given the applicability of a MBR to meet the needs of mothers of paediatric heart transplant recipients it is proposed within this pilot study as an intervention with potential to enhance maternal well-being through the development of coping skills, social connectedness, and psychological health.[5,14,16,19,20]

Study Aims

To investigate the feasibility and efficacy of this intervention the research objectives of this pilot study are to: (1) examine implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility, fidelity*)[22] of the MBR, and (2) to assess the efficacy of the MBR on maternal quality of life, distress tolerance, coping and perceived social support. This is

a pilot study and application of the results from this research will inform the study design of a future randomized clinical trial.

METHODS AND ANALYSIS

Study Design

A convergent parallel, mixed method design was chosen for this pilot study wherein quantitative and qualitative data will be collected simultaneously and analyzed independently, with results merged during the final interpretative phase to address the study's overall purpose.[22] This mixed methods design will allow for a comprehensive understanding of the study phenomena by incorporating both qualitative description methods to gather a rich account of participant experiences as well as quantitative measures to document the potential changes in participant coping styles, distress tolerance, perceived quality of life and social support.[23] The participant sample size will be equal across both quantitative and qualitative arms of data collection.

Qualitative research is highly valuable in this area because of the subjective impact of a child's illness on a family, and the individualized nature of each mother's parenting experience through transplantation. Qualitative data will be gathered through participation in a focus group on the final day of the retreat and an individual interview three months post-retreat. Focus groups are an efficient and effective method of qualitative data collection to yield anecdotal information about personal experiences and perceptions.[24,25] Group dialogue with mothers about their experiences of the retreat will offer a reflective opportunity to gather participant insights and to address implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility, fidelity*)[26] of this intervention for this clinical population. A focus group fits well with the group model of this retreat and is an opportune and feasible way to collect qualitative data from

this particular sample, given their geographic diversity. Both the focus group and interview will gather participant feedback of parallel variables.

The quantitative instruments selected (*Coping Health Inventory for Parents, Five Facet Mindfulness Questionnaire, Pediatric Quality of Life (PedsQL™), Distress Tolerance Scale, Multidimensional Scale of Perceived Social Support*) will capture a measurable and generalizable assessment of maternal coping. The focus group and individual interview will highlight detailed and individualized perspectives of the mothering experience through paediatric heart transplantation, as well as provide insights to the participant experience of the MBR. Integration of the qualitative and quantitative data will highlight a depth of understanding that could not be obtained by either data separately.

Patient and Public Involvement

Caregiver needs and perspectives have been prioritized throughout the MBR pilot study design. At the project's inception, a mother of a pediatric heart transplant recipient was recruited to be a member of the research team as a patient partner (JM). Her lived caregiving experience informed many decisions concerning intervention design as well as methodological choices for outcome measures. The data collection measures identified dually prioritize the need to gather the richest possible data set, with a commitment to refrain from burdening participants with lengthy and arduous measures in consideration of their time.

Intervention Design

The intervention will be a two-day retreat held over a weekend. The MBR will be held at a resort in northern Ontario, Canada and will consist of a structured schedule of mindfulness and compassion-based teaching and practices, including formal meditation, circle sharing, and

deep relaxation.[27] The competencies developed in these exercises will be incorporated into all other retreat activities such as mealtimes, mindful movement (including yoga), and walking meditations. Mindfulness talks will be held on each day of the retreat, offering opportunities for participants to learn about and develop mindfulness skills. Each mindfulness talk in the retreat series will build upon the content of the previous talk, with the goal of moving participants from introspective personal mindfulness practice to interpersonal community building. Opportunities for guided circle sharing (i.e., group practice of mindfulness and interpersonal sharing) and deep relaxation (i.e., personal practice bringing mindful attention to the body to relieve stress) will be integrated throughout the retreat.

The MBR will have two primary facilitators who are both mental health professionals (social worker and psychologist) with longstanding personal mindfulness practices. In addition, both facilitators have completed teacher training in mindfulness (Mindful Self-Compassion and Mindfulness-Based Cognitive Therapy), as well as certificates in both Foundations of Applied Mindfulness Meditation and Applied Specialization in Mindfulness Meditation from the University of Toronto, Canada. Lastly, both facilitators have extensive experience practicing in tertiary care hospitals adapting MBIs to support caregivers in chronic

disease populations. The facilitators, alongside the research team's patient partner (JM), adapted the MBR specifically to the paediatric heart transplantation context.

Sample Recruitment

A total of 20 participants will be recruited from The Hospital for Sick Children (SickKids) Labatt Family Heart Centre who meet the following criteria: (1) a mother residing in Ontario who is the primary caregiver of a paediatric heart transplant recipient, who is (2) a minimum of four months post-transplant. Within this study, '*mother*' is defined as a female-identifying caregiver to a paediatric heart transplant recipient. Participants are not required to be biologically related to the heart transplant recipient but must be the primary female-identifying caregiver and share residence with the child. Purposive sampling will be used to obtain a sample with maximum variation.[28] Purposive sampling will ensure (1) demographic variation amongst participants, specifically regarding: the mother's age, their child's age, stage of development and gender, and the family's race, ethnicity, composition, and geographic location of residence, and (2) that any mother selected to participate is coping well enough at baseline so as not to be overburdened by participation in the study. Due to resource limitations that prohibit access to language and accessibility services, non-English speaking mothers and those with severe cognitive impairment as determined by a mental health professional will be excluded from participation in this study. Limited resources have also resulted in the restriction for participation in this study to Ontario residents only.

Participant recruitment began in January 2020 and is ongoing. The retreat will be hosted when it is safe to do so according to local COVID-19 public health guidelines. Participant recruitment has involved social work and nursing staff from the Heart Transplant Program at the SickKids Labatt Family Heart Centre, who each received a study description from the research

team and were asked to select and refer mothers for eligibility review. The recruitment request stipulated that each participant must be referred by the social worker or nurse, with whom they have a pre-existing clinical relationship. This ensured that a baseline assessment of coping was included in the referral, to confirm that study participation would not overburden the mother. If the mother consented to participate in this study, she was then referred to the research team who ensured that all eligibility criteria were met. Written informed consent was obtained from each study participant at that time.

Data Collection

Quantitative: Standardized questionnaires will be completed by all study participants at three time-periods: (T1) 24-hours prior to attending the retreat, (T2) 24-hours after attending the retreat, and (T3) three months post-retreat. At each time point, the questionnaires will be completed by participants online through REDCap.[29] Paper copies can be mailed to participants upon request. The three time points will allow for the comparison of outcomes assessed by pre- and post-intervention measures. The following quantitative measures will be used in this study:

(1) *Coping Health Inventory for Parents* is a 45-item scale measuring the demands experienced by parents/caregivers of a child with a chronic health condition.[30] The scale evaluates family integration and cooperation, maintenance of social support, self-esteem and psychological stability, and comprehension of the child's medical situation. Reliability has been previously established for this measure.[31]

(2) *Five Facet Mindfulness Questionnaire* is a 39-item scale measuring one's propensity to be mindful in their daily life (i.e., observing, describing, acting with awareness, non-

judging of inner experience, and non-reactivity to inner experience).[32] Construct validity has been previously established as well as its use in assessing the utilization of mindfulness skills.[33]

(3) *Pediatric Quality of Life (PedsQL™) Family Impact Module* is a 36-item scale measuring the impact of chronic health conditions of children on parents through eight subscales: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; and family relationships. The PedsQL™ Family Impact Module is a widely used measure for the evaluation of parental quality of life.[34] Internal consistency and reliability have been previously established.[34]

(4) *Distress Tolerance Scale* is a 14-item scale measuring distress tolerance across three domains: tolerance of distress, appraisal of being distressed, and emotional regulation.[35] Construct validity of this measure has been previously established.[35]

(5) *Multidimensional Scale of Perceived Social Support* has 12-items and measures perceived social support across three groups: family, friends and a significant other.[36] Validity and reliability have been previously demonstrated for this instrument.[36]

Demographic and medical forms will be administered to all participants to collect maternal information (e.g., age, race, ethnicity, number of children, annual household income, highest level of education etc.) and child information (e.g., date of transplant, underlying diagnosis, age at time of transplant, and co-morbidities etc.). These forms will be completed by participants using REDCap.[29] Paper copies will be made available upon request.

Qualitative: Qualitative data will be collected at (T2) on the last day of the retreat intervention and (T3) three months post-intervention. Participants will be randomized into two groups of ten

to participate in focus groups on the last day of the retreat. The focus group will be organized by open-ended questions and probes facilitated by members of the research team with extensive experience in qualitative methodology. A second researcher will be present to observe each group and document topics and concepts discussed by participants. Both focus group discussions will be audio-recorded and transcribed verbatim. A subsequent semi-structured telephone interview will be completed individually with each participant three months post-intervention with transcription and data analysis to follow.

Data Analysis

Quantitative: Each standardized instrument will be scored individually, and group data will be summarized by the calculation of means and standard deviations. T1 data will be assessed in comparison to T2 and T3 data. Notable changes in scores between each time-point will be descriptively analyzed. Should multiple characteristics present as significantly correlated with the same outcome, repeated measures ANOVA with post-hoc analysis will be used to discern the etiology of this correlation. Descriptive statistics will be used to describe and characterize the sample in this pilot.

Qualitative: All data will be read and analyzed by multiple members of the research team. Deductive thematic analysis will be used, and codes will be determined through line-by-line review of the focus group discussion and individual interviews using NVivo.[37] Through this review process, codes emerging repeatedly in various parts of the transcript will be noted and comparatively analyzed by multiple research team members for purposes of consistency.[37]

Interpretation: Quantitative and qualitative data will be merged to compare both similarities and differences across findings.[22] The research team will compile quantitative statistical results

and compare findings to the qualitative themes present within the focus group and individual interview data. Further analysis will consider how the two sets of data relate, diverge, and interconnect to create a comprehensive understanding of the phenomena.

ETHICS AND DISSEMINATION

Ethical Approval

This research study has received approval from the SickKids Research Ethics Board (Number:1000064719). All participants will provide informed consent prior to their involvement in the study. This research study sample will not include participants incapable of providing informed consent or any participants under the age of 18.

Confidentiality and Information Security

All data collected over the course of the research study, including written transcription from the study's qualitative focus group and the subsequent individual telephone interviews, will be de-identified to protect participant confidentiality. Anonymous study identifiers will replace all identifying information present in the transcripts. All identifying information, both paper copy and electronic information, will be kept confidential. Use of data over the course of the study, and dissemination of results will follow standard practice guidelines as determined by the SickKids Research Institute.

Discussion and Dissemination

When a child undergoes heart transplantation, the role of the primary caregiver is notably linked to poor mental health outcomes and pervasive, illness-related parenting stress.[7] Previous research has correlated mindfulness-based practices with positive psychosocial outcomes in

highly distressed populations,[16,38] and specifically in chronic disease populations, MBIs have demonstratively reduced psychological distress and symptoms of mental illness.[14,15] Aside from the benefits derived from direct participation, there is also potential for mindfulness interventions to yield larger systemic rewards. Supporting mothers to improve their coping can increase familial preparedness for post-transplant care management and any potential post-transplant hospitalizations.[6] With the length of hospitalization contributing the largest percentage of any transplant-associated costs,[6] positive caregiver coping and readiness for discharge could ultimately decrease healthcare spending per transplant patient. This innovative research leverages the MBR as an evidence-based intervention to engage mothers meaningfully by acknowledging the complexity of their role as a caregiver and addressing the impact of chronic stress and high caregiver burden.[5,7,39] While this pilot study is a preliminary step in addressing a wider gap in psychosocial intervention support to caregivers, the potential benefits derived are equally promising for individual patients and caregivers as well as the broader healthcare system.

This research is a necessary first step to advance the field of evidence-informed psychosocial interventions within paediatric cardiology and results will inform future iterations of the intervention across other participant groups. While caregiver experiences are unique, the need for support and disease-specific community building within paediatric healthcare is universal. This promising intervention will serve as a critical template for expansion across other clinical caregiving populations in paediatric solid organ transplant and other chronic illness care programs. Additionally, meeting the needs of all family members is vital to address family functioning, coping and resilience over the course of a child's chronic illness. Findings from this pilot study will provide the necessary evidence-base for future investigations examining the

transferability of a MBR to support the needs of other caregivers and family members affected by paediatric chronic illness.

The proposed research will inform a future randomized clinical trial to assess implementation outcomes and intervention effectiveness of a MBR within this population. This pilot study will greatly increase the breadth of knowledge about interventions that may support primary caregivers of paediatric heart transplant recipients. Findings will be translated and disseminated throughout cardiology and transplant communities and communicated to local, provincial, and national stakeholders. In addition, findings will be presented at national cardiology and transplant conferences and a manuscript will be submitted for publication in a peer-reviewed journal. Dissemination of results is anticipated to begin in September 2022 and will depend on the scheduled date of the retreat as permitted by provincial COVID-19 gathering restrictions.

This innovative research posits the MBR as an evidence-based intervention to effectively address and support the familial impact of chronic stress and high caregiver burden for mothers.[5,7,39] While this pilot study is a preliminary step in addressing a wider gap in psychosocial intervention support mothers, the potential benefits derived are promising for individual patients and their caregivers.

Abbreviations

MBI - Mindfulness-Based Intervention; MBR– Mindfulness-based Retreat; PTSD–Post Traumatic Stress Disorder

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions TR, SJA, SAK, HT, MS-H, and JM participated in the study design. All these individuals are involved in the management of the study. TR drafted this protocol. All authors read, revised, and approved the final protocol.

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SickKids
THE HOSPITAL FOR SICK CHILDREN

Mr. Adrian Aldcroft
Editor-in-Chief
British Medical Journal Open
December 20, 2021

Dear Mr. Adrian Aldcroft and *BMJ Open* Editorial Team,

Please find attached a study protocol entitled "**Mindfulness-based retreat for mothers of paediatric heart transplant recipients: A pilot intervention study protocol**," that we herein submit for publication in *BMJ Open.*

Mothers are the most common caregivers for pediatric heart transplant recipients and their ability to cope with the chronic parenting stress associated with their caregiving role is inextricably linked with patient health outcomes. Despite this correlation, the psychosocial needs of caregivers for children with chronic illness are historically underserved in pediatric healthcare.

Our research posits an innovative mindfulness-based retreat intervention that is novel to the caregiving group of mothers of heart transplant recipients. The research goals of this protocol are to assess the efficacy of the mindfulness-based weekend retreat intervention on maternal quality of life, distress tolerance, coping and perceived social support through a convergent parallel, mixed-method study design. Caregiver experiences will be dually captured through participation in a qualitative focus group and individual interview, as well as through five standardized quantitative instruments completed at three time points.

This pilot protocol will significantly increase the breadth of knowledge on interventions that effectively support primary caregivers of pediatric heart transplant recipients. Given the stature of *BMJ Open* as one of the leading communication tools for professionals in the medical field, we are confident that our research will be of interest to the readership.

We confirm that participant recruitment is ongoing. The study has undergone full internal peer review as part of the funding process and has received institutional research ethics board approval. Relevant documentation has been submitted. All authors confirm that this research protocol has not been previously published, nor is it presently under consideration for publication elsewhere. We have no conflicts of interest to disclose.

Thank you for your time and consideration. We look forward to further correspondence with your office.

Yours sincerely,

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Research Ethics Board (REB)
Study Approval Letter

2019-09-17

Dr. Samantha Anthony
Social Work

REB number: 1000064719
Study Title: Mindfulness Based Stress Reduction (MBSR) Retreat for Mothers of Pediatric Heart Transplant Recipients

Date of Approval: 2019-09-17
Expiry Date: 2020-09-17

Thank you for the application submitted on **2019-07-08.** The above referenced study was reviewed through a delegated process (not by Full Board review). Any concerns arising from this review have been documented and resolved.

The REB voted to approve this study, and your participation as Principal Investigator, as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act (PHIPA), 2004.

The Hospital for Sick Children Research Ethics Board hereby issues approval for the above named study. This approval is effective from **2019-09-17** to **2020-09-17.** Continuation beyond that date will require further review of REB approval.

The following documents have been reviewed and are approved:

1. **Protocol version dated August 29, 2019**
   [MBSR Protocol - 28Aug2019 clean.docx (1.0)]
2. **Participant Consent Form version dated August 20, 2019**
   [Consent Form 20Aug2019 clean.docx (1.0)]
3. **Verbal Introduction Script version dated**
   [Verbal study introduction script for participants delivered by member of circle of care 28Aug2019.docx (1.0)]
4. **Demographic Form version dated August 20, 2019**
   [Demographic Form 20Aug2019 clean.docx (1.0)]
5. **Recruitment Email For Members of Circle of Care version dated August 28, 2019**
   [Recruitment Email from study team to members of circle of care 28Aug2019 clean.docx (1.0)]
6. **Introduction Script for Recruitment version dated August 28, 2019**
   [Verbal study introduction script for participants delivered by member of circle of care 28Aug2019.docx (1.0)]
7. **Interview Guide version dated August 28, 2019**
   [INTERVIEW GUIDE 28Aug2019 clean.docx (1.0)]
8. **Focus Group Script version dated August 20, 2019**
   [FOCUS GROUP SCRIPT 20Aug2019 clean.docx (1.0)]
9. **Exit Interview Guide version dated August 20, 2019**
   [Exit Interview Guide 22Aug2019.docx (1.0)]
10. **Verbal Telephone Consent Script version dated August 22, 2019**
    [Verbal Consent telephone script for study team 22Aug2019.docx (1.0)]

11. **Master Linking Log version dated August 20, 2019**
    [MBSR Master linking log 20Aug2019 clean.xlsx (1.0)]
12. **Follow-up Communications version dated August 22, 2019**
    [Lost to follow up email template and telephone script.docx (1.0)]
13. **Study Questionnaires version last modified August 20, 2019**
    [Validated Instruments for Participants to Complete 20Aug2019.docx (1.0)]

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

Elizabeth Stephenson
REB Chair
555 University Avenue, Toronto, ON M5G 1X8
Tel: (416) 813-8279 Fax: (416) 813-6515

The SickKids REB operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing. The REB has reviewed and approved the clinical trial protocol and informed consent form for the trial. All investigational drug trials at SickKids are conducted by qualified investigators.

Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	7-9	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	4-7	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	9-10	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	N/A	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	7-9	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	5-6	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	5-6	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	8	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	8-9	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	N/A	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	N/A	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	N/A	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions[5]and public health interventions[14]. This guidance should therefore be followed when describing a developed intervention.	N/A	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	N/A	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.

BMJ Open

Mindfulness-based retreat for mothers of paediatric heart transplant recipients: protocol for a pilot intervention study

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Mindfulness-based retreat for mothers of paediatric heart transplant recipients: protocol for a pilot intervention study

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Abstract

Introduction: Mothers are often the primary caregivers for children requiring heart transplantation. Given that a mother's ability to successfully cope with the demands of her caregiving role may be predictive of positive familial psychosocial outcomes, it is critical that maternal coping is assessed and supported in paediatric health care. Mindfulness-based programs are proposed as one intervention that may enhance quality of life, improve distress tolerance and coping, and reduce social isolation in caregiving populations. This pilot study aims to investigate: (1) the implementation success of a mindfulness-based retreat (MBR), and (2) the effectiveness of the MBR at improving quality of life, distress tolerance, coping and perceived social support for mothers of paediatric heart transplant recipients.

Methods and analysis: A convergent parallel, mixed method design is proposed for this pilot, exploratory study. Twenty mothers will participate in this pilot MBR held at a resort in Ontario, Canada. Quantitative data will be obtained using five standardized instruments completed at three timepoints: (T1) 24-hours prior to the intervention, (T2) immediately upon completion of the intervention, and (T3) three months post-intervention. Qualitative data will be collected from all participants both through semi-structured focus groups at T2 and individual telephone interviews at T3. Focus groups and individual interviews will be transcribed verbatim for thematic analysis. Quantitative and qualitative data will be merged and compared during interpretation to ensure that the intervention implementation and effectiveness of the MBR retreat are described with comprehensive accuracy. The primary outcomes will be feasibility in

relation to implementation effectiveness and participants' perception of social support for efficacy of the MBR intervention.

Ethics and dissemination: This study received Institutional Research Ethics Board approval from The Hospital for Sick Children (Number:1000064719). Informed consent will be obtained prior to participant enrollment. Findings will be disseminated via conference presentations and submitted for publication in a peer-reviewed journal.

Keywords: quality in health care, transplant medicine, mental health, paediatrics, paediatric transplant surgery, qualitative research

Strengths and limitations of this study

- Our mixed-methods study design will allow for a comprehensive understanding of the study phenomena that could not be ascertained by qualitative or quantitative methods alone.
- Patient engagement is prioritized throughout this protocol, with the inclusion of a patient partner as a member of the research team to guide decisions concerning intervention design, as well as methodological choices for outcome measures.
- The completion of quantitative outcome measures at three timepoints will allow for intervention efficacy description across five domains of functioning (i.e., quality of life, utilization of mindfulness skills, distress tolerance, coping and perceived social support).

- This pilot study is exploratory in nature and designed to assess and inform a richer understanding of the implementation outcomes of this novel mindfulness-based retreat intervention for this clinical population.
- This is a single-centre study with a proposed small sample, which may limit the generalizability of the findings.

INTRODUCTION

From the time of diagnosis, caring for a child with a chronic illness is often a source of persistent stress for a family system.[1-4] Within paediatric heart transplantation, recipients face life-long medical follow-up that includes regular clinic visits, frequent, often invasive, medical tests and procedures, and immunosuppressive drug therapy with many accompanying side-effects (e.g., high blood pressure, kidney dysfunction, growth delay, infection risks, possible malignancies, and cosmetic effects).[5,6,7] This strict care regimen is disruptive to a family's daily life, their self-care and sleep routine[8], and places chronic social, psychological, and financial strain on family systems.[3,7]

Maternal caregiving impact in paediatric heart transplant

Mothers are most commonly the primary caregivers for paediatric heart transplant recipients.[5] As such, mothers' quality of life is impacted more than any other family member, by the mounting demands and parenting stressors associated with a child's illness.[5] Previous research on maternal coping in paediatric heart transplantation demonstrates clinically significant levels of psychosocial risk for poor mental health outcomes in 40% of respondents.[3] Additionally, the elevated psychosocial risk and significant emotional impact of transplantation on mothers appears to be enduring,[9,10] with high levels of caregiver burden reported several years post-transplantation.[9] Recent studies have cited the experience of

paediatric transplantation as an ongoing source of trauma for parents.[7,11] In a study on parents of heart transplant recipients, (75% of which were mothers), 19% of participants were found to meet the Diagnostic and Statistical Manual – IV diagnostic criteria for post-traumatic stress disorder (PTSD), amounting to a prevalence rate that is two and half times higher than the general population.[7] Untreated symptoms of PTSD are commonly felt within the wider family system as they directly impact parenting capacity, and consequently, child health and development, well-being, and adjustment.[12,13]

Increased clinical attention and accessible interventions to support the emotional coping and well-being of mothers may be efficacious to increase maternal coping and instrumental to support paediatric heart transplant recipients' health and well-being. The psychosocial needs of mothers of children with chronic illness are consistently underserved across healthcare settings.[1] Evidence-based interventions to support caregivers in paediatric healthcare are scarce and not prioritized,[14] and existing interventions (e.g., weekly support groups and individual counseling) are time-consuming which parents have cited as their primary barrier to participation in such health interventions.[1] To our knowledge this pilot study will be the first of its kind to specifically target the psychosocial needs of mothers of paediatric heart transplant recipients through an retreat-based mindfulness intervention.

Mindfulness-based interventions

There is empirical evidence that mindfulness-based interventions (MBIs) significantly reduce psychological distress, anxiety, and depressive symptoms, and improve physical and mental health across many populations.[15,16] Mindfulness-Based Stress Reduction is currently the most widely recognized and utilized MBI for the treatment of PTSD and general stress management.[17-19] MBIs more broadly have been shown to improve mental and physical

health in populations of caregivers for children with chronic illnesses.[20,21] MBIs are structured programs that incorporate tenets of mindful meditation and assume that the cultivation of compassionate and non-judgmental awareness will lead to a reduction in stress, suffering and symptoms of mental illness.[17-19] In MBIs, participants are guided through exercises that develop mindfulness skills through formal practice.[15,16] These supported opportunities to build capacity practicing mindfulness skills increase the likelihood for post-intervention use of these skills as reliable coping tools to minimize distress in everyday life.[15,16] This exploratory study proposes a novel, two-day mindfulness-based weekend retreat adapted for mothers of paediatric heart transplant recipients. It is recognized that an increased level of social support is derived from the shared experience of MBIs when offered in a retreat format.[15,20] This may provide benefit to the target population of this study as high prevalence of social isolation has been identified amongst mothers of heart transplant recipients, as well as their shared interest to connect with other mothers in similar positions.[5] MBIs facilitated through a mindfulness-based weekend retreat (MBR) increase the opportunity for social connection amongst participants because of environmental facilitators such as shared accommodations, meal times and free time. The remote location while attending the retreat is essential to provide mothers some space from their caregiving demands at home to focus both on their own needs and on the mindfulness curriculum. The shared physical space while at the retreat is intentional to increase community amongst participants over the two-day retreat.

Mindfulness is ideally suited for this population to address the inherent stress they experience through their caregiving roles,[7] and group mindfulness practice has the ability to catalyze community building that is sustained beyond a research setting.[22] Given the applicability of a MBR to meet the needs of mothers of paediatric heart transplant recipients it

is proposed within this pilot study as an intervention with potential to enhance maternal well-being through the development of coping skills, social connectedness, and psychological health.[5,15,17,20,21]

Study aims

To investigate the feasibility and efficacy of this intervention, the research objectives of this pilot study are to: (1) examine implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility, fidelity*)[23] of the MBR, and (2) assess the efficacy of the MBR on maternal quality of life, distress tolerance, coping and perceived social support. The primary outcomes will be feasibility in relation to implementation effectiveness and participants' perception of social support for efficacy of the MBR intervention.

METHODS AND ANALYSIS

Study design

A convergent parallel, mixed method design was chosen for this pilot study wherein quantitative and qualitative data will be collected simultaneously and analyzed independently, with results merged during the final interpretative phase to address the study's overall purpose.[23] This mixed methods design will allow for a comprehensive understanding of the study phenomena by incorporating both qualitative description methods to gather a rich account of participant experiences as well as quantitative measures to document the potential changes in participant coping styles, distress tolerance, perceived quality of life and social support.[24] The participant sample size will be equal across both quantitative and qualitative arms of data collection.

Qualitative research is highly valuable in this area because of the subjective impact of a child's illness on a family, and the individualized nature of each mother's parenting experience through transplantation. Qualitative data will be gathered through participation in a focus group on the final day of the retreat and an individual interview three months post-retreat. Focus groups are an efficient and effective method of qualitative data collection to yield anecdotal information about personal experiences and perceptions.[25,26] Group dialogue with mothers about their experiences of the retreat will offer a reflective opportunity to gather participant insights and to address implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility, fidelity*)[27] of this intervention for this clinical population. 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.[28] A focus group fits well with the group model of this retreat and is an opportune and feasible way to collect qualitative data from this particular sample, given their geographic diversity. Both the focus group and interview will gather participant feedback of parallel variables.

The quantitative instruments selected (*Coping Health Inventory for Parents, Five Facet Mindfulness Questionnaire, Pediatric Quality of Life (PedsQL™), Distress Tolerance Scale, Multidimensional Scale of Perceived Social Support*) will capture a measurable and generalizable assessment of maternal coping. The focus group and individual interview will highlight detailed and individualized perspectives of the mothering experience through paediatric heart transplantation, as well as provide insights to the participant experience of the MBR. Integration of the qualitative and quantitative data will highlight a depth of understanding that could not be obtained by either data separately.

Patient and public involvement

Caregiver needs and perspectives have been prioritized throughout the MBR pilot study design. At the project's inception, a mother of a pediatric heart transplant recipient was recruited to be a member of the research team as a patient partner (JM). Her lived caregiving experience informed many decisions concerning intervention design as well as methodological choices for outcome measures. The data collection measures identified dually prioritize the need to gather the richest possible data set, with a commitment to refrain from burdening participants with lengthy and arduous measures in consideration of their time.

Intervention design

The intervention will be a two-day retreat held over a weekend. The MBR will be held at a resort in northern Ontario, Canada and will consist of a structured schedule of mindfulness and compassion-based teaching and practices, including formal meditation, circle sharing, and deep relaxation.[29] The competencies developed in these exercises will be incorporated into all other retreat activities such as mealtimes, mindful movement (including yoga), and walking meditations. Mindfulness talks will be held on each day of the retreat, offering opportunities for participants to learn about and develop mindfulness skills. Each mindfulness talk in the retreat series will build upon the content of the previous talk, with the goal of moving participants from introspective personal mindfulness practice to interpersonal community building. Opportunities for guided circle sharing (i.e., group practice of mindfulness and

interpersonal sharing) and deep relaxation (i.e., personal practice bringing mindful attention to the body to relieve stress) will be integrated throughout the retreat.

The MBR will have two primary facilitators who are both mental health professionals (social worker and psychologist) with longstanding personal mindfulness practices. In addition, both facilitators have completed teacher training in mindfulness (Mindful Self-Compassion and Mindfulness-Based Cognitive Therapy), as well as certificates in both Foundations of Applied Mindfulness Meditation and Applied Specialization in Mindfulness Meditation from the University of Toronto, Canada. Lastly, both facilitators have extensive experience practicing in tertiary care hospitals adapting MBIs to support caregivers in chronic disease populations. The facilitators, alongside the research team's patient partner (JM), adapted the MBR specifically to the paediatric heart transplantation context.

Sample recruitment

A total of 20 participants will be recruited from The Hospital for Sick Children (SickKids) Labatt Family Heart Centre who meet the following criteria: (1) a mother residing in Ontario who is the primary caregiver of a paediatric heart transplant recipient, who is (2) a minimum of four months post-transplant. Within this study, '*mother*' is defined as a female-identifying caregiver to a paediatric heart transplant recipient. Participants are not required to be biologically related to the heart transplant recipient but must be the primary female-identifying caregiver and

share residence with the child. Purposive sampling will be used to obtain a sample with maximum variation.[30] Purposive sampling will ensure demographic variation amongst participants, specifically regarding: the mother's age, their child's age, stage of development and gender, and the family's race, ethnicity, composition, and geographic location of residence. Due to resource limitations that prohibit access to language and accessibility services, non-English speaking mothers and those with severe cognitive impairment as determined by a mental health professional will be excluded from participation in this study. Limited resources have also resulted in the restriction for participation in this study to Ontario residents only.

Participant recruitment began in January 2020 and is ongoing. The retreat will be hosted when it is safe to do so according to local COVID-19 public health guidelines. Participant recruitment has involved social work and nursing staff from the Heart Transplant Program at the SickKids Labatt Family Heart Centre, who each received a study description from the research team and were asked to select and refer mothers for eligibility review. If the mother consented to participate in this study, she was then referred to the research team who ensured that all eligibility criteria were met. Written informed consent was obtained from each study participant at that time.

Sample size

A sample size of 20 participants is adequate to obtain data saturation in qualitative studies[31,32] and aligns with the recommended class size for traditional MBSR teaching which informed the overall intervention design.[29] This sample size is also intentional to facilitate social connection within the participant group and to allow for richer discussion within mindfulness practices, such as circle sharing.[29] Mixed- method mindfulness research predominantly describes a sample size ranging from 10-20 participants for optimal intervention delivery.[31]

Data collection

Quantitative: Standardized questionnaires will be completed by all study participants at three time-periods: (T1) 24-hours prior to attending the retreat, (T2) 24-hours after attending the retreat, and (T3) three months post-retreat. At each timepoint, the questionnaires will be completed by participants online through REDCap.[33] Paper copies can be mailed to participants upon request. The three timepoints will allow for the comparison of outcomes assessed by pre- and post-intervention measures. The following quantitative measures will be used in this study:

(1) *Coping Health Inventory for Parents* is a 45-item scale measuring the demands experienced by parents/caregivers of a child with a chronic health condition.[34] The scale evaluates family integration and cooperation, maintenance of social support, self-esteem and psychological stability, and comprehension of the child's medical situation. Reliability has been previously established for this measure.[35]

(2) *Five Facet Mindfulness Questionnaire* is a 39-item scale measuring one's propensity to be mindful in their daily life (i.e., observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience).[36] Construct validity has been previously established as well as its use in assessing the utilization of mindfulness skills.[37]

(3) *Pediatric Quality of Life (PedsQL™) Family Impact Module* is a 36-item scale measuring the impact of chronic health conditions of children on parents through eight subscales: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; and family relationships. The PedsQL™ Family

Impact Module is a widely used measure for the evaluation of parental quality of life.[38] Internal consistency and reliability have been previously established.[38]

(4) *Distress Tolerance Scale* is a 14-item scale measuring distress tolerance across three domains: tolerance of distress, appraisal of being distressed, and emotional regulation.[39] Construct validity of this measure has been previously established.[39]

(5) *Multidimensional Scale of Perceived Social Support* has 12-items and measures perceived social support across three groups: family, friends and a significant other.[40] Validity and reliability have been previously demonstrated for this instrument.[40]

Demographic and medical forms will be administered to all participants to collect maternal information (e.g., age, race, ethnicity, number of children, annual household income, highest level of education etc.) and child information (e.g., date of transplant, underlying diagnosis, age at time of transplant, and co-morbidities etc.). These forms will be completed by participants using REDCap.[33] Paper copies will be made available upon request.

Qualitative: Qualitative data will be collected at (T2) on the last day of the retreat intervention and (T3) three months post-intervention. Participants will be divided into two groups of ten to participate in focus groups on the last day of the retreat, again utilizing purposive selection to ensure maximum variation in focus groups demographics. The focus group will be organized by open-ended questions and probes facilitated by members of the research team with extensive experience in qualitative methodology. 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 A second researcher will be present to observe each group and document topics and concepts discussed by participants. Both focus group discussions will be audio-recorded and transcribed verbatim. A subsequent semi-structured telephone interview will be completed individually with each participant three months post-intervention with transcription and data analysis to follow.

Data analysis

Quantitative: Each standardized instrument will be scored individually, and group data will be summarized by the calculation of means and standard deviations. T1 data will be assessed in comparison to T2 and T3 data. Notable changes in scores between each time-point will be descriptively analyzed. Should multiple characteristics present as significantly correlated with the same outcome, repeated measures ANOVA with post-hoc analysis will be used to discern the etiology of this correlation. Descriptive statistics will be used to describe and characterize the sample in this pilot.

Qualitative: All data will be read and analyzed by multiple members of the research team. Deductive thematic analysis will be used, and codes will be determined through line-by-line review of the focus group discussion and individual interviews using NVivo.[41] Through this review process, codes emerging repeatedly in various parts of the transcript will be noted and comparatively analyzed by multiple research team members for purposes of consistency.[41]

Interpretation: Quantitative and qualitative data will be merged to compare both similarities and differences across findings.[23] The research team will compile quantitative statistical results and compare findings to the qualitative themes present within the focus group and individual interview data. Further analysis will consider how the two sets of data relate, diverge, and interconnect to create a comprehensive understanding of the phenomena.

ETHICS AND DISSEMINATION

This research study has received approval from the SickKids Research Ethics Board (Number:1000064719). All participants will provide informed consent prior to their involvement in the study. This research study sample will not include participants incapable of providing informed consent or any participants under the age of 18.

The proposed research will inform a future randomized clinical trial to assess implementation outcomes and intervention effectiveness of a MBR within this population. This pilot study will greatly increase the breadth of knowledge about interventions that may support primary caregivers of paediatric heart transplant recipients. Findings will be translated and disseminated throughout cardiology and transplant communities and communicated to local, provincial, and national stakeholders. In addition, findings will be presented at national cardiology and transplant conferences and a manuscript will be submitted for publication in a peer-reviewed journal. Timing for dissemination of results will depend on the scheduled date of the retreat as permitted by provincial COVID-19 gathering restrictions.

All data collected over the course of the research study, including written transcription from the study's qualitative focus group and the subsequent individual telephone interviews, will be de-identified to protect participant confidentiality. Anonymous study identifiers will replace

all identifying information present in the transcripts. All identifying information, both paper copy and electronic information, will be kept confidential. Use of data over the course of the study, and dissemination of results will follow standard practice guidelines as determined by the SickKids Research Institute.

DISCUSSION

When a child undergoes heart transplantation, the role of the primary caregiver is notably linked to poor mental health outcomes and pervasive, illness-related parenting stress.[7] Previous research has correlated mindfulness-based practices with positive psychosocial outcomes in highly distressed populations,[17,42] and specifically in chronic disease populations, MBIs have demonstratively reduced psychological distress and symptoms of mental illness.[15,16] Aside from the benefits derived from direct participation, there is also potential for mindfulness interventions to yield larger systemic rewards. Supporting mothers to improve their coping can increase familial preparedness for post-transplant care management and any potential post-transplant hospitalizations.[6] With the length of hospitalization contributing the largest percentage of any transplant-associated costs,[6] positive caregiver coping and readiness for discharge could ultimately decrease healthcare spending per transplant patient. This innovative research leverages the MBR as an evidence-based intervention to engage mothers meaningfully by acknowledging the complexity of their role as a caregiver and addressing the impact of chronic stress and high caregiver burden.[5,7,43] While this pilot study is a preliminary step in addressing a wider gap in psychosocial intervention support to caregivers, the potential benefits derived are equally promising for individual patients and caregivers as well as the broader healthcare system.

This research is a necessary first step to advance the field of evidence-informed psychosocial interventions within paediatric cardiology and results will inform future iterations of the intervention across other participant groups. While caregiver experiences are unique, the need for support and disease-specific community building within paediatric healthcare is universal. This promising intervention will serve as a critical template for expansion across other clinical caregiving populations in paediatric solid organ transplant and other chronic illness care programs. Additionally, meeting the needs of all family members is vital to address family functioning, coping and resilience over the course of a child's chronic illness.

Some study limitations should be considered. This is an exploratory single-centre study with a small sample size, which could potentially limit the generalizability of the results. Exclusion of non-English speaking mothers and mothers residing outside of Ontario is another limitation of the study that was necessary for the delivery of mindfulness teachings in a group retreat-based format, but one that must be noted when considering the demographics of study participants.

Abbreviations

MBI - Mindfulness-Based Intervention; MBR– Mindfulness-based Retreat; PTSD–Post Traumatic Stress Disorder

Contributors TR, SJA, SAK, HT, MS-H, and JM participated in the study design. All these individuals are involved in the management of the study. TR drafted this protocol. All authors read, revised, and approved the final protocol.

Competing interests

The authors declare that they have no competing interests.

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 and 19
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 5-7
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	Page 8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 8-11
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 11-12
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 11-12

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 12-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14-17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 16-17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.