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

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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

1
2
3 mothers of paediatric heart transplant recipients and will inform a future randomized clinical trial
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5 to assess implementation outcomes and intervention effectiveness of MBRs within this
6
7 population.
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10 11 **Article Summary – Strengths and Limitations** 12

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15 • This pilot study will be the first mindfulness intervention to specifically target the
16
17 psychosocial needs of mothers of paediatric heart transplant recipients through an acute
18
19 retreat-based mindfulness intervention.
20
- 21
22 • Results of this study will significantly increase the breadth of knowledge on interventions
23
24 that may effectively support primary caregivers of paediatric heart transplant recipients
25
26 and will inform a future randomized clinical trial.
27
- 28
29 • This is a single-centre study with a proposed small sample which may limit
30
31 generalizability of findings.
32

33
34 **Keywords:** quality in health care, transplant medicine, mental health, paediatrics, paediatric
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36 transplant surgery, qualitative research
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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

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2
3 system as they directly impact parenting capacity, and consequently, child health and
4
5 development, well-being, and adjustment.[11,12]
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7
8 Increased clinical attention and accessible interventions to support the emotional coping
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10 and well-being of mothers may be efficacious to increase maternal coping and instrumental to
11
12 support paediatric heart transplant recipients' health and well-being. The psychosocial needs of
13
14 mothers of children with chronic illness are consistently underserved across healthcare
15
16 settings.[1] Evidence-based interventions to support caregivers in paediatric healthcare are
17
18 scarce and not prioritized,[13] and existing interventions (e.g., weekly support groups and
19
20 individual counseling) are time-consuming which parents have cited as their primary barrier to
21
22 participation in such health interventions.[1] To our knowledge this pilot study will be the first
23
24 of its kind to specifically target the psychosocial needs of mothers of paediatric heart transplant
25
26 recipients through an acute retreat-based mindfulness intervention.
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30 31 **Mindfulness-Based Interventions**

32
33 There is empirical evidence that Mindfulness Based Interventions (MBI) significantly
34
35 reduce psychological distress, anxiety, and depressive symptoms, and improve physical and
36
37 mental health across many populations.[14,15] Mindfulness-Based Stress Reduction is
38
39 currently the most widely recognized and utilized MBI for the treatment of PTSD and general
40
41 stress management.[16-18] MBIs more broadly have been shown to improve mental and
42
43 physical health in populations of caregivers for children with chronic illnesses.[19,20] MBIs
44
45 are structured programs that incorporate tenets of mindful meditation and assume that the
46
47 cultivation of compassionate and non-judgmental awareness will lead to a reduction in stress,
48
49 suffering and symptoms of mental illness.[16-18] In MBIs, participants are guided through
50
51 exercises that develop mindfulness skills through formal practice.[14,15] These supported
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3 opportunities to build capacity practicing mindfulness skills increase the likelihood for post-
4 intervention use of these skills as reliable coping tools to minimize distress in everyday
5 life.[14,15]
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10 This study proposes a novel, two-day mindfulness-based weekend retreat adapted for
11 mothers of paediatric heart transplant recipients. It is recognized that an increased level of
12 social support is derived from the shared experience of MBIs when offered in a retreat
13 format.[14,19] This may provide benefit to the target population of this study as high
14 prevalence of social isolation has been identified amongst mothers of heart transplant
15 recipients, as well as their shared interest to connect with other mothers in similar positions.[5]
16 MBIs facilitated through a mindfulness-based weekend retreat (MBR) increase the opportunity
17 for social connection amongst participants because of environmental facilitators such as shared
18 accommodations, meal times and free time. Mindfulness is ideally suited for this population to
19 address the inherent stress they experience through their caregiving roles,[7] and group
20 mindfulness practice has the ability to catalyze community building that is sustained beyond a
21 research setting.[21] Given the applicability of a MBR to meet the needs of mothers of
22 paediatric heart transplant recipients it is proposed within this pilot study as an intervention
23 with potential to enhance maternal well-being through the development of coping skills, social
24 connectedness, and psychological health.[5,14,16,19,20]
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44 **Study Aims**

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47 To investigate the feasibility and efficacy of this intervention the research objectives of
48 this pilot study are to: (1) examine implementation outcomes (*i.e., appropriateness,*
49 *acceptability, adoption, feasibility, fidelity*)[22] of the MBR, and (2) to assess the efficacy of the
50 MBR on maternal quality of life, distress tolerance, coping and perceived social support. This is
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3 a pilot study and application of the results from this research will inform the study design of a
4
5 future randomized clinical trial.
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7 8 **METHODS AND ANALYSIS**

9 10 **Study Design**

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12 A convergent parallel, mixed method design was chosen for this pilot study wherein
13
14 quantitative and qualitative data will be collected simultaneously and analyzed independently,
15
16 with results merged during the final interpretative phase to address the study's overall
17
18 purpose.[22] This mixed methods design will allow for a comprehensive understanding of the
19
20 study phenomena by incorporating both qualitative description methods to gather a rich account
21
22 of participant experiences as well as quantitative measures to document the potential changes in
23
24 participant coping styles, distress tolerance, perceived quality of life and social support.[23] The
25
26 participant sample size will be equal across both quantitative and qualitative arms of data
27
28 collection.
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33 Qualitative research is highly valuable in this area because of the subjective impact of a
34
35 child's illness on a family, and the individualized nature of each mother's parenting experience
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37 through transplantation. Qualitative data will be gathered through participation in a focus group
38
39 on the final day of the retreat and an individual interview three months post-retreat. Focus groups
40
41 are an efficient and effective method of qualitative data collection to yield anecdotal information
42
43 about personal experiences and perceptions.[24,25] Group dialogue with mothers about their
44
45 experiences of the retreat will offer a reflective opportunity to gather participant insights and to
46
47 address implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility,*
48
49 *fidelity*)[26] of this intervention for this clinical population. A focus group fits well with the
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51 group model of this retreat and is an opportune and feasible way to collect qualitative data from
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3 this particular sample, given their geographic diversity. Both the focus group and interview will
4
5 gather participant feedback of parallel variables.
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8 The quantitative instruments selected (*Coping Health Inventory for Parents*, *Five Facet*
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10 *Mindfulness Questionnaire*, *Pediatric Quality of Life (PedsQL™)*, *Distress Tolerance Scale*,
11
12 *Multidimensional Scale of Perceived Social Support*) will capture a measurable and
13
14 generalizable assessment of maternal coping. The focus group and individual interview will
15
16 highlight detailed and individualized perspectives of the mothering experience through paediatric
17
18 heart transplantation, as well as provide insights to the participant experience of the MBR.
19
20 Integration of the qualitative and quantitative data will highlight a depth of understanding that
21
22 could not be obtained by either data separately.
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24

25 26 **Patient and Public Involvement**

27
28 Caregiver needs and perspectives have been prioritized throughout the MBR pilot study
29
30 design. At the project's inception, a mother of a pediatric heart transplant recipient was recruited
31
32 to be a member of the research team as a patient partner (JM). Her lived caregiving experience
33
34 informed many decisions concerning intervention design as well as methodological choices for
35
36 outcome measures. The data collection measures identified dually prioritize the need to gather
37
38 the richest possible data set, with a commitment to refrain from burdening participants with
39
40 lengthy and arduous measures in consideration of their time.
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44 45 **Intervention Design**

46
47 The intervention will be a two-day retreat held over a weekend. The MBR will be held
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49 at a resort in northern Ontario, Canada and will consist of a structured schedule of mindfulness
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51 and compassion-based teaching and practices, including formal meditation, circle sharing, and
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4 deep relaxation.[27] The competencies developed in these exercises will be incorporated into
5
6
7 all other retreat activities such as mealtimes, mindful movement (including yoga), and walking
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9
10 meditations. Mindfulness talks will be held on each day of the retreat, offering opportunities
11
12
13 for participants to learn about and develop mindfulness skills. Each mindfulness talk in the
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15
16 retreat series will build upon the content of the previous talk, with the goal of moving
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18
19 participants from introspective personal mindfulness practice to interpersonal community
20
21
22 building. Opportunities for guided circle sharing (i.e., group practice of mindfulness and
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25 interpersonal sharing) and deep relaxation (i.e., personal practice bringing mindful attention to
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28 the body to relieve stress) will be integrated throughout the retreat.
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34 The MBR will have two primary facilitators who are both mental health professionals
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36
37 (social worker and psychologist) with longstanding personal mindfulness practices. In
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39
40 addition, both facilitators have completed teacher training in mindfulness (Mindful Self-
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43 Compassion and Mindfulness-Based Cognitive Therapy), as well as certificates in both
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46 Foundations of Applied Mindfulness Meditation and Applied Specialization in Mindfulness
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48
49 Meditation from the University of Toronto, Canada. Lastly, both facilitators have extensive
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54 experience practicing in tertiary care hospitals adapting MBIs to support caregivers in chronic
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4 disease populations. The facilitators, alongside the research team's patient partner (JM),
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6
7 adapted the MBR specifically to the paediatric heart transplantation context.
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10 **Sample Recruitment**

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12 A total of 20 participants will be recruited from The Hospital for Sick Children
13
14 (SickKids) Labatt Family Heart Centre who meet the following criteria: (1) a mother residing in
15
16 Ontario who is the primary caregiver of a paediatric heart transplant recipient, who is (2) a
17
18 minimum of four months post-transplant. Within this study, '*mother*' is defined as a female-
19
20 identifying caregiver to a paediatric heart transplant recipient. Participants are not required to be
21
22 biologically related to the heart transplant recipient but must be the primary female-identifying
23
24 caregiver and share residence with the child. Purposive sampling will be used to obtain a sample
25
26 with maximum variation.[28] Purposive sampling will ensure (1) demographic variation amongst
27
28 participants, specifically regarding: the mother's age, their child's age, stage of development and
29
30 gender, and the family's race, ethnicity, composition, and geographic location of residence, and
31
32 (2) that any mother selected to participate is coping well enough at baseline so as not to be
33
34 overburdened by participation in the study. Due to resource limitations that prohibit access to
35
36 language and accessibility services, non-English speaking mothers and those with severe
37
38 cognitive impairment as determined by a mental health professional will be excluded from
39
40 participation in this study. Limited resources have also resulted in the restriction for participation
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42 in this study to Ontario residents only.
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49 Participant recruitment began in January 2020 and is ongoing. The retreat will be hosted
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51 when it is safe to do so according to local COVID-19 public health guidelines. Participant
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53 recruitment has involved social work and nursing staff from the Heart Transplant Program at the
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55 SickKids Labatt Family Heart Centre, who each received a study description from the research
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3 team and were asked to select and refer mothers for eligibility review. The recruitment request
4 stipulated that each participant must be referred by the social worker or nurse, with whom they
5 have a pre-existing clinical relationship. This ensured that a baseline assessment of coping was
6 included in the referral, to confirm that study participation would not overburden the mother. If
7 the mother consented to participate in this study, she was then referred to the research team who
8 ensured that all eligibility criteria were met. Written informed consent was obtained from each
9 study participant at that time.
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22 **Data Collection**

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24 Quantitative: Standardized questionnaires will be completed by all study participants at three
25 time-periods: (T1) 24-hours prior to attending the retreat, (T2) 24-hours after attending the
26 retreat, and (T3) three months post-retreat. At each time point, the questionnaires will be
27 completed by participants online through REDCap.[29] Paper copies can be mailed to
28 participants upon request. The three time points will allow for the comparison of outcomes
29 assessed by pre- and post-intervention measures. The following quantitative measures will be
30 used in this study:
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- 40 (1) *Coping Health Inventory for Parents* is a 45-item scale measuring the demands
41 experienced by parents/caregivers of a child with a chronic health condition.[30] The
42 scale evaluates family integration and cooperation, maintenance of social support, self-
43 esteem and psychological stability, and comprehension of the child's medical situation.
44 Reliability has been previously established for this measure.[31]
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51 (2) *Five Facet Mindfulness Questionnaire* is a 39-item scale measuring one's propensity to
52 be mindful in their daily life (i.e., observing, describing, acting with awareness, non-
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3 judging of inner experience, and non-reactivity to inner experience).[32] Construct
4
5 validity has been previously established as well as its use in assessing the utilization of
6
7 mindfulness skills.[33]
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10 (3) *Pediatric Quality of Life (PedsQL™) Family Impact Module* is a 36-item scale measuring
11
12 the impact of chronic health conditions of children on parents through eight subscales:
13
14 physical functioning; emotional functioning; social functioning; cognitive functioning;
15
16 communication; worry; daily activities; and family relationships. The PedsQL™ Family
17
18 Impact Module is a widely used measure for the evaluation of parental quality of life.[34]
19
20 Internal consistency and reliability have been previously established.[34]
21
22

23
24 (4) *Distress Tolerance Scale* is a 14-item scale measuring distress tolerance across three
25
26 domains: tolerance of distress, appraisal of being distressed, and emotional
27
28 regulation.[35] Construct validity of this measure has been previously established.[35]
29
30

31 (5) *Multidimensional Scale of Perceived Social Support* has 12-items and measures
32
33 perceived social support across three groups: family, friends and a significant other.[36]
34
35 Validity and reliability have been previously demonstrated for this instrument.[36]
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38
39 Demographic and medical forms will be administered to all participants to collect
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41 maternal information (e.g., age, race, ethnicity, number of children, annual household income,
42
43 highest level of education etc.) and child information (e.g., date of transplant, underlying
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45 diagnosis, age at time of transplant, and co-morbidities etc.). These forms will be completed by
46
47 participants using REDCap.[29] Paper copies will be made available upon request.
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51 Qualitative: Qualitative data will be collected at (T2) on the last day of the retreat intervention
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53 and (T3) three months post-intervention. Participants will be randomized into two groups of ten
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2
3 to participate in focus groups on the last day of the retreat. The focus group will be organized by
4
5 open-ended questions and probes facilitated by members of the research team with extensive
6
7 experience in qualitative methodology. A second researcher will be present to observe each
8
9 group and document topics and concepts discussed by participants. Both focus group discussions
10
11 will be audio-recorded and transcribed verbatim. A subsequent semi-structured telephone
12
13 interview will be completed individually with each participant three months post-intervention
14
15 with transcription and data analysis to follow.
16
17
18

19 **Data Analysis**

20
21 Quantitative: Each standardized instrument will be scored individually, and group data will be
22
23 summarized by the calculation of means and standard deviations. T1 data will be assessed in
24
25 comparison to T2 and T3 data. Notable changes in scores between each time-point will be
26
27 descriptively analyzed. Should multiple characteristics present as significantly correlated with
28
29 the same outcome, repeated measures ANOVA with post-hoc analysis will be used to discern the
30
31 etiology of this correlation. Descriptive statistics will be used to describe and characterize the
32
33 sample in this pilot.
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38 Qualitative: All data will be read and analyzed by multiple members of the research team.
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40 Deductive thematic analysis will be used, and codes will be determined through line-by-line
41
42 review of the focus group discussion and individual interviews using NVivo.[37] Through this
43
44 review process, codes emerging repeatedly in various parts of the transcript will be noted and
45
46 comparatively analyzed by multiple research team members for purposes of consistency.[37]
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51 Interpretation: Quantitative and qualitative data will be merged to compare both similarities and
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53 differences across findings.[22] The research team will compile quantitative statistical results
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3 and compare findings to the qualitative themes present within the focus group and individual
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5 interview data. Further analysis will consider how the two sets of data relate, diverge, and
6
7 interconnect to create a comprehensive understanding of the phenomena.
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10 **ETHICS AND DISSEMINATION**

11 **Ethical Approval**

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15
16 This research study has received approval from the SickKids Research Ethics Board
17
18 (Number:1000064719). All participants will provide informed consent prior to their involvement
19
20 in the study. This research study sample will not include participants incapable of providing
21
22 informed consent or any participants under the age of 18.
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26 **Confidentiality and Information Security**

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30 All data collected over the course of the research study, including written transcription
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32 from the study's qualitative focus group and the subsequent individual telephone interviews, will
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34 be de-identified to protect participant confidentiality. Anonymous study identifiers will replace
35
36 all identifying information present in the transcripts. All identifying information, both paper copy
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38 and electronic information, will be kept confidential. Use of data over the course of the study,
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40 and dissemination of results will follow standard practice guidelines as determined by the
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42 SickKids Research Institute.
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46 **Discussion and Dissemination**

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50 When a child undergoes heart transplantation, the role of the primary caregiver is notably
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52 linked to poor mental health outcomes and pervasive, illness-related parenting stress.[7] Previous
53
54 research has correlated mindfulness-based practices with positive psychosocial outcomes in
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3 highly distressed populations,[16,38] and specifically in chronic disease populations, MBIs have
4
5 demonstratively reduced psychological distress and symptoms of mental illness.[14,15] Aside
6
7 from the benefits derived from direct participation, there is also potential for mindfulness
8
9 interventions to yield larger systemic rewards. Supporting mothers to improve their coping can
10
11 increase familial preparedness for post-transplant care management and any potential post-
12
13 transplant hospitalizations.[6] With the length of hospitalization contributing the largest
14
15 percentage of any transplant-associated costs,[6] positive caregiver coping and readiness for
16
17 discharge could ultimately decrease healthcare spending per transplant patient. This innovative
18
19 research leverages the MBR as an evidence-based intervention to engage mothers meaningfully
20
21 by acknowledging the complexity of their role as a caregiver and addressing the impact of
22
23 chronic stress and high caregiver burden.[5,7,39] While this pilot study is a preliminary step in
24
25 addressing a wider gap in psychosocial intervention support to caregivers, the potential benefits
26
27 derived are equally promising for individual patients and caregivers as well as the broader
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29 healthcare system.
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37 This research is a necessary first step to advance the field of evidence-informed
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39 psychosocial interventions within paediatric cardiology and results will inform future iterations
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41 of the intervention across other participant groups. While caregiver experiences are unique, the
42
43 need for support and disease-specific community building within paediatric healthcare is
44
45 universal. This promising intervention will serve as a critical template for expansion across other
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47 clinical caregiving populations in paediatric solid organ transplant and other chronic illness care
48
49 programs. Additionally, meeting the needs of all family members is vital to address family
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51 functioning, coping and resilience over the course of a child's chronic illness. Findings from this
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53 pilot study will provide the necessary evidence-base for future investigations examining the
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3 transferability of a MBR to support the needs of other caregivers and family members affected
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5 by paediatric chronic illness.
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9 The proposed research will inform a future randomized clinical trial to assess
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11 implementation outcomes and intervention effectiveness of a MBR within this population. This
12
13 pilot study will greatly increase the breadth of knowledge about interventions that may support
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15 primary caregivers of paediatric heart transplant recipients. Findings will be translated and
16
17 disseminated throughout cardiology and transplant communities and communicated to local,
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19 provincial, and national stakeholders. In addition, findings will be presented at national
20
21 cardiology and transplant conferences and a manuscript will be submitted for publication in a
22
23 peer-reviewed journal. Dissemination of results is anticipated to begin in September 2022 and
24
25 will depend on the scheduled date of the retreat as permitted by provincial COVID-19 gathering
26
27 restrictions.
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33 This innovative research posits the MBR as an evidence-based intervention to effectively
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35 address and support the familial impact of chronic stress and high caregiver burden for
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37 mothers.[5,7,39] While this pilot study is a preliminary step in addressing a wider gap in
38
39 psychosocial intervention support mothers, the potential benefits derived are promising for
40
41 individual patients and their caregivers.
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45

46 **Abbreviations**

47
48 MBI - Mindfulness-Based Intervention; MBR– Mindfulness-based Retreat; PTSD–Post
49
50 Traumatic Stress Disorder
51

52 **Competing interests**

53
54
55 The authors declare that they have no competing interests.
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8 Dear Mr. Adrian Aldcroft and *BMJ Open* Editorial Team,
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10 Please find attached a study protocol entitled “**Mindfulness-based retreat for mothers of paediatric heart**
11 **transplant recipients: A pilot intervention study protocol**,” that we herein submit for publication in *BMJ*
12 *Open*.
13

14
15 Mothers are the most common caregivers for pediatric heart transplant recipients and their ability to cope with
16 the chronic parenting stress associated with their caregiving role is inextricably linked with patient health
17 outcomes. Despite this correlation, the psychosocial needs of caregivers for children with chronic illness are
18 historically underserved in pediatric healthcare.
19

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21 Our research posits an innovative mindfulness-based retreat intervention that is novel to the caregiving group
22 of mothers of heart transplant recipients. The research goals of this protocol are to assess the efficacy of the
23 mindfulness-based weekend retreat intervention on maternal quality of life, distress tolerance, coping and
24 perceived social support through a convergent parallel, mixed-method study design. Caregiver experiences
25 will be dually captured through participation in a qualitative focus group and individual interview, as well as
26 through five standardized quantitative instruments completed at three time points.
27

28
29 This pilot protocol will significantly increase the breadth of knowledge on interventions that effectively
30 support primary caregivers of pediatric heart transplant recipients. Given the stature of *BMJ Open* as one of
31 the leading communication tools for professionals in the medical field, we are confident that our research will
32 be of interest to the readership.
33

34
35 We confirm that participant recruitment is ongoing. The study has undergone full internal peer review as part
36 of the funding process and has received institutional research ethics board approval. Relevant documentation
37 has been submitted. All authors confirm that this research protocol has not been previously published, nor is it
38 presently under consideration for publication elsewhere. We have no conflicts of interest to disclose.
39

40 Thank you for your time and consideration. We look forward to further correspondence with your office.
41

42 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)]



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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.

A handwritten signature in black ink, appearing to read "ES".

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060461.R1
Article Type:	Protocol
Date Submitted by the Author:	25-May-2022
Complete List of Authors:	Robertson, Taylor; The Hospital for Sick Children, Social Work Ahola Kohut, Sara; Hospital for Sick Children, Department of Gastroenterology, Hepatology and Nutrition; University of Toronto, Psychiatry Telfer, Heather; SickKids, Social Work; SickKids, Transplant and Regenerative Medicine Centre Seifert-Hansen, Mirna; SickKids, Transplant and Regenerative Medicine Centre Mitchell, Joanna; Canadian Donation and Transplantation Research Program Anthony, Samantha; The Hospital for Sick Children,
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Qualitative research, Paediatrics
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Transplant medicine < INTERNAL MEDICINE, MENTAL HEALTH, PAEDIATRICS, Paediatric transplant surgery < PAEDIATRIC SURGERY, QUALITATIVE RESEARCH

SCHOLARONE™
Manuscripts

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3 **1 Mindfulness-based retreat for mothers of paediatric heart transplant recipients: protocol**
4 **2 for a pilot intervention study**

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7 3 Taylor Robertson¹, Sara Ahola Kohut^{2,3,4}, Heather Telfer^{1,5}, Mirna Seifert-Hansen⁵, Joanna
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1 **Abstract**

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

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

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

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

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

9 **Strengths and limitations of this study**

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

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

6 INTRODUCTION

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

15 **Maternal caregiving impact in paediatric heart transplant**

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

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3 1 paediatric transplantation as an ongoing source of trauma for parents.[7,11] In a study on
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5 2 parents of heart transplant recipients, (75% of which were mothers), 19% of participants were
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7 3 found to meet the Diagnostic and Statistical Manual – IV diagnostic criteria for post-traumatic
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9 4 stress disorder (PTSD), amounting to a prevalence rate that is two and half times higher than the
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11 5 general population.[7] Untreated symptoms of PTSD are commonly felt within the wider family
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13 6 system as they directly impact parenting capacity, and consequently, child health and
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15 7 development, well-being, and adjustment.[12,13]
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19 8 Increased clinical attention and accessible interventions to support the emotional coping
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21 9 and well-being of mothers may be efficacious to increase maternal coping and instrumental to
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23 10 support paediatric heart transplant recipients' health and well-being. The psychosocial needs of
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25 11 mothers of children with chronic illness are consistently underserved across healthcare
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27 12 settings.[1] Evidence-based interventions to support caregivers in paediatric healthcare are
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29 13 scarce and not prioritized,[14] and existing interventions (e.g., weekly support groups and
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31 14 individual counseling) are time-consuming which parents have cited as their primary barrier to
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33 15 participation in such health interventions.[1] To our knowledge this pilot study will be the first
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35 16 of its kind to specifically target the psychosocial needs of mothers of paediatric heart transplant
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37 17 recipients through an retreat-based mindfulness intervention.
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42 18 **Mindfulness-based interventions**

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44 19 There is empirical evidence that mindfulness-based interventions (MBIs) significantly reduce
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46 20 psychological distress, anxiety, and depressive symptoms, and improve physical and mental
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48 21 health across many populations.[15,16] Mindfulness-Based Stress Reduction is currently the
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50 22 most widely recognized and utilized MBI for the treatment of PTSD and general stress
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52 23 management.[17-19] MBIs more broadly have been shown to improve mental and physical
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1 health in populations of caregivers for children with chronic illnesses.[20,21] MBIs are
2 structured programs that incorporate tenets of mindful meditation and assume that the
3 cultivation of compassionate and non-judgmental awareness will lead to a reduction in stress,
4 suffering and symptoms of mental illness.[17-19] In MBIs, participants are guided through
5 exercises that develop mindfulness skills through formal practice.[15,16] These supported
6 opportunities to build capacity practicing mindfulness skills increase the likelihood for post-
7 intervention use of these skills as reliable coping tools to minimize distress in everyday
8 life.[15,16] This exploratory study proposes a novel, two-day mindfulness-based weekend
9 retreat adapted for mothers of paediatric heart transplant recipients. It is recognized that an
10 increased level of social support is derived from the shared experience of MBIs when offered
11 in a retreat format.[15,20] This may provide benefit to the target population of this study as
12 high prevalence of social isolation has been identified amongst mothers of heart transplant
13 recipients, as well as their shared interest to connect with other mothers in similar positions.[5]
14 MBIs facilitated through a mindfulness-based weekend retreat (MBR) increase the opportunity
15 for social connection amongst participants because of environmental facilitators such as shared
16 accommodations, meal times and free time. The remote location while attending the retreat is
17 essential to provide mothers some space from their caregiving demands at home to focus both
18 on their own needs and on the mindfulness curriculum. The shared physical space while at the
19 retreat is intentional to increase community amongst participants over the two-day retreat.

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

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

4 **Study aims**

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

12 **METHODS AND ANALYSIS**

13 **Study design**

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

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3 1 Qualitative research is highly valuable in this area because of the subjective impact of a
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5 2 child's illness on a family, and the individualized nature of each mother's parenting experience
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7 3 through transplantation. Qualitative data will be gathered through participation in a focus group
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9 4 on the final day of the retreat and an individual interview three months post-retreat. Focus groups
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11 5 are an efficient and effective method of qualitative data collection to yield anecdotal information
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13 6 about personal experiences and perceptions.[25,26] Group dialogue with mothers about their
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15 7 experiences of the retreat will offer a reflective opportunity to gather participant insights and to
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17 8 address implementation outcomes (*i.e., appropriateness, acceptability, adoption, feasibility,*
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19 9 *fidelity*)[27] of this intervention for this clinical population. Fidelity of this intervention will be
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21 10 assessed through the components of treatment fidelity (facilitator factors include design, training,
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23 11 and delivery and participant factors include receipt and enactment) put forth by The Treatment
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25 12 Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium.[28] A
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27 13 focus group fits well with the group model of this retreat and is an opportune and feasible way to
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29 14 collect qualitative data from this particular sample, given their geographic diversity. Both the
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31 15 focus group and interview will gather participant feedback of parallel variables.
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37 16 The quantitative instruments selected (*Coping Health Inventory for Parents, Five Facet*
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39 17 *Mindfulness Questionnaire, Pediatric Quality of Life (PedsQL™), Distress Tolerance Scale,*
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41 18 *Multidimensional Scale of Perceived Social Support*) will capture a measurable and
42
43 19 generalizable assessment of maternal coping. The focus group and individual interview will
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45 20 highlight detailed and individualized perspectives of the mothering experience through paediatric
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47 21 heart transplantation, as well as provide insights to the participant experience of the MBR.
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49 22 Integration of the qualitative and quantitative data will highlight a depth of understanding that
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51 23 could not be obtained by either data separately.
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1 **Patient and public involvement**

2 Caregiver needs and perspectives have been prioritized throughout the MBR pilot study design.

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

9 **Intervention design**

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

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4 1 interpersonal sharing) and deep relaxation (i.e., personal practice bringing mindful attention to
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7 2 the body to relieve stress) will be integrated throughout the retreat.
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10 3 The MBR will have two primary facilitators who are both mental health professionals
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13 4 (social worker and psychologist) with longstanding personal mindfulness practices. In
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17 5 addition, both facilitators have completed teacher training in mindfulness (Mindful Self-
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20 6 Compassion and Mindfulness-Based Cognitive Therapy), as well as certificates in both
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23 7 Foundations of Applied Mindfulness Meditation and Applied Specialization in Mindfulness
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27 8 Meditation from the University of Toronto, Canada. Lastly, both facilitators have extensive
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30 9 experience practicing in tertiary care hospitals adapting MBIs to support caregivers in chronic
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34 10 disease populations. The facilitators, alongside the research team's patient partner (JM),
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37 11 adapted the MBR specifically to the paediatric heart transplantation context.
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40 12 **Sample recruitment**

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42 13 A total of 20 participants will be recruited from The Hospital for Sick Children (SickKids)
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44 14 Labatt Family Heart Centre who meet the following criteria: (1) a mother residing in Ontario
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47 15 who is the primary caregiver of a paediatric heart transplant recipient, who is (2) a minimum of
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49 16 four months post-transplant. Within this study, 'mother' is defined as a female-identifying
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52 17 caregiver to a paediatric heart transplant recipient. Participants are not required to be biologically
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54 18 related to the heart transplant recipient but must be the primary female-identifying caregiver and
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1 share residence with the child. Purposive sampling will be used to obtain a sample with
2 maximum variation.[30] Purposive sampling will ensure demographic variation amongst
3 participants, specifically regarding: the mother's age, their child's age, stage of development and
4 gender, and the family's race, ethnicity, composition, and geographic location of residence. Due
5 to resource limitations that prohibit access to language and accessibility services, non-English
6 speaking mothers and those with severe cognitive impairment as determined by a mental health
7 professional will be excluded from participation in this study. Limited resources have also
8 resulted in the restriction for participation in this study to Ontario residents only.

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

17 **Sample size**

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

1 **Data collection**

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

- 9 (1) *Coping Health Inventory for Parents* is a 45-item scale measuring the demands
10 experienced by parents/caregivers of a child with a chronic health condition.[34] The
11 scale evaluates family integration and cooperation, maintenance of social support, self-
12 esteem and psychological stability, and comprehension of the child's medical situation.
13 Reliability has been previously established for this measure.[35]
- 14 (2) *Five Facet Mindfulness Questionnaire* is a 39-item scale measuring one's propensity to
15 be mindful in their daily life (i.e., observing, describing, acting with awareness, non-
16 judging of inner experience, and non-reactivity to inner experience).[36] Construct
17 validity has been previously established as well as its use in assessing the utilization of
18 mindfulness skills.[37]
- 19 (3) *Pediatric Quality of Life (PedsQL™) Family Impact Module* is a 36-item scale measuring
20 the impact of chronic health conditions of children on parents through eight subscales:
21 physical functioning; emotional functioning; social functioning; cognitive functioning;
22 communication; worry; daily activities; and family relationships. The PedsQL™ Family

1 Impact Module is a widely used measure for the evaluation of parental quality of life.[38]

2 Internal consistency and reliability have been previously established.[38]

3 (4) *Distress Tolerance Scale* is a 14-item scale measuring distress tolerance across three

4 domains: tolerance of distress, appraisal of being distressed, and emotional

5 regulation.[39] Construct validity of this measure has been previously established.[39]

6 (5) *Multidimensional Scale of Perceived Social Support* has 12-items and measures

7 perceived social support across three groups: family, friends and a significant other.[40]

8 Validity and reliability have been previously demonstrated for this instrument.[40]

9 Demographic and medical forms will be administered to all participants to collect

10 maternal information (e.g., age, race, ethnicity, number of children, annual household income,

11 highest level of education etc.) and child information (e.g., date of transplant, underlying

12 diagnosis, age at time of transplant, and co-morbidities etc.). These forms will be completed by

13 participants using REDCap.[33] Paper copies will be made available upon request.

14 Qualitative: Qualitative data will be collected at (T2) on the last day of the retreat intervention

15 and (T3) three months post-intervention. Participants will be divided into two groups of ten to

16 participate in focus groups on the last day of the retreat, again utilizing purposive selection to

17 ensure maximum variation in focus groups demographics. The focus group will be organized by

18 open-ended questions and probes facilitated by members of the research team with extensive

19 experience in qualitative methodology. Focus group guiding questions will probe several areas

20 around implementation and efficacy of the MBR intervention, including but not limited to: i)

21 decision-making around attending the retreat (e.g., hopes, expectations, worries), ii) experience

22 and acceptability of participating in the retreat (e.g., impact on domains of well-being), iii)

1 appropriateness of the retreat content (e.g., what components are useful and not useful), iv)
2 feasibility (e.g., ease of participation), and v) post-retreat impressions (e.g., would the participant
3 recommend the retreat to other mothers of heart transplant recipients?). While the questions are
4 important, we plan to remain flexible in terms of probing (e.g., asking follow-up questions)
5 based on participant answers and interactions. A second researcher will be present to observe
6 each group and document topics and concepts discussed by participants. Both focus group
7 discussions will be audio-recorded and transcribed verbatim. A subsequent semi-structured
8 telephone interview will be completed individually with each participant three months post-
9 intervention with transcription and data analysis to follow.

10 **Data analysis**

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

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

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3 1 Interpretation: Quantitative and qualitative data will be merged to compare both similarities and
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5 2 differences across findings.[23] The research team will compile quantitative statistical results
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7 3 and compare findings to the qualitative themes present within the focus group and individual
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9 4 interview data. Further analysis will consider how the two sets of data relate, diverge, and
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11 5 interconnect to create a comprehensive understanding of the phenomena.
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14 6 **ETHICS AND DISSEMINATION**

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18 7 This research study has received approval from the SickKids Research Ethics Board
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20 8 (Number:1000064719). All participants will provide informed consent prior to their involvement
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22 9 in the study. This research study sample will not include participants incapable of providing
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24 10 informed consent or any participants under the age of 18.
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29 11 The proposed research will inform a future randomized clinical trial to assess
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31 12 implementation outcomes and intervention effectiveness of a MBR within this population. This
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33 13 pilot study will greatly increase the breadth of knowledge about interventions that may support
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35 14 primary caregivers of paediatric heart transplant recipients. Findings will be translated and
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37 15 disseminated throughout cardiology and transplant communities and communicated to local,
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39 16 provincial, and national stakeholders. In addition, findings will be presented at national
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41 17 cardiology and transplant conferences and a manuscript will be submitted for publication in a
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43 18 peer-reviewed journal. Timing for dissemination of results will depend on the scheduled date of
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45 19 the retreat as permitted by provincial COVID-19 gathering restrictions.
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50 20 All data collected over the course of the research study, including written transcription
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52 21 from the study's qualitative focus group and the subsequent individual telephone interviews, will
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54 22 be de-identified to protect participant confidentiality. Anonymous study identifiers will replace
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1 all identifying information present in the transcripts. All identifying information, both paper copy
2 and electronic information, will be kept confidential. Use of data over the course of the study,
3 and dissemination of results will follow standard practice guidelines as determined by the
4 SickKids Research Institute.

5 **DISCUSSION**

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

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

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

15 **Abbreviations**

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

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

22 **Competing interests**

1
2
3 1 The authors declare that they have no competing interests.
4

5
6 2 **Funding**

7
8 3 Funding for this study is provided by the SickKids Labatt Family Heart Centre Innovation Fund
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10 4 (Grant/Award Number: NA).
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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

1	Introduction			
2				
3	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	Page 5-7
4	rationale		studies (published and unpublished) examining benefits and harms for each intervention	<hr/>
5				
6		6b	Explanation for choice of comparators	N/A
7				<hr/>
8	Objectives	7	Specific objectives or hypotheses	Page 8
9				<hr/>
10	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	
11			allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 8-11
12				<hr/>
13				
14	Methods: Participants, interventions, and outcomes			
15				
16	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	Page 10
17			be collected. Reference to where list of study sites can be obtained	<hr/>
18				
19	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	Page 11-12
20			individuals who will perform the interventions (eg, surgeons, psychotherapists)	<hr/>
21				
22				Page 10-11
23	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	<hr/>
24			administered	
25				N/A
26		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	<hr/>
27			change in response to harms, participant request, or improving/worsening disease)	
28				N/A
29		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	<hr/>
30			(eg, drug tablet return, laboratory tests)	
31				N/A
32		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	<hr/>
33				
34	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	Page 8
35			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	<hr/>
36			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
37			efficacy and harm outcomes is strongly recommended	
38				
39				
40	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	Page 11-12
41			participants. A schematic diagram is highly recommended (see Figure)	<hr/>
42				

1	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
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
5				
6				
7	Methods: Assignment of interventions (for controlled trials)			
8	Allocation:			
9				
10				N/A
11	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	
12				
13				
14				
15				
16	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
17				
18				
19				
20				
21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
28				
29				
30				
31	Methods: Data collection, management, and analysis			
32				
33	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
34				
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39		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
40				
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1 Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality
 2 (eg, double data entry; range checks for data values). Reference to where details of data management
 3 procedures can be found, if not in the protocol

5 Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the
 6 statistical analysis plan can be found, if not in the protocol

8 20b Methods for any additional analyses (eg, subgroup and adjusted analyses)

10 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any
 11 statistical methods to handle missing data (eg, multiple imputation)

14 **Methods: Monitoring**

16 Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of
 17 whether it is independent from the sponsor and competing interests; and reference to where further details
 18 about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not
 19 needed

22 21b Description of any interim analyses and stopping guidelines, including who will have access to these interim
 23 results and make the final decision to terminate the trial

25 Harms 22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse
 26 events and other unintended effects of trial interventions or trial conduct

28 Auditing 23 Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent
 29 from investigators and the sponsor

32 **Ethics and dissemination**

34 Research ethics 24 Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
 35 approval

37 Protocol 25 Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes,
 38 amendments analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals,
 39 regulators)

1	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
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
5				
6				
7	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
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 19
11				
12				
13	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
14				
15				
16	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
17				
18				
19				
20	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
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
32				
33				
34	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
35				
36				

*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”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.