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CLINICAL CORRESPONDENCE

A mindfulness-based intervention for caregivers of allogeneic hematopoietic stem cell transplant patients: Pilot results

Christine Vinci[1,2] | Joseph Pidala[1,2] | Penny Lau[1] | Maija Reblin[1,2] | Heather Jim[1,2]

[1]Moffitt Cancer Center, Tampa, Florida

[2]Moffitt Cancer Center, Tampa, University of South Florida

Correspondence
Christine Vinci, Moffitt Cancer Center, Health Outcomes and Behavior, 4115 E Fowler Ave., Tampa, FL 33617.
Email: christine.vinci@moffitt.org

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Abstract

Despite high levels of stress, there are few empirically supported stress management interventions for caregivers of allogeneic hematopoietic stem cell transplant (HCT) cancer patients. This study examined the feasibility, acceptability, and various stress-related outcomes from pre- to post-treatment of a pilot, single-arm trial of a 6-week mindfulness-based intervention (FOCUS) for stress management. Caregivers (N = 21; 76% female; mean age = 57.43) were enrolled prior to patient transplant and received FOCUS during the first 90 days post-transplant. Findings indicated that FOCUS was highly feasible and acceptable (e.g., 71% attended at least four of six sessions; 100% reported using the skills learned at follow-up; high treatment engagement). Significant increases in mindfulness, post-traumatic growth, and general mental health were observed, along with significant decreases in negative affect (all ps < .05).

KEYWORDS

cancer, caregivers, hematopoietic stem cell transplant, intervention, mindfulness, oncology

1 | INTRODUCTION

Caring for an allogeneic hematopoietic cell transplant (HCT) patient is a significant responsibility, involving a commitment to be available 24/7 to provide emotional and physical support.[1] Allogeneic HCT caregivers have indicated poor mental health pre- and post-transplant,[2,3] which may also have implications for patient health outcomes.[4] It is important to consider how to better aid caregivers in managing their own distress.

There has been only one well-designed and adequately powered intervention for caregivers of allogeneic HCT patients that utilized cognitive behavioral therapy (CBT).[5] Results indicated good acceptability and feasibility, retention, and caregiver mental health outcomes. Challenges/limitations included participants not engaging in all treatment aspects and the need for scheduling flexibility. A recent systematic review/meta-analysis found the impact of CBT on psychological outcomes among cancer caregivers was negligible, suggesting that new treatment approaches should be explored.[6]

Mindfulness-based interventions (MBIs) aim to increase directed, flexible cognitive processing to facilitate observing one's current experience (thoughts/emotions/sensations) with a sense of acceptance, as opposed to trying to change or react to it.[7] MBIs may be ideal for HCT caregivers, as mindfulness has been shown to reduce reactivity to stress and may be most beneficial for those who experience high stress.[8] Although MBIs have not been tested for a HCT caregiver population, initial qualitative research suggests that allogeneic HCT caregivers would be willing to participate in a MBI and that they believed it would have been helpful for stress management.[9]

Our aim was to develop and evaluate a theoretically driven, efficacious intervention (FOCUS) among allogeneic HCT caregivers while addressing limitations identified in prior research. Primary outcomes were feasibility and acceptability (see Table 1). We also assessed stress/affect, mindfulness, and coping at baseline, end of treatment (EOT), and 1-month follow-up.

2 | METHODS

2.1 | Participants

The study was approved by the Cancer Center's Institutional Review Board (#19451). Eligibility criteria included: ≥18 years of age; caring for a

TABLE 1 Feasibility and acceptability outcomes

Feasibility	
Accrual	47% consented
Retention	71% completed 4-6 sessions 62% completed six sessions
Assessment visit completion	100% completed baseline 62% completed EOT 67% completed follow-up Of those who attended these visits, there was 100% questionnaire completion
Homework completion	Engagement in at least one mindfulness practice daily occurred on 58% of days enrolled in study
Acceptability (M, SD)	
Client satisfaction questionnaire	3.69 (0.28)
Usefulness of program*	5.36 (0.93)
Usefulness of program for stress management*	5.14 (0.95)
Likelihood of continuing to use skills learned*	5.50 (1.16)

Note: * = 6-point Likert scale, *1 = not very* to *6 = very*.

patient receiving an allogeneic HCT at the cancer center; intending to remain primary caregiver (defined as providing the majority of informal care through 90 days post-discharge; those who reported sharing care responsibilities were ineligible); able to provide informed consent; willing to provide two hair samples for cortisol sample (data not provided here); able to read and write English.

2.2 | Measures

See Table 1 for descriptions of feasibility and acceptability measures. Demographic data was collected at baseline. Measures of stress/affect included Perceived Stress Scale, Impact of Events Scale Revised, and Positive and Negative Affect Schedule. Measures of mindfulness included Mindful Attention Awareness Scale and the Nonjudging subscale of the Five Facet Mindfulness Questionnaire. Measures of coping included Zarit Burden Measure, Post-Traumatic Growth Inventory, Social Isolation Scale from PROMIS, and Global Health Scale from PROMIS. Both PROMIS measures were scored by converting raw scores to *t*-scores (*t*-score of 50 = average; SD = 10). Higher scores on all above measures indicate greater levels of each construct. Supplemental Table 1 provides additional details of all measures.

Intervention feedback included usefulness and enjoyment of in-session mindfulness exercises, weekly home practices, and video conferencing. Open-ended questions assessed barriers, as well as participants' favorite/least favorite aspects of the program. At follow-up, continued use of mindfulness practices was assessed.

2.3 | Procedure

Participants were recruited via social workers on the Blood and Marrow Transplant Unit, and via chart review by study staff. Those eligible after the phone screen were invited to an in-person consenting visit, which occurred in clinic about 1-2 weeks prior to the patient's transplant date (day 0) and coinciding with an outpatient, patient visit. Baseline measures were administered in-person to consenting caregivers, and treatment visits were scheduled. Participants completed follow-up measures at post-treatment (around day +36) and at 1-month follow-up (around day +66; 1 month post-intervention). Participants were compensated.

2.3.1 | Intervention

The MBI, FOCUS, was provided to all participants (the name is not an acronym, but a goal of the intervention). The development of FOCUS was informed by: qualitative research by the study team;[9,10] existing mindfulness and cancer caregiver literature; feedback from BMT staff; and feedback from a small subset of caregivers. We used intervention mapping to cross personal determinants of behavior change (knowledge, self-efficacy, and skill building) with performance objectives (decreases in perceived stress and worry/uncontrollability; increases in quality of life and management of social isolation) relevant to this intervention and population.

The final version of FOCUS comprised of six one-on-one, 45-60 min sessions delivered either in-person on the transplant unit (sessions 1-3; through day +15 post-transplant) or via video conference (sessions 4-6; through day +36). Sessions were facilitated by a clinical psychologist. Supplemental Table 2 provides an overview of intervention content. All participants were provided with a study phone to borrow, a CD and web-link of meditations, headphones, and a booklet with session content. Participants tracked daily mindfulness practices in the booklet.

3 | RESULTS

Participants (*N* = 21) were 76% female; average age of 57.43 (SD = 15.49). Most were married/living with a partner (81%), white (91%), and non-Hispanic (91%). The majority had at least a college degree (71%). Most reported being the spouse (62%) of the patient they were caring for, followed by parent (14.3%), sibling (4.8%), and other (19%). Regarding treatment fidelity, a checklist was completed post-session to indicate what topics were discussed/practices were completed. Results from the checklists indicated that at Visits 2, 4, and 5,100% of participants received all components of the treatment content. At Visit 1, 1 participant did not complete the raisin activity; at Visit 3, one participant did not complete mountain meditation; at Visit 6, one participant did not complete the lovingkindness meditation.

3.1 | Feasibility and acceptability

See Figure 1 for the consort diagram. Of the 45 caregivers identified as potentially eligible, 47% consented to the study. Of the 24 who did not consent, 14 declined/were not interested (eight spouses, two parents, one friend, and three unknown relationship). Table 1 provides results of additional feasibility and acceptability outcomes.

3.1.1 | Outcome measures

Participants were included in analyses if they attended four or more sessions. Paired sample *t*-tests revealed that from baseline to EOT, there were significant decreases in trauma symptoms (p = .049) and negative affect (p = .008), and significant increases in mindfulness (both measures [p = .048; p = .010]), post-traumatic growth (p = .001), and mental health (p = .032). Given the small sample size, the impact of outliers was assessed. The only outcome impacted by outliers was trauma symptoms, as upon re-running the paired sample *t*-test with the two outliers removed, the initial effect dropped from significance (p = .058). No significant changes emerged on any measure from EOT to follow-up. All non-significant findings trended in the expected direction. Supplemental Table 3 presents detailed results for each measure.

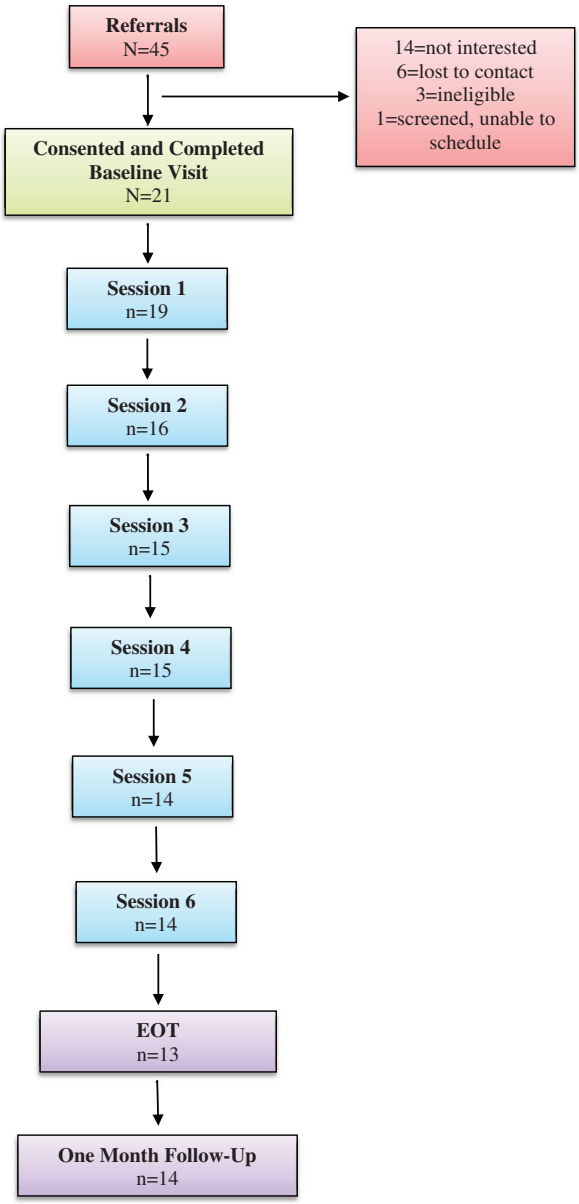

FIGURE 1 Consort diagram

3.2 | Intervention feedback

Overall, 93% of participants reported that the number of meditations assigned each week was "just right." For usefulness of the video conferencing app and face-to-face communication during sessions 4-6, the mean scores were 5.07 (SD = 0.73) and 5.21 (SD = 0.80), respectively (on 6-point Likert scales). Participants reported high engagement with mindfulness skills between the EOT and follow-up visits; information on what practices were most useful/enjoyable, as well as barriers and most/least favorite parts of program were also reported (see Supplemental Table 4).

4 | DISCUSSION

Findings from this pilot study demonstrated that FOCUS, a 6-week MBI, was both feasible and acceptable among allogeneic HCT caregivers. Accrual was 47%, 62% attended all treatment sessions (71% attended the majority), and mindfulness exercises were practiced on the majority of days during treatment. Satisfaction was high, as participants rated the program as very useful for managing stress and affirmed that they were very likely to continue using mindfulness strategies. Furthermore, 100% indicated that they were still using mindfulness skills at the 1-month follow-up; >85% reported engaging in mindfulness exercises 2-3 times per week; and >40% engaged in them four or more times per week. From baseline to EOT, participants reported significant increases (with medium to large effect sizes) in mindfulness, post-traumatic growth, and mental health, and a decrease in negative affect. No additional changes were observed from post-treatment to follow-up, suggesting that initial treatment gains were maintained (i.e., participant scores did not fall back to baseline).

Our study attempted to circumvent issues encountered in previous research by: meeting with caregivers on the inpatient unit for sessions 1-3 to increase proximity; scheduling assessment visits to coincide with patient visits; utilizing video conferencing; and rescheduling sessions as needed. Nonetheless, limitations include the small sample from a predominately white, non-Hispanic population; a single-arm design with no control group; covariates not considered given the small sample size; and potential influence of demand characteristics on self-report responses. At the end of treatment session,

71.4% of participants indicated having ever used mindfulness before, which is higher than would be expected. We did ask this question post-treatment, so it is possible that more people understood what mindfulness was at this point than is typical in most surveys. Nonetheless, prior experience with meditation could have influenced who agreed to participate.

This pilot study determined that delivering a MBI to allogeneic HCT caregivers is not only very feasible and highly accepted, but also demonstrated preliminary efficacy on multiple psychological outcome variables. Future research is needed to compare FOCUS to a matched comparison group in order to fully test treatment efficacy and to consider possible moderators of treatment outcome.

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CONFLICT OF INTEREST

H.J. has conflicts with RedHill Biopharma, Janssen Scientific Affairs, and Merck. There are no other conflicts to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Christine Vinci https://orcid.org/0000-0001-8883-0989
Maija Reblin https://orcid.org/0000-0003-3108-465X

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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