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# Randomized Controlled Pilot Trial of Mindfulness-Based Stress Reduction Compared to Psychoeducational Support for Persistently Fatigued Breast and Colorectal Cancer Survivors

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## Abstract

**Purpose—**Cancer-related fatigue (CRF) is a disruptive symptom for many survivors. Despite promising evidence for efficacy of Mindfulness-Based Stress Reduction (MBSR) in reducing CRF, no trials comparing it to an *active comparator* for fatigued survivors have been published. The purpose of this trial was to compare MBSR to psychoeducation for CRF and associated symptoms.

**Methods—**Breast ($n$=60) and colorectal ($n$=11) cancer survivors (stage 0–III) with clinically significant CRF after completing chemotherapy and/or radiation therapy an average of 28 months prior to enrollment were randomized to MBSR or psychoeducation/support groups (PES). MBSR focused on mindfulness training; PES focused on CRF self-management. Outcomes included CRF interference (primary), CRF severity and global improvement, vitality, depression, anxiety, sleep

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disturbance, and pain. Outcomes were assessed at baseline (T1), post-intervention (T2), and 6-month follow-up (T3) using intent-to-treat analysis.

**Results—**Between-group differences in CRF interference were not significant at any time point; however, there was a trend favoring MBSR ($d$=−0.46, $p$=0.073) at T2. MBSR participants reported significantly greater improvement in vitality ($d$=0.53, $p$=0.003) and were more likely to report CRF as moderately-to-completely improved compared to the PES group ($\chi^2$ (1)=4.1765, $p$=0.041) at T2. MBSR participants also reported significantly greater reductions in pain at T2 ($d$=0.53, $p$=0.014). In addition, both MBSR and PES produced moderate-to-large and significant *within-group* improvements in all fatigue outcomes, depression, anxiety, and sleep at T2 and T3 compared to T1.

**Conclusion—**MBSR and PES appear efficacious for CRF and related symptoms. Larger trials including a usual care arm are warranted.

### Keywords

Cancer; fatigue; mindfulness; MBSR; meditation; psychoeducation

## BACKGROUND

Fatigue is the most common and distressing cancer-related symptom [1,2], affecting approximately 30% of breast and colorectal cancer survivors years into disease-free survivorship [3,4]. Cancer-related fatigue (CRF) negatively impacts survivors' quality of life[5] and ability to work [6], and places survivors at increased risk for cancer recurrence [7]. Moreover, CRF is drastically under-treated [8], with <15% of fatigued patients reporting having received any guidance in CRF management from their health care team [9].

Clinical practice guidelines for CRF recommend symptom management [10]. Mindfulness-Based Stress Reduction (MBSR) is a non-pharmacologic intervention that has shown promise in the treatment of CRF [11–13]. MBSR is a group meditation intervention that provides experiential training in mindfulness, a non-judging mental state whereby one attends to and purposefully manages one's awareness of what is happening in the present moment. The goal of MBSR is not necessarily to decrease symptom severity, but to enhance survivors' ability to live with their symptoms in a non-reactive way, thereby reducing symptom-related interference with quality of life. Recent meta-analyses have established MBSR as efficacious in improving mental health outcomes in cancer [14–16]. Systematic reviews in adults with cancer [17,18,15] and in non-cancer populations [19,20] have concluded that mindfulness-based interventions are promising but require further investigation, particularly with respect to treating fatigue and its correlates [1,21]. Although clinical practice guidelines added MBSR as an evidence-based intervention for fatigue following cancer treatment in 2014 [10], to date only trials comparing MBSR to wait-list controls on fatigue outcomes have been conducted [11–13]. Of these, only one used fatigue as the primary outcome of the trial and enrolled participants based on presence of clinically significant fatigue. In that trial, Johns and colleagues reported that the MBSR group experienced large post-intervention improvements in fatigue interference, fatigue severity,

and vitality compared to the wait list group, and the improvements were maintained at 1- and 6-month follow-up [11].

Because the impact of MBSR on CRF has already been evaluated using wait-list controls, a necessary step to establish the specific effects of MBSR [22] is to conduct a more rigorous trial comparing MBSR specifically targeting CRF to another active treatment. In the current trial, we employed an active treatment control group intended to help rule out the possibility that placebo or related non-specific effects might be responsible for MBSR's beneficial impact. Therefore, the aim of the current trial was to determine the effect size of MBSR compared to an active treatment in reducing fatigue and associated symptoms among cancer survivors following chemotherapy and/or radiotherapy. Because it is recommended as a treatment for CRF [10] and prior research has shown it is efficacious in treating CRF and its correlates [23–25], psychoeducation and support (PES) was selected as the active comparator for this study.

## METHODS

### Design

This was a 2-arm randomized clinical pilot trial. Study procedures were approved by the Indiana University and Community Health Network institutional review boards. Written informed consent was obtained from all participants. The study was funded by the Walther Cancer Foundation and the Indiana Clinical and Translational Sciences Institute. The study is registered with ClinicalTrials.gov (NCT01919853).

### Participants

Breast (n=60) and colorectal (n=11) cancer survivors (BCS and CRCS, respectively) with persistent fatigue were consecutively recruited over 5 months in 2012–2013 from clinics affiliated with a National Cancer Institute-designated cancer center and through tumor registry mailings. BCS and CRCS were chosen as populations of interest as they are two of the most prevalent cancer diagnoses within our setting.

Individuals were told the study purpose was to test two potentially helpful behavioral treatments for CRF. Individuals were eligible if they were age 18 or older, had a first-time diagnosis of non-metastatic (stages 0–III) breast or colorectal cancer treated with chemotherapy and/or radiation therapy, and had clinically significant CRF (Fatigue Symptom Inventory severity composite ≥ 4) [26] that had persisted for at least 2 months. Individuals were excluded if they had received any cancer treatment (i.e., chemotherapy, radiation therapy, or surgery) less than 3 months or more than 5 years prior to enrollment (current endocrine therapy for breast cancer was allowed), reported severe depressive symptoms (Patient Health Questionnaire-8 score ≥ 20) [27], or reported past participation in a mindfulness class and/or ongoing meditation practice.

### Randomization and Blinding

Eligible participants attended a group enrollment session, including completion of baseline surveys, and randomization to MBSR or PES. The allocation ratio was 1:1, with the

sequence generated by coin toss in randomly varied block sizes of 4 to 6 and concealed in opaque sequentially-numbered envelopes. Participants and research assistants were blinded to the allocation sequence. Outcomes were self-reported on study questionnaires, to which group facilitators lacked access. Participants were blinded to study hypotheses and had no knowledge of the content of the course to which they were not assigned.

## Interventions

Participants in both interventions met for 2 hours each week for 8 weeks. The difference between the interventions was the active component of guided meditation in MBSR; topics related to mindfulness, meditation, and relaxation were not included in the PES intervention. Groups averaged 10 participants each to ensure equal amounts of time and attention. To limit contamination, groups met in separate locations.

**Mindfulness-Based Stress Reduction (MBSR)—**MBSR provides guided training during class and through audio recordings outside of class on mindfulness meditation practices (i.e., body scan, sitting meditation, hatha yoga, walking meditation, and compassion meditation). Through these practices, present-centered awareness is enhanced, facilitating non-reactive and non-judgmental acceptance of thoughts, feelings, and bodily sensations [15,18,28]. Relating to symptoms such as fatigue in this adaptive way has been shown to reduce symptom-related interference with quality of life [29]. MBSR was delivered in a manner consistent with the standard MBSR curriculum [30], tailored to the needs of fatigued survivors. Adaptations included 2-hour classes, no retreat, brief psychoeducation related to CRF, a 10-minute bedtime body scan to support rest, and shorter guided home practices (20 min). Participants tracked daily meditation practices on weekly logs. Notably, the MBSR intervention implemented in the present study was highly similar to the MBSR intervention implemented in our earlier study with fatigued post-treatment cancer survivors comparing MBSR to wait-list control [11]. MBSR instructors were a physician and a doctoral-level clinical health psychologist with 9 and 3 years of MBSR teaching experience, respectively. Further details on MBSR for CRF are published elsewhere [11]. A description of the MBSR sessions used in this study is presented in Table 1.

**Psychoeducation and support (PES)—**To provide a rigorous test of MBSR effects, a PES group intervention was included as an active comparator. The goal of PES is to educate and support patients to better cope with the side effects of their illness. For cancer survivors, PES programs include group discussions of CRF and its impact on psychological and social functioning; sharing, listening to, and affirming patients' CRF-related experiences; and offering evidenced-based tips and strategies for managing CRF (e.g., sleep, nutrition, exercise) [31].

The study team developed a manualized PES intervention, in accordance with PES programs used in other published studies of CRF [23]. Specific topics were addressed each week, and sessions included sharing of experiences living with CRF and strategies for CRF self-management. The details of each 8 week session are presented in Table 2. For between-session home practice, participants received supplemental readings on fatigue self-management from *After Cancer Treatment: Heal Faster, Better, Stronger* [32], as well as the

American Cancer Society, American Society of Clinical Oncology, National Cancer Institute, and CURE Magazine websites. Participants tracked time spent doing reading assignments and other self-care strategies discussed in class on weekly logs. PES facilitators were master's level social workers each with approximately 4 years of experience facilitating PES groups. Participants in PES were provided with information on how to access MBSR courses at the end of the study.

## Treatment Fidelity

Fidelity to MBSR and PES was ensured through the use of standardized manuals and audio recordings and evaluation of sessions for adherence to the protocol using checklists created for each intervention condition. Mean treatment fidelity ratings across a randomly selected 25% of sessions were 85.1% for MBSR facilitators and 95.8% for PES facilitators.

## Measures

Demographic data collected included gender, race, educational level, employment status, marital status, and income level, as determined by participants' response to the question, "When you consider your household income from all sources today, would you say that you are comfortable, have just enough to make ends meet, or not enough to make ends meet." Patient-reported outcomes were assessed on printed study surveys at baseline (T1), post intervention (T2), and 6 months later (T3) at the study site. Intent-to-treat participants completed T2 and T3 surveys by mail.

**Primary Outcome—**The Assessing the Symptoms of Cancer using Patient-Reported Outcomes (ASCPRO) group [33] recommends selecting CRF measures based upon study and intervention intent (e.g., reducing the negative impact of fatigue on functioning). Thus, fatigue interference was selected as the primary outcome, as the intent of MBSR is to reduce symptom-related functional interference. Prior studies of the effects of the active comparator have included fatigue interference among their outcomes [23] as interference tends to be of greater concern to survivors than the presence or severity of fatigue [34].

The 7-item interference subscale of the Fatigue Symptom Inventory (FSI) [35] was used in this study to assess the degree to which fatigue has interfered with functioning across multiple domains (e.g., general activity level, ability to bathe/dress, work, relationships, mood) over the past week. Items are rated on 11-point scales (0=no interference; 10=extreme interference) and then averaged.

**Secondary Outcomes—**Fatigue severity was assessed using the 4-item *FSI severity subscale* [35]. FSI severity scores ≥ 3 (range 0 – 10) are considered clinically significant [26]. Vitality was measured with the 4-item *SF-36 Vitality Scale* [36]. Scores range from 0 to 100, with higher scores indicating greater vitality. Vitality scores ≤ 45 are indicative of clinically-significant CRF [26]. *Fatigue global improvement* was assessed with a single item asking respondents to rate their CRF compared to when they started the study, with the options being worse, about the same, or a little, somewhat, moderately, a lot, or completely better [37]. Additional secondary outcome measures included the *Patient Health Questionnaire 8-item depression scale (PHQ-8)* [27] and 7-item *Generalized Anxiety*

*Disorder scale (GAD-7)* [38], the 7-item *Insomnia Severity Index (ISI)* [39], and a 3-item version of the *Brief Pain Inventory* [40].

**Additional Outcomes—**At the beginning of session 2, participants were asked to complete a 5-item *expectancy-credibility* scale adapted from Devilly and Borkovec that measures participants' perceptions of the expected benefits and credibility of treatment on a 0–9 scale [41]. Participants' overall *satisfaction* with the study was rated at T3 on an 11-point scale (0=not at all satisfied; 10=completely satisfied). Also at T3, MBSR participants were asked to report the average number of days per week, if any, they had continued to participate in *mindfulness practice*, both formal (e.g., body scan, sitting practice, yoga) and informal (doing everyday activities mindfully).

## Statistical Power

Because this was a pilot study, the principal aim was to estimate an effect size for a definitive phase 3 randomized clinical trial. The sample size of 71 had 80% power to detect a medium-to-large effect size (0.65–0.70) difference between means for tests of between-group efficacy.

## Statistical Analysis

Intent-to-treat analyses were conducted using imputation to fill in missing data according to randomly assigned group membership regardless of degree of adherence to their intervention. Available data from all participants were included in the analyses regardless of attendance or engagement in the intervention. Groups were compared on T1 demographic and medical characteristics using Chi square and Fisher's Exact tests for categorical variables and t-tests for continuous variables. Although there were no statistically significant differences between groups on these variables at $p<0.05$, we controlled for characteristics thought to be clinically/theoretically relevant in an investigation of CRF and/or those where the between group difference was $p<0.10$ [42], including cancer type and income.

Analysis of covariance (ANCOVA) was used to test efficacy by comparing MBSR to PES on primary and secondary outcomes at T2 and separately at T3 while adjusting for covariates and baseline scale scores for each variable. When computing scale scores, a person-specific and scale-specific mean of non-missing items was substituted for missing items if 33% or fewer of the scale's items were missing. However, missing data occurred infrequently. Effect sizes (Cohen's $d$) were calculated for each outcome variable at T2 and T3 as the standardized mean difference between the MBSR and PES groups divided by the pooled baseline standard deviation of the outcome variable. CRF global improvement (defined as those reporting their CRF as being moderately to completely better since T1) was compared at T2 and at T3 with Chi square. Between-group comparisons on expectancy-credibility and satisfaction were analyzed with t-tests. The paired t-test was used to assess within-group improvements on all outcomes for each group at T2 and T3 as compared to T1 scores on each variable. Within-group effect sizes were assessed by the standardized response mean (SRM), which is the difference between means (T1 to T2; or T1 to T3) divided by the SD of changes scores. Analyses were performed using SAS version 9.3 (SAS Institute Inc, Cary, NC).

# RESULTS

## Enrollment and Attrition

As shown in Figure 1, 224 consecutive BCS and CRCS were screened for eligibility, of which 79 were found ineligible and excluded. Of the remaining 145 eligible survivors, 71 (49%) agreed to participate and were enrolled in the study and randomized. Overall, retention exceeded 97% at T2 and 94% at T3 in both groups.

## Baseline Participant Characteristics

As summarized in Table 3, the sample was predominantly female (90.1%) and white (70.4%), with less than a college degree (56.3%). Approximately half were employed (52.1%), endorsed having a comfortable income (52.1%), and were married/partnered (54.9%). All had received chemotherapy and/or radiation therapy, and the average time since completion of these treatments was approximately 2.4 years. Many BCS (46%) were taking endocrine therapy at enrollment. With the exception of income ($p = 0.07$), there were no statistically significant group differences in baseline characteristics.

## Between-Group Intervention Effects

**Primary Outcome—**CRF interference did not significantly differ between groups at T2 or T3 (Table 4). However, there was a non-significant trend favoring MBSR ($d$=-0.46, $p$=0.073) at T2. The PES group experienced accumulating benefits over time, with a mean CRF interference score similar to the MBSR group at T3.

**Secondary Outcomes—**As shown in Table 4, the MBSR group demonstrated a moderate and significant effect size in vitality at T2 compared to the PES group ($d$=0.53, $p$=0.003). Although the MBSR group maintained their improvement in vitality at T3, the between-group difference was no longer significant ($d$=0.27, $p$=0.136) because of continued improvement in the PES group. On the CRF global improvement item, MBSR participants were significantly more likely than PES participants [58.8% vs. 34.3%, respectively; $\chi^2$ (1)=4.176, $p$=0.041] to report their CRF as being moderately to completely better at T2. Groups reported similar levels of global improvement in CRF at T3, with approximately half of each group [MBSR 45.5% vs. PES 54.3%; $\chi^2$ (1)=0.530, $p$=0.467] reporting their fatigue as moderately to completely better. As shown in Table 5, the MBSR group reported moderate and significant reduction at the end of the intervention in pain compared to PES participants ($d$=−0.50, $p$= 0.014). There were no significant between-group differences on any other secondary outcomes at any time point (Table 5).

Both groups reported high expectations that their assigned intervention would be helpful and that the intervention was credible on the 0–9 expectancy-credibility scale [MBSR mean (*SD*)=7.6 (1.5); PES mean (*SD*)=7.2 (1.5); $p$=0.255]. Likewise, satisfaction was rated similarly high across groups, with the MBSR group reporting a mean (*SD*) of 8.7 (1.9) compared to 8.4 (2.1) in the PES group ($p$=0.54) on the 0–10 satisfaction scale.

### Within-Group Intervention Effects

Moderate-to-large and significant within-group improvements on all fatigue outcomes were found at T2 and T3 compared to T1 in both MBSR and PES groups (Table 4). Participants in both interventions also experienced moderate-to-large and significant improvements at both time points on depression, anxiety, and sleep disturbance. Effects on pain were moderate and significant for the MBSR group at both time points and significant for the PES group only at T3 (Table 5).

### Attendance and Home Practice

Attendance was similar between groups. MBSR participants attended an average of 5.8 (*SD*=2.1) sessions compared to 6.3 (*SD*=1.9) for PES participants [$t(68)=0.96$, $p=0.30$]. Participants in both groups also reported a similar amount of time completing home practice assignments each week. MBSR participants reported an average of 117.6 (*SD*=85.9) minutes per week of home practice compared to 92.5 (*SD*=92.1) minutes per week for PES participants [$t(69)=1.19$ $p=0.2398$)]. At 6-month follow-up, 75.8% of MBSR participants reported continued “formal” mindfulness practice; however, only 36.4% reported frequent practice (≥3 days/week). Almost all MBSR participants (84.8%) reported continued “informal” mindfulness practice after completing the MBSR course.

## DISCUSSION

This pilot trial revealed several important findings regarding MBSR compared to PES for CRF. First, there was a trend favoring MBSR on fatigue interference, and a clear advantage favoring MBSR in vitality and global improvement in fatigue immediately post intervention. However, these between group differences were not evident at 6 months follow-up as PES participants experienced ongoing improvements in fatigue. Second, both MBSR and PES participants experienced significant, moderate-to-large, within-group improvements in fatigue and its correlates that were maintained 6 months post intervention. As there were no statistically significant differences in baseline scores on fatigue or its correlates, these findings suggest that both interventions are efficacious in alleviating fatigue, although MBSR might yield results sooner than PES. Lastly, both interventions proved feasible and acceptable as evidenced by high rates of retention, attendance, satisfaction, and adherence to home practice, indicating that cancer survivors are open to participating in weekly 2-hour classes and daily home practice despite their persistent fatigue. The results of this pilot trial are rather promising as they demonstrate two potentially acceptable and efficacious interventions for ameliorating fatigue.

The significant between-group differences in vitality and fatigue global improvement at T2 combined with the significant within-group fatigue improvements for MBSR at T2 and T3 support its use as a potential treatment for CRF. These results are consistent with those of a recent randomized controlled trial testing an 8-week mindfulness-based intervention in which the mindfulness group reported significant improvements in fatigue outcomes compared to participants in the wait-list control group post-intervention, and these improvements were maintained for the mindfulness group through the 6-month follow-up [43]. Although our study lacked a usual care (UC) group for comparison, results of extant

studies strongly suggest that the persistent fatigue that defined our sample was unlikely to have remitted spontaneously [11,43]. These findings suggest that mindfulness may be efficacious in improving vitality and patients' perceptions of fatigue.

The purpose of this pilot trail was to provide a rigorous test of MBSR, yet surprisingly this study also strengthened support for the use of PES interventions for CRF. In developing the PES intervention, we intended to provide a credible treatment that did not include mindfulness training and controlled for nonspecific factors (e.g., amount of social contact and attention from an empathic clinician) [22]. Although we expected psychoeducation to be helpful, we were surprised by the magnitude and durability of the within-group effect sizes of the PES intervention. The mechanisms by which PES interventions lead to reductions in fatigue and associated symptoms are unclear, but there are at least two possible explanations. First, the sharing of experiences and interacting with other cancer survivors within group sessions may have contributed to patients' perceptions of social support and validation, a factor critical to helping patients adjust during survivorship [44]. In addition, our intervention may have fostered patients' sense of self-efficacy, or their beliefs in their abilities to cope. By providing information about fatigue and potential strategies to manage fatigue, patients may have felt better equipped to deal with fatigue and other lingering side effects of cancer treatment [45]. Additional studies are needed to elucidate the mechanisms of PES interventions and their effects on CRF.

This pilot study had several strengths. Care was taken to match the PES intervention to MBSR in facilitator skill, class duration, and home practice expectations, which allowed for a direct comparison of the effects of MBSR relative to an active comparator. The trial also included a 6-month follow-up, which has been missing in most trials of integrative CRF treatments. A strength related to generalizability is the demographic heterogeneity of the sample.

This study also had limitations. There was a lack of power for efficacy testing. However, this pilot study was designed to estimate effect sizes for future work, which was accomplished. A larger trial is warranted that includes a UC arm to assess differential efficacy between MBSR and PES interventions compared to UC. Another limitation was the heterogeneity regarding cancer stage and time since completion of cancer treatment, as these variables could potentially contribute to differential responses to MBSR or PES. Yet, these characteristics were balanced between groups, and thus any potential effects likely were negligible. Although gender, too, was balanced across groups, the relatively low percentage of male participants may limit the generalizability of the results. Finally, MBSR's quicker impact might have been due in part to the doctoral level training of the facilitators in that arm, as opposed to the master's level facilitators in the PES arm. However, the fidelity checks were uniformly high, and in fact a little higher in the PES arm.

## CONCLUSIONS

Our trial provides promising support for MBSR as well as PES for the treatment of CRF. This is especially important given the current lack of evidenced-based pharmacological therapies for CRF. Phase 3 trials comparing these potentially efficacious behavioral

treatments compared to UC are warranted. When more than one efficacious behavioral treatment exists, patient preferences should play a central role.

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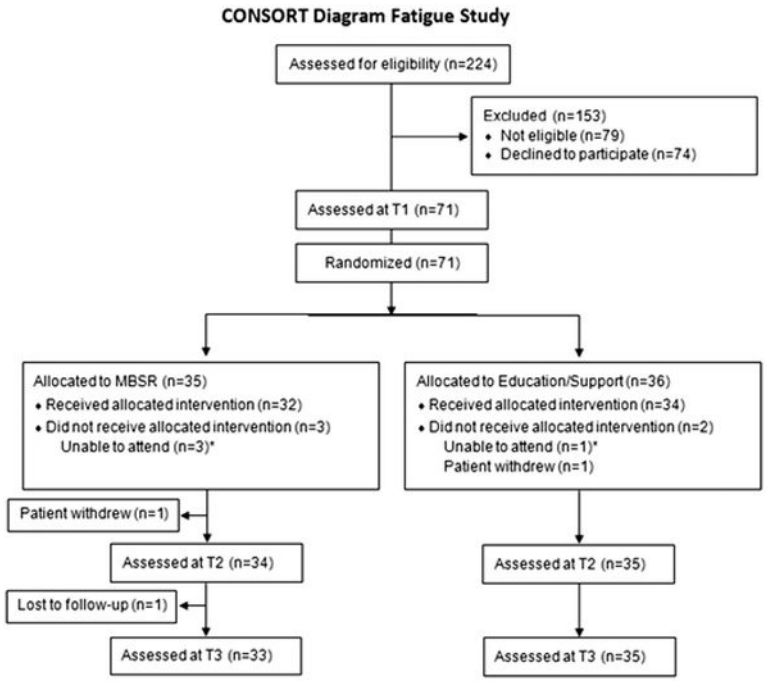


**Fig. 1.**
CONSORT diagram for trial accrual, intervention delivery, and data collection

**Table 1**

Description of Mindfulness-Based Stress Reduction Sessions

| | Session Theme | Meditation Exercises | Didactic Teaching | Home Practice |
|---|---|---|---|---|
| 1 | Awareness: Meeting ourselves where we are in honesty and kindness | • Body scan<br>• Brief mindful movement | • Introduction and guidelines<br>• Defining mindfulness<br>• Raisin exercise | • Body scan daily<br>• Eat one meal mindfully (handout provided)<br>• Mindfulness of one daily activity |
| 2 | Perception and creative responding: Wholeness no matter what is here | • Body scan<br>• Yoga<br>• Awareness of breath (AOB) sitting meditation | • Power of perception (with puzzles)<br>• Sleep and exercise<br>• Self-responsibility and health-related behaviors | • Alternate body scan and yoga daily<br>• Sit quietly 10 min daily with AOB<br>• Pleasant events calendar* <br>• Sleep hygiene handout and optional Arriving For Sleep practice |
| 3 | The pleasure and power of being present | • Yoga<br>• Sitting meditation | • Purposeful pauses<br>• Pleasant events reflection<br>• Science of exercise in cancer | • Alternate body scan and yoga daily<br>• Sit quietly 10 min daily with AOB<br>• Unpleasant events calendar* <br>• Reading with suggestions for increasing daily activity |
| 4 | Reacting on autopilot: mindfulness skills supporting healthy responsiveness | • Yoga with body scan<br>• Sitting meditation | • Stress reactivity (fight-or- flight response)<br>• Science of mindfulness, stress, and cancer | • Alternate body scan and yoga daily<br>• Unguided sitting meditation 10 min daily<br>• Stress reactivity calendar* |
| 5 | Creative ways of responding to stress | • Open awareness sitting meditation<br>• Yoga<br>• On-the-spot brief practice for use in times of stress | • New ways of responding to stress (topics from calendar including CRF)<br>• Emotion- and problem-focused coping reflection | • Sitting meditation, yoga, or body scan daily<br>• Problem- and emotion-focused coping handout<br>• Reading on mindful communication<br>• Communications calendar |
| 6 | Mindful communication; cultivating compassion; responsiveness in speech and action | • Open awareness sitting meditation<br>• Yoga<br>• Walking meditation | • Mindful listening and speaking exercise on topic of CRF<br>• Stress hardiness | • Sitting meditation, yoga, or body scan daily<br>• Guided lovingkindness practice<br>• Mind/body input reading |

| | Session Theme | Meditation Exercises | Didactic Teaching | Home Practice |
|---|---|---|---|---|
| | | • Lovingkindness practice | | |
| 7 | Taking care of yourself: Healthy living choices arising from practice | • Yoga<br>• Sitting meditation | • Mind/body input<br>• Reflection on what is nurturing/depleting | • Sitting meditation, yoga, or body scan without guidance daily<br>• Practice informally by pausing throughout the day<br>• Develop plan for continuing practice |
| 8 | The rest of your life: Making the practice your own | • Body scan<br>• Yoga<br>• Sitting meditation | • Review of the course; sharing of participant perspectives<br>• Continuing the practice & making it your own | • Mindfulness resources handout |

* "Calendars" are 2-page handouts facilitating brief daily journaling.

**Table 2**

Description of Psychoeducational Support Intervention Sessions

| | Session Theme | Didactic Teaching | Invited Sharing | Readings & Home Practice |
|---|---|---|---|---|
| 1 | Orientation | • Explain purpose of group<br>• Group guidelines<br>• Overview of 8 sessions<br>• Provision of FSI and scoring instructions to track CRF over time | • Experiences living with CRF | • Read “Fight Fatigue”<br>• Read ASCO handout on common side effects/late effects of treatment<br>• Complete FSI on regular basis to track CRF over time (optional) |
| 2 | Fatigue & Lingering Effects of Cancer | • CRF and other lingering and late effects of treatment<br>• Strategies for symptom management | • Steps taken to manage fatigue and related symptoms<br>• How symptoms have affected daily living | • Read “A Good Night’s Rest”<br>• Practice at least 1 strategy from “The Rules of Good Sleep Hygiene” |
| 3 | Restorative Sleep | • Sleep and sleep problems<br>• Relationship between sleep disturbance and CRF<br>• Sleep hygiene | • Factors that improve and interfere with sleep quality | • Read “Monitor Your Mood”<br>• Read ACS “Getting Help for Fatigue”<br>• Sleep problems survey (optional)<br>• Complete 7-night sleep log (optional) |
| 4 | Mood | • Common emotional responses to cancer, treatment, side effects, and survivorship<br>• Monitoring mood and distress triggers<br>• Strategies for improving moods | • How emotions have varied from diagnosis, through treatment, and during post-treatment survivorship<br>• Effective strategies for coping with difficult emotions | • Read “Nourishing Your Body”<br>• Keep food diary<br>• Notice patterns between intake and energy level |
| 5 | Nutrition | • Eating to maximize energy and maintain healthy weight (e.g., healthy food choices, eating small/frequent meals/snacks, adequate protein, limiting concentrated sweets, staying hydrated)<br>• Risks of eating in response to emotional triggers | • Patterns of food choices and the impact of daily activities and stress on these<br>• Challenging cultural and societal influences on food intake | • Read “Love and Be Loved” |

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| | Session Theme | Didactic Teaching | Invited Sharing | Readings & Home Practice |
|---|---|---|---|---|
| 6 | Relationships | • Impact of CRF on relationships<br>• Caring for others and oneself | • Positive and negative changes in relationships since cancer diagnosis<br>• New things learned about self and others while dealing with fatigue and other aspects of the cancer experience | • Read one article per day from *CURE* magazine |
| 7 | Exercise & Survivorship Care | • Link between lack of exercise and fatigue<br>• Review of evidence supporting exercise as an effective intervention for fatigue<br>• Starting and maintaining a safe exercise program<br>• Survivorship care plans<br>• Cancer surveillance | • Potential benefits of and barriers to increasing physical activity<br>• Being healthfully responsible for continued well-being as a cancer survivor | • Daily practice at least one skill learned from previous group sessions |
| 8 | Conclusion/Wrap-up | • Provision of clinical practice guidelines for CRF, with encouragement to discuss with medical team if fatigue persists<br>• Summary of key points of sessions<br>• Suggestions on how to maintain progress made during the course | • Discussion of what was most helpful/memorable and what each participant hopes to continue practicing<br>• Final comments and feedback about the group experience | |

*Note*. Abbreviations: FSI=Fatigue Symptom Inventory. CRF=cancer-related fatigue. ASCO=American Society of Clinical Oncology. ACS=American Cancer Society.

**Table 3**

Demographic and Medical Characteristics

| | MBSR n=35 | Education/Support n=36 | *p*-value |
|---|---|---|---|
| **Demographic Characteristics** | | | |
| Age, mean (SD) | 56.9 (9.9) | 56.4 (12.7) | 0.85 |
| Female, % | 94.3 | 86.1 | 0.43 |
| White, % | 77.1 | 63.9 | 0.22 |
| Married/Partnered, % | 62.9 | 47.2 | 0.19 |
| College degree, % | 42.9 | 44.4 | 0.89 |
| Employed, % | 51.4 | 52.8 | 0.91 |
| Comfortable income, % | 62.9 | 41.7 | 0.07 |
| **Medical Characteristics** | | | |
| Cancer type | | | 0.35 |
| Breast cancer, % | 51.7 | 48.3 | |
| Colorectal cancer, % | 36.4 | 63.6 | |
| Cancer stage at diagnosis, % | | | 0.75 |
| 0 | 12.8 | 5.3 | |
| I | 41.0 | 36.8 | |
| II | 20.5 | 23.7 | |
| III | 20.5 | 29.0 | |
| Years since cancer treatment completion, mean (SD) | 2.2 (1.4) | 2.5 (1.6) | 0.48 |
| Chemotherapy, % | 65.7 | 80.6 | 0.16 |
| Radiation, % | 80.0 | 75.0 | 0.61 |
| Chemo-radiation, % | 45.7 | 55.6 | 0.41 |
| Current endocrine therapy, % | 46.0 | 46.0 | 1.00 |
| Co-morbid medical conditions in addition to cancer, mean (SD) | 1.80 (1.5 ) | 1.7(1.2) | 0.75 |
| Current Mental Health Treatment, % | 17.1 | 22.2 | 0.59 |
| Past Mental Health Treatment, % | 25.7 | 41.7 | 0.16 |

*Note.* MBSR=Mindfulness-Based Stress Reduction. SD=standard deviation.

**Table 4**

Within-group and Between-group Fatigue Outcomes

| Fatigue Outcome | Within-Group Effects | | | | | | | | Between-Group Effects | |
|---|---|---|---|---|---|---|---|---|---|---|
| | MBSR (n=35)[1] | | | | Education/Support (n=36)[2] | | | | | |
| | Mean | (SD) | SRM | (95% CI) | Mean | (SD) | SRM | (95% CI) | d | (95% CI) |
| **FSI Fatigue Interference** | | | | | | | | | | |
| Baseline | 4.91 | (2.17) | | | 5.06 | (1.50) | | | | |
| Post-intervention | 2.63 | (1.97) | −1.07*** | (−1.42, −0.73) | 3.32 | (1.83) | −0.87*** | (−1.22, −0.53) | −0.46 | (−0.93, 0.01) |
| 6-Months Post | 3.16 | (2.31) | −0.76*** | (−1.11, −0.40) | 2.93 | (2.39) | −0.86*** | (−1.20, −0.52) | 0.21 | (−0.28, 0.69) |
| **FSI Fatigue Severity** | | | | | | | | | | |
| Baseline | 5.24 | (1.57) | | | 5.48 | (1.30) | | | | |
| Post-intervention | 3.79 | (1.81) | −0.71*** | (−1.06, −0.37) | 4.11 | (1.57) | −0.72*** | (−1.06, −0.37) | −0.14 | (−0.65, 0.38) |
| 6-Months Post | 4.17 | (2.26) | −0.51** | (−0.87, −0.16) | 3.78 | (1.84) | −0.81*** | (−1.16, −0.47) | 0.30 | (−0.19, 0.80) |
| **SF-36 Vitality** | | | | | | | | | | |
| Baseline | 30.54 | (15.81) | | | 33.33 | (13.77) | | | | |
| Post-intervention | 52.21 | (17.60) | 1.11*** | (0.77, 1.46) | 43.57 | (17.25) | 0.74*** | (0.40, 1.08) | 0.53** | (0.12, 0.94) |
| 6-Months Post | 49.05 | (21.32) | 0.98*** | (0.62, 1.33) | 46.79 | (19.79) | 0.91*** | (0.57, 1.26) | 0.27 | (−0.17, 0.71) |

*Note*. For within-group and between-group comparisons, post-intervention was compared to baseline and 6-months post was compared to baseline for each variable. Abbreviations: FSI=Fatigue Symptom Inventory. SD=standard deviation. SRM=standardized response mean. CI=confidence interval. d=Cohen's d effect size. Significant p-values are designated as follows:

* p < .05,

** p<.01,

*** p<.001

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**Table 5**

Within-group and Between-group Secondary Symptom Outcomes

| Fatigue Outcome | Within-Group Effects | | | | | | | | Between-Group Effects | |
|---|---|---|---|---|---|---|---|---|---|---|
| | MBSR (n = 35)[1] | | | | Education/Support (n = 36)[2] | | | | | |
| | Mean | (SD) | SRM | (95% CI) | Mean | (SD) | SRM | (95% CI) | d | (95% CI) |
| **Depression PHQ-8** | | | | | | | | | | |
| Baseline | 11.35 | (5.57) | | | 12.53 | (4.90) | | | | |
| Post-intervention | 6.27 | (3.90) | −1.05*** | (−1.40, −0.70) | 7.80 | (4.67) | −0.94*** | (−1.28, −0.59) | −0.27 | (−0.72, 0.18) |
| 6-Months Post | 6.55 | (4.67) | −0.98*** | (−1.33, −0.62) | 8.51 | (6.08) | −0.66*** | (−1.01, −0.32) | −0.16 | (−0.64, 0.31) |
| **Anxiety GAD-7** | | | | | | | | | | |
| Baseline | 7.47 | (5.50) | | | 8.57 | (5.31) | | | | |
| Post-intervention | 3.21 | (3.76) | −0.89*** | (−1.24, −0.55) | 5.28 | (4.27) | −0.85*** | (−1.20, −0.51) | −0.33 | (−0.73, 0.08) |
| 6-Months Post | 3.76 | (5.14) | −0.74*** | (−1.10, −0.39) | 5.69 | (6.11) | −0.63*** | (−0.97, −0.28) | −0.07 | (−0.47, 0.34) |
| **Sleep Disturbance ISI** | | | | | | | | | | |
| Baseline | 15.34 | (6.45) | | | 17.33 | (6.27) | | | | |
| Post-intervention | 10.82 | (5.74) | −0.93*** | −1.27, −0.58) | 12.31 | (5.04) | −1.16*** | (−1.50, −0.81) | −0.10 | (−0.44, 0.25) |
| 6-Months Post | 9.45 | (6.01) | −0.94*** | (−1.29, −0.58) | 12.10 | (6.84) | −0.83*** | (−1.18, −0.49) | −0.20 | (−0.65, 0.26) |
| **Pain PEG** | | | | | | | | | | |
| Baseline | 3.95 | (3.09) | | | 3.43 | (2.80) | | | | |
| Post-intervention | 2.10 | (2.07) | −0.77*** | (−1.12, −0.42) | 2.73 | (2.44) | −0.27 | (−0.62, 0.07) | −0.50* | (−0.90, −0.10) |
| 6-Months Post | 2.56 | (3.00) | −0.53** | (−0.88, −0.17) | 2.37 | (2.68) | −0.38* | (−0.73, −0.04) | 0.08 | (−0.36, 0.51) |

*Note*. For within-group and between-group comparisons, post-intervention was compared to baseline and 6-months post was compared to baseline for each variable. Abbreviations: PHQ-8 = 8-item Patient Health Questionnaire depression scale (range, 0–24). GAD-7 = 7-item Generalized Anxiety Disorder anxiety scale (range, 0–21). ISI = Insomnia Severity Index (range, 0–28). PEG = 3-item abbreviated version of Brief Pain Inventory (range 0–10). SD=standard deviation. SRM= standardized response mean. CI=confidence interval. d=Cohen's d effect size. Significant p-values are designated as follows:

* p<.05,

** p<.01,

*** p<.001