Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer

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Abstract

Objectives: Considerable morbidity persists among survivors of breast cancer (BC) including high levels of psychological stress, anxiety, depression, fear of recurrence, and physical symptoms including pain, fatigue, and sleep disturbances, and impaired quality of life. Effective interventions are needed during this difficult transitional period.

Methods: We conducted a randomized controlled trial of 84 female BC survivors (Stages 0–III) recruited from the H. Lee Moffitt Cancer and Research Institute. All subjects were within 18 months of treatment completion with surgery and adjuvant radiation and/or chemotherapy. Subjects were randomly assigned to a 6-week Mindfulness-Based Stress Reduction (MBSR) program designed to self-regulate arousal to stressful circumstances or symptoms ($n = 41$) or to usual care ($n = 43$). Outcome measures compared at 6 weeks by random assignment included validated measures of psychological status (depression, anxiety, perceived stress, fear of recurrence, optimism, social support) and psychological and physical subscales of quality of life (SF-36).

Results: Compared with usual care, subjects assigned to MBSR(BC) had significantly lower (two-sided $p < 0.05$) adjusted mean levels of depression (6.3 vs 9.6), anxiety (28.3 vs 33.0), and fear of recurrence (9.3 vs 11.6) at 6 weeks, along with higher energy (53.5 vs 49.2), physical functioning (50.1 vs 47.0), and physical role functioning (49.1 vs 42.8). In stratified analyses, subjects more compliant with MBSR tended to experience greater improvements in measures of energy and physical functioning.

Conclusions: Among BC survivors within 18 months of treatment completion, a 6-week MBSR(BC) program resulted in significant improvements in psychological status and quality of life compared with usual care.
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Keywords: breast cancer; oncology; mindfulness-based stress therapy

Introduction

Breast cancer (BC) is a major health problem accounting for 182 460 of all cancer cases in the United States among women [1]. The 5-year survival rate for all stages of BC is 89% and varies by race [1]. After treatment ends for BC, survivors continue to report high levels of psychological stress, anxiety, depression, fear of recurrence, residual physical symptoms of pain, fatigue, and sleep dysfunction, and impaired quality of life [2,3]. Despite this significant morbidity, only a limited number of studies have tested interventions during the difficult transitional period of post-treatment survivorship. Instead, the majority of intervention studies have been designed to decrease distress and improve physical and psychological functioning among BC patients *while on treatment or at diagnosis*. Briefly, the primary types of interventions evaluated have included telephone counseling, face to face and peer cognitive therapy, group intervention education counseling, and short-term support [4–9].

The limited number of interventions designed for distress in *post-treatment survivorship* have included: short-term socio-education [10]; combined stress management, psycho-education, and physical activity [11]; various psycho-educational materials [12]; education and nutrition support [13]; telephone-delivered cognitive-behavioral strategies

[14]; self-management skills programs [15]; peer counseling programs [16]; supportive-expressive group therapy [17]; and cognitive behavioral therapy [18–20]. In general, these studies have focused on a limited number of patient outcomes, and in aggregate, have shown that the various interventions may be effective in reducing fatigue, sleep disturbance, depression, anxiety, and emotional distress at large, while improving coping skills, physical functioning, and quality of life.

In addition to conventional educational counseling and cognitive behavioral interventions, several recent studies have examined the use of complementary and alternative medicine (CAM) therapies among BC survivors. This is due, in part, to the increasing use of CAM among cancer patients. Specifically, Lengacher and colleagues [21] estimated that 64–86% of women with BC used some form of CAM interventions with the most frequent reason for such use to reduce psychological distress [22]. Similarly, research in CAM use by BC survivors showed an increase from 66.7 % in 1998 to 81.9% in 2005 with visits to CAM practitioners also increasing from 39.4% in 1998 to 57.4% in 2005 [23]. Among the different types of CAM, use of acupuncture, music therapy, and cognitive behavior therapy have shown relief of symptoms of pain and vomiting in BC patients [24–28]. Nonetheless, very few CAM studies have been published during the survivorship period. Among the few, use of an imagery intervention showed improvements in depression, stress and anxiety [29], and use of guided imagery improved stress, coping, and quality of life [30].

One particularly promising type of CAM is Mindfulness-Based Stress Reduction (MBSR), a standardized form of meditation and yoga. Briefly, MBSR has been shown to be effective in reducing anxiety [31,32], depression [33], and stress in patients with chronic pain [34]. Among BC patients, limited data suggest that MBSR may decrease mood disturbances and stress [35] and significantly improve sleep quality [36]. However, there are no known published randomized trials on the use of MBSR among women with BC during the *critical transition period* from end of treatment to resuming normal daily life activities as a cancer survivor.

Therefore, on the basis of these MBSR observations and the Evans' logic model [37], a heuristic device for psychosocial nursing research, we postulated that the clinical utility of MBSR would extend to improved psychological and physical symptoms and quality of life among BC patients during the survivorship period. Thus, we conducted a randomized controlled clinical trial designed to: (i) determine whether an MBSR intervention compared with usual care is efficacious in improving psychological and physical status in BC survivors; and (ii) whether such favorable effects are modified by the extent of compliance with the MBSR(BC) program.

Methods

Sample and setting

A total of 84 women aged 21 or older previously diagnosed with Stage 0, I, II, or III BC who underwent surgery and received adjuvant radiation and/or chemotherapy were recruited from the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida. Recruitment for the study was initiated on March 1, 2006, and data collection ended on July 23, 2007. All subjects had to have completed treatment within the prior 18 months and had to be able to read and speak English at the eighth grade level, as judged by their ability to complete a battery of self-report measures (see Instruments and Outcome Measures). Exclusion criteria included Stage IV BC, prophylactic mastectomy prior to the current treatment for BC, severe psychiatric diagnosis (e.g. bipolar disorder), and treatment for recurrent BC. All subjects provided written informed consent, and the study protocol was approved by Institutional Review Boards at the University of South Florida and H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida. Subjects received $50 at the beginning and $50 at the completion of the study.

Study design and random assignment

A two-armed randomized controlled design was used with randomization stratified by stage of cancer (0, I, II, and III) and treatment received (radiation alone vs. radiation+chemotherapy). Consenting subjects were randomly assigned in a 1:1 ratio to either an MBSR(BC) intervention program or a usual care group. The usual care group was waitlisted to receive the MBSR(BC) intervention (if desired) after 6 weeks of followup from the time of randomization.

Data collection procedures

Assessments were completed at an initial baseline orientation and within 2 weeks at the end of the 6-week intervention or control period. One week before MBSR classes started, a baseline orientation was held. At this session, informed consent was obtained, baseline data were collected, and a brief overview of the MBSR(BC) program was provided which highlighted the 6-week class schedule. At the end of this session, subjects were notified of their random assignment. Thus, although patients were not blinded to treatment group, data collectors were blinded to treatment assignment when the baseline data were collected.

MBSR(BC) intervention

Forty-one subjects assigned to the MBSR(BC) group received weekly 2-hour sessions conducted by a psychologist certified and trained in MBSR. Class sizes ranged from four to eight with seven groups in total completing the sessions over 15 months. All the sessions were standardized and followed the training manual developed to maintain consistency in the program. A single trained psychologist delivered the intervention. In addition, an independent observer monitored the weekly sessions for consistency by recording the timing of the intervention activities, and the quality of each session was assessed in a qualitative post-observation report. Subjects received a training manual and four audiotapes to support home practice of various forms of meditation practices (sitting meditation, body scan, and walking meditation) and gentle yoga. The training manual included weekly objectives, exercises, and program content related to the content identified below. In addition, the manual included the daily diary for recording homework practice activities.

The original 8-week MBSR program, developed by Kabat-Zinn, trains subjects to reduce their perceived level of stress by self-regulating arousal to stressful circumstances or symptoms [31,34]. The MBSR(BC) intervention is a 6-week program adapted for consideration of the BC survivors' health status. At the beginning of each week, time was provided for participants to discuss their experience with the homework, thus enhancing group interaction. More specifically, during week 1, participants were given an overview of the intervention to establish a learning contract and to learn initial meditation and body scan procedures. In week 2, participants learned visualization and were introduced to sitting meditation with awareness of breathing as primary object of attention. During week 3, participants gained an understanding of one's reaction to a pleasant event, body scan with response to stress, introduction of yoga postures, and how physiological correlates. Week 4 was similar to week 3 substituting gaining an understanding of one's reaction to unpleasant rather than pleasant events. During week 5, participants expanded their field of awareness to allow for modification of stress inducing patterns, and continued to monitor their awareness to allow for modification of stress inducing patterns, such as mountain meditation/and or lake meditation; awareness was expanded to include objects such as bodily sensations, sounds, thoughts, and feelings. In the final week 6, participants were encouraged to internalize practice sessions and develop for themselves a pattern. Participants were told that week 6 is the first week of being on their own and to develop a lifetime program with the emphasis that meditation is a means to access wellness.

This modified intervention provides for management of specific emotional/psychological symptoms (anxiety, depression, and fear of recurrence) and physical symptoms, such as pain and sleep. Through the use of meditation practices (sitting meditation, body scan and walking meditation) and yoga, subjects are taught to increase awareness of their thoughts and feelings and to observe their emotional and physical responses during stressful situations [34,38]. Through the process of mindful attention, subjects take an active role in regulating their stress and managing symptoms and emotions, thus enabling them to cope better with the distress of having cancer. Administratively, the intervention has three specific components: (1) educational material related to relaxation, meditation, and the mind-body connection; (2) practice of meditation in group meetings and homework assignments; and (3) discussion among group members related to barriers to practicing meditation, application of mindfulness in daily situations, and group support.

Throughout the 6-week MBSR(BC) program, all subjects were requested to formally meditate (sitting, walking, and body scan exercises) and perform yoga exercises for a minimum of 15–45 min per day, 6 days per week; this time increased per week as participants became more experienced. They were also asked to informally practice 15–45 min per day. Daily practice was recorded in a diary each day. Indicators of MBSR(BC) 'compliance' were established *a priori* as $\geqslant 75\%$ attendance at the MBSR(BC) sessions and completion of $\geqslant 75\%$ of the homework assigned based on a minimum of 45 min practiced each day. The total number of minutes/hours practiced over the 6-week program was also assessed.

Usual care regimen

For subjects randomized to usual care (waitlisted control group), the MBSR(BC) intervention was offered after the initial 6-week study period. These subjects did not attend the MBSR(BC) classes but did continue to have standard post-treatment clinic visits with their practitioner, which varied depending on the subject's treatment plan. Also, to avoid possible overlap (contamination) with components of the MBSR program, the investigators specifically asked subjects in the waitlisted control group not to use or practice meditation, yoga techniques, or MBSR during the study. After completion of the study, each usual care subject was provided with a brief orientation to MBSR(BC), a manual on the program, four CDs for practice, and a schedule of optional classes to be held within 5 months of the post assessment.

Instruments and outcome measures

Measures of health status before and at the end of the study (6 weeks) included psychological status and quality of life subscales of physical and emotional health. Self-reported psychological measurements included the following: (1) fear of recurrence (cancer) measured by the 30-item Concerns about Recurrence Scale which measures the extent and nature of women's fears about the possibility of BC recurrence (a higher score indicates more fear) [39]; (2) state and trait anxiety measured by the State-Trait Anxiety Inventory a two 20-item instrument which measures both state anxiety (present anxiety) and trait anxiety (long-term characteristic anxiety); higher scores are indicative of more anxiety [40]; (3) depressive symptoms were measured by the 20-item Center for Epidemiological Studies Depression Scale; higher scores indicate more depressive symptoms [41]; (4) optimism was measured by the 6-item Life Orientation Test, which assesses expectancy for positive and negative life outcomes, higher scores indicate better optimism [42]; and (5) perceived stress was measured by the 10-item Perceived Stress Scale which assesses 'how often in the past month one appraises life situations as stressful'; higher scores indicate more stress [43]. Quality of life was measured by the Medical Outcomes Studies Short-form General Health Survey which measures Physical Functioning, Physical Role Functioning, Bodily Pain, General Health, Vitality, Social Functioning, Emotional Role Functioning and Mental Health; higher scores indicate better quality of life, i.e. better physical functioning, no problems with daily activities, no limitations due to pain, excellent personal health, high energy, normal social activity, no problems due to emotional distress, and feeling peaceful, calm and happy all the time [44]. Social support was measured by the 19-item Medical Outcomes Social Support Survey which measures tangible, affectionate, positive social interactions, and emotional or informational support; higher scores are indicative of more social support [45]. Spirituality was measured by two Likert-scaled items widely used in epidemiological research to assesses the degree of spirituality, strength, and comfort derived from religion; higher scores indicate greater spirituality [46,47]; Self-reported indicators of individual residual symptoms were measured by the M. D. Anderson Symptom Inventory (results not reported herein). Finally, standard demographic data were collected along with a detailed clinical history form completed by self-report and chart review to document prior medical history, lifestyle behaviors (e.g. smoking and exercise), and concomitant medication use. For this analysis, all measures of physical and psychological status were treated as co-equal outcomes.

Statistical methods

The intent to treat principle was used for all analyses. Baseline data were compared between the two groups by use of chi-square tests for categorical variables and Student t or Wilcoxon tests for continuous variables. Although no significant differences (at $p < 0.05$) existed between the groups, based on distributions, demographic characteristics of age, black race, stage of cancer, and time since cancer treatment completion were sufficiently different to warrant use as covariates in all multivariable models to minimize potential confounding. Analysis of covariance (ANCOVA) was used to assess whether MBSR favorably influenced baseline to 6-week changes in physical and psychological status and quality of life. This included calculation of adjusted mean scores.

In secondary analyses, general linear models were developed to compare outcomes between three groups of subjects: MBSR 'compliers', MBSR 'non-compliers', and the waitlisted control group. As with the initial ANCOVA analyses, adjusted mean scores on outcome measures were compared across the three groups. Similarly, Pearson correlation coefficients were calculated to assess the strength of association between the number of minutes practiced for individual components of the MBSR(BC) intervention, and physical and psychological status and quality of life.

Statistical power

An *a priori* target sample of 90 subjects provided 80% power (two-sided type I error rate of 0.05) to detect a modest effect size (i.e. differences in means of the two treatment groups/standard deviation) [48] of 0.60 or higher. The final study sample of 82 subjects with baseline and 6-week data (see below) corresponds to a detectable effect size of 0.63 or higher. As stated above, all measures of physical and psychological status were treated as co-equal outcomes and no correction procedure was used for multiple comparisons.

Results

Subjects

Of the 84 subjects enrolled in the study, 82 (97.6%) completed both the baseline and 6-week assessments. Figure 1 provides an overview of the numbers of subjects screened, randomized, and retained. Six of the seven groups followed protocol with six class sessions; one group completed all of the training in five rather than six sessions due to a tropical storm predicted to hit the area on the scheduled meeting day. Of the seven groups, three
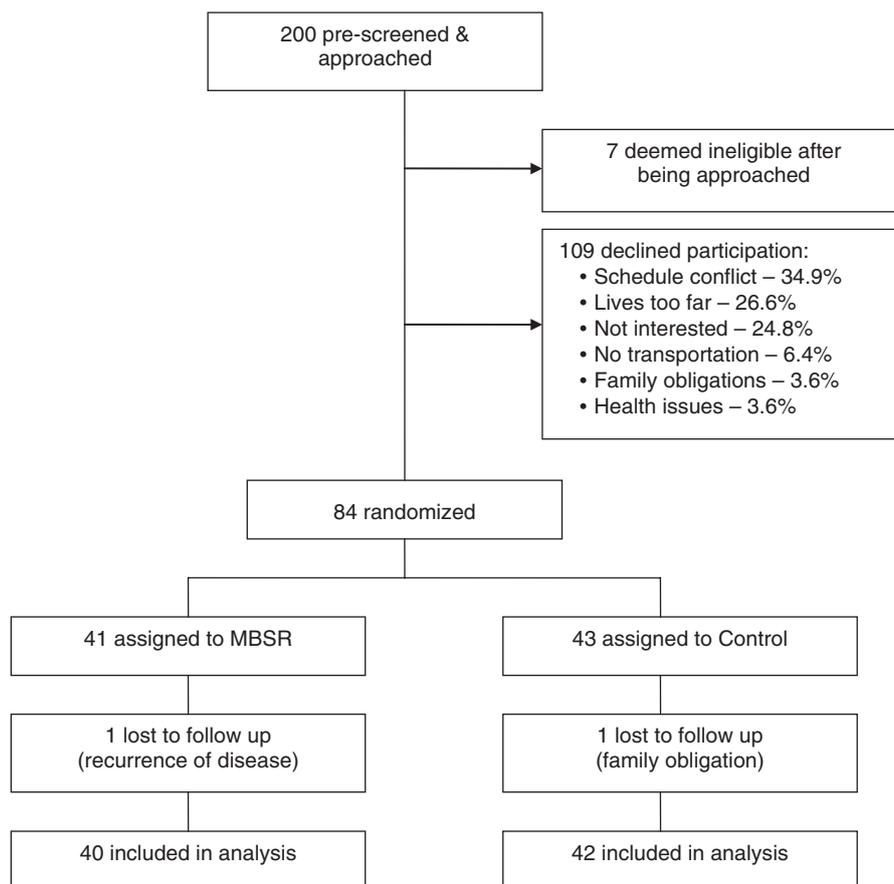
Figure 1. Flowchart showing recruitment and enrollment of 84 subjects into the trial, of whom 82 completed the study and were included in outcome analyses

varied from protocol by having less than six patients per group attending the sessions.

Demographics

The two treatment arms were generally similar on baseline characteristics, with the notable exception of Blacks being more often assigned to the usual care regimen vs. MBSR (18.6% vs 4.9%, $p = 0.05$) (Table 1). The mean age of study patients was 57.5 ± 9.4 years. Most patients (70%) had Stage 0 or I cancer, whereas 30% had Stage II or III, and 39% had received chemotherapy in combination with radiation therapy. Hypertension was present in 30% of all subjects, diabetes in 10%, and 25% of all subjects were taking anti-depressive medications at study entry. The mean number of weeks from treatment completion to study entry was 19 ± 17 indicating that subjects were, in fact, enrolled during the 18-month post-treatment survivorship period.

Efficacy

Subjects randomized to the MBSR(BC) group showed significantly lower (better) adjusted mean scores at 6 weeks compared with the waitlisted control group on psychological outcomes of fear of recurrence (9.3 vs 11.6, $p = 0.007$), recurrence

concerns (26.7 vs 36.5, $p = 0.01$), state anxiety (28.3 vs 33.0, $p = 0.03$), trait anxiety (30.4 vs 34.5, $p = 0.004$), and symptoms of depression (6.3 vs 9.6, $p = 0.03$) (Table 2, Figure 2). Similarly, subjects assigned to the MBSR(BC) intervention showed higher (better) adjusted mean quality of life scores at 6 weeks including physical functioning (50.1 vs 47.0, $p = 0.01$), role limitations related to physical health (49.1 vs 42.8, $p = 0.03$), and energy (53.5 vs 49.2, $p = 0.02$) (Table 2, Figure 3). At 6-week followup, adjusted means scores for the MBSR group exceeded the population norm value of 50 for six of the eight SF-36 subscales compared with only three of eight subscales for the waitlisted control group (Figure 3). However, adjusted mean scores at 6 weeks for social support, perceived stress, optimism, and spirituality did not differ significantly by treatment assignment.

Compliance

Compliance with MBSR(BC) was assessed by the number of classes attended, completion of diaries, and minutes practiced. Of the 40 MBSR-assigned subjects who completed the program, 34 (85%) attended at least 75% of the classes, 39 (97.5%) recorded their practice times in a daily diary, and 28 (70%) were classified as compliant. Participants

Table 1. Baseline characteristics by random assignment

Characteristic	Total (*N* = 84)	Usual care (*N* = 43)	MBSR (*N* = 41)	*p*-Value
Age, %				
<55	39.3	34.9	43.9	0.08
55–64	33.3	44.2	22	
65 or older	27.4	20.9	34.1	
Race/ethnicity, %				
White, non-Hispanic	72.6	72.1	73.2	0.05
White, Hispanic	10.7	7	14.6	
Black, non-Hispanic	11.9	18.6	4.9	
Ashkenazi Jewish	2.4	2.3	2.4	
White, NH and Nat American	2.4	0	4.9	
Educational status, %				
High school or less	21.4	20.9	22	0.97
Some college	33.3	32.6	34.1	
College or professional degree	45.2	46.5	43.9	
Employment status, %				
Employed	56.0	51.2	61	0.64
Retired	23.8	25.6	22	
Other	20.2	23.3	17.1	
Stage of disease, %				
Stage 0	16.7	20.9	12.2	0.32
Stage I	53.6	44.2	63.4	
Stage II	22.6	27.9	17.1	
Stage III	7.1	7	7.3	
Stratification Group, %				
Stage 0 with radiation	16.7	20.9	12.2	0.71
Stage I/II with radiation	44	39.5	48.8	
Stage I/II w/radiation and chemo	32.1	32.6	31.7	
Stage III w/radiation and chemo	7.1	7	7.3	
Treatment type, %				
Radiation only	60.7	60.5	61	0.96
Radiation and chemo	39.3	39.5	39	
Co-morbidities %				
Diabetes	9.5	11.6	7.3	0.71
Asthma	3.6	4.7	2.4	1.00
Hypertension	29.8	25.6	34.2	0.48
Cardiovascular problems	2.4	2.3	2.4	1.00
Medications				
Depression	25	27.9	22	0.52
Anxiolytics	14.3	11.6	17.1	0.54
♯ weeks from end of treatment to study start (mean ± SD)	18.8 ± 17.4	17.6 ± 17.3	20.1 ± 17.1	0.44

in the MBSR(BC) group practiced an average of 1077 ± 691 min (18.0 ± 11.5 h) over the full intervention period. As seen in Table 3, adjusted 6-week scores on psychological measures of fear of recurrence, trait anxiety, and depression were lower (better) in all MBSR(BC) subjects compared with the waitlisted control group irrespective of compliance status. On the other hand, being 'compliant' with the MBSR(BC) intervention was associated with higher (better) adjusted 6-week quality of life scores for bodily pain, energy, physical functioning, and aggregate physical health.

Table 4 shows results of the relationships between hours of MBSR(BC) practiced and baseline to 6-week changes in psychological status and quality of life. As seen, subjects in the MBSR(BC) intervention who practiced more tended to have larger reductions in perceived stress ($r = 0.33$, $p = 0.04$) and improvements in physical function-ing, pain, and emotional well-being. Unexpectedly, there was an inverse relationship between minutes practiced and positive change in optimism. Among the individual types of mindfulness practice, total minutes of sitting meditation and body scan were significantly related to positive changes in several measures of psychological status and quality of life. Similarly, minutes of walking meditation were associated with positive changes in fear of recurrence and physical functioning. In contrast, the total number of minutes of yoga practiced was not significantly related to positive changes in psychological status or quality of life.

Discussion

Results from this first clinical trial indicate that MBSR(BC) is a beneficial stress-reducing intervention and that BC survivors are willing to participate

Table 2. Adjusted[a] Mean scores on social support, psychological, and quality of life measures at 6 weeks by random assignment

Measure	N	Usual care group (N = 42)			MBSR group (N = 40)			p-Value
		Mean	95% C.I.		Mean	95% C.I.		
			Lower	Upper		Lower	Upper	
Social support and spirituality[b]								
MOSS:emotional/informational support	82	34.5	33.1	36.0	33.0	31.5	34.5	0.16
MOSS:affectionate support	82	13.4	12.9	14.0	13.2	12.6	13.8	0.56
MOSS:positive social interaction	82	12.8	12.2	13.3	12.4	11.8	13.0	0.39
MOSS:tangible support	82	16.2	15.4	17.0	15.8	15.0	16.7	0.58
Spirituality	82	7.6	7.1	8.1	7.5	7.0	8.0	0.83
Strength derived from religion	81	2.5	2.3	2.6	2.6	2.4	2.7	0.45
Psychological[c]								
Overall concerns about recurrence	82	11.6	10.5	12.7	9.3	8.2	10.5	0.007
Problems from recurrence concerns	82	36.5	31.3	41.7	26.7	21.4	32.1	0.01
State anxiety	82	33.0	30.2	35.9	28.3	25.5	31.2	0.03
Trait anxiety	82	34.5	33.6	37.3	30.4	28.4	32.3	0.004
Depression (CESD)	82	9.6	7.6	11.6	6.3	4.2	8.3	0.03
Life orientation (LOT)	82	44.9	42.6	47.2	46.7	44.3	49.1	0.29
Perceived stress	82	14.4	13.0	16.0	12.6	11.1	14.2	0.10
Quality of life[d]								
Physical functioning	82	47.0	45.4	48.7	50.1	48.4	51.8	0.01
Role limitations—physical health	82	42.8	39.0	46.6	49.1	45.2	53.0	0.03
Pain	82	50.3	48.4	52.2	52.3	50.4	54.3	0.15
General health	82	50.9	49.2	52.6	52.4	50.7	54.2	0.22
Energy	82	49.2	46.8	51.7	53.5	51.0	56.0	0.02
Social functioning	82	49.3	47.2	51.4	51.3	49.1	53.4	0.20
Role limitations—emotional problems	82	46.1	41.9	50.3	49.8	45.5	54.2	0.23
Emotional well-being	82	51.6	49.5	53.6	54.1	52.0	56.2	0.10
Aggregate physical health	82	46.9	44.7	49.2	50.3	47.9	52.6	0.05
Aggregate mental health	82	50.1	47.0	53.3	53.0	49.8	56.2	0.22

[a]Adjusted for score at study entry, age, black race, stage of cancer, and time since treatment completion.
[b]Higher scores represent higher social support/spirituality.
[c]Lower scores represent better psychological status except for optimism (LOT) in which a higher score represents being more optimistic.
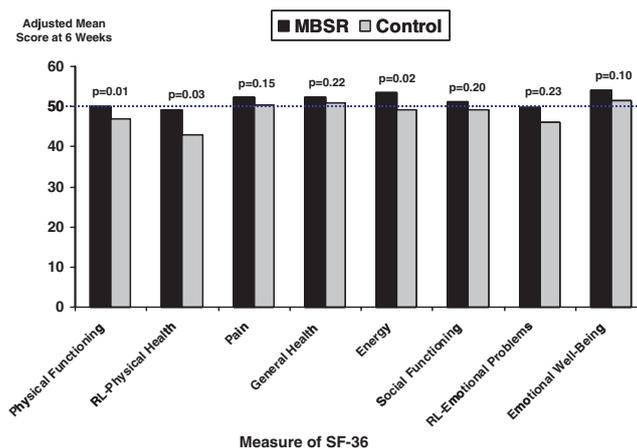[d]Higher scores represent better quality of life; scores are normed to the general population (mean value of 50).
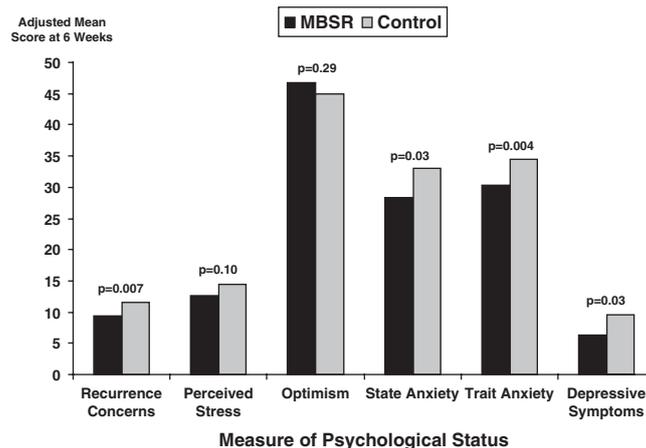
Figure 2. Comparison of MBSR Group to Control group at 6 weeks for psychological status variables. The scores at 6 weeks are adjusted for psychological score at study entry, age, black race, stage of cancer, and time since treatment completion. Lower scores represent better psychological status except for optimism (LOT) in which a higher score represents being more optimistic

in this type of program as evidenced by 84 of the 200 patients (42%) who were approached and consented to the trial. Favorable effects from MBSR(BC) among BC survivors included significantly reduced symptoms of depression, anxiety, fear of recurrence (of cancer), and improved indicators of physical and emotional quality of life. This is the first study we are aware of to examine and show significant reductions in fear of recurrence (of cancer) associated with MBSR. Importantly, fear of recurrence remains prominent over time with 70% of cancer survivors continuing

Figure 3. Comparison of MBSR group to control group at 6 weeks for SF-36 scores. The scores at 6 weeks are adjusted for SF-36 score at study entry, age, black race, stage of cancer, and time since treatment completion. Higher scores represent better quality of life; scores are normed to the general population (mean value of 50 as indicated by the dotted horizontal line). RL: Role limitations

Table 3. Adjusted[a] Mean scores on psychological, and quality of life measures at 6 weeks by random assignment and MBSR treatment compliance

Measure	MBSR(BC)[b]		Control	p-Value
	Non-compliers	Compliers	N = 42	
	N = 12	N = 28		
Psychological[c]				
Fear of recurrence	9.3	9.3	11.6	0.03
Recurrence concerns	9.4	9.7	11.3	0.23
State anxiety	29.3	27.9	33.1	0.08
Trait anxiety	30.5	30.2	35.4	0.002
Depression (CESD)	4.1	7.2	9.5	0.03
Life orientation (LOT)	48.0	46.1	44.9	0.45
Perceived stress	13.6	12.2	14.5	0.29
Quality of life[d]				
Physical functioning	48.2	50.9	47.0	0.02
Role limitations—physical health	41.5	52.3	42.7	0.004
Pain	49.5	53.5	50.3	0.06
General health	50.8	53.2	50.9	0.22
Energy	51.1	54.5	49.2	0.03
Social functioning	53.2	50.4	49.3	0.22
Role limitations—emotional problems	50.5	49.5	46.1	0.47
Emotional well-being	56.2	53.1	51.6	0.10
Aggregate physical health	44.3	52.9	46.8	0.0005
Aggregate mental health	55.5	51.9	50.2	0.29

[a]Adjusted for score at study entry, age, black race, stage of cancer, and time since treatment completion.
[b]Compliance was defined as completion of ⩾75% of class sessions ⩾75% of homework assignments completed.
[c]Lower scores represent better psychological status except for optimism (LOT) in which a higher score represents being more optimistic.
[d]Higher scores represent better quality of life; scores are normed to the general population (mean value of 50).

to have such fears after 5 years [49]. These fears are associated with considerable psychological distress influenced by both family-related and individual (e.g. treatment experience) concerns [50].

Our findings of improved psychological status are consistent with Speca *et al.* [35] who reported that use of MBSR in a heterogeneous group of cancer patients was associated with significant reductions in mood disturbance, depression, anxiety, and anger, as well as fewer symptoms of stress. A followup study [51] combined the MBSR intervention and waitlisted control groups and followed them for 6 months after MBSR. Results showed that improvements in depression, anxiety, and anger were maintained over time. Since we did not follow our cohort long term, we could not assess whether initial significant improvements in psychological status due to MBSR(BC) are sustained by BC survivors over time.

Table 4. Pearson R-correlation coefficients between hours practiced and differences from baseline to 6 weeks in 40 participants in the MBSR group

Difference scores baseline to 6 weeks[a]	Total hours of mindfulness practice	Individual mindfulness practices			
		Yoga	Body scan	Walking meditation	Sitting meditation
Psychological					
Overall concerns about recurrence	0.08	0.01	−0.05	0.37*	−0.09
Problems from recurrence concerns	0.13	0.03	0.07	0.27	0.00
State anxiety	0.09	−0.10	0.15	−0.02	0.013
Trait anxiety	0.28	−0.03	0.37*	−0.04	0.35*
Depression (CESD)	0.23	−0.12	0.35*	0.01	0.28
Life Orientation (LOT)	−0.32*	−0.04	−0.12	−0.38*	−0.22
Perceived stress	0.33*	−0.09	0.34*	0.16	0.34*
Quality of life					
Physical functioning	0.45**	0.001	0.31	0.33*	0.42***
Role limitations–physical health	0.31*	0.06	0.25	0.13	0.31
Pain	0.38*	0.18	0.29	0.26	0.27
General health	0.22	0.02	0.10	0.20	0.20
Energy	0.27	0.08	0.30	0.02	0.27
Social functioning	0.18	0.00	0.23	0.11	0.12
Role limitations–emotional problems	0.34*	−0.12	0.31	0.18	0.38*
Emotional well-being	0.33*	−0.07	0.43***	0.14	0.31*
Aggregate physical health	0.22	0.15	0.33	0.14	0.17
Aggregate mental health	0.28	−0.10	0.31*	0.11	0.31

[a]Positive correlation coefficients indicate that an increase in practice is associated with a positive change in the relevant outcome. Negative correlation coefficients show that increase in practice is associated with a negative change in outcome.
*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

Quality of life is also an important outcome in studies of MBSR. Our findings that MBSR(BC) improves physical and emotional quality of life in BC survivors are consistent with Carlson et al. [52,53] who evaluated 49 BC and 10 prostate cancer patients and found significant improvements in overall quality of life and symptoms of stress and sleep quality.

In addition, our findings are consistent with non-randomized studies showing favorable effects from MBSR in diverse medical settings including treatment of anxiety disorders [31,32], fatigue, and chronic pain [34,38]. Thus, on balance, MBSR appears to be beneficial in a variety of medical settings among both cancer and non-cancer patients, with our findings extending to women who have recently transitioned from completion of BC treatment to resuming normal daily life activities necessary as a cancer survivor.

In terms of mechanisms of efficacy, the MBSR(BC) program provides supportive interaction between group members to practice meditation and apply mindfulness in daily situations. Such supportive interaction alone may be expected to yield positive health effects. Our study did not include an 'attention only' or 'support group' as a separate control group, yet we examined perceived social support in all subjects and found no appreciable differences between the two randomized groups. Therefore, while not definitive, these data suggest that the favorable health effects associated with MBSR(BC) are not simply due to greater social support associated with participation in the program.

Compliance

We observed that BC survivors are able to comply with complex stress-reducing interventions, such as MBSR(BC). Of the 84 participants in the full trial, virtually all (irrespective of random assignment) completed the full 6-week program following an orientation session. Moreover, using a relatively strict definition of compliance with the MBSR program, 70% of the MBSR subjects were considered compliant. These data indicate that, with considerable administrative effort (i.e. instructors, class scheduling), MBSR programs are feasible to implement to BC patients who have recently completed treatment and remain in need of symptom management.

While limited by sample size, our results using a binary definition of 'compliant' with the MBSR(BC) program and its effectiveness were mixed: compliers with MBSR(BC) had better quality of life scores for bodily pain, energy, and physical functioning, whereas psychological status was significantly improved in the MBSR(BC) group irrespective of compliance status. The latter results are seemingly at odds with Speca et al. [35] who reported that the best predictor of improvement in measures of psychological status among cancer patients was the amount of time spent in meditation. Similarly, a randomized study among Stage II BC patients with high levels of cancer anxiety [54] reported that the amount of time practicing the stress-reducing intervention

predicted sleep efficiency. Carlson *et al.* [51] also found that total minutes practiced improved mood disturbance. In our study, using total minutes of practice as a measure of compliance (rather than our primary binary definition), MBSR(BC) subjects who practiced more had significant reductions in perceived stress and improvements in optimism, physical functioning, pain, and emotional well-being. Collectively, these findings suggest that compliance is indeed a significant predictor of benefit achieved from MBSR when measured on a continuous scale in terms of number of hours/ minutes practiced.

A novel aspect of our study was the assessment of outcomes among the MBSR(BC) group by the number of minutes practiced for individual components of the program. We generally found that greater practice in all components of the MBSR(BC) program was beneficial, yet practicing sitting meditation and body scan seemed to confer the greatest benefit and practicing yoga the least benefit. These data reaffirm the notion that simply attending MBSR(BC) classes is likely to result in limited therapeutic benefit as opposed to consistent practice of the basic tenets of MBSR. This postulate is consistent with Shapiro *et al.* [36] who reported that greater practice significantly improved sleep quality, as well as Speca *et al.* who found that the amount of minutes practiced predicted mood improvement whereas attendance alone did not [35]. Thus, successful implementation of the MBSR(BC) intervention requires strong emphasis on the need for practice (outside of class) at the start of the MBSR(BC) program, as well as interim reinforcement.

Limitations

This clinical trial was limited by a modest sample size, reliance on self-reported outcomes by validated measures, limited followup (6-weeks), and lack of an attention only control group. Although not suggested by our data, we cannot exclude the possibility that at least some of the favorable effects of MBSR in BC survivors are attributed to group support benefits that are non-specific to the program. Given our 6-week follow-up protocol, we do not know the long-term sustainability of the positive effects seen with the MBSR intervention. In addition, the statistical significance achieved among many of the outcome measures in this trial may not necessarily equate to large, clinically significant effects for individual patients. On the other hand, our results indicated that MBSR subjects tended to report quality of life scores at 6 weeks that equaled or exceeded population-based norms, thereby suggesting clinically significant improvements.

We did not employ a correction procedure for the large number of outcome measures compared by random assignment in this trial. While this may be viewed as a limitation, results were consistently in the direction of better psychological and physical status with MBSR, which argues against isolated chance findings emerging due simply to multiple comparisons. Despite our large battery of outcome measures, assessment of a wider set of specific symptoms, such as sleep disturbance, would have permitted an even more comprehensive evaluation of the MBSR (BC) program. Finally, the MBSR(BC) program was administered in a nationally recognized academic setting; the feasibility and benefits of administering the program in other settings remains to be determined.

Given the positive effects on psychological status and quality of life observed with the MBSR(BC) program, future studies should examine 'how' MBSR(BC) works specifically to BC survivors. This may include self-regulation of attention [55] and/or through reductions in fear of recurrence of cancer, as suggested by our data. In addition, future studies should evaluate the long-term sustainability of the MBSR program. Since our results appear to be quite promising, use of MBSR in other cancer populations should be evaluated for both feasibility and efficacy, such as among advanced or late-stage cancer patients.

Conclusions

We conclude that the MBSR(BC) program significantly improves psychological distress, fear of recurrence, and quality of life among BC survivors who have recently transitioned off treatment. In addition, the extent of practice with the program influences its overall therapeutic benefit, yet attendance alone appears to favorably affect psychological status. These findings have important implications outside of our study population. Specifically, for cancer patients who are more severely distressed and limited in their ability to attend 2-hour weekly in-class sessions (e.g. Stage IV patients), modifications that reduce the demands of the MBSR(BC) program (e.g. number and length of in-class sessions) may still be of clinical value in terms of improving overall psychological well-being. Future studies should evaluate modified MBSR programs for advanced-stage cancer patients.

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