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Effectiveness of Mindfulness-Based Stress Reduction in Mood, Breast- and Endocrine-Related Quality of Life, and Well-Being in Stage 0 to III Breast Cancer: A Randomized, Controlled Trial

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ABSTRACT

Purpose
To assess the effectiveness of mindfulness-based stress reduction (MBSR) for mood, breast- and endocrine-specific quality of life, and well-being after hospital treatment in women with stage 0 to III breast cancer.

Patients and Methods
A randomized, wait-listed, controlled trial was carried out in 229 women after surgery, chemotherapy, and radiotherapy for breast cancer. Patients were randomly assigned to the 8-week MBSR program or standard care. Profile of Mood States (POMS; primary outcome), Functional Assessment of Cancer Therapy–Breast (FACT-B), Functional Assessment of Cancer Therapy–Endocrine Symptoms (FACT-ES) scales and the WHO five-item well-being questionnaire (WHO-5) evaluated mood, quality of life, and well-being at weeks 0, 8, and 12. For each outcome measure, a repeated-measures analysis of variance model, which incorporated week 0 measurements as a covariate, was used to compare treatment groups at 8 and 12 weeks.

Results
There were statistically significant improvements in outcome in the experimental group compared with control group at both 8 and 12 weeks (except as indicated) for POMS total mood disturbance (and its subscales of anxiety, depression [8 weeks only], anger [12 weeks only], vigor, fatigue, and confusion [8 weeks only]), FACT-B, FACT-ES, (and Functional Assessment of Cancer Therapy subscales of physical, social [8 weeks only], emotional, and functional well-being), and WHO-5.

Conclusion
MSBR improved mood, breast- and endocrine-related quality of life, and well-being more effectively than standard care in women with stage 0 to III breast cancer, and these results persisted at three months. To our knowledge, this study provided novel evidence that MBSR can help alleviate long-term emotional and physical adverse effects of medical treatments, including endocrine treatments. MBSR is recommended to support survivors of breast cancer.

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INTRODUCTION

Approximately 550,000 people are living with breast cancer in the United Kingdom.[1] Surgery, chemotherapy, radiotherapy, and hormonal treatments for breast cancer have physical and psychological sequelae that last from months to years beyond hospitalization.[2-4] Symptoms such as anxiety,[5] depression,[6] pain,[7] fatigue,[2] endocrine symptoms,[8] and insomnia[9] can reduce quality of life.

Psychoeducational support and integrative therapies for survivors, including the development of self-management skills to cope better, are unevenly provided worldwide. One increasingly popular approach to support people who are living with cancer is the cultivation of mindfulness.[10-12] Mindfulness (ie, bringing attention and awareness to each moment in a nonjudgemental way) is a way of being.[13] Its origins are clearest in Buddhist philosophy, but elements of mindfulness are used in psychological approaches including cognitive-behavioral therapy. Mindfulness can be taught via a systematic 8-week mindfulness-based stress reduction (MBSR) program.[13] The benefits of MBSR have been researched in long-term health conditions including chronic pain,[14-16] anxiety,[17,18] fibromyalgia,[19]

psychological symptoms,[20] psoriasis,[21] increased stress and mood in outpatients with general cancer,[10,11] and insomnia,[10-12] but methodological rigor was limited in all studies either as a result of problems, such as small sample sizes,[10-12] no randomization, or intention-to-treat analysis, or impeded by poor reporting. A review of 13 articles that evaluated mindfulness-based interventions and cancer since 2007[22] cited only one randomized controlled trial of MBSR and breast cancer.[23] This randomized controlled trial of MBSR in stage 0 to III breast cancer (70% of participants had early stage 0 or I breast cancer) found improvements in fear of recurrence, depression, anxiety, physical functioning, physical role functioning, energy, and pain,[23] but the sample size was small (N = 84), there was no follow-up period, and no correctional measures were applied for the large number of outcome measures used. Earlier MSBR in cancer and breast cancer studies showed improvements in mood including anxiety,[10,11] stress,[10,11] and sleep quality.[12]

To our knowledge, this study was unique from other MBSR and cancer studies. Participants were recruited from The London Haven, which is one of the day centers of the charity that provides free psychological and integrative therapies for patients with breast cancer. Participants received an average of 30 hours of Haven support before study entry.

PATIENTS AND METHODS

A randomized controlled trial design was used to test the hypothesis that there would be a difference in the intervention group compared with controls as a consequence of being exposed to MBSR in mood, disease-related quality of life, including endocrine symptoms, and well-being for women with stage 0 to III breast cancer measured at baseline (T1; weeks −2 to 0), weeks 8 to 12 (T2), and weeks 12 to 14 (T3). An additional secondary study-specific analytic question was as follows: Is there a dose-related effect from doing formal mindfulness practice during the 8-week program?

Sample and Setting

Patients were recruited over 15 months from The Haven. Potentially eligible patients were contacted by letter and interviewed, and eligibility was strictly assessed by using the following inclusion criteria: women diagnosed with stage 0 to III breast cancer, aged between 18 and 80 years, who were aware of their cancer diagnosis, able to complete questionnaires, within 2 months to 2 years after the completion of surgery, chemotherapy, and/or radiotherapy. Patients excluded were diagnosed with stage IV breast cancer, men, did not speak English, could not give informed consent as a result of psychosis or intellectual impairment, or suffered from substance misuse, suicidal thoughts, or current psychosis. The study gained approval from the National Health Service's Local Research Ethics Committee.

After patients provided signed informed consent, participants were allocated to receive either MBSR or a wait-listed control. Random assignment was performed by operations director of the organization, who was independent from the study, by using an externally computer-generated randomization program in blocks of four, which ensured allocation concealment because no clinician/researcher could anticipate or direct the allocation of participants. The clinician-researcher conducting the study and delivering MBSR could not be blinded to the allocation of participants to either the treatment or control group. Anonymized data were collected by a research assistant who was blinded to group assignment and independent from MBSR delivery.

Sample Size

From related data,[10] the sample-size calculation was based on a difference in primary outcome (Profile of Mood States [POMS] score) of 13 points with a standard deviation (SD) of 30. The use of results from nQuery Advisor Version 5 (Statistical Solutions Software, Saugus, MA) indicated that the recruitment of 85 participants per arm provided 80% power for a two-sided *t* test by using a 5% level of significance. To allow for dropouts and nonattendance, we planned to recruit 120 patients per arm for a total of 240 patients. Adjustment for T1 covariates was likely to increase the statistical power.

Intervention: Mindfulness-Based Stress Reduction

The 8-week MSBR program closely followed that of Kabat-Zinn[13] and has been run in the United States for 30 years.[24] The program aims to cultivate mindfulness, which is defined as bringing complete attention of the individual to the experience that occurs in the present moment in a nonjudgemental or accepting way.[13,25-28] Mindfulness can be practiced as a valuable self-help technique without requiring any belief system.

From a consensus within the literature,[10-13] a standardized MBSR program was divided into 8 weekly classes of 2 hours in length, except the first and last classes were 2.25 hours in length, plus one 6-hour day of mindfulness in week 6. The classes consisted of the following formal mindfulness practices: a body scan, gentle and appropriate lying and standing yoga-based stretches, sitting meditation, some group discussions, didactic teaching, and home practice on topics including perceptions of and reactions to life events, stress physiology, and mindfulness in communication and everyday life. Home practice was delivered by four 45-minute compact discs of formal mindfulness practices and a manual. Participants were asked to practice for 40 to 45 minutes for 6 or 7 d/wk. Time and the amount of formal home practice were recorded by using weekly record sheets. The clinician/researcher was qualified as an MBSR instructor at the University of Massachusetts Center for Mindfulness in 2004 and the Senior Teacher Trainer of the clinician/researcher provided clinical supervision during the study.

Between 2005 and 2006, a pilot feasibility 8-week MSBR group was run with 10 Haven staff and two women treated for breast cancer (who were not Haven attendees). The pilot was designed to give the instructor practice running the program under clinical supervision and to resolve any practical delivery problems. These data were not analyzed. After this pilot was run, 12 MBSR groups with 12 to 20 participants were run by the clinician-researcher. In the autumn of 2006, an additional MSBR group was run for the remaining wait-listed control group. Participants on the MBSR program with any study-related concerns could contact the clinician-researcher during or after the study period.

Wait-Listed Controls

Wait-listed controls continued with their lives as usual before participating in MSBR after the study period. Controls were offered measurement tools at T1, T2, and T3 while the experimental group had their MBSR program.

Outcome Measures

All outcome measures were completed at T1, T2, and T3. The primary outcome was mood and measured by using the POMS (65-item).[29] The POMS total mood disturbance comprises subscales that evaluate anxiety, depression, anger, vigor, fatigue, and confusion. Lower scores indicated an improvement in mood.

Secondary outcomes included the following: Functional Assessment of Cancer Therapy-Breast (FACT-B) 37-item (Version 4) scale,[30] which contains subscales of physical, social, emotional, and functional well-being in addition to the 10-item breast-specific subscale, which included concerns about body image, shortness of breath, and pain. The Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES) scale, which contains the aforementioned subscales of physical, social, emotional, and functional well-being in addition to a 19-item endocrine-specific subscale that measures menopausal symptoms, including hot flashes, vaginal dryness, and loss of libido, and the WHO five-item well-being questionnaire (WHO-5).[31,32] Higher scores in the Functional Assessment of Cancer Therapy and WHO-5 measures indicated an improvement in quality of life or well-being. All previously mentioned outcome measures were validated (J. Soulsby, personal communication, May 2003).[29,30,32-35]

Data Analysis

The numbers of questionnaires analyzed from the treatment and control groups were 103 and 111 questionnaires, respectively. The numbers of questionnaires returned at T2 and T3 were 97 and 91 questionnaires, respectively,

in the treatment group and 109 and 106 questionnaires, respectively, in the control group. The proration method (standard mean imputation) was used to address missing data within questionnaires as advised in the questionnaire manuals.[33,36] When whole questionnaires were missing at T2 or T3, data were imputed by using previous values carried forward. There were three instances (two patients in the intervention group and one patient in the control group) in which more than 20% of data was missing from participants at T1, and thus, according to rules set by the questionnaire manuals, their data was excluded because it was too sparse to analyze. An intention-to-treat between-group analysis was performed because results of participants were analyzed in the groups to which they were randomly assigned. Data from the POMS and other scales were analyzed with a repeated-measures analysis of variance model by using SPSS version 18 software (SPSS, Chicago, IL). For each outcome variable, measurement occasions T2 and T3 formed the within-patients factor, the measurement made at T1 was used as a covariate, and treatment group was the between-patients factor. In this model, the between-patients factor indicated the treatment effect, and the interaction between the measurement occasion and treatment group indicated whether the treatment effect differed between T2 and T3. Treatment effects at T2 and T3 are presented as adjusted mean differences and 95% CIs. The clinical significance of results for Functional Assessment of Cancer Therapy scales and the WHO-5 are reported according to questionnaire-specific criteria (B. Brown, personal communication, February 2008).[37-39]

To test whether hours of formal mindfulness practice done both in the classroom and at home were associated with improved outcomes at T2 and T3, a series of multiple linear regressions was done separately for each outcome at each time point. For each analysis, the measurement made at T1 was included as a covariate.

RESULTS

Sociodemographic and Clinical Characteristics

We recruited 229 women, and sociodemographic, clinical, and medical treatment details are listed in Table 1. The mean (SD) age was 49.0 years (9.26 years) in the experimental group and 50.1 years (9.14 years) in the control group. By using British socioeconomic status classifications, most participants were classified in the highest social class (73.7% of participants in the experimental group and 78.3% of participants in the control group). Two hundred fourteen women (93%), (mean age, 49 years) completed the study, which indicated a low dropout rate (the CONSORT diagram of the study is shown in Fig 1).

Quality-of-Life Measures

There were no significant between-group differences found at T1 for any of the scales.

Mood State

There were statistically significant differences between treatment groups for POMS total mood disturbance, anxiety, depression, anger, vigor, fatigue, and confusion (Table 2). The T1-adjusted mean differences and 95% CIs at T2 and T3 suggested statistically significant lower mood-state scores in the experimental group than in the control group at both measurement occasions except for depression (T2 only), anger (T3 only), and confusion (T2 only). There were no statistically significant interactions between treatment group and measurement occasion.

No established methods for calculating levels of clinical significance exist for POMS, and thus, this calculation was not undertaken (B. Brown, personal communication, February 2008).

Secondary Outcomes

Disease-related quality-of-life and endocrine symptoms. Results for quality of life were measured by using the breast-specific quality-of-life scale FACT-B and the FACT-ES scale for endocrine symptoms. Higher numbers indicated better scores on all FACT scales.

After adjustment for the outcome measurement made at T1, there were statistically significant treatment effects for FACT-ES, FACT-B, physical well-being, social well-being, emotional well-being, and functional well-being (Table 3). Mean scores in the experimental group compared with the control group were greater at both T2 and T3 for all six measures (except social well-being which was significant at T2 only). For emotional well-being, there was some evidence that treatment effects at T3 were statistically significantly greater that at T2. No other interactions were statistically significant.

The mean treatment effect was 7 for FACT-B at T2 and 8 for FACT-B at T3, which were the same as the minimum clinically important difference of 7 to 8 reported in the literature.[37]

Well-being. After adjustment for T1 measurements, there were statistically significant increases in the WHO-5 in the experimental group compared with controls, and these were apparent at T2 and T3 (Table 3).

For the WHO-5, the minimum clinically important difference has been suggested to be a change of 10% on standardized percentage scores, which are obtained by multiplying the raw scores by four.[37]The adjusted mean differences, which are listed in Table 3 and expressed as standardized percentage scores, were 8.04% at T2 and 8.60% at T3. These scores were close to the minimum clinically important difference of 10%.

Dose-related effects of mindfulness. The mean (SD) number of hours of formal home practice of mindfulness in the experimental group was 19.58 hours (11.49 hours) over 8 weeks, which equates to an average of 21 min/d. From their reports, participants changed their behavior and complied with home practice. When the mean classroom mindfulness practice time was added (average of 12 min/d over 8 weeks), 33 min/d of practice was undertaken. Attendance of MBSR classes in the experimental group was high with a mean (SD) of 17.45 hours (6.55 hours) over the course, averaging 2.18 h/wk. The mean (SD) number of weekly sessions attended (excluding the 6-hour day) was 6.26 sessions (2.12 sessions) of a possible eight sessions, which suggested participants were motivated.

Increased hours of formal mindfulness classroom and home practice in the experimental group was associated with improved scores in POMS total mood disturbance at T3 ($P = .004$), anxiety at T3 ($P = .01$), anger at T2 ($P = .005$) and T3 ($P = .02$), vigor at T3 ($P = .02$), fatigue at T3 ($P = .03$), and confusion at T2 ($P = .04$) and T3 ($P = .001$). These increased hours were also associated with improved scores in FACT-ES at T2 ($P = .05$) and T3 ($P = .005$), FACT-B at T3 ($P = .006$), FACT physical well-being at T3 ($P = .04$), and WHO-5 at T2 ($P = .01$) and T3 ($P = .001$). No serious adverse events were reported in this study.

DISCUSSION

To our knowledge, this study was the largest adequately powered trial to date that tested the effects of the MBSR program in women with stage 0 to III breast cancer. Important findings from this study

Table 1. Sociodemographic and Clinical Characteristics of Sample at Baseline

Characteristic	Experimental Group (n = 114)		Control Group (n = 115)	
	No. of Patients	%	No. of Patients	%
Age, years				
Mean	49.0		50.1	
SD	9.26		9.14	
Social grade				
AB: higher and intermediate managerial/ administrative/professional	84	74	90	78
C1: supervisory clerical junior managerial/ administrative/professional	20	18	16	14
C2: skilled manual workers	2	2	2	2
D: semiskilled and unskilled manual workers	6	5	5	4
E: on state benefits, unemployed, lowest-grade workers	2	2	2	2
Stage of breast cancer				
0	11	10	6	5
I	34	30	45	39
II	47	41	47	41
III	22	20	17	15
Breast cancer is a recurrence	6	5	8	7
Surgery	113	99	115	100
Wide local excision/partial mastectomy, No. of operations				
Mean	0.75		0.93	
SD	1		1	
0	38	33	28	23
1	67	59	67	59
2	8	7	20	17
≥ 3	1	1	0	0
Mastectomy, No. of operations				
Mean	0.54		0.45	
SD	1		1	
0	57	50	68	59
1	52	46	40	34
2	5	4	5	4
Breast reconstruction, No. of operations				
Mean	0.36		0.30	
SD	1		1	
0	83	73	87	76
1	24	21	22	19
2	5	4	5	4
3	1	1	1	1
4	1	1	0	0
Chemotherapy	67	59	60	52
Neoadjuvant chemotherapy	20	18	8	7
No. of neoadjuvant cycles				
Mean	1.07		0.39	
SD	2		1	
Range	0-10		0-8	
Adjuvant chemotherapy	54	47	56	49
No. of adjuvant cycles				
Mean	3.03		3.01	
SD	4		3	
Range	0-12		0-8	
Radiotherapy	92	81	84	73
Endocrine treatment				
Yes	56	49	54	47
Total	112		113	
Missing	2		2	
Type of endocrine treatment frequency				
Anastrozole	15	13	13	11
Goserelin	0		2	2
Letrozole	3	3	0	
Tamoxifen	36	32	39	34
Toremifene				
Not stated	1	1	0	
Not applicable	57	50	59	51
Second type of endocrine treatment				
Anastrozole	0		1	1
Goserelin	5	4	2	2
Megestrol acetate	0		0	
Tamoxifen	0		0	
Not applicable	107	94	110	96
Herceptin				
Yes	4	4	3	3
Missing	2	2	1	1
Time between diagnosis of breast cancer and random assignment, months				
Mean	17.44		18.98	
SD	13		15	
Time between completion of surgery, chemotherapy, and radiotherapy and random assignment, months				
Mean	9.27		9.50	
SD	6		6	
No. of additional hours of Haven program attended				
Before T1				
Mean	30.09		31.48	
SD	17		14	
Between T1 and T2				
Mean	0.97		0.68	
SD	2		1	
Between T2 and T3				
Mean	0.59		0.32	
SD	2		1	

Abbreviations: SD, standard deviation; T1, baseline (weeks −2 to 0); T2, weeks 8 to 12; T3, weeks 12 to 14.

included statistically significant improvements after MBSR compared with those of controls in overall mood, anxiety, depression, anger, vigor, fatigue and confusion, breast- and endocrine-related quality of life, emotional, physical, social, and role functional well-being, and general well-being. The improvement in mood reinforced and extended results found in other studies that evaluated mood in patients with cancer after MBSR[10,11] and in patients with breast and prostate cancer.[40] To our knowledge, our study is the first to show significant benefits of MBSR on mood in cancer at 3 months. Carlson et al[11] measured follow-up in outpatients with cancer at 6 months, but positive changes were not maintained by

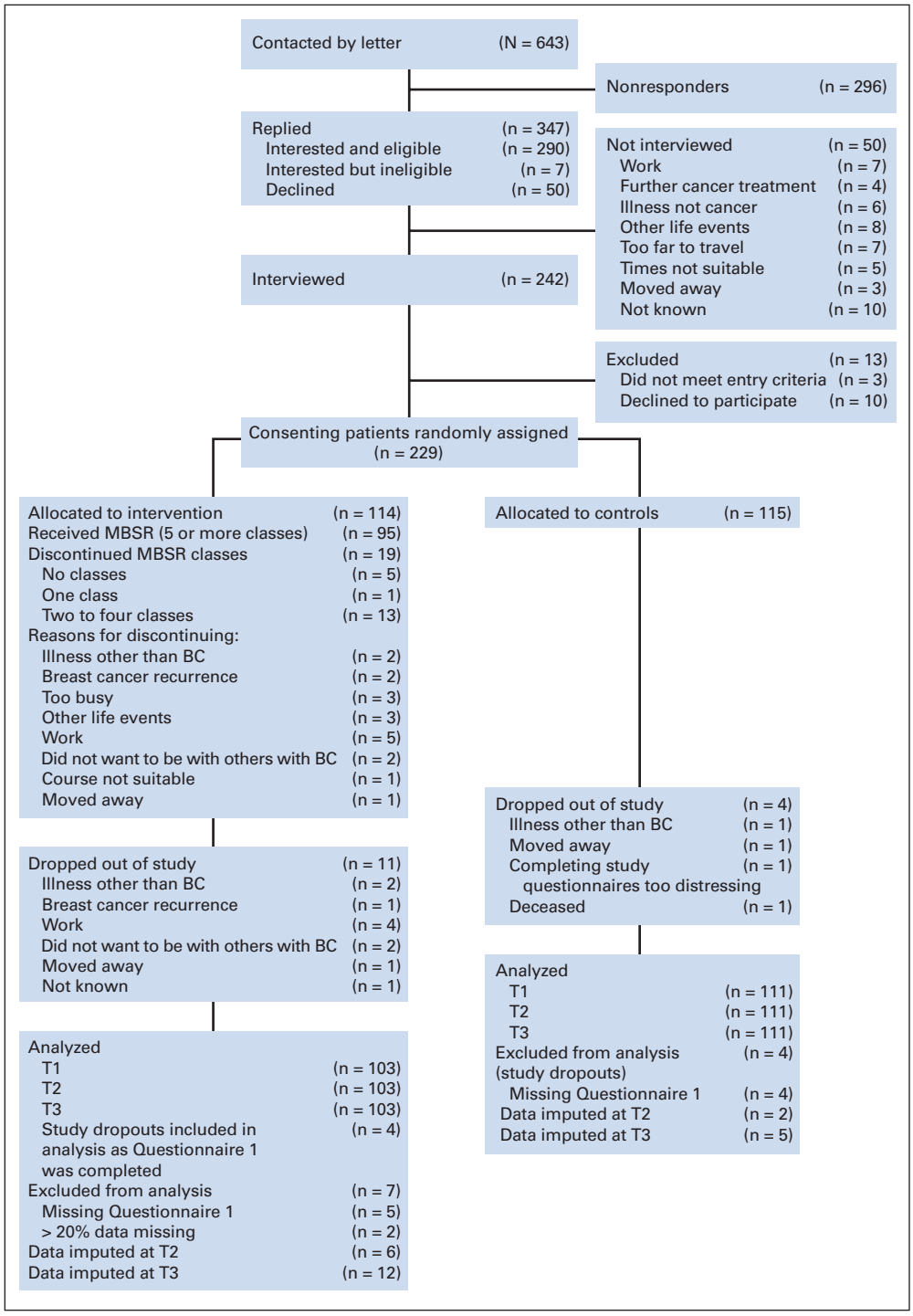

Fig 1. CONSORT diagram. BC, breast cancer; MBSR, mindfulness-based stress reduction.

that time point. Future research should include the measurement of longer-term follow-ups to determine the duration of the effects of the MBSR intervention.

Significant improvements in anxiety reinforced and extended findings from studies of anxiety and MBSR[17,18] and anxiety in cancer[10,23] and breast cancer.[23] One explanation is that the process of becoming more aware of thoughts and feelings and relating to them as mental events from a decentered perspective, rather than as aspects of self or as true reflections of reality, can be applied to anxious and depressed thoughts.[23] The finding that MBSR improves depression, anxiety, anger, confusion, fatigue, and vigor in patients with breast cancer extended findings from MBSR found in outpatients with general cancer.[10] The improvements in depression was an important finding that added to the evidence base not only for MBSR for depression in breast cancer but also to the effectiveness of mindfulness for depression.[41] The T1 total mood disturbance was worse than in earlier MBSR and general cancer studies[10] and in cancer norms,[42] perhaps because our sample had

Table 2. Primary Outcome for POMS Total Mood Disturbance and Subscales and Estimates of Treatment Effects

Outcome Measure	Experimental (n = 103)		Control (n = 111)		Difference Between Groups at T2 and T3 Adjusted for Baseline	
	Mean	SD	Mean	SD	Mean	95% CI
Total score						
T1 total mood disturbance	43.65	34.73	49.23	39.37		NA
T2 total mood disturbance	30.02	31.60	48.08	39.89	−15.30	−23.75 to −6.86
T3 total mood disturbance	29.83	34.19	45.47	35.67	−12.91	−21.02 to −4.81
Interaction time × treatment group, *P*						.558
Treatment group main effect, *P*						< .001
Subscales						
T1 tension/anxiety	13.16	7.20	13.42	7.24		NA
T2 tension/anxiety	10.32	7.0	13.36	7.20	−2.93	−4.67 to −1.20
T3 tension/anxiety	10.33	7.02	12.73	6.59	−2.30	−3.96 to −0.63
Interaction time × treatment group, *P*						.493
Treatment group main effect, *P*						< .001
T1 depression/dejection	12.79	10.76	15.70	12.79		NA
T2 depression/dejection	10.0	9.95	14.96	13.23	−3.39	−6.06 to −0.71
T3 depression/dejection	10.34	10.32	14.10	11.60	−2.32	−4.86 to 0.22
Interaction time × treatment group, *P*						.365
Treatment group main effect, *P*						.017
T1 anger/hostility	10.75	8.08	11.60	8.62		NA
T2 anger/hostility	8.78	7.57	11.11	8.88	−1.96	−3.96 to 0.05
T3 anger/hostility	7.87	6.72	11.04	8.95	−2.69	−4.44 to −0.95
Interaction time × treatment group, *P*						.458
Treatment group main effect, *P*						.005
T1 vigor/activity	−14.31	6.53	−14.06	6.19		NA
T2 vigor/activity	−15.91	6.0	−13.57	6.61	−2.21	−3.67 to −0.75
T3 vigor/activity	−16.23	6.63	−13.47	6.22	−2.63	−4.12 to −1.15
Interaction time × treatment group, *P*						.606
Treatment group main effect, *P*						< .001
T1 fatigue/inertia	11.17	6.64	11.75	7.20		NA
T2 fatigue/inertia	8.71	6.10	11.62	7.16	−2.68	−4.31 to −1.04
T3 fatigue/inertia	9.27	6.90	11.39	6.73	−1.84	−3.45 to −0.22
Interaction time × treatment group, *P*						.324
Treatment group main effect, *P*						.002
T1 confusion/bewilderment	10.11	5.58	10.65	5.57		NA
T2 confusion/bewilderment	8.13	4.71	10.33	5.30	−1.91	−3.01 to −0.81
T3 confusion/bewilderment	8.24	5.32	9.63	4.31	−1.09	−2.20 to 0.01
Interaction time × treatment group, *P*						.141
Treatment group main effect, *P*						.002

NOTE. For each outcome measure, repeated-measures ANOVA was used with time (T2 and T3) as the within-patients factor, treatment group as the between-patients factor, and baseline measure (T1) as a covariate. The group × time interaction tested the null hypothesis that differences between groups at T2 and T3 were identical. The group effect tested whether there were significant differences in T2 and T3 between groups (ie, did the intervention have an impact?). Mean differences were used to compare groups at T2 and T3 after adjustment for values at T1 as a covariate.

Abbreviations: NA, not applicable; POMS, Profile of Mood States; SD, standard deviation; T1, baseline (weeks −2 to 0); T2, weeks 8 to 12; T3, weeks 12 to 14.

already identified themselves as needing help by coming to The Haven. The end of hospital treatment is known as a critical point for psychological problems[4] and is a time when people are more likely to seek the help of MBSR at an integrative center like The Haven. A previous psychosocial supportive-expressive group-therapy intervention trial for patients with metastatic breast cancer showed beneficial effects only among patients who had more mood disturbance at T1.[43] Therefore, it is possible that the enrollment of patients with stage 0 to III breast cancer with more mood disturbance in this study may have resulted in the positive effects observed.

To our knowledge, data of improvements in breast- and endocrine-specific quality of life from MSBR were novel as were the significant improvements in endocrine symptoms as measured by the FACT-ES scale. This is an important finding for women who take endocrine treatments for ≥ 5 years. Findings for improvements in overall well-being extended positive findings of MBCT[44] in cancer (N = 25).

Participants showed a commitment to mindfulness practice by practicing 33 min/d, which compared well with 30 to 32 min/d in cancer (M. Speca, L.E. Carlson, personal communication, June 2008)[10] and breast cancer,[23] and all measurements were taken in the same way to include both classroom time and home practice combined. Most improvements were maintained, and some improvements were further improved at 4 weeks post-MBSR completion. Increased hours of formal mindfulness predicted significant improvements in mood disturbance, anxiety, anger, vigor, fatigue, confusion, endocrine- and breast-related quality of life, physical well-being, and general well-being. There was no other opportunity to learn meditation at The Haven during the study. Key limitations of this study included the following

Table 3. Secondary Outcomes for FACT-B, FACT-ES, WHO-5, and Estimates of Treatment Effects

Outcome Measure	Experimental Group (n = 103)				Control Group (n = 111)				Difference Between Groups at T2 and T3 Adjusted for Baseline	
	No. of Patients	Mean	SD	%	No. of Patients	Mean	SD	%	Mean	95% CI
FACT-ES										
T1	102	127.02	18.84		107	127.08	23.20		NA	
T2	102	134.97	19.26		107	127.37	23.58		7.65	3.95 to 11.36
T3	102	135.34	19.54		107	127.42	21.26		7.98	4.46 to 11.49
Interaction time × treatment group, *P*										.814
Treatment group main effect, *P*										< .001
FACT-B										
T1	101	96.57	17.22		106	96.68	21.05			NA
T2	101	103.56	17.91		106	96.84	21.14		6.81	3.48 to 10.14
T3	101	103.78	17.85		106	96.22	19.43		7.65	4.61 to 10.68
Interaction time × treatment group, *P*										.493
Treatment group main effect, *P*										< .001
FACT PWB										
T1	102	21.88	4.29		111	21.89	4.35			NA
T2	102	22.86	4.22		111	21.84	4.54		1.03	0.19 to 1.87
T3	102	22.97	4.34		111	21.67	4.87		1.31	0.49 to 2.12
Interaction time × treatment group, *P*										.521
Treatment group main effect, *P*										.002
FACT SWB										
T1	102	17.59	5.91		109	18.78	6.01			NA
T2	102	18.36	5.65		109	18.26	5.88		1.06	0.17 to 1.94
T3	102	18.09	5.81		109	18.30	5.75		0.71	−0.24 to 1.65
Interaction time × treatment group, *P*										.436
Treatment group main effect, *P*										.032
FACT EWB										
T1	102	16.91	3.84		109	15.97	4.58			NA
T2	102	18.14	3.82		109	16.59	4.40		0.93	0.09 to 1.78
T3	102	18.59	3.75		109	16.28	4.42		1.72	0.86 to 2.57
Interaction time × treatment group, *P*										.042
Treatment group main effect, *P*										.001
FACT FWB										
T1	102	17.83	5.03		110	17.65	5.83			NA
T2	102	19.46	5.27		110	17.41	6.06		1.91	0.87 to 2.95
T3	102	19.45	5.32		110	17.53	5.37		1.80	0.77 to 2.83
Interaction time × treatment group, *P*										.804
Treatment group main effect, *P*										< .001
WHO-5										
T1	103	13.04	4.48	52.2	111	12.53	4.68	50.1		NA
T2	103	14.91	4.23	59.6	111	12.60	4.92	50.4	2.01	1.00 to 3.01
T3	103	15.08	4.62	60.3	111	12.65	4.30	50.6	2.15	1.16 to 3.15
Interaction time × treatment group, *P*										.768
Treatment group main effect, *P*										< .001

NOTE. For each outcome measure, repeated-measures ANOVA was used with time (T2 and T3) as the within-patients factor, treatment group as the between-patients factor, and baseline measure (T1) as a covariate. The group × time interaction tested the null hypothesis that differences between groups at T2 and T3 were identical. The group effect tested whether there were significant differences in T2 and T3 between groups (ie, Did the intervention have an impact?). Mean differences were used to compare groups at T2 and T3 after adjustment for values at T1 as a covariate.

Abbreviations: EWB, emotional well-being subscale; FACT, Functional Assessment of Cancer Therapy; FACT-B, Functional Assessment of Cancer Therapy–Breast; FACT-ES, Functional Assessment of Cancer Therapy–Endocrine Symptoms; FWB, functional well-being subscale; NA, not applicable; PWB, physical well-being subscale; SD, standard deviation; T1, baseline (weeks −2 to 0); T2, weeks 8 to 12; T3, weeks 12 to 14; SWB, social well-being subscale; WHO-5, WHO five-item well-being questionnaire.

points: tensions of having a clinician-researcher role, although to reduce this bias, a research assistant handled data. After MBSR, during weeks 9 to 12 of the follow-up period, there was no record kept of the time spent practicing mindfulness. A self-report is a potentially biased measure, and cost effectiveness was not evaluated. The study setting was atypical of widely available support services. Generalizability was limited to women with stage 0 to III breast cancer who seek psychological services. Of note, patients less inclined to join this study included people with stage III disease and patients who received more chemotherapy and hormone therapy.

The importance of this study is that it demonstrated, within the boundaries of the limitations mentioned, statistically and clinically significant improvements in breast-related quality of life, including breast- and endocrine-specific symptoms, and general well-being. The

results of this study support the recommendation for breast cancer survivors to use MBSR to enhance mood and quality of life including endocrine symptoms.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

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