A Randomized Controlled Trial of Mindfulness-Based Stress Reduction for Women With Early-Stage Breast Cancer Receiving Radiotherapy

Virginia P. Henderson, MD, MPH[1], **Ann O. Massion, MD**[2], **Lynn Clemow, PhD**[3], **Thomas G. Hurley, MS**[1], **Susan Druker, MEd**[4], and **James R. Hébert, ScD**[1]

[1]University of South Carolina, Columbia, SC, USA

[2]Coastal Psychiatric Medical Associates, Inc, Del Mar, CA, USA

[3]Columbia University, New York, NY, USA

[4]University of Massachusetts Medical School, Worcester, MA, USA

Abstract

Purpose—To testthe relative effectiveness of a mindfulness-based stress reduction program (MBSR) compared with a nutrition education intervention (NEP) and usual care (UC) in women with newly diagnosed early-stage breast cancer (BrCA) undergoing radiotherapy.

Methods—Datawere available from a randomized controlled trialof 172 women, 20 to 65 years old, with stage I or II BrCA. Data from women completing the 8-week MBSR program plus 3 additional sessions focuses on special needs associated with BrCA were compared to women receiving attention control NEP and UC. Follow-up was performed at 3 post-intervention points: 4 months, and 1 and 2 years. Standardized, validated self-administered questionnaires were used to assess psychosocial variables. Descriptive analyses compared women by randomization assignment. Regression analyses, incorporating both intention-to-treat and post hoc multivariable approaches, were used to control for potential confounding variables.

Results—A subset of 120 women underwent radiotherapy; 77 completed treatment prior to the study, and 40 had radiotherapy during the MBSR intervention. Women who actively received radiotherapy (art) while participating in the MBSR intervention (MBSR-art) experienced a significant ($P < .05$) improvement in 16 psychosocial variables compared with the NEP-art, UC-art, or both at 4 months. These included health-related, BrCA-specific quality of life and psychosocial coping, which were the primary outcomes, and secondary measures, including meaningfulness, helplessness, cognitive avoidance, depression, paranoid ideation, hostility, anxiety, global severity, anxious preoccupation, and emotional control.

Conclusions—MBSR appears to facilitate psychosocial adjustment in BrCA patients receiving radiotherapy, suggesting applicability for MBSR as adjunctive therapy in oncological practice.

Keywords

mindfulness-based stress reduction program; breast cancer; quality of life; psychosocial intervention; radiotherapy; radiation therapy

Corresponding Author: James R. Hébert, Cancer Prevention & Control Program, University of South Carolina, 915 Greene Street, Suite 241-2, Columbia, SC 29208, USA. jhebert@mailbox.sc.edu.

Introduction

Radiotherapy is considered to be a key component of breast cancer (BrCA) treatment, particularly for reducing tumor recurrence.[1] The adverse consequences of radiotherapy are well known, including fatigue, skin toxicity, insomnia, depression, anxiety,[2-5] and generally poorer quality of life (QOL).[6,7]

Given that these issues are stress and distress provoking, a stress reduction intervention seems logical to evaluate. Stress management interventions for women with BrCA have been studied in at least 4 randomized controlled trials.[8-12] These studies generally showed some decrease in anxiety and depression, with one also finding an improvement in physical function.[10,11] However, these studies have been limited by one or more of the following: using a waitlist control, lack of an attention control for nonspecific therapist effects, and/or short follow-up.

Although there have been no studies of a mindfulness-based stress reduction program (MBSR) for women with BrCA undergoing radiotherapy, there have been several randomized trials using yoga interventions, which is one component of MBSR[13-15]; guided imagery[16]; relaxation and imagery[17]; and a cognitive behavioral therapy plus hypnosis intervention.[2,18] Benefits were found for general health perception, physical function, QOL, and stress and depression. The studies were limited by small sample size, lack of attention control, use of a waitlist control, short follow-up, and/or use of a single nonspecific assessment measure or measurement of 1 single dimension.

We previously reported on a randomized 2-year study of 172 women with early-stage BrCA that evaluated a standard 8-week MBSR plus 3 extra sessions compared with usual care (UC) as well as a nutrition education intervention (NEP) matched for time and attention to the MBSR intervention.[19] At 4 months, the MBSR group showed significant benefit over either UC or NEP on measures of anxiety, unhappiness, meaningfulness, depression, active cognitive coping, need for overcontrol, paranoid ideation, hostility, and spirituality. The study was designed to address some of the limitations of previous studies—namely, short follow-up, lack of attention control, and paucity of larger samples with a randomized controlled design.

The current article looks at the subset of women in our study undergoing radiotherapy during the course of the intervention, comparing MBSR with NEP and UC within this population of patients.

Methods

The Breast Research Initiative for Determining Effective Strategies for Coping With Breast Cancer (BRIDGES) is a randomized clinical trial (RCT) of 172 women diagnosed with BrCA. Participants were enrolled from 4 practice sites: The University and Memorial Hospital Campuses of the University of Massachusetts Medical Center, now named UMass Memorial Health Care, Worcester, MA; Fallon Community Health Plan, Worcester, MA; and Miriam Hospital, Providence, RI. The institutional review board of each participating institution reviewed and approved the protocol and assessment procedures, and the institutional review board of the University of Massachusetts Medical School approved all recruitment and measurement procedures.

Eligibility

Women eligible to be in this study had newly diagnosed (within the previous 2 years) stage I or II cancer of the breast; were between 20 and 65 years of age; spoke English; planned to maintain residence in the study area for at least 2 years following recruitment; were Eastern Cooperative Oncology Group performance status 0, 1, or 2; were willing to accept randomization; and had a working home telephone on which they were willing to be contacted. Specific exclusion criteria included a previous diagnosis of cancer in the previous 5 years, except nonmelanoma skin cancer, current chronic substance abuse, and past or present psychiatric or neurological disorder.

Description of the Randomization Conditions

Once enrolled, women were randomized into 1 of 3 study conditions: MBSR, NEP, or UC. Women were block randomized by stage of disease (I or II), age (±5 years) within menopausal group, and institution. Each of the interventions was delivered at a single site.

The MBSR intervention consisted of 3 parts: (1) an introductory meeting for BRIDGES-only participants; (2) 8 weekly 2.5- to 3.5-hour sessions in groups of 25 to 30 women, with an additional 7.5-hour intensive retreat session given in the sixth week; and (3) 3 additional 2-hour sessions at monthly intervals following completion of the MBSR intervention, for the purpose of support and discussing practice issues. The MBSR was delivered by instructors with either masters' or doctorate degrees and long-term meditation practice. The 3 additional sessions were led by a psychiatrist who had MBSR internship training and long-term meditation practice.

The NEP intervention, led by registered dieticians, was a group intervention focused on dietary change through education and group meal preparation. Practices followed the principles of social cognitive theory[20-23] and patient-centered counseling.[24,25] The NEP was equivalent to the MBSR in terms of contact time and homework assignments but did not contain any meditation or yoga. The UC condition received no formal intervention but was presented to women as "individual" choice, in that they could choose other activities, excluding the MBSR or NEP.

Measures

Measures were obtained on all study participants (patients with and without radiotherapy) at 4 points: recruitment into the study (baseline) and at 4 months, 12 months, and 24 months from beginning the intervention. Data were collected on demographic factors and medical history and updated quarterly.

Psychological variables were assessed using standardized and validated self-administered questionnaires. Primary outcome measures included cancer-specific QOL, as measured by the BrCA version of the Functional Assessment of Cancer Therapy (FACT-B),[7,19,26-28] using the overall scores and additional spirituality items, and coping mechanisms, measured by the Dealing With Illness questionnaire.[19,29]

Secondary measurements included the following: anxiety (Beck Anxiety Inventory[30]); depression (Beck Depression Inventory[31]); self-esteem (Rosenberg Self-Esteem Scale[32]); resilience to stress and adversity (Sense of Coherence Scale[33-35]); subjective social support (Revised UCLA Loneliness Scale[36]); adjustment to cancer (Mini-Mental Adjustment to Cancer Scale[37]); emotional control (Courtauld Emotional Control Scale[38,39]); and general psychological distress (Symptom Checklist 90–Revised[40]).

Statistical Methods

Outcome variables were measured on a continuous scale. χ^2 Analyses for categorical variables and t tests for continuous variables were conducted on all study participants to test the effectiveness of randomization. Characteristics that differed by assignment were included for adjustment in statistical models. Univariate statistics were performed on all outcomes to check for adherence to the assumptions of normality and equal variance as well as for the detection of outliers.

Because of the variation between the date of enrollment into the study (recorded as baseline) and the actual start date of the intervention, an adjusted baseline-start date was created as a calculation of the 4-month anthropometric measurement date minus 4 months. The adjusted start-of-study date was used to determine time from diagnosis to intervention initiation as well as the temporal relationship between radiotherapy and intervention initiation.

To test the hypothesis of improved measures in outcome variables with the MBSR intervention versus the control inventions for women undergoing radiotherapy during the intervention, each dependent variable (psychosocial variable) was fit using PROC MIXED for the subset of patients with a history of receiving radiotherapy while controlling for the timing of radiotherapy. Data reported are the least-squares means of the psychosocial factor scale scores generated from the mixed model. This modeling approach adjusts the error mean squared for participant dropout and imbalance caused by missing data.

Assuming 50 participants per randomization group and adjusting for the baseline level of the outcome measure (QOL from the FACT-B), there was 83% power to detect a difference of 2.5 on a 28-point scale in the functional dimension, 99% power for the social dimensions, and 92% power to detect a 7.5-point difference (on a 112-point scale) in overall QOL. Even with a smaller sample resulting from a focus on the radiotherapy subset, we still had >80% power for our primary statistical tests. It is important to note that significance testing was done without any adjustment after the fact.

Results

In all, 199 women were eligible for the study; 180 (91%) enrolled and were randomized. The analytical sample consisted of the 159 women for whom initial radiotherapy status (yes/no) was reported. Of these 159 women, 39 had no radiation therapy, and 120 women underwent radio-therapy; of the 120 women, 77 completed treatment prior to the study, and 40 had radiotherapy (art—actively received radiotherapy) during the 8-week MBSR intervention (Figure 1).

Baseline characteristics by intervention group for all study participants (regardless of radiotherapy status) are presented in Table 1. Participants were on average 50 (±8) years old and tended to be white, married, well-educated, and employed. Exploratory analyses of demographic and medical factors indicated adequate control from study randomization. Analysis showed no statistically significant differences between intervention groups that would influence future analyses.

Additional χ^2 testing indicated adequate distribution for both radiotherapy (yes or no) as well as the timing of radio-therapy in relation to the study start date (completion of treatment before the study or undergoing treatment during the study).

Table 2 shows comparisons of major study outcomes that differ significantly (ie, $P < .05$) across the MBSR-art, NEP-art, and UC-art groups (ie, all women undergoing radiotherapy during the study). Data are reported as the mean score values ± standard error for the

psychosocial factor scales. At 4 months, improvements in several outcome measures were shown for women in the MBSR-art group compared with women in the UC-art and NEP-art groups, notably in the following: (1) On the Dealing With Illness instrument, there was more active-behavioral coping and more active-cognitive coping for MBSR-art versus UC-art; there was less avoidance-coping for MBSR-art versus NEP-art and UC-art; (2) on the FACT, there was significant improvement on measures of emotional well-being and spirituality for MBSR-art versus NEP-art and UC-art and on social-family well-being for MBSR-art versus NEP-art; (3) on the Sense of Coherence Scale, results showed increased sense of coherence or meaning for the MBSR-art versus NEP-art and UC-art; (4) on the Mini Mental Adjustment to Cancer Scale, results showed decreased helplessness in MBSR-art versus NEP-art and decreased cognitive avoidance in MBSR-art versus UC-art; (5) on the SCL-90R, there was improvement on measures of anxiety (MBSR-art vs UC-art), hostility (MBSR-art vs UC-art), the Global Severity Index (MBSR-art vs NEP-art and UC-art), depression (MBSR-art vs NEP-art), and paranoid ideation (MBSR-art vs UC-art); and (6) on the Courtauld Emotional Control Scale, there was improvement in anxious preoccupation (MBSR-art vs UC-art) and need for control (MBSR-art vs UC-art).

When the 16 significant MBSR-art outcome measures were compared side by side with the outcome measures of the overall BRIDGES study, improvements in 8 of the 16 variables were specific to radiotherapy (Figure 2), not solely a function of the MBSR detected in initial study outcome results (Online Resource 1). In comparison to initial study results, at 4 months, the Courtauld Emotional Control measure of unhappiness no longer showed significant improvement.

The largest improvements in the MBSR intervention group appeared to be at 4 months (immediately following program completion), involving 16 psychosocial factors (43 factors were measured in total). At 12 months, only the following were significant: active behavioral coping, active cognitive coping, spirituality, and meaningfulness. At 24 months, significant improvement remained for 3 factors: active cognitive coping, sense of meaningfulness, and anxious preoccupation (Table 2).

Discussion

To the best of our knowledge, this is the first RCT to evaluate the specific effects of MBSR in women with BrCA undergoing radiotherapy. Results showed improvements at 4 months on 16 psychosocial factor outcomes with an MBSR program.

In the evaluation of radiotherapy patients receiving MBSR, results were consistent with previously proven MBSR reductions in cancer-related anxiety,[44,45] hostility,[19] paranoid ideation,[19] and depression[19,46]; better stress management (as a measure of coping)[12,47]; improved emotional control[19]; meaningfulness of life[19]; and improved QOL,[19,48,49]especially as related to spirituality. Additional findings specific to the subset of BrCA patients receiving MBSR and radiotherapy included the following: better QOL through an enhanced sense of emotional and social-family well-being, greater coping abilities, decreased feelings of helplessness and need for avoidance, and a larger decrease in general psychological distress, including global factors. Study results did not indicate an improvement in overall levels of happiness in radiotherapy patients participating in MBSR.

Improvements in radiotherapy patients' overall emotional QOL are similar to findings in postchemotherapy treatment studies.[47,50] It is becoming more evident that stress reduction programs designed to teach mindfulness, social-emotional awareness, and deep breathing ease the side effects of treatment (eg, inability to perform usual tasks and social enjoyment of eating and recreational activities)[51] and the resulting mental exhaustion[52] that inhibits

QOL. Also, by unlearning bad habits and applying mindfulness in daily situations, direct improvements are made in QOL while indirectly increasing chances of survival.[53,54]

Various studies in cancer patients,[19,55,56] posttreatment patients,[57,58] and fibromyalgia patients[59,60] have shown that stress reduction interventions have demonstrated significant improvements in various SOC subscale variables and that practices are effective in training the patient to react by coping and responding rather than avoiding or reacting to emotions and thoughts.[50] As patients focus on short-term goals and activities that are meaningful, they avoid unrealistic denial of negative outcomes.[61,62] The MBSR's persistent ability to decrease the general psychological symptoms of depression and paranoid ideation, in addition to improvements in anxiety, global orientation (a stress protector that assists the individual in improving health), and mental adjustment, are encouraging. Such improved recognition and coping may be extremely useful if the patient identifies cancer as a perceived threat.

Effects were most strongly evident at the 4-month point but not maintained beyond the immediate posttreatment interval. This may be secondary to a gradual reduction in symptoms of distress over the 1-year and 2-year follow-ups, which would lead to attenuating baseline intervention effectiveness and, possibly, lower compliance levels. In addition, baseline mean levels of distress are well below any clinical cutoffs for depression and anxiety, and as has been noted,[63-65] this creates a "floor" effect that makes it difficult to show significant treatment effects.

Positive aspects in the design of the study include the following: the use of 2 control groups, which minimizes nonspecific therapist effects that may be related to social support provided by program participation; a homogeneous patient population in terms of demographics, stage of cancer, and treatment modality; and a 2-year follow-up period. Our study assumes that emotional distress modifications and QOL improvements lead to improved health, and there is growing evidence that psychological factors do result in an overall improvement in health outcomes.[66] The demographics of this patient population may limit the study's external validity. Finally, because the study was not designed to specifically address radiotherapy, factors such as side effects were given only minimal consideration in the study's design.

It is important to note that we did not make any adjustment to the significant tests applied to the data. At 4 months, we observed 16 of 43 tests significant at the nominal $\alpha \leq .05$ (about 37% of all tests). At 12 months, we found 4 tests significant at nominal α .05 ($\approx$9%, or about twice that predicted by chance). At 24 months, we found 2 significant test ($\approx$5%, or about equal to that predicted by chance). One might apply Bayesian statistics[67] to assist with interpreting results. However, innovation implies being at the vanguard of the field. So, there is very little "context" in which to place the results. In the absence of established empirical data on which to fit the "priors" (ie, prior likelihood of a relationship), we concluded that it is not realistic to use a Bayesian statistical approach. Likewise, we chose not to apply some arbitrary statistical rule to adjust the level of statistical "significance." So results are presented without any manipulation or distortion. At this juncture, any inference that a reader draws from this work will be based on the results presented in conjunction with whatever judgment he or she might wish to apply. This work will contribute context to future studies in which Bayesian statistical methods could be applied.

Conclusion

Throughout the various stages of the treatment experience, questions arise pertaining to the meaning of life as well as new strategies for coping with illness and dealing with uncertainty.[68] Even though the BRIDGES study was not specifically designed for patients

undergoing radiotherapy, results show that a complementary stress reduction program has potential benefits to improve QOL and decrease distress among this particular subset of patients. Because better QOL is associated with better survival rates in cancer patients,[69] and stress-reduction practices pose no risk to the patient, there may be relevance to further consideration, research, and refinement of MBSR-based programs as complementary therapy in oncological practice, especially for radiotherapy patients.

Acknowledgments

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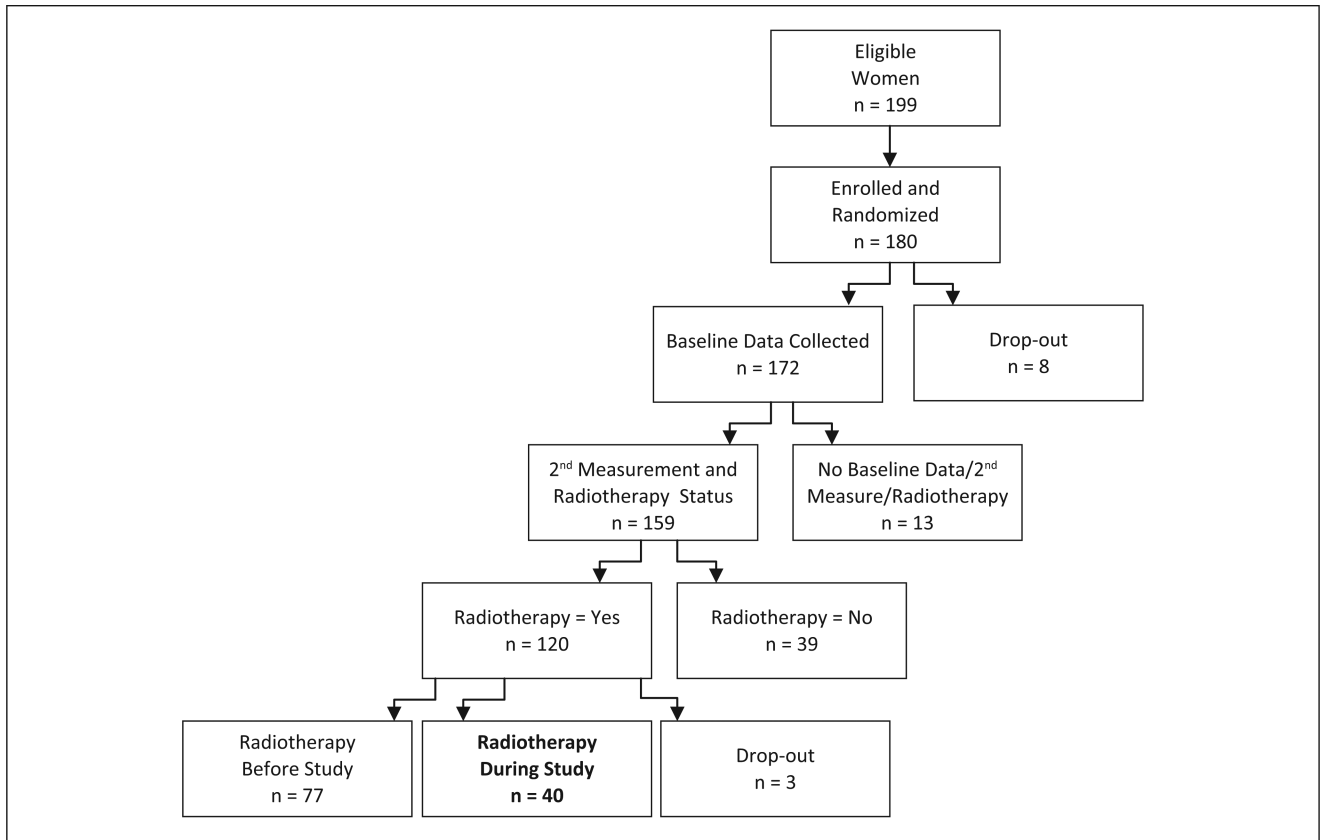
Figure 1.
Flow-chart of study design and randomization

Initial Study Outcomes vs. Radiotherapy*		
	MBSR-Overall Study	MBSR-Radiation
Active Behavioral Coping		·
Active Cognitive Coping	·	·
Avoidance Coping		·
FACT-Social-Family Well-Being		·
FACT-Emotional Well-Being		·
FACT-Spirituality	·	·
MMAC-Helplessness		·
MMAC-Cognitive Avoidance		·
SCL-Anxiety		·
SCL-Depression	·	·
SCL-Hostility	·	·
SCL-Global Severity		·
SCL-Paranoid Ideation	·	·
CEC-Anxious	·	·
CEC-Unhappy	·	
CEC-Total Control	·	·
SOC-Meaningfulness	·	·

*Improvement in eight of the sixteen variables was specific to radiation therapy, not solely a function of the MBSR detected in initial study outcome results.

Figure 2.
Summary of Table 2: a comparison of significant psychosocial factors at 4 months, initial study outcomes versus radiotherapy[a]
Abbreviations: MBSR, mindfulness-based stress reduction program; FACT, Functional Assessment of Cancer Therapy; MMAC, Mini-Mental Adjustment to Cancer Scale; SCL, Symptom Checklist 90-Revised; CEC, Courtauld Emotional Control Scale; SOC, Sense of Coherence Scale.
[a]Improvement in 8 of the 16 variables was specific to radiation therapy, not solely a function of the MBSR detected in initial study outcome results.

Table 1

Characteristics of All BRIDGES Study Participants (Regardless of Radiotherapy Status)

	Usual Care, n = 58		Nutritional Education, n = 52		Stress Reduction (MBSR), n = 53	
	n	**Percentage**	**n**	**Percentage**	**n**	**Percentage**
Education						
High school or less	15	26	13	25	9	17
Some college	16	28	22	42	21	39
Bachelor's degree	10	17	7	14	11	21
Graduate school	17	29	10	19	12	23
Marital status						
Single	15	26	16	31	14	26
Stable union	43	74	35	69	39	74
Race						
White	56	97	48	92	51	96
Other	2	3	4	8	2	4
Employment status						
No	14	24	8	15	10	19
Part-time	10	17	10	19	14	26
Full-time	34	59	34	65	29	55
Menopausal status						
Premenopausal	18	31	21	40	20	38
Postmenopausal	40	69	31	60	33	62
Stage of disease						
Stage I	30	52	31	60	29	55
Stage II	28	48	21	40	24	45
Estrogen receptor status						
Positive	34	65	35	76	37	82
Negative	18	35	11	24	8	18
Tamoxifen use						
Yes	22	39	19	38	27	56
No	34	61	31	62	21	44
Chemotherapy use						
None	24	46	20	42	22	47
Before the study	21	40	23	48	18	38
During the study	7	13	5	10	7	15
Radiotherapy before study						
None	11	19	14	29	14	28
Before the study	32	56	21	43	24	48
During the study	14	25	14	29	12	24
Time since diagnosis						
0 to 6 months	20	35	12	26	14	27
7 to 12 months	13	23	14	30	16	31

	Usual Care, n = 58		Nutritional Education, n = 52		Stress Reduction (MBSR), n = 53	
	n	Percentage	n	Percentage	n	Percentage
12+ months	24	42	21	45	21	41

Abbreviations: BRIDGES, Breast Research Initiative for Determining Effective Strategies for Coping With Breast Cancer; MBSR, mindfulness-based stress reduction.

Table 2

Description of Significant (*P* < .05) MBSR Outcomes by Intervention/Control Group Comparison for Women Receiving Radiotherapy During the Intervention Study

	4 Months	12 Months	24 Months
DWI—Active Behavioral Coping	MBSR (63.1 ± 1.6)	MBSR (62.9 ± 1.7)	
	UC (58.8 ± 1.5)	UC (56.6 ± 1.5)	
DWI—Active Cognitive Coping	MBSR (64.8 ± 1.4)	MBSR (62.6 ± 1.4)	MBSR (62.8 ± 1.4)
	UC (58.6 ± 1.2)	UC (58.2 ± 1.3)	NEP (57.8 ± 1.4)
DWI—Avoidance Coping	MBSR (24.1 ± 1.0)		
	UC (26.7 ± 0.9)		
	NEP (28.0 ± 1.0)		
FACT—Social-Family Well-Being	MBSR (22.2 ± 0.7)		
	NEP (19.8 ± 0.8)		
FACT—Emotional Well-Being	MBSR (18.0 ± 0.4)		
	UC (16.9 ± 0.3)		
	NEP (16.7 ± 0.4)		
FACT—Spirituality	MBSR (8.9 ± 0.4)	MBSR (8.9 ± 0.4)	
	UC (7.6 ± 0.4)	NEP (7.0 ± 0.5)	
	NEP (6.8 ± 0.5)		
SOC—Meaningfulness	MBSR (47.3 ± 1.3)	MBSR (48.1 ± 1.4)	MBSR (48.4 ± 1.3)
	UC (43.8 ± 1.2)	NEP (44.1 ± 1.4)	UC (44.6 ± 1.2)
	NEP (42.8 ± 1.3)		
MMAC—Helplessness	MBSR (10.1 ± 0.6)		
	NEP (11.7 ± 0.6)		
MMAC—Cognitive Avoidance	MBSR (8.2 ± 0.4)		
	UC (9.4 ± 0.4)		
SCL-90-R—Anxiety	MBSR (0.14 ± 0.05)		
	UC (0.28 ± 0.05)		
SCL-90-R—Hostility	MBSR (0.12 ± 0.06)		
	UC (0.32 ± 0.05)		
SCL-90-R—Global Severity Index	MBSR (0.22 ± 0.05)		
	UC (0.36 ± 0.04)		
	NEP (0.36 ± 0.05)		
SCL-90-R—Depression	MBSR (0.31 ± 0.08)		
	NEP (0.58 ± 0.08)		
SCL-90-R—Paranoid Ideation	MBSR (0.12 ± 0.05)		
	UC (0.26 ± 0.05)		
CEC—Anxious Preoccupation	MBSR (14.1 ± 0.7)		MBSR (14.5 ± 0.7)
	UC (15.9 ± 0.6)		UC (16.4 ± 0.7)
CEC—Overall Emotional Control	MBSR (41.7 ± 1.7)		
	UC (46.3 ± 1.5)		

Abbreviations: MBSR, mindfulness-based stress reduction; DWI, Dealing With Illness questionnaire[29]; UC, usual care; NEP, nutrition education intervention; FACT, Breast Cancer Version of the Functional Assessment of Cancer Therapy (FACT-B) additional spirituality items[26,41-43];

SOC, Sense of Coherence Scale[33-35]; MMAC, Mini-Mental Adjustment to Cancer Scale[37]; SCL-90, Symptom Checklist-90-Revised[40]; CEC, Courtauld Emotional Control Scale.[38,39]