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Effect of Mindfulness-Based Stress Reduction Intervention on Pain and Fatigue in Women with Breast Cancer

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ABSTRACT

Aims Pain and fatigue are common in women with breast cancer. Mindfulness-based stress reduction training has shown varying results regarding pain and fatigue scores. Therefore, this study was conducted to determine the effect of mindfulness-based stress reduction intervention on pain and fatigue in women with breast cancer in Yazd, Iran.

Materials & Methods This quasi-experimental study was conducted on 56 women with breast cancer in Yazd City, Iran. Using a simple randomization method, participants were assigned to the intervention and control groups (28 patients per group). Mindfulness-based stress reduction training was conducted via WhatsApp in eight virtual sessions for the intervention group. Data were collected using an electronic demographic form and the Fatigue Severity Scale Questionnaire (FSS) and Brief Pain Inventory (BPI) before the intervention, immediately after the intervention (week eight), and four weeks after the intervention (week 12). Descriptive statistics and both parametric and nonparametric analyses were performed using SPSS 16 software.

Findings There was no significant difference in demographic and clinical characteristics between the groups. The mean fatigue score of the intervention group improved at week eight compared to the control group ($p<0.001$). However, there was no significant difference between the two groups in the average pain score after the intervention, although a decreasing trend was observed ($p>0.05$).

Conclusion MBSR training reduces fatigue in women with breast cancer, and although it decreases pain, this reduction is not significant.

Keywords Mindfulness; Stress, Physiological; Pain; Fatigue

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Introduction

Breast cancer is considered the most common malignant disease among women worldwide [1] and is a major and increasing health problem both globally and in Iran [2]. Despite a decrease in breast cancer mortality in developed countries, it accounts for 60% of the reported deaths in these nations. This disease remains one of the primary challenges in the health policies of developing countries, such as Iran [3, 4].

Cancers, particularly breast cancer, act as significant negative stressors that can severely impact the physical and mental health of those affected [5]. This condition manifests in various negative aspects, including both physical and psychological symptoms [6]. The most commonly reported physical symptoms include pain, sleep disorders, and fatigue [7-9]. Even after the conclusion of breast cancer treatment, survivors continue to report high levels of physical symptoms such as pain, fatigue, and sleep disturbances, as well as a decline in quality of life [2, 10, 11]. Despite the increase in long-term survival rates following a breast cancer diagnosis due to early detection and advancements in treatment methods [12], many survivors are unprepared for the effects of the disease or treatment, as well as the emotional distress that accompanies the diagnosis and treatment process. This can lead to issues such as depression, anxiety, sleep disorders, and fear of recurrence, along with physical problems like pain and fatigue [11]. It can be stated that pain and fatigue are the most prevalent physical symptoms that negatively affect the quality of life and functioning of these individuals [13].

Cancer-related fatigue is one of the most commonly reported symptoms among breast cancer patients and, as previously mentioned, is a frequent side effect of related treatments. This type of fatigue is not associated with the level of activity and does not improve with rest [14]. Radiation therapy and chemotherapy account for nearly 70% of this complication [15]. The National Comprehensive Cancer Network (NCCN) reports that the degree of fatigue in cancer patients undergoing treatment ranges from approximately 70% to 100% [16, 17].

Additionally, cancer-related fatigue is an unpleasant experience that many patients fear. While there are various methods to manage pain at different times, chronic pain following breast cancer treatment is considered a significant clinical issue due to its impact on quality of life and overall treatment resistance [18, 19]. The prevalence of pain after breast cancer treatment is reported to be around 20-30% in various studies [20, 21].

Psychological interventions are effective in reducing these symptoms [22-24]. Today, one of the treatments that examines the interactions between the mind, body, and emotions is mindfulness therapy [25]. In mindfulness and moment-to-moment awareness training, individuals strive to gain insight into their patterns of thoughts, emotions, and interactions with others [26], which provides them the opportunity to control their own behaviors [27]. The most common method of mindfulness training is mindfulness-based stress reduction (MBSR) [28], which aims to achieve four primary goals: focusing attention on the present moment, developing metacognitive awareness alongside breathing, fostering acceptance of mental states and contents, and practicing non-judgment regarding feelings and events [29]. In the MBSR program, participants are taught to observe their mental processes, including their feelings, thoughts, and physical sensations [30], allowing them to analyze their current experiences and behaviors [31]. Individuals should reflect on their life circumstances and respond in new ways rather than relying on habitual reactions [32]. Recent studies based on mindfulness emphasize the reduction of physical and psychological symptoms in people with breast cancer, including a study conducted by Lengacher *et al.*, who evaluated the effect of mindfulness on reducing stress and improving symptoms in breast cancer survivors in the United States. They reported that the group that received a mindfulness program, compared to the group that received usual care, achieved improvements in both psychological and physical symptoms and could better control the fear of relapse and fatigue; however, they reported no statistically significant difference regarding pain between the groups [33]. In addition, Wu *et al.* assessed the effectiveness of MBSR compared to usual care in breast cancer patients. They found no significant difference between the two groups, and regarding the reduction of fatigue, the results were heterogeneous [34]. Additionally, Johannsen *et al.* evaluated the effectiveness of mindfulness-based cognitive therapy on late pain after treatment in women treated for early breast cancer. They concluded that the intensity of pain after the intervention significantly decreases [35].

Considering that people's behaviors and attitudes toward disease and its treatment vary across different cultures and that studies should be conducted in diverse cultures and societies, as well as the fact that breast cancer is one of the health priorities in Iran [36], and taking into account the heterogeneity of results from various studies and the significance of mindfulness, we investigated the effect of a mindfulness-based intervention on the physical symptoms of pain and fatigue in women with breast cancer in Yazd, Iran.

Materials and Methods

This semi-experimental study, which included two groups—an intervention group and a control group—assessed the participants before the intervention, immediately after the intervention, and during follow-up. Sampling and intervention were conducted from July 15, 2020, to October 27, 2020.

Participants, eligibility criteria, and setting

The participants were breast cancer patients referred to Ramzanzadeh Radiation Therapy Center in Yazd, Iran, who had completed two months of radiation therapy and chemotherapy or were candidates for radiation therapy and chemotherapy at the time of the study. Initially, addresses and names were extracted from the patients' files.

Inclusion criteria included individuals diagnosed with breast cancer who had passed at least one month since their diagnosis or at most two months since completing radiation and chemotherapy, or who were candidates for radiation and chemotherapy. Participants were required to have stage I to III breast cancer at the time of initial diagnosis, the ability to read and write, the capability to participate in counseling sessions, a willingness to cooperate in the study, a history of surgeries such as lumpectomy or mastectomy (radical, total, etc.), access to a smartphone, and the ability to use it or have a companion to assist them in this regard.

Exclusion criteria included having other cancers, illnesses, or disabilities that prevent participation in meetings, having a mental illness under treatment; experiencing significant stress, such as the death of a loved one or divorce in the last six months; substance abuse, and simultaneous participation in the same psychological study. Additionally, unwillingness to continue participating in meetings, the occurrence of major stressors and unexpected events at any stage of the intervention, and failure to complete homework for more than three sessions were also considered grounds for excluding participants from the study.

Sample size and randomization

The sample size was calculated using the following formula, with a confidence level of 95% and a test power of 80%. Based on the study by Rahmani & Talepasand [37], the sample size was determined to be 25 individuals in each group; however, accounting for a 10% attrition rate, 28 individuals were included in each group:

$$N=2s^2p[z_{1-\alpha/2}+z_{1-\beta}]^2/\mu^2d$$
$$S^2p=s_1^2+s_2^2/2$$

Eligible participants were assigned to two groups: the intervention group (28 individuals) and the control group (28 individuals) using a simple randomization method and a random numbers table.

Intervention

The intervention utilized was the MBSR protocol. During a phone call with the individuals, and after confirming their eligibility to participate in the study, the objectives of the research were explained to them, and they completed the informed consent form if they wished to participate. Due to the COVID-19 pandemic, the meetings were held online. Participants in both the intervention and control groups joined separate virtual WhatsApp groups. Initially, the study objectives and methods were presented, and for the intervention group, information was provided in the form of PowerPoint files and podcasts over eight consecutive weeks during eight 2-hour online sessions. The content of the sessions included training based on the Kabat-Zinn MBSR protocol [38], which had been validated by experts (Table 1).

Table 1. The content of mindfulness-based stress reduction sessions

Session	Subject	Content
First	Automatic guidance	-A general statement about breast cancer, including its definition, symptoms, and complications -Practicing eating raisins and discussing the experience of this practice -Physical examination exercise, beginning with a focus on short breathing, followed by feedback and discussion about the physical examination -Focus on short breathing for 2 to 3 minutes
Second	Facing obstacles	-Physical examination exercise -Practicing thoughts and feelings (walking on the street -Recording pleasant events -Expression of complications of breast cancer -Sitting meditation
Third	Breathing with the presence of mind	-Practicing seeing and hearing and sitting meditation -Practicing the 3-minute breathing space and reviewing it -Expressing the effects of breast cancer on quality of life and pain and fatigue -Preparing a list of unpleasant events
Fourth	Presence in the present	-Practicing seeing or hearing and meditating awareness of breathing, body, voice, and thoughts -Practicing the 3-minute breathing space and reviewing it -Breast cancer treatment methods and the effect of mindfulness on the symptoms and quality of life and pain and fatigue of women with breast cancer
Fifth	Acceptance	-Sitting meditation and expressing the difficulties that occur during the exercise and their effects on the body and reaction to them -Emphasizing the use of mindfulness techniques when facing breast cancer treatment complications -Practicing the 3-minute breathing space and reviewing it
Sixth	Thoughts are not facts	-Sitting meditation and awareness of breathing, body, sounds, and then thoughts (in addition to paying attention to reactions given to problems -Creating, thinking, and practicing points of view or substitute thoughts -Providing general recommendations to patients in relation to mental and psychological issues of this course and the necessity of using mindfulness in times of problems.

The training was conducted by the third researcher, who had obtained certification to lead a mindfulness course focused on stress reduction from a licensed psychology and counseling center. Additionally, participants could ask questions of the researcher, receive necessary guidance, and submit their homework via chat. The researcher ensured participation and provided advice through phone calls and chats, monitored homework, and obtained feedback from participants, ensuring they were online during meetings. Expert researchers also supervised the weekly sessions. During the follow-up period, those in the intervention group could communicate with the researcher, who would provide guidance based on the training techniques and emphasize the importance of continuing the exercises.The control group received routine care and was placed on a waiting list to receive MBSR after the completion of the intervention and follow-up. The follow-up period for this research was four weeks. After the study, due to the effectiveness of the intervention and in accordance with ethical considerations, MBSR training was provided to the control group.

Research tools and data collection method

Before the MBSR sessions, the demographic information checklist, the Fatigue Severity Scale (FSS), and the Brief Pain Inventory (BPI) were shared with the group via a link to the electronic questionnaire, and participants were requested to complete them (baseline). These questionnaires were also administered at the end of the eighth session (week eight) and four weeks after the intervention as a follow-up (week 12). Participants in both the control and intervention groups were asked to complete the questionnaires again using the Porsline software.

Demographic information form

The personal information form includes questions such as questionnaire code, age, level of education, occupation, marital status, and menopause status, which were completed by individuals during the first meeting.

Fatigue Severity Scale (FSS)

This questionnaire was designed by Cropp *et al.* in 1989 to measure the severity of fatigue and has undergone psychometric analysis. This nine-item scale assesses individuals' personal perceptions of their fatigue. The scoring of the questionnaire is based on a Likert scale ranging from one to seven. The internal structure and reliability of the questionnaire were examined and confirmed through internal consistency at the item level, calculation of Cronbach's alpha coefficient, and repeatability across test administrations in the research conducted by Shahvarughi-Farahani *et al.* [39].

Brief Pain Inventory (BPI)

The BPI is a standard questionnaire developed by Cleeland to measure the intensity of chronic pain in cancer patients and other clinical patients suffering from chronic pain. This questionnaire consists of two main parts: one measuring the intensity of pain and the other assessing the level of interference with daily activities, along with background questions. The scoring for these components ranges from zero (absence of pain) to ten (unimaginable pain). A higher score indicates more severe pain. Vakilzadeh and Nakhaie evaluated and confirmed the reliability and validity of this questionnaire for cancer patients [40-42].

Data analysis

Data were analyzed using SPSS 16. An independent t-test was employed to analyze quantitative data, while Mann-Whitney and Chi-square tests were utilized for qualitative data. Since the study was designed based on three intervals (baseline and weeks 8 and 12), intra-group analysis was conducted using repeated measures analysis of variance (ANOVA). A p-value of < 0.05 was considered significant. As the data did not follow a normal distribution, non-parametric tests were used for statistical analysis.

Findings

The average age of women participating in the intervention group was 47.57±9.36 years, while in the control group, it was 51.86±10.75 years (p=0.117). In both groups, the majority of female participants were housewives and had below-diploma education. The mean time to diagnosis in the intervention and control groups was 8.39±3.36 and 8.36±2.87 weeks, respectively (p=0.301). Also, the mean time to surgery, chemotherapy, and radiotherapy in the intervention group were 7.54±2.77, 5.32±2.91, and 2.07±1.21 weeks, whereas these parameters were 7.39±1.79, 3.54±2.19, and 1.57±1.37 weeks in the control groups (0.414, 0.153, and 0.118, respectively). The two groups showed no statistically significant differences in terms of demographic and background factors, such as age, duration of disease diagnosis, surgery, chemotherapy, radiation therapy, marital status, occupation, and education level (Table 2).

Table 2. Frequency of demographic characteristics in the intervention and control groups

Parameter	Category	Intervention Group	Control Group	p-Value
Occupation	Housewife	21(75)	21(75)	1.000*
	Practitioner	7(25)	7(25)	
	Total	28(100)	28(100)	
Education	Less than a diploma	12(42.9)	10(35.7)	0.496*
	Diploma	10(35.7)	8(28.6)	
	Academic	6(21.4)	10(35.7)	
	Total	28(100)	28(100)	
Marital status	Single	1(3.6)	2(7.1)	0.553*
	Married	27(96.4)	26(29.9)	
	Total	28(100)	28(100)	
Surgical status	Lumpectomy	23(82.1)	25(89.3)	0.445*
	Mastectomy	5(17.9)	3(10.7)	
	Total	28(100)	28(100)	

*Calculated based on the Chi-square test.

The Kolmogorov-Smirnov test showed that the fatigue scores after the intervention (week eight) in both groups followed a normal distribution; however, the baseline and the follow-up scores, i.e., four weeks after the intervention (week 12), did not follow a normal distribution. Before the intervention, there was no statistically significant difference in the mean fatigue score between the intervention and control groups, as determined by the Mann-Whitney test (p=0.710). The average fatigue score immediately after the intervention (week eight) was higher in the control group than in the intervention group, and the results of the independent t-test indicated that this increase was significant between the two groups (p<0.001). However, although the average fatigue score in the intervention group at follow-up (week 12) was lower than that in the control group, the Mann-Whitney test results showed that this difference was not significant (p=0.298).

The average fatigue score in the intervention group decreased in the post-test (week eight) compared to the pre-test (baseline), and this decrease continued into the follow-up phase (week 12). The average score in the follow-up was lower than in the post-test, and the difference in fatigue scores among the three stages was significant (p<0.001).

The Kolmogorov-Smirnov test results showed that the pain values in the 8th week for the two groups followed a normal distribution; however, the values at baseline and week 12 did not show a normal distribution. Before the intervention, there was no statistically significant difference in the average pain score between the intervention and control groups, as determined by the Mann-Whitney test (p=0.724). Although the average pain score in the 8th week was higher in the control group than in the intervention group, this difference was not significant (p=0.747). In the 12th week, there was also no significant difference in the pain score between the intervention and control groups (p=0.593). There was no significant difference in the average pain score at the three time points between the intervention and control groups (p>0.05; Table 3).

Table 3. Comparison of fatigue and pain scores between the intervention and control groups at different time points

Parameter	Intervention Group	Control Group	p-value
Fatigue			
Baseline	31.67±13.06	32.85±10.39	0.710**
Week 8	18.07±10.89	34.78±12.83	0.001*
Week 12	17.82±13.36	22.07±16.79	0.298**
p-value ***	0.001	0.020	
Pain			
Baseline	2.92±2.83	2.30±2.09	0.724**
Week 8	1.52±1.37	1.66±1.87	0.747*
Week 12	2.41±2.57	2.01±2.04	0.593**
p-value ***	0.549	0.534	

*Independent-samples t-test; **: Mann-Whitney U test; ***Multivariate analysis.

In a pairwise comparison, the difference in fatigue scores was found to be significant between the baseline and week eight, as well as between the baseline and week twelve (p<0.001). However, between weeks eight and twelve, despite the reduction in fatigue scores, the difference was not significant.

In the control group, the fatigue score increased in the 8th week but decreased in the 12th week, with the difference being significant (p<0.020; Table 3). In the paired comparison of pain scores in the control group, significant differences were observed between weeks 0 and 12 (p<0.027) and between weeks 8 and 12 (p<0.020; Table 4).

Table 4. Pairwise comparison of fatigue score of women with breast cancer in the intervention and Control groups at different time points

Parameter	Mean difference	Standard error	p-Value*
Intervention group			
Baseline-week 8	13.607	3.332	0.001
Baseline-week 12	13.857	3.320	0.001
week 8-week 12	0.250	2.795	1
Control group			
Baseline-week 8	-1.929	2.882	1
Baseline-week 12	10.786	3.822	0.027
week 8-week 12	12.714	4.322	0.020

*Bonferroni post hoc test.

The present study investigated the effect of mindfulness-based intervention on pain and fatigue in women with breast cancer in Yazd, Iran. The MBSR intervention reduced the average fatigue score in women with breast cancer after eight weeks of intervention; however, this reduction was not significant in the following four weeks. Although the pain score decreased during the intervention and post-intervention, this decrease was not significant compared to the control group.

The MBSR intervention led to a decrease in the fatigue score of women with cancer, which aligns with the results of Lengacher *et al.*, who reported that immediately after the study, as well as at 6 weeks and 12 weeks post-intervention, the MBSR intervention improved specific breast cancer symptoms and mental fatigue; however, there was no statistically significant difference regarding pain scores [33]. In the present study, a decrease in the average fatigue score was observed immediately after the intervention, but after four weeks, this difference was not significant. Additionally, in Johns *et al.*'s study, MBSR not only resulted in greater vitality but also led to a moderate to complete improvement in fatigue both post-intervention and six months after the intervention [43]. Furthermore, in the study by Gok Metin *et al.*, two methods—progressive muscle relaxation and mindfulness meditation—showed similar results in reducing fatigue and improving coping styles among patients with early-stage breast cancer [44]. By creating a higher level of energy, MBSR can reduce mood disorders, mental disorders, and especially fatigue. However, in the present study, four weeks after the intervention, there was no significant improvement in patients' fatigue. One possible

reason for this difference is the virtual nature of the MBSR intervention. Additionally, the passage of time and the distancing from radiation and chemotherapy sessions, as well as the effects of treatments on the control group, may contribute to this result. MBSR is an evidence-based, group-based intervention that focuses on improving awareness and acceptance of thoughts and feelings, including physical discomfort and difficult emotions [38]. The main components of MBSR include meditation exercises that help increase awareness of feelings, emotions, and thoughts, provide self-regulation strategies, and promote healthy and adaptive responses to stress [45].

Ahmadi Gharagasloo *et al.* demonstrated an improvement in cancer-related fatigue among breast and colorectal cancer patients participating in the MBSR training program [46]. When a person achieves the principles of mindfulness, it enhances their physical, mental, and emotional well-being and health, allowing them to better control their behaviors [47]. In the present study, mindfulness reduced fatigue by fostering mental and emotional peace. Kubo *et al.* reported a reduction in distress levels and improvements in quality of life, as well as physical and psychological symptoms, including sleep problems and fatigue, in people with cancer and their caregivers following MBSR intervention [48]. This study aligns with the present research, considering the eight-week online mindfulness-based intervention using a mobile phone app, which affected quality of life by reducing physical and psychological symptoms and increasing participant satisfaction, thereby facilitating faster access to mindfulness training programs. In the present study, due to the COVID-19 pandemic and the risk of infection, as the subjects were in a high-risk group, the training was conducted virtually. The findings indicated that mindfulness-based training was effective in reducing fatigue, with no significant difference compared to face-to-face training. However, it is evident that face-to-face counseling, eye contact, close conversation, and practical training in techniques could have more pronounced effects on individuals.

Contrary to the results of the present study, Wu *et al.* showed that MBSR did not have a significant effect on reducing fatigue and improving the quality of life in breast cancer patients [34], while the current study demonstrated a significant reduction in the severity of fatigue among patients who participated in eight sessions of MBSR. The differences in the results of this study compared to ours, as well as the lack of significant improvement in fatigue four weeks after the intervention in the present study, may be attributed to variations in the sample size, the training and follow-up methods, the severity of the patient's illnesses, and the duration of follow-up.

The results of the present study showed that although the MBSR intervention caused a decreasing trend in the pain scores of breast cancer patients, this difference was not significant. In a systematic review, MBSR was found to reduce pain in patients with chronic diseases [49], which may be due to variations in the methods of delivering MBSR education and the different types of diseases studied, as well as a potential need for a longer duration of MBSR interventions. Additionally, Johannsen *et al.* demonstrated the effectiveness of mindfulness-based cognitive therapy (MBCT) in alleviating late pain after treatment in women treated for primary breast cancer. It can be concluded that MBCT may serve as an effective pain rehabilitation strategy for women undergoing breast cancer treatment [35]. In the present study, although the reduction in pain was not significant, this decrease is still valuable from a clinical perspective.

Similar to our results, Shergill *et al.*'s research found that MBSR did not reduce pain in 98 breast cancer survivors with chronic neuropathic pain (CNP). Many breast cancer survivors continue to experience CNP after treatment. Despite pharmacological management of CNP, many women still report debilitating pain and reduced quality of life, and it is often recommended to address pain with psychosocial interventions as an adjunct to drug therapy for CNP [50]. The recurrence of pain symptoms during follow-up can be attributed to the fact that physical and neuropathic pain in breast cancer survivors requires additional pain reduction methods and longer follow-ups. On the other hand, it should be noted that if these mental techniques are not continued and do not become a dominant part of daily life, they can lead to a return of pain and fatigue symptoms. In the present study, there was no significant difference in fatigue one month after the intervention compared to immediately after the intervention.

Due to the COVID-19 pandemic, the virtual implementation of this educational intervention and the online completion of the questionnaires to maintain the health of breast cancer patients is considered a key strength of this intervention. Additionally, while having a follow-up period is a strength of this study, the one-month duration of the follow-up cannot represent a lasting effect.

The main limitations of the study included the lack of an active control program. Another limitation was the absence of a cut-off point regarding pain for entry into the study, resulting in participants not reporting significant pain at the beginning of the study. Furthermore, this study did not examine the role of mediators such as perceived stress, negative stimuli, emotion regulation, etc. It is suggested that future studies investigate the role of these mediators.

The need for an interdisciplinary approach in the treatment of this disease, along with the implementation of the mindfulness method based on stress reduction in cancer treatment centers, is suggested as a complementary strategy for treating patients. Therefore, utilizing experienced healthcare

providers, particularly senior midwifery consultation experts, can play a crucial role in education, improving quality of life, and reducing complications, as well as mental and physical symptoms related to breast cancer during the treatment period. A clinical trial study with a larger sample size, employing a face-to-face training method and conducting all MBSR intervention sessions under the supervision of psychologists who are subject matter experts, is recommended for a longer follow-up period.

Conclusion

MBSR training reduces fatigue in women with breast cancer, and although it decreases pain, this reduction is not significant.

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Ethical Permissions: Participants were informed about the study through a written letter. All participants completed an informed consent form and had the option to withdraw their consent to participate at any time. The study protocol and the instruments used for evaluation were approved by Shahid Sadoughi University of Medical Sciences in Yazd (grant No. 7233 and ethical code IR.SSU.RSI.REC.1398.050). All methods were performed in accordance with the relevant guidelines and regulations.

Conflicts of Interests: The authors reported no conflicts of interests.

Authors' Contribution: Enjezab B (First Author), MAin Researcher/Methodologist/Discussion Writer (35%); Zare Hoseinabadi M (Second Author), Assistant Researcher/Discussion Writer (20%); Shokrirafsanjani F (Third Author), Original Researcher/Introduction Writer/Discussion Writer (45%)

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