


# The Effect of Mindfulness-Based Stress Reduction Group Counseling on Psychological and Inflammatory Responses of the Women With Breast Cancer

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## Abstract

**Introduction:** Breast cancer is common among women and reduces their quality of life. The current study aimed to investigate the effectiveness of mindfulness-based stress reduction group counseling in alleviating psychological responses such as anxiety, depression, stress, and regulating laboratory tests including cortisol and C-reactive protein (CRP) in women with breast cancer. **Methods:** This randomized clinical trial was conducted based on convenience sampling. Participants were divided into 2 groups (control and intervention groups) with block randomization. The intervention group received mindfulness-based stress reduction group counseling during 8 weeks. The participants completed the Beck anxiety inventory, Beck-II depression inventory, and perceived stress scale before and after the intervention and their blood samples were taken to check their cortisol and CRP. **Results:** After the intervention, the MBSR group had significantly lower anxiety compared with the control group ( $P < .001$ ). No significant difference was found between the 2 groups in the reduction of perceived stress and depression ( $P < .05$ ). In addition, no significant difference was found between the 2 groups in CRP and cortisol levels after the intervention ( $P > .05$ ). **Conclusion:** The present study showed the effectiveness of mindfulness-based cognitive therapy in improving anxiety rather than the stress, depression, and inflammatory laboratory factors such as cortisol and CRP in women with breast cancer. Therefore, the psychological symptoms of these patients can be improved at different stages of treatment by providing this type of training.

## Keywords

stress, anxiety, depression, breast cancer, mindfulness, group therapy, mindfulness-based stress reduction, inflammatory factors

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## Introduction

Cancer is the second leading cause of mortality in the world after cardiovascular disease.<sup>1</sup> Approximately, 1.6 million cancers were diagnosed in the US in 2018, of which 271 000 were breast cancers.<sup>2</sup> Breast cancer has the highest mortality rate throughout the world.<sup>3</sup> In Iran, breast cancer is on the top of malignancies diagnosed in females,<sup>4</sup> with approximately 33.21 cases per 100 000 population.<sup>5,6</sup>

Patients with breast cancer have numerous physical and psychological problems.<sup>7</sup> Various factors such as fear of illness recurrence, body dysmorphic disorder, chemotherapy, surgery, young age, higher degree of illness, and lack of

social support can lead to psychological responses in breast cancer patients.<sup>8,9</sup> Psychological responses such as stress, depression, and anxiety are all associated with the disease diagnosis and treatment.<sup>10</sup> Studies have shown the variable

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prevalence of depression (from 9% to 66%), stress (14.3%), anxiety (from 17.9% to 33%), and psychological disorders (from 15% to 60%) in women with breast cancer.<sup>11-14</sup> Psychological problems not only impair the patients' immune systems, but also severely affect their quality of life.<sup>15,16</sup> They also increase inflammatory responses.<sup>17</sup> Inflammatory factors such as cortisol and C-reactive protein (CRP) are associated with breast cancer progression<sup>18</sup> and psychological problems.<sup>19</sup> Studies have shown that regulated inflammatory factors are important indicators, reduce morbidity, and prolong life expectancy.<sup>20</sup>

According to the American Cancer Society Guideline, one of the keys to survival in these patients is the evaluation and management of long-term physical and mental health conditions related to breast cancer and its complications.<sup>21</sup> Therefore, cognitive-behavioral interventions may be necessary for these patients in addition to drug therapy.<sup>22,23</sup> One of these is mindfulness-based stress reduction (MBSR).<sup>24,25</sup> Mindfulness focuses on the 3 elements of paying attention in the present moment, capacity to hold the object and non-judgment.<sup>26,27</sup> This attitude leads to awareness of negative thoughts and prevents mind rumination.<sup>28</sup> Many clinical psychologists believe that MBSR induces neuronal changes in the gray matter and regulates emotions.<sup>29,30</sup>

Some previous studies showed the effectiveness of mindfulness in improving psychological status,<sup>31-33</sup> regulating cortisol level<sup>31,33</sup> improving the immune system in breast cancer patients,<sup>34</sup> and reducing CRP levels in healthy individuals.<sup>33,34</sup> However, some other studies did not confirm the effectiveness of MBSR. Zhang et al showed the effectiveness of mindfulness intervention in the quality of life of breast cancer patients, but not in their sleep quality and pain.<sup>35</sup> The results of a review study showed the effectiveness of mindfulness in lowering cortisol, heart rate, blood pressure, and tumor necrosis factor (TNF), but had little effect on CRP.<sup>32</sup> Therefore, the impact of mindfulness on inflammatory factors is still unclear. The psychological problems of patients with breast cancer may affect and impair other family members' quality of life and function.<sup>36</sup> A few Iranian studies have assessed the effectiveness of MBSR in psychological problems and inflammatory factors of the patients with breast cancer. Therefore, the current study aimed to determine the effectiveness of mindfulness in psychological problems and inflammatory factors of breast cancer patients.

## Method and Materials

### Study Design and Setting

This study is a parallel-randomized clinical trial with allocation ratio of 1:1. The research settings were the medical offices of oncologists and medical centers affiliated to the Medical Science Universities of Kerman, southeast Iran.

The intervention was performed in Bahonar Hospital. The study lasted from August 2017 to November 2019.

### Sample Size and Sampling

The sample size was 22 individuals for each group according to a previous study (anxiety score:  $x_1=47.53$ ;  $S_1=4.18$  and  $x_2=43.06$ ;  $S_2=4.39$ ),<sup>33</sup> the confidence coefficient of 95% and the test power of 90%.

Inclusion criteria were diagnosed disease between 3 months and 5 years, no use of psychological treatment before and during the intervention, no drug addiction, no acute psychiatric disorders (psychosis, severe mood disorder, etc.), no mental disorders,<sup>37</sup> no use of anxiolytic and antidepressant medications, undergoing at least 1 chemotherapy period or surgery, ages between 18 and 70 years,<sup>37</sup> breast cancer without metastasis,<sup>38</sup> and no use of corticosteroids, psychoactive and hormonal drugs. Exclusion criteria were being absent in more than 3 sessions of MBSR, physical disability due to illnesses and treatments, use of corticosteroids, psychoactive and hormonal drugs,<sup>38</sup> suffering from a major crisis during or about 3 months before intervention such as death of loved ones, comorbidity with autoimmune diseases, previous involvement in mindfulness groups,<sup>37</sup> or endocrine diseases such as Cushing's disease.<sup>39</sup>

All eligible patients were included in the study using convenience sampling. Of 57 eligible participants (17 patients from Yas center, 10 from the Jawad-al-Aemah Clinic, and 30 from the oncologist's office), 6 patients refused participation in the study. Finally, 44 patients completed the study (22 participants per group; Figure 1).

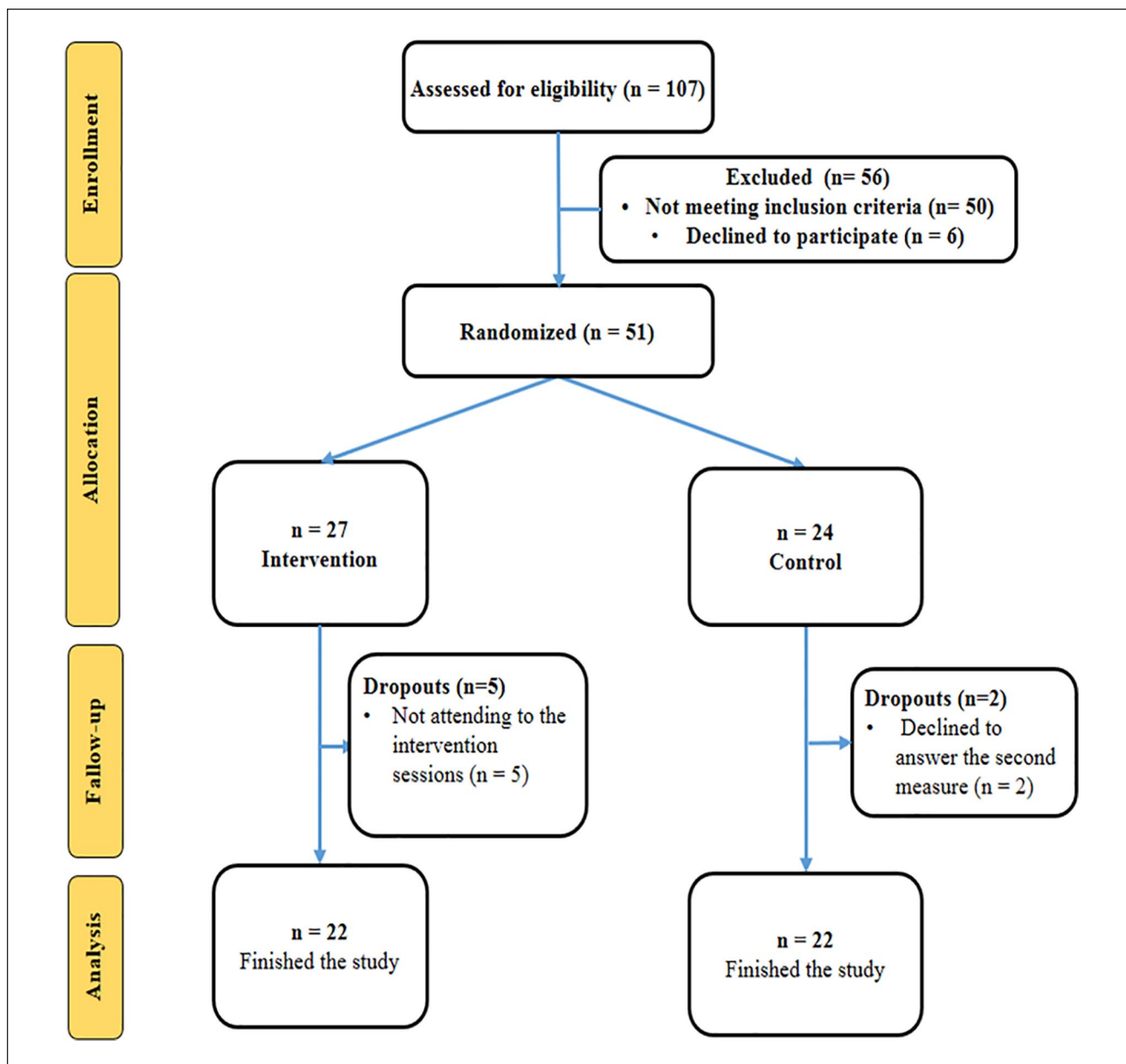
Samples were divided into 2 groups (routine care and mindfulness-based stress reduction group therapy) using block randomization. Labels of A, or B (A=MBSR and B=routine care) were assigned to each group, and the block size was considered 4. Then the randomization list was generated by free online software (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). The fourth researcher generated the random allocation sequence, and the first researcher enrolled and assigned participants to the groups.

### Measurements

Demographic characteristics questionnaire, Beck depression inventory, Beck anxiety inventory, perceived stress scale, and laboratory test form were used in this study.

### Demographic Characteristics

Demographic characteristics questionnaire includes age, sex, education, occupation, monthly income, type of insurance, disease duration, type of treatment, type of surgery, lymph node surgery, duration of chemotherapy, history of specific disease, and use of specific chemotherapy drugs.



**Figure 1.** The flow diagram of the study.

### Beck Anxiety Inventory (BAI)

Beck et al designed the anxiety inventory in 1988.<sup>40</sup> The inventory specifically measures the severity of clinical anxiety symptoms. The BAI was scored on a scale value of 0 (not at all) to 3 (severely). The scores totally range from 0 to 63 (scores ranging from 0 to 7 would be considered minimal anxiety, scores ranging from 8 to 15 would be considered mild anxiety, scores ranging from 16 to 25 would be considered moderate anxiety, and scores ranging from 26 to 63 would be considered severe anxiety).<sup>40,41</sup> The validity and reliability of the scale have been confirmed in Iran.<sup>41</sup>

### Beck Depression Inventory-II (BDI-II)

Beck et al developed the depression inventory in 1971.<sup>42</sup> This questionnaire is the new version of a 21-item self-report questionnaire for measuring depression severity in adults and adolescents over 13 years old. The items of this questionnaire measure the physical, behavioral, and cognitive symptoms of depression. The instrument was scored on the scale value of 0 (no specific sign) to 3 (severe signs). The scores totally range from 0 to 63. The cut-off point of this test is 13, meaning that scores ranging from 0 to 3 would be considered healthy, scores ranging from 14 to 19

**Box 1.** The Intervention Protocol.

**Session 1:** The study purpose and a summary of sessions were explained. Participants were then asked to eat a dried grape with full sensation, and practiced body scan meditation for 30 minutes (while drawing their attention to a part of their body).

**Session 2:** Participants discussed the practice of body scan meditation at home, the obstacles (such as restlessness and mind wandering), the solutions (non-judgment and abandoning intrusive thoughts), and the difference between thoughts and feelings. The participants practiced meditation in a sitting position.

**Session 3:** Participants saw and listened in a non-judging manner for 2 minutes, practiced meditation and breathing in a sitting position with focus on the physical sensations.

**Session 4:** Participants focused on the body sounds and thoughts, discussed about stress responses, reaction to difficult situations, alternative attitudes and behaviors, and practiced mindful walking.

**Session 5:** The participants did meditation in a sitting position and presented the second series of mindful body movements and mountain meditation.

**Session 6:** Participants talked to each other about home practices. Then, the following theme was practiced: the content of thoughts is not often real. Thereafter, 4 types of meditation were practiced in 1 hour.

**Session 7:** 4D meditation and awareness about everything at the present moment were practiced. The main theme of this session was as follows: what is the best way to take care of myself? Then, participants identified pleasant and unpleasant events, and planned an enjoyable program.

**Session 8:** The participants used whatever they learned. They began with body scan meditation and discussed about the obstacles of meditation.

would be considered mild depression, scores ranging from 20 to 28 would be considered moderate depression, and scores ranging from 29 to 63 would be considered severe depression. The validity and reliability of the scale have been confirmed in Iran.<sup>43</sup>

### *Perceived Stress Scale (PSS)*

Cohen et al developed the perceived stress scale.<sup>44</sup> The scale was scored based on a 5-point Likert scale (never=0, almost never=1, sometimes=2, often=3, and most of the time=4). Phrases 4, 5, 6, 7, 9, 10, and 13 were scored inversely. Therefore, for the 14-item scale used in this study, the scores range from 0 to 56 with the higher score indicating more perceived stress. The validity and reliability of the scale have been confirmed in Iran.<sup>45</sup>

### *Laboratory Tests*

To assess laboratory data including cortisol and CRP levels, the researcher took 4 cc brachial vein blood samples at 8 am. Fasting was not necessary for these tests. All tests were sent to the laboratory of Afzalipour hospital in Kerman. Only 1 person had to do the laboratory tests with the same device. The normal cortisol level in the morning is 7 to 28 µg/dL.<sup>46</sup> The normal CRP level is also 0 to 10 mg/L.<sup>39</sup>

### *Data Collection and Intervention*

At the beginning of the study, the patients completed demographic information, depression, anxiety, and perceived stress questionnaires and then, the researcher took 4 cc brachial vein blood samples to check laboratory tests for both groups. The intervention and control groups simultaneously recompleted the questionnaires and tests after the last session.

Samples in the control group received the routine care, which included consulting with the psychiatric nurses, and psychologists if requested. In addition, additional information for referral to psychologist offices and centers were provided to each participant.

Samples in the intervention group were divided into 2 groups of 12 to 14. They received the mindfulness-based stress reduction intervention in 90-minute sessions for 8 weeks (1 session a week; Box 1).

One of the researchers (AA) skillful in MBSR prepared the intervention package. She trained the first researcher during 6 months, who in return trained participants in the intervention group.

### *Statistical Analysis*

SPSS 18 was used in the study. Chi-square and Fisher's exact tests were used to compare demographic characteristics between the 2 groups. Wilcoxon and Mann-Whitney tests were used to compare the mean stress scores in and between groups, respectively. Wilcoxon and independent *t*-tests were used to compare the mean scores of depression and anxiety in and between groups, respectively. Independent *t*-test and paired *t*-test were used to compare the mean laboratory data in and between the groups. ANCOVA test was also used to consider the confounding effect of variables. Significance level was considered 0.05.

### *Ethical Consideration*

The Ethics Committee of Kerman University of Medical Sciences approved the present study (Code of Ethics: IR.KMU.REC.1396.2291). The protocol of the study was registered in the Iran clinical trial registration system (Clinical trial registration number: IRCT20180113038333N1). Informed consent

**Table 1.** Comparison of Demographic Characteristics Between Intervention and Control Groups.

Variable	Control Group		Intervention Group		Statistical Test	P Value
	Mean	SD	Mean	SD		
Age (years)	45.64	10.11	44.14	11.19	$t=0.47$	.64
Disease duration (months)	14.82	10.0	27.14	32.11	$Z=-1.27$	.20
	Frequency	%	Frequency	%		
Education level						
Uneducated	3	13.6	2	9.1	Fisher's exact test = 1.91	.81
Middle/high school	2	9.2	4	18.2		
Diploma	4	18.2	5	22.7		
Associate/bachelor	12	54.5	9	40.9		
Master/higher	1	4.5	2	9.1		
Job						
Housewife	5	22.7	11	50	$\chi^2=3.96$	.18
Employed	12	54.6	9	40.9		
Self-employed	5	22.7	2	9.1		
Insurance type						
Self-employed	3	13.6	1	4.5	$\chi^2=3.73$	.18
Social security	13	59.1	9	40.9		
Therapeutic services	6	27.3	12	54.5		
Monthly family income						
<1 million	3	13.6	7	31.8	$\chi^2=3.34$	.36
1-2 million	10	45.5	5	22.7		
2-3 million	6	27.3	7	31.8		
>3 million	3	13.6	3	13.6		
History of other diseases						
Yes	21	95.5	21	95.5	—	—
No	1	4.5	1	4.5		
Type of treatment						
Chemotherapy	10	45.5	3	13.6	Fisher's exact test = 12.10	.009
Radiotherapy	1	4.5	0	0		
Surgery	3	13.6	0	0		
Chemotherapy and radiotherapy	0	0	1	4.5		
Chemotherapy and surgery	1	4.5	4	18.2		
Chemotherapy, radiotherapy and surgery	7	31.8	14	63.6		
Chemotherapy sessions						
≤6	12	54.5	7	31.8	$\chi^2=2.32$	.11
>6	10	45.5	15	68.2		

Abbreviations: T, independent-t test; Z, Mann-Whitney U test.

was obtained from the participants. Samples were explained about the purpose of the study and were assured that their information would be kept confidential.

## Results

The mean ages of the patients in the control and intervention groups were 45.64 and 44.14, respectively. Table 1 shows no significant difference between the 2 groups in the demographic and clinical characteristics except for the type of treatment.

The mean scores of anxiety in the control group were 25.41 and 35 before and after the study, respectively. In

other words, anxiety increased in the control group over time. The mean score of anxiety in the intervention group decreased from 31.18 to 23.50 after the intervention. Mean anxiety score was significantly different after the intervention (Table 2). ANCOVA test was used to control the confounding effect of treatment type indicating a significant anxiety score between the intervention and control groups after the intervention ( $P=.01$ , mean difference = -10.88).

The mean depression scores in the control group were 21.04 and 21.59 before and after the study, respectively. The mean depression score in the intervention group decreased from 29 to 17.18 after the intervention. Since the pre-intervention score was different between the 2 groups,



**Table 2.** Comparison of Scores of Psychological Responses Between the Control and Intervention Groups Before and After the Intervention.

Time		Before Intervention		After Intervention		Wilcoxon Test	P Value	Pre- and Posttest Mean Difference	
		Mean	SD	Mean	SD			Mean	SD
Anxiety	Control	25.41	14.99	35.0	13.52	3.04	.006	9.59	14.77
	Intervention	31.18	14.05	23.50	11.35	-2.96	.007	-7.68	12.17
	Independent-t test	-1.32		3.06				4.23	
	P value	.20		.004				<.001	
Depression	Control	21.04	11.17	21.59	11.97	0.17	.86	0.54	14.91
	Intervention	29.00	13.01	17.18	9.46	-4.35	<.001	-11.82	12.75
	Independent-t test	-2.18		1.36				2.96	
	P value	.04		.18				.005	
Perceived stress	Control	28.64	3.0	28.04	2.28	-0.86	.39	-0.6	3.38
	Intervention	33.68	7.29	28.09	4.82	-3.30	.001	-5.6	6.21
	Mann-Whitney U test	-2.32		-1.12				-2.96	
	P value	.02		.26				.003	

**Table 3.** Comparison of Mean CRP and Cortisol Levels Between Control and Intervention Groups Before and After Intervention.

Time		Before Intervention		After Intervention		Paired-t test	P Value	Pre- and Posttest Mean Difference	
		Mean	SD	Mean	SD			Mean	SD
CRP	Control	12.09	6.24	11.50	6.28	-2.35	.03	-0.59	1.18
	Intervention	15.50	5.21	14.32	5.26	-3.42	.003	-1.18	1.62
	Independent t-test	-1.97		-1.61				1.38	
	P value	.06		.11				.18	
Cortisol	Control	16.45	3.78	16.68	3.98	0.60	.55	0.23	1.77
	Intervention	18.77	4.05	18.27	4.28	-1.33	.2	-0.5	1.77
	Independent t-test	-1.96		-1.28				1.36	
	P value	.06		.21				.18	

the pre- and post-test score difference was calculated. The results showed a significant difference between the 2 groups (Table 2). ANCOVA test was performed to control the effects of pre-test score and the type of treatment indicating no significant difference in the depression score between the 2 groups after the intervention ( $P=.15$ ).

The mean scores of perceived stress in the control group were 28.64 and 28.04 before and after intervention, respectively. The mean score of perceived stress in the intervention group decreased from 33.68 to 28.09 after the intervention. The perceived stress of the intervention group was significantly higher than that of the control group before the intervention, but this difference was not significant after the intervention (Table 2). Considering the confounding effect of treatment type and perceived stress score before the study, ANCOVA test showed no significant difference in perceived stress score after intervention ( $P=.14$ ).

The mean CRP levels of the control group were 12.09 mg/dL and 11.50 mg/dL before and after the study, respectively. The mean CRP levels in the intervention

group were 15.50 mg/dL and 14.32 mg/dL before and after the intervention, respectively. The mean CRP was not significantly different between the 2 groups before and after the intervention (Table 3). Considering the confounding effect of treatment, ANCOVA test showed no significant difference in the CRP score between the intervention and control groups after intervention ( $P=.61$ , mean difference=1.15).

The mean cortisol levels of the control group were 16.45  $\mu$ g/dL and 16.68  $\mu$ g/dL before and after the study, respectively. The mean cortisol levels in the intervention group were 18.77  $\mu$ g/dL and 18.27  $\mu$ g/dL before and after the intervention, respectively. The mean cortisol level was not significantly different between the 2 groups before and after the intervention (Table 3). Considering the confounding effect of treatment, the ANCOVA test showed no significant difference in the mean cortisol level between the intervention and control groups after intervention ( $P=.08$ , mean difference=2.31). In addition, the participants reported no adverse effect during the study.

## Discussion

The results showed the effectiveness of MBSR in improving anxiety of the patients with breast cancer. Although, MBSR clinically improved patients' stress and depression, it was not statistically significant. Furthermore, MBSR had no significant effect on the reduction of cortisol and CRP levels.

Many studies have supported the effect of mindfulness on psychological variables. The current study only showed the effect of mindfulness on anxiety. Zeinal et al<sup>15</sup> have confirmed this result. Some studies showed the effectiveness of psychological interventions in the autonomic nervous system and endocrine system leading to reduction of anxiety. Some articles such as that of Khoury et al showed ineffectiveness of mindfulness in anxiety.<sup>47</sup> Patients with breast cancer experience great anxiety, so they may follow mindfulness practices more. In addition, participants had severe anxiety at the beginning of the study. This may be a reason why the MBSR has been more effective in patients with breast cancer than healthy individuals.

The present study showed no significant effect of MBSR on depression. Khoury et al showed no significant effect of the MBSR method on depressed healthy subjects because of subjects' bias in filling questionnaires, inadequate number of sessions, or improper quality of training.<sup>19</sup> On the other hand, Johns et al examined the effectiveness of mindfulness-based stress reduction program in the US breast and colorectal cancer survivors. MBSR has been effective in reducing depression.<sup>48</sup> Armani Kian et al also showed the effectiveness of mindfulness in emotional health, depression, and glucose control in patients with type-II diabetes mellitus.<sup>49</sup> Different results may be due to self-report questionnaires, which might be completed by patients pessimistically. Other possible causes may be the quantity and quality of interventions, different types of disease and their effects on patients' general condition, different treatments or medications and their side effects on general condition, cultural differences, support, patients' interest, and mindfulness practices at home. In addition, participants had moderate depression at the beginning of the study showing that the MBSR was less effective in alleviating depression of the patients with breast cancer in the present study.

Mindfulness had no significant effect on stress in the current study. Nyklíček and Kuijpers in the Netherlands performed MBSR on men with distress symptoms and found no significant difference between the 2 groups.<sup>50</sup> However, Zhang et al in China studied the effectiveness of Mindfulness-Based Stress Reduction Program (MBSR) in post-traumatic growth of the breast cancer survivors and showed a significant decrease in their stress 8 weeks after intervention.<sup>35</sup> The ineffectiveness of MBSR in the present study may be due to the disease type, its psychological effects, and inadequate social support. Shaban et al reported that cancer patients undergoing chemotherapy in Iran

experienced several problems. The Iranian society has less addressed the patients' quality of life and its associated factors.<sup>51</sup> Different results may be due to different tools, type of illness, number and arrangement of educational sessions, cultural differences including family self-care communication, social, organizational, and governmental support, different health care costs in different countries or even different beliefs. According to Pourghane et al, stress coping strategies employed by people in stressful situations can be influenced by religious beliefs, culture, social support, and knowledge.<sup>52</sup>

Some studies supported the ineffectiveness of MBSR in inflammatory factors. Matchim et al showed ineffectiveness of mindfulness in regulating laboratory tests (lymphocytes in cancer patients, melatonin, and cortisol), blood pressure, and heart rate.<sup>32</sup> Moreover, Pascoe et al showed the effectiveness of mindfulness in decreasing cortisol level, heart rate, blood pressure, and TNF, but little effect on CRP.<sup>53</sup> Some studies also confirmed the effect of mindfulness on inflammatory factors.<sup>31,32</sup> Meyer et al showed the effectiveness of mindfulness in reducing CRP levels of the healthy individuals.<sup>34</sup> These differences can be due to the number of intervention sessions, the number of samples, the amount of stress, support, the study population, and the type of drug therapy affecting the body and the immune system.

The psychological responses of people are intense after cancer diagnosis depending on the prognosis of the disease, the experiences of pain and suffering, and the costs of treatment. Therefore, health care providers, particularly physicians and nurses, should support patients, their families, and psychological interventions. It is recommended that psychological techniques be considered for both patients and families. In addition to changing educational and counseling techniques, governmental organizations should support patients to reduce their stress and improve their quality of life.

The present study had some limitations. Many individual and family characteristics, and individual motivations might influence the study results, however the researcher has attempted to choose participants with the most similarities. Since patients with cancer and their families were experiencing a stressful situation, several were reluctant to participate in the study. Many patients with breast cancer were unaware of their disease or treatment process, so the sampling process lasted nearly a year; this long period of study may influence the results. Finally, these results should be generalized to other populations with caution.

## Conclusion

The results of the present study suggest the effectiveness of MBSR only in anxiety of the women with breast cancer, however the clinical effect of MBSR on stress and depression should not be ignored. MBSR also had no effect on inflammatory factors such as cortisol and CRP. Further

studies are recommended to investigate the effect of MBSR on psychological responses and inflammatory factors of both patients with cancer and their spouses.

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### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Ethical Considerations

The Ethics Committee of Kerman University of Medical Sciences approved the present study (code of ethics: IR.KMU.REC.1396.2291 and the clinical trial code no. IRCT20180113038333N1). Before the sampling, a written letter of introduction from Razi School of Nursing and Midwifery was presented to the authorities of the study setting. Informed consent was obtained from the participants. Samples were adequately explained about the purpose of the study and were assured that their information would be kept confidential.

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