

The Effectiveness of Mindfulness-based Stress Reduction on Fear of Cancer Recurrence in Colorectal and Breast Cancer Patients: A Randomized Controlled Trial

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Abstract

Background: Strong fear of cancer recurrence is frequently reported among the cancer survivors. Such influential and universal fear is one of the factors that cause considerable emotional distress, anxiety, and decreasing quality of life among such patients. Given the importance of the subject, it is necessary to select psychological interventions in which the efficiency and feasibility have been proved in different trials. The present study aims to determine the efficacy of mindfulness-based stress reduction on fear of cancer recurrence in patients with colorectal and breast cancer.

Methods: The current study is a randomized clinical trial with experiment and control groups. We selected 38 patients with breast and colorectal cancer who referred to Shahid Motahari Clinic and Amir Oncology Hospital in Shiraz (96-97), then randomly assigned them to intervention and control groups. They filled out questionnaires in the pre-test and post-test. The data were analyzed by multivariate statistical test with SPSS v. 23 software.

Results: Findings show that the post-test mean scores in the fear of cancer inventory have decreased in the intervention group and there was a significant difference between experimental and control groups in the components of fear of cancer inventory as follows: triggers ($F=55.289, P<0.0001$), severity ($F=75.785, P<0.0001$), psychological distress ($F=24.078, P<0.0001$), dysfunction ($F=62/025, P<0.0001$), coping strategies ($F=15.592, P<0.0001$), reassurance ($F=6.235, P<0.017$), and except insight ($F=1.396, P<0.245$).

Conclusion: The results from this study showed that MBSR is an efficacious intervention to reduce fear of cancer recurrence in patients with breast and colorectal cancer.

Keywords: Mindfulness-based stress reduction, Fear of cancer recurrence, Breast cancer, Colorectal cancer

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Introduction

Developments in the early detection and treatment of cancer have led to the improvement of cancer survival rates. However, one of the most common concerns among cancer patients is fear of cancer recurrence (FCR). FCR is defined as a fear or concern about the return or progression of the disease in the same organ or other parts of the body.¹ According to studies, 22% to 87% of patients with cancer experience moderate to strong FCR throughout survivorship. Those who have high level of FCR can experience negative behavioral changes including personal examination behaviors, avoidance behavior, increased use of health services, inability to plan for the future, and psychological distress including depression and anxiety.²⁻¹⁰ FCR is often considered as a multidimensional phenomenon with the emotional components and cognitive dimensions, including fear, anxiety, mental preoccupation, and disturbing thoughts.¹¹ Physical symptoms, perceived risk, psychological disturbances, loss of quality of life, and functional impairment are of underlying factors in FCR. While a normal level of FCR can hinder a person's awareness of symptoms, the high levels can negatively affect the quality of life and social activities of the individuals.¹²⁻²⁰ Because FCR is one of the sources of significant emotional disturbances among the survivors of cancer, it is a logical and relevant goal for clinical interventions.^{21, 22}

Mindfulness is defined as a moment to moment awareness in being present and the attitude of non-judgmentally, non-reactively, openheartedly, and acceptance. Training of mindfulness-based stress reduction (MBSR) is an 8-week group training program. In 1979, John Kabat Zein applied mindfulness to treat patients with chronic pain and showed how changing the way patients relate to their pain can alter their experience of pain.^{23, 24} Recent efforts have identified three specific components of mindfulness: 1) the intention that involves motivation and knowing why they are paying attention 2) attention, which directly knows what is happening, 3) attitudes

that address attention through admission, preservation of the properties of the mindfulness, or attention with kindness. For cancer survivors, the meditation and training approach in the context of the mindfulness cognitive process facilitates self-regulation of emotions during distress and suffering. This training emphasizes the moment to moment, non-judgmental, and non-reactive attitude to internal and external experiences which reduce mental rumination and employment with unpleasant experiences.²⁵ Mindfulness-based interventions are simple as they do not need any specific equipment, whether at home or outside, and can be practiced anywhere. Similarly, stress reduction through long-term meditation practice can be especially helpful for the prevention of cancer.²⁶⁻³⁴ Sarizadeh et al., in a randomized clinical trial, showed the efficacy of acceptance and commitment therapy on FCR and post-traumatic growth in breast cancer patients.³⁵ In a randomized clinical trial, Lengacher et al. showed that MBSR has favorable effects on reducing FCR in intervention group compared to the control group.³⁶ Riech et al. examined the effectiveness of MBSR on cancer patients. Their results indicated improvement especially in both clusters of psychological symptoms and fatigue compared to baseline as well as sustained recovery after 12 weeks of follow-up. However, the follow-up study did not show any improvement compared to post-test.³⁷ Similarly, Lengacher et al., in their study on breast cancer patients, demonstrated that the group which received MBSR intervention showed a greater reduction in FCR than control.³⁸ In another study, Chambers et al. showed the only tendency to reduce FCR as a result of participating in MBSR course among the 19 survivors of prostate cancer.³⁹ Given the significant disturbances caused by FCR and a few studies conducted to determine the usefulness of psychological interventions to reduce this pervasive fear, the current research poses an important question: Is MBSR effective to reduce FCR in the breast and colorectal cancer patients who live in Iran?

Methods and Materials

The present study is a randomized controlled trial (IRCT20180331039163N1) with control and experimental groups, approved by the Ethics Committee of Research in Shiraz University of Medical Sciences (IR.SUMS.REC.1396.192). The statistical population of the present study included all patients with colorectal and breast cancer in Shiraz in 2017. To determine the sample size based on a prevalence of 22% FCR among

patients with cancer, a sample size of 30 people was obtained from the Cochran formula, 8 of whom were added to the sample to prevent the loss. They were randomly assigned to either experimental (19) or control (19) groups by using the table of random numbers. The CONSORT diagram is shown in figure 1. Through interviews with patients, the entry criteria would be evaluated and included in the study, if eligible. The criteria to enter this study included receiving a diagnosis

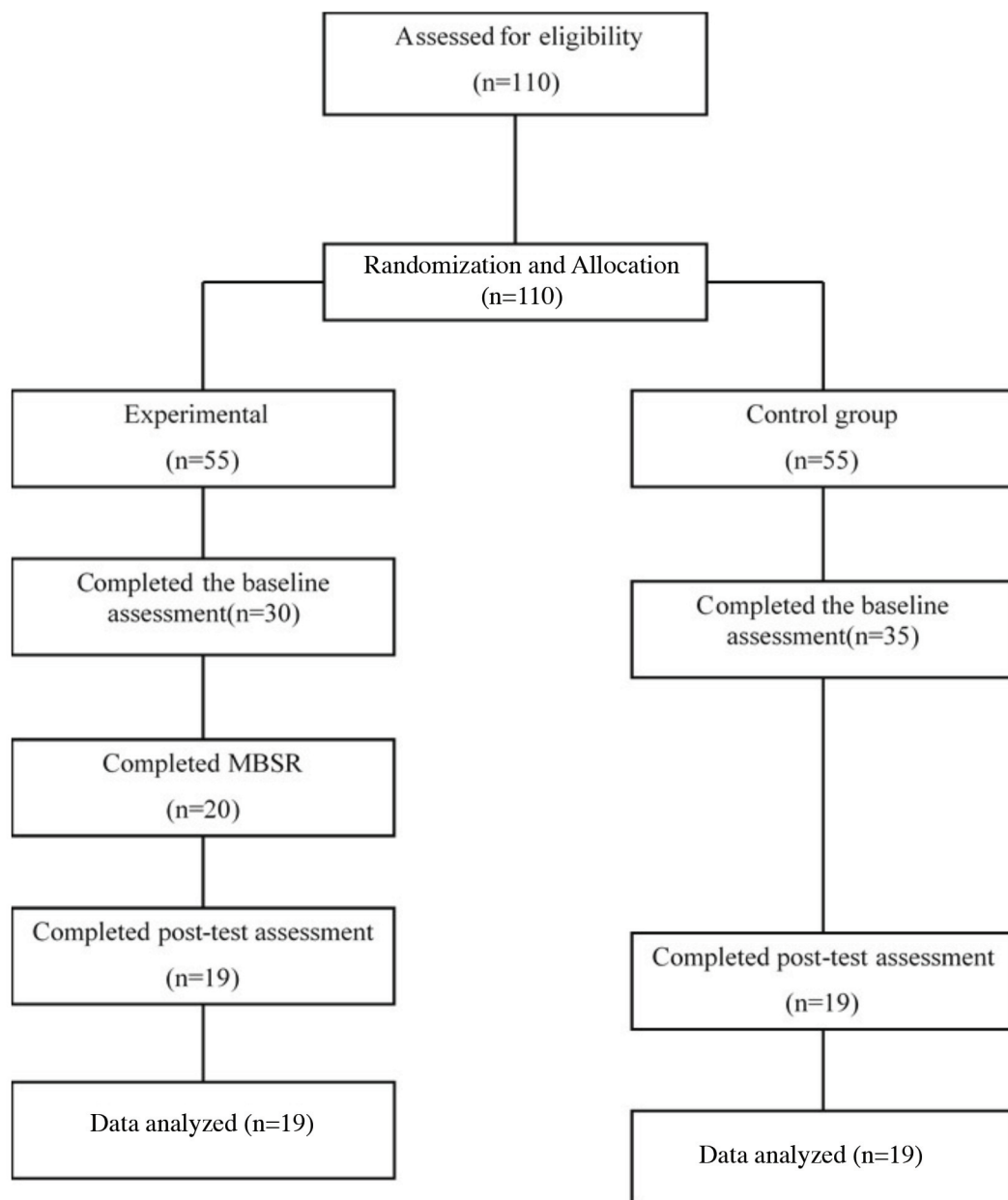


Figure 1. CONSORT Diagram. People declined to participate due to transportation issues, not interested, family obligations, and health issues.

Table 1. The content of the therapeutic sessions

Sessions	Session content
Session 1	This session includes a review of MBSR approach and creating a therapeutic commitment and motivation in patients. The patients experientially practice the mindful eating. The session continues with group discussion and then the body scan meditation is done. Homework is assigned by using the body scan meditation recorded audio file to become aware of the body. Informal practice involves eating at least one meal mindfully. Experiential mindfulness training and cultivation of mindful awareness, body scan meditation, 30 minute focused conversation about patient's experience of body scan, and reflection on home practice. Standing yoga. Home practice is assigned with an emphasis on the regular daily practice of the body scan for a second week, as well as, introduction of short periods of sitting meditation, and asking the patients to bring mindfulness into their daily life.
Session 2	Patients practiced several distinct but interrelated formal mindfulness practices –mindfulness hatha yoga (ending with a brief body scan), sitting meditation and walking meditation which extended formal practices by query into and exploration of participant's experiences with in-class and assigned homework. Focused dialogue about challenges and insights at the time of formal practice and integrating mindfulness into daily life.
Session 3	Patients practice a combination of the three major formal mindfulness practices that they have also been doing at home within the preceding three weeks. Directions emphasize on the cultivation of concentration, embodiment, the capability to teach and re-direct attention, and the systematic development of the realm of awareness.
Session 4	This session indicates the halfway point of the program underscoring the ability of patients to adapt more quickly and effectively to daily challenges and stressors. Experiential skills of mindfulness proceeds with an emphasis on responding instead of reacting to stressors and the value and efficiency of mindfulness in learning to stop, step back and observe more distinctly/objectively and then to be in a better position to make informed choices (responding) in facing various situations.
Session 5	Experiential training in MBSR continues with an emphasis on the growing ability to self-manage and copes more effectively with stress. Discussion is oriented about the ongoing cultivation of "transformational coping strategies": Awareness, ideas, and behaviors that improve the psychological characteristic known as "stress hardness" or resilience.
Session 6	Empirical training continues in mindfulness. Participants are asked to practice more expansive personal experiences instead of formal mindfulness practices done as homework during the week leading up to the eighth session. Emphasis is on 45 minutes of daily practice, without recorded instructions.
Session 7	Experiential mindfulness practice continues and patients are given sufficient opportunities to inquire into and clear any remaining questions about the different practices and their applications in daily life.
Session 8	Opportunities to inquire into and clear any remaining questions about the different practices and their applications in daily life. A review of the course is involved with an emphasis on daily strategies for maintaining and amplifying the skills achieved during the program. Time is also allocated for a satisfying closure by admiring both the end of this course and starting living one's life enlightened with mindfulness.

of colorectal and breast cancer approved by an oncologist, patients who have completed treatment or were still receiving treatment, aged over 18 years. The excluded patients included those who were absent for more than two sessions, attended yoga classes and meditated before the study, had

hearing and speaking problems, participated in mindfulness-based stress reduction intervention, received psychotherapy or psychiatrist, and participated in other psychosocial programs.

Measurement

Demographic information questionnaire: This questionnaire contains demographic information such as gender, age, marital status, education, and duration of illness that was prepared by researchers.

FCR Inventory: Simard and Savard, empirically prepared the questionnaire to provide a multidimensional self-report scale to assess fear of cancer recurrence.⁴⁰ The questionnaire had 42 items that evaluated seven aspects related to FCR encompassing triggers (potential triggers that activate fear of cancer recurrence), severity (the presence and severity of intrusive thoughts associated with FCR), psychological disturbance (emotional dysfunction associated with FCR), functional impairment (the effect of FCR on functional areas), insight (self-blaming against the intensity of FCR), reassurance (reassurance through examination, recurring medical counseling), and coping strategies (strategies to address FCR). Each item of this questionnaire was ranked on a Likert scale between Zero (at all or never) to four (very or always). The overall score could be obtained for each subscale which was done to get the overall scores by aggregating item rankings and higher scores indicate more fear of cancer recurrence. The original version of the French report has a high internal consistency scale (0.75) and a test-retest reliability (0.85).

Intervention Protocol

After randomly assigning eligible patients to the experimental and control groups, both groups were asked to complete demographic information and FCR questionnaires. After collecting questionnaires, the participants of the experimental group participated in the two-hour weekly mindfulness-based stress reduction program which was held at the Faculty of Rehabilitation, Shiraz University of Medical Sciences and the control group did not receive intervention. At the end of the program, both groups were asked to respond to FCR questionnaire. This research was done with ethical considerations including obtaining informed written consent, confidentiality of their information, and using a suitable place for

Table 2. Demographics and participants' characteristics

Gender	
Female	30
Male	8
Mean age \pmSD (years)	
Intervention	44.4 \pm 0.7
Control	48.4 \pm 9.7
Cancer type	
Colorectal	16
Breast	22
Marital status	
Single	4
Married	34
Education	
Below high school	4
High school	13
B.A	19
Ph.D.	2
Job status	
Unemployed	20
Full time job	8
Part time Job	4
Retired	6
Duration of disease (months)	20.5 – 120 \pm 25.2

intervention group. In addition, the used tools did not have any side-effect for the participants.

The summary of the content of the therapeutic sessions is presented in table 1.

Results

The result of demographic information was shown in the table 2. After examining the preconditions of the multivariate covariance test, this test was used to examine the differences between the two groups in FCR variable. Kolmogorov -Smirnov test showed that the data was normal. One of the important preconditions of the analysis of covariance was the homogeneity of covariance matrices. The result of the Mbox test ($P < 0.0001$) showed that this precondition was not provided. Therefore, the Lambda-wilkes was used ($F = 16.525, P < 0.0001$). Leven test was used to measure the error variance equation in different stages including ($F = 0.889, P = 0.352$),

Table 3. The mean and standard deviation of the components of FCR* in experimental and control groups in pre-test and post-test

Subscale	Group	Pre-test	Post-test
		(mean±standard deviation)	(mean±standard deviation)
Trigger	Intervention	7.9±0.7	1±0.3
	Control	8.9±1.2	8.2±1.2
Severity	Intervention	16.6±0.9	6±0.6
	Control	16.8±1	15.8±1
Psychological distress	Intervention	6.9±0.5	2.3±0.6
	Control	6.8±0.5	7.6±1
Coping strategies	Intervention	11.6±1	4±0.5
	Control	9.7±1.1	9.4±1.3
Dysfunction	Intervention	8.1±0.96	1.4±0.22
	Control	6.9±1.3	6.7±0.7
Insight	Intervention	1.7±0.46	0.5±0.2
	Control	1.8±0.62	0.9±0.5
Reassurance	Intervention	5±0.52	2.3±0.6
	Control	4.53±0.5	4±0.4

*FCR: Fear of cancer recurrence

in the post-test component of insight, ($F=1.019$, $P=0.319$) in the post-test component of psychological distress, ($F=3.611$, $P=0.065$) in the post-test component of triggers, ($F=2.569$, $P=0.118$) in post-test component of severity, ($F=3.722$, $P=0.062$) in the post-test component of reassurance it was determined that the variance of the error of the various components of the test, except for the dysfunction component ($F=4.638$, $P=0.038$), and coping strategies ($F=9.616$, $P=0.004$) is similar in the post-test. Regarding the obtained significant level ($P=0.59$), we conclude that there is no interaction and regression lines that do not interrupt each other and their slope is homogeneous. Therefore, multivariate covariance analysis was used with regard to adherence to the preconditions. In table 3, values related to the test of effects of between the subjects are reflected.

Based on the results of the table 4, there was a significant difference between the experimental and control groups in the all subscales of FCR inventory in the post-test, just insight ($P=0.245$). And MBSR had the greatest effect on the trigger and dysfunction. As table 5 shows, there is a

significant difference ($P=0.001$), between the two groups in the post-test.

Discussion

According to the results, participating in this course had a favorable effect on all subscales of FCR and led to reduction of FCR in these patients. Findings from several studies illustrated the effectiveness of MBSR on FCR.^{33,35-37} Although the scales used to measure FCR were different in these studies, the results have shown the effectiveness of MBSR on FCR reduction improving other symptoms associated with cancer and its treatment such as cognitive impairment, fatigue, stress, and anxiety. According to the patient reports, physical symptoms are the most stressful triggers that evoke FCR, while negative thoughts, emotions, and reappraisals about cancer recurrence or progression may unconsciously continue and affect the psychological and physical well-being of the patients. Hall et al. showed that concerns about recurrence or progression of cancer are the underlying cause of stress for the survivors of cancer and they suggest that teaching strategies can help these patients in order to manage the

Table 4. Multivariate covariance analysis of FCR* with control of the effect of pre-test.

source	Dependent variable	df.	Sum of squares	F.	Sig. squared.	Partial Eta power	Observed
Group	Trigger	1	528.51	55.28	0.000	0.61	1.00
	Severity	1	946.71	75.78	0.000		1.00
	Psychological distress	1	285.36	24.07	0.000	0.40	0.998
	Coping strategies	1	277.93	15.59	0.000	0.30	0.97
	Dysfunction	1	277.98	62.02	0.000	0.63	1.00
	Insight	1	3.36	1.39	0.245	0.03	0.21
	Reassurance	1	30.36	6.23	0.017	0.15	0.68

*FCR: Fear of cancer recurrence

cancer-related uncertainties and stress deriving from physical symptoms.⁴¹ To explain the effectiveness of mindfulness-based stress reduction on FCR, MBSR has a direct impact on antecedents causing FCR, such as physical symptoms and cancer reminders. It requires more studies to examine this issue in different types of cancer populations. In other words, mindfulness meditation is similar to exposure therapy situation because the goals of exposure therapy are to prevent the response of fear, instead of gaining a sense of security in the presence of previously frightening stimuli by confronting those stimuli and preventing the respondent from responding to the usual way. MBSR participants get this capacity to observe their emotional experiences and unpleasant thoughts without reacting to them.⁴² The principles of MBSR program are based on the mindfulness therapeutic power which is utilized through two cognitive processes of awareness and attention. Through MBSR program, patients learn self-regulation of awareness and attention and develop a non-judgmental attitude to make a change. Through awareness of cognitive process, internal experiences are processed in the form of imaginations and emotions. These imaginations and emotions are transiently evoked, but they continue to be judged by the fact that they are pleasant or unpleasant. These reactions depend on the past experiences and can be linked with a memorable one and they are easily absorbed in other schemas. In the context of processing attention, there is a step back in which feelings and thoughts are perceived objectively as they appear which is observed through the record of raw facts. Generally, they are taught to be present in reality rather than to react to reality or to rumble

on past emotional experiences.²³ The limitations of the present study are small sample size; cases in both groups were not matched for age, sex, and level of education; a small number of male participants who make it impossible to analyze gender-related data in this study; and the variety of the stages of the disease. The lack of follow-up has the difficulty of estimating the duration of the intervention effectiveness. It is suggested that future studies should be done with a large number of individuals and also considering the gender differences in the level of FCR and other related factors from both men and women in equal numbers, as well as other necessary reconciliations as much as possible to obtain reliable results for matching interventions. It is difficult to determine the effectiveness of MBSR on different stages of cancer which is recommended to be considered in future studies. Also, in order to assess the duration of effectiveness of MBSR, the follow-up studies were recommended. The strength of this study is showing that MBSR is a feasible and acceptable intervention for colorectal and breast cancer patients in any stage of disease and treatment who live in Iran. Given the efficacy of MBSR, it is suggested to consider this intervention as a complementary therapy to reduce the psychological disturbances and disorders that result from FCR and interfere with daily functioning and also lead to reduced quality of life of the patients with cancer.

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Table 5. Univariate covariance analysis of FCR by controlling the effect of pre-test scores

source	df.	Sum of squares	F.	Sig. squared.	Partial Eta squared.	Observed power
Pre FCR	1	1399.218	17.966	0.0001	0.346	0.984

FCR: Fear of cancer recurrence

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Conflict of Interest

None declared.

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