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Effects of progressive muscle relaxation and mindfulness meditation on fatigue, coping styles, and quality of life in early breast cancer patients: An assessor blinded, three-arm, randomized controlled trial

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ABSTRACT

Purpose: This study aimed to investigate the effects of progressive muscle relaxation (PMR) and mindfulness meditation (MM) on fatigue, coping styles, and quality of life (QOL) in patients with early breast cancer receiving adjuvant paclitaxel.

Methods: The participants were randomly assigned to either a 12-week (PMR) (n = 31) and MM (n = 32) interventions or control group (CG) (n = 29). The intervention groups continued PMR or MM for 20-min every day, for a total of 12 weeks. The CG received only a single time attention-matched education (15-min) on breast cancer before the start of the paclitaxel regimen. Data collection tools included the Patient Information Form, Brief Fatigue Inventory (BFI), Brief COPE, and Functional Living Index-Cancer (FLIC). Data were collected at baseline, week 12, and week 14.

Results: A significant reduction in the BFI scores was reported in the PMR and MM groups when compared with the CG at weeks 12 and 14 (p = .002). Similarly, the use of emotional support and positive reframing sub-dimension scores of Brief COPE were significantly higher in the PMR and MM than in the CG at weeks 12 (p = .017) and 14 (p = .042). Furthermore, the planning and active coping sub-dimension scores were significantly higher in the PMR and MM than in the CG at week 14 (p = .000). Regarding QOL scores, no significant differences were observed between the groups at weeks 12 (p = .486) and 14 (p = .095).

Conclusions: PMR and MM are effective interventions that if initiated concurrently with the adjuvant paclitaxel demonstrate similar effects on fatigue and coping styles.

1. Introduction

Early-stage (stage 0, I, II, or III) breast cancer (EBC) patients usually receive taxane-anthracyline combination regimen, which improves the disease-free survival (Gandhi et al., 2015). However, literature reports that following this treatment, patients may experience several physical symptoms, including myelosuppression, myalgia, arthralgia, hypersensitivity reactions, chemotherapy-induced peripheral neuropathy, and fatigue (Ho and Mackey, 2014; Tao et al., 2015). Of these, fatigue is one of the most common and distressing symptoms, affecting 25.0%–75.0% of patients with EBC receiving paclitaxel (Haghighat et al., 2003). Patients suffering from fatigue have reported impairments in the functional and cognitive status, vocational loss, and disruption of social relationships (Anagnostopoulos et al., 2004). Along with fatigue and other physical symptoms patients with EBC face emotional and social challenges such as loneliness, anxiety, depression, hopelessness, disturbance in body image, loss of effeminacy, reduction in spending time with friends, and other limited social activities (Avis et al., 2004; Boyle et al., 2017; İzci et al., 2016).

Other factors that contribute to reduced ability while coping with stressful events and causing deterioration in the quality of life (QOL) include long-term treatment period, uncertainty about the disease progression, and physical and psychosocial problems reported by EBC patients. In this regard, previous reports emphasized that patients with breast cancer using ineffective emotional coping strategies had greater disease-related distress and showed poor adjustment to their treatment (Lake et al., 2019; Seib et al., 2018). A previous report also indicated that lower QOL was associated with ineffective emotional coping styles in patients with breast cancer (Kershaw et al., 2004).

Due to high symptom burden, and physical and psychological

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morbidity during adjuvant paclitaxel regimen, most patients with EBC show willingness to take a proactive role in their treatment and seek different complementary approaches to relax their bodies to reach the state of mental calmness (Boon et al., 2007; Greenlee et al., 2009; Matsuno et al., 2012). These complementary approaches are classified into five categories including alternative medical systems, biologically based therapies, manipulative and body-based methods, energy therapies, and mind-body interventions by National Center for Complementary and Integrative Health (Lindquist et al., 2018). Mind-body interventions involve a variety of techniques designed to enhance the mind's capacity to affect bodily functions and symptoms. These techniques include biofeedback, yoga, Tai-chi, hypnosis, guided imagery, praying, relaxation, and meditation (Complementary and Health, 2015; Lindquist et al., 2018).

Progressive muscle relaxation (PMR) is one of the most well-known mind-body interventions tried by patients with cancer to manage the heavy symptom burden. PMR was first defined by Jacobson (1938) and includes voluntary continuous and systematic stretching and relaxing of various muscle groups. Such movements attract individual's attention to skeletal muscles, thereby relaxing the whole body. Previous studies conducted in patients with cancer revealed PMR to be effective in reducing stress, relieving nausea, vomiting, pain, and fatigue severity, and improving QOL (Charalambous et al., 2016; Kashani et al., 2012; Parás-Bravo et al., 2017; Zhou et al., 2015).

Mindfulness meditation (MM) is another form of mind–body-based intervention, structured by Kabat-Zinn et al. and has increasingly been preferred among patients with cancer as a coping strategy to achieve personal control over their symptoms (Kabat-Zinn, 2013; Ledesma and Kumano, 2009; Zainal et al., 2013). The main principle of MM is mindfulness, defined as present-centered and purposive non-judgmental awareness. Mindfulness involves bringing an individual's attention to the experiences of the present moment, including thoughts, feelings, and physical sensations, with openness, curiosity, and acceptance (Kabat-Zinn, 2013). Previous studies on patients with different cancers suggested MM to exert promising effects on reducing nausea, pain, and fatigue; strengthening coping strategies with stressful events and spiritual well-being; and enhancing QOL (Ando et al., 2009; Bower et al., 2015; Boyle et al., 2017).

Owing to the beneficial and relaxing effects of PMR and MM on the body and contributions on the state of mental calmness, recent studies have primarily focused on investigating the effects of these interventions on stress and emotional well-being in clinical trials among patients with cancer (Ando et al., 2009; Bower et al., 2015; Boyle et al., 2017). However, till date, only a few clinical trials have been performed to examine the effects of these interventions on fatigue, coping styles, and QOL among patients with breast cancer (Carlson et al., 2003; Jang, 2013; Kang and Oh, 2012; Kim et al., 2013). Moreover, to the best of our knowledge, no study has determined the effects of PMR and MM on fatigue, coping styles, and QOL in patients with EBC receiving adjuvant paclitaxel regimen. Thus, the present clinical trial was designed to examine the effects of PMR and MM initiated along with the adjuvant paclitaxel regimen on fatigue, coping styles, and QOL in patients with EBC. The study hypothesized that PMR and MM would (1) alleviate fatigue severity, (2) increase coping styles scores, and (3) improve the QOL in patients with EBC receiving adjuvant paclitaxel regimen.

2. Materials and methods

2.1. Study design and setting

The present assessor-blinded, three-arm, prospective, randomized controlled trial was performed in the chemotherapy outpatient clinic of the University of Health Sciences, Dr. A. Y. Ankara Oncology Hospital in Turkey. Patients with EBC, scheduled to receive the first dose of adjuvant paclitaxel regimen included in this study, were allocated to either a PMR, MM, or control group (CG). The participants in the PMR or MM group continued these interventions daily, once a day for 20 min for a total of 12 weeks until the completion of the regimen. The PMR and MM sessions were finalized at week 12. Like the intervention groups, the participants in the CG were received only a single time session (attention-matched education) with a booklet containing the breast anatomy, recognition of early signs of breast cancer, and the importance of early diagnosis in a silent room located in the same chemotherapy outpatient clinic, lasting for 15 min before the paclitaxel regimen. Following 12-week adjuvant paclitaxel regimen, all of the participants in the study setting were directed to receive radiotherapy or undergo surgery within two weeks. So, only a single time follow-up assessment (at week 14) was conducted to control the influential effects of radiotherapy or surgery on fatigue, coping styles and QOL scores of the participants. Study findings were reported based on the 2017 CONSORT Statement for Randomized Trials of Non-Pharmacological Treatments.

2.2. Sample size

As no similar study was found in the literature, a priori sample size calculation would not be possible at first. So, the power of the study was calculated based on completed data set covering all groups in the current study. G*Power 3.1. software was used to calculate the sample size of the study. As fatigue score was the main outcome, the power of the study was calculated based on the mean differences in total Brief Fatigue Inventory (BFI) scores from the baseline to the week 12. The corresponding scores for PMR, MM, and CG were 16.10 ± 19.6, 15.42 ± 23.56, and 2.03 ± 17.44, respectively. After the calculation with these scores, with a two-sided α of 5%, and a minimum effect size (0.33), the power of the study was found to be 90.0.

2.3. Randomization, allocation, and blinding

The list of potential participants was reported to the researchers by a patient consultant working at chemotherapy outpatient clinic every week. The principal investigator (PI) evaluated the participants based on eligibility criteria and defined the study protocol to the selected patients. Eligible participants were recruited from June 2018 to January 2019. A total of 38 participants were excluded because of not meeting the inclusion criteria ($n = 12$), declining to participate in the study ($n = 21$), and unable to be contacted by phone calls ($n = 5$). After obtaining their informed consent, the PI who was not involved in intervention procedures divided remaining 92 participants into three groups (Group A: 31, Group B: 32, and Group C: 29) using a random number allocation list including six different combinations: ABC, ACB, BCA, BAC, CAB, CBA generated by the software MS Excel 2013. The PI informed the randomization results to the participants by delivering stickers coded either Group A (PMR), Group B (MM), or Group C (CG). All training sessions were conducted by the second co-author who certified and experienced in PMR, and MM, and was not blinded to the study groups. Due to the nature of kinds of both mind-body interventions, PMR and MM, the participants were also not blinded to the interventions. All assessments were performed by a single data collector who was blinded to the study groups, and data were analyzed by an independent statistician. Blinding status of data collector was confirmed in the study by two steps: Firstly, the PI asked the participants to not give any information on their allocated group to the data collector and other participants in the study. Secondly, the data collector reminded all the participants to not share their allocated group with her in each data collection time point. Thus, the data collector kept blindness condition to the groups during the study. Therefore, the condition of assessor-blind study design was maintained by masking the data collector and the statistician. During the study period, three participants in the PMR, due to lack of sufficient time ($n = 2$) and not responding to phone calls ($n = 1$); one participant in the MM due to continuing treatment in a different city; and one participant in the CG

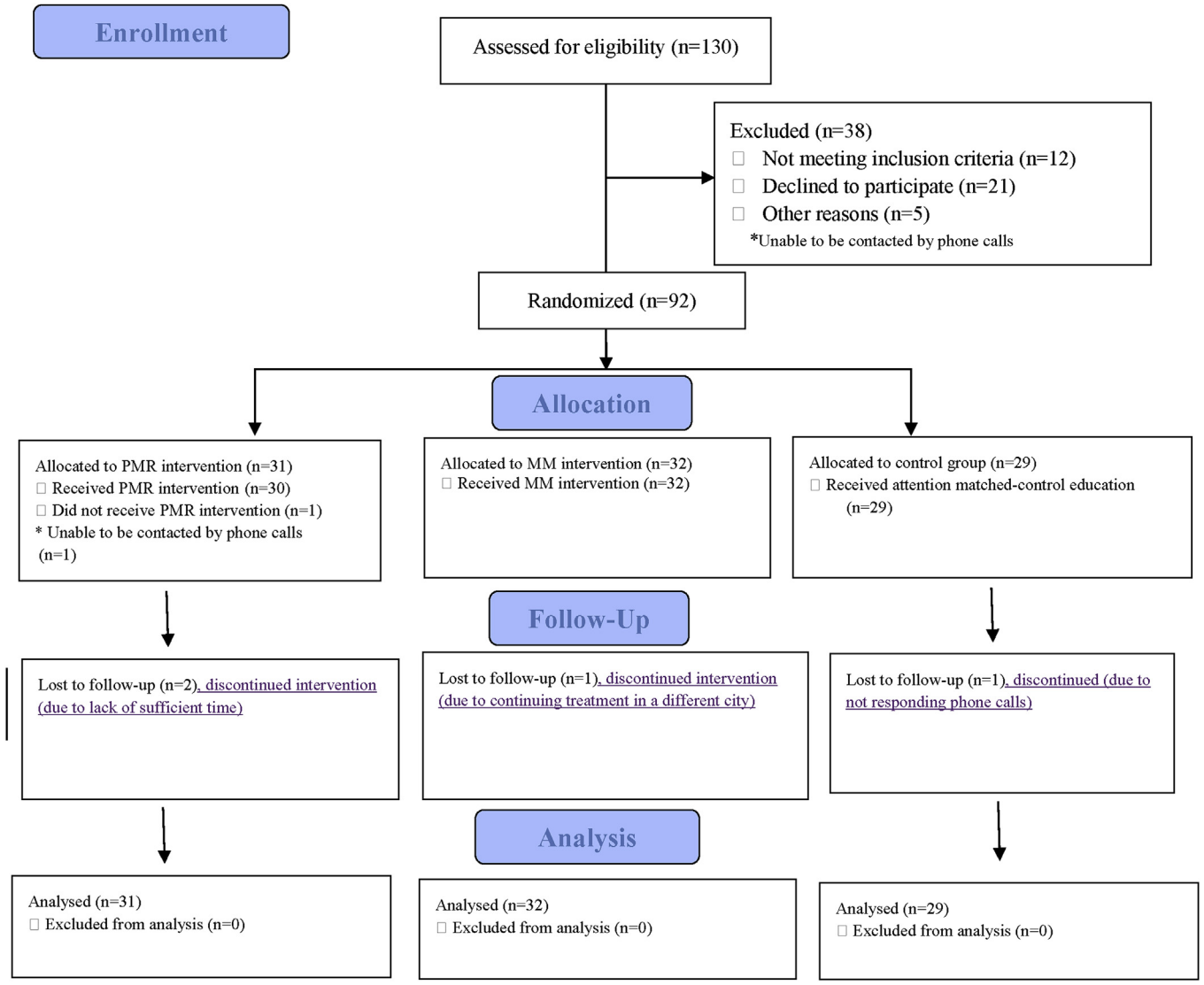

Fig. 1. Flow diagram of the study sample.

due to not responding phone calls were dropped out from the study. Therefore, the study was completed with a total of 87 patients with EBC as following: PMR (n = 28), MM (n = 31), and CG (n = 28) (Fig. 1).

2.4. Eligibility criteria and study sample

Eligible female patients included in the study were those who (a) diagnosed with stage I, II, and III breast cancer (b) had already completed 4-cycle Adriamycin and Cyclophosphamide (AC) regimen; (c) were planned to receive 80 mg/m^2 dose of adjuvant paclitaxel once a week for 12 weeks; (d) were starting the first cycle of adjuvant paclitaxel; (e) had at least 9 mg/dL hemoglobin (Hgb) level; and (f) had a graduation degree, at least primary school. Exclusion criteria were (a) history of end-stage renal failure, chronic obstructive pulmonary disease, advanced heart failure, chronic hepatic failure, muscle-skeletal disorders, hypothyroidism and depression; (b) illiteracy; and (c) using any kind of complementary modality during the study period.

2.5. Study procedure

The participants were required to receive mind-body interventions in the oncology outpatient clinic in a special patient room with a dim atmosphere. Training on both kinds of interventions was provided by face to face sessions. The participants in the PMR or MM group were first thought the description, using fields, and effects on the body of PMR and MM. Then instructions on PMR or MM were explained step by step by the second co-author who was certified and experienced in PMR and MM interventions. These theoretical sessions took 20 min. After the completion of theoretical sessions on PMR, or MM, all PMR and MM steps were practiced by the participants under the supervision of the second co-author within 20 min. Thus, each participant in the intervention groups received totally 40 min training including theoretical and practical sessions on PMR, or MM. Then, PMR and MM booklets prepared by the research team were distributed to the participants in the training session. Moreover, the PI and the second co-author recorded PMR and MM instructions with a voice recorder using their own voices, and the voice recorder files were sent via WhatsApp Messenger to the participants based on their groups. The participants were asked to practice PMR or MM sessions at their home using the recorded audio files. The intervention groups continued PMR or MM for 20 min each day, for a total of 12 weeks at their home. Daily reminders (text messages or phone calls) were sent to participants in the intervention groups to motivate them for practicing PMR or MM. A WhatsApp Messenger group, known as “Exercise Volunteers”, was designed by the second co-author, and the participants were asked to respond to reminder messages each day during the study period. In case of no

response from the participants, reminder phone calls were performed and their compliance with study protocol was checked. With regard to CG, the participants were invited to the same patient room and received only a single time attention-matched education on breast cancer including the breast anatomy, recognition of early signs of breast cancer, and the importance of early diagnosis. The attention-matched education was performed face to face and lasted for 15 min. Moreover, training booklets designed by the research team were given to the participants. All participants in the three study groups also received usual care by a clinical training nurse. The usual care contained an assessment of vital signs, checking of blood counts before the adjuvant paclitaxel regimen, and training on side effects of chemotherapy regimen and food-drug interactions related to the adjuvant paclitaxel. During the study period, no additional intervention was applied, neither to the intervention groups nor to the CG after the completion of adjuvant paclitaxel regimen until the follow-up assessment. The follow-up assessment was conducted only a single time, at week 14 (2 weeks following completion of adjuvant paclitaxel regimen).

2.5.1. Progressive muscle relaxation procedure

The PMR intervention lasted for 20 min and comprised sessions involving tensing and relaxing the body with deep breathing. The participants performed PMR for each body part in order, starting with the facial muscles and head, followed by neck, shoulders, chest, abdomen, legs, and feet; all muscle tension and relaxation procedures were performed accompanied with deep breathing. The participants were instructed to tense a specified group of muscles for 5 s and relax it for 10 s while breathing out. Throughout this exercise, the participants visualized a wave of relaxation flowing over their body using the deep-breathing technique. The researchers told each participant to close the stores and sit in a silent room before each session at their home.

2.5.2. Mindfulness meditation procedure

The MM intervention is a part of the mindfulness-based stress reduction program originally developed in 1985 (Kabat-Zinn, 2013). In this study, the research team used MM intervention. The second co-author asked participants to sit up straight and take a comfortable position on a chair, then requested the participants to focus on deep breathing and the present moment during the meditative practice that lasted for 20 min in each session. The participants were instructed the deep-breathing technique: inhale through the nose and exhale through the mouth using the diaphragm. The researchers told each participant to close the curtains and sit in a silent room before each session at their home.

2.6. Outcome measures and study instruments

The primary outcome of this study was the mean difference in fatigue scores between the groups following the 12-week PMR or MM intervention. The secondary outcomes included coping styles and QOL scores. To assess the fatigue severity BFI, coping styles Brief COPE and QOL Functional Living Index-Cancer (FLIC) were used for data collection. The data were collected at three time-points: baseline, week 12, and week 14.

2.6.1. Patient information form

This form was developed based on literature (Castellar et al., 2014; Cohen and Fried, 2007; Gudenkauf et al., 2015; Haghighat et al., 2003) and contained five questions on descriptive characteristics (age, marital status, educational level, employment status, and income level) and three questions on clinical characteristics including time since diagnosis, stage of cancer, and Hgb value.

2.6.2. Brief Fatigue Inventory

The BFI, developed by Mendoza et al. (1999), was used to rapidly assess the severity and impact of cancer-related fatigue on daily living activities. This scale has nine items and measures fatigue severity (questions 1, 2, and 3) and fatigue interference in daily life activities (questions 4a, 4b, 4c, 4d, 4e, and 4f). Its reliability and validity, in the Turkish context, were determined by Usta Yeşilbalkan and Karadakovan (2015) and had a Cronbach's alpha value of Turkish version of 0.97. Each item in BFI is scored between 0 and 10; higher scores indicate greater fatigue scores. Fatigue severity score is calculated by summation of questions 1, 2, and 3, whereas fatigue interference score is calculated by summation of questions 4a, 4b, 4c, 4d, 4e, and 4f.

2.6.3. Brief COPE

The Brief COPE is a 28-item multi-dimensional measure of strategies used for coping in response to stressors. It was initially a 53-item scale that was improved and translated by Carver (1997) to the current 28-item short form. The Brief COPE has 14 sub-dimensions and is rated by the 4-point Likert scale, ranging from “I have not been doing this at all” (score 1) to “I have been doing this a lot” (score 4). Fourteen dimensions are ordered as self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioral disengagement, venting, positive reframing, planning, humor, acceptance, religion, and self-blame. The Brief COPE sub-dimensions are classified into three categories: problem-focused coping strategies, emotion-focused coping strategies, and ineffective coping strategies (Bacanlı et al., 2013).

While active coping, planning, self-distraction, and use of instrumental support dimensions compose problem-focused coping strategies, the use of emotional support, positive reframing, acceptance, humor, and religion sub-dimensions are related to emotion-focused coping strategies. As for venting, denial, behavioral disengagement, self-blame, and substance use sub-dimensions, these are considered as ineffective coping strategies (Bacanlı et al., 2013). Its reliability and validity were tested by Bacanlı et al. (2013) for the Turkish version and Cronbach's alpha value was 0.79. The higher score represents greater coping strategies used by the participants.

2.6.4. Functional Living Index-Cancer

The FLIC was developed to evaluate the functional status in all adult cancer patients (Schipper et al., 1984). The 22-item scale is rated on a 7-point Likert-type scale, and is divided into five sub-dimensions: physical functioning (9 items), psychological functioning (6 items), current well-being (3 items), social functioning (2 items), and gastrointestinal symptoms (2 items). The reliability and validity of the Turkish version were determined by Bektas and Akdemir (2006) and had a Cronbach's alpha coefficient of 0.88. The scale scores vary between 22 and 154, with higher scores indicating higher levels of QOL.

2.7. Data collection procedure

The baseline data were collected using the patient information form, BFI, Brief COPE, and FLIC during the first interview with the participants in the oncology outpatient clinic on the first day of adjuvant paclitaxel infusion. The BFI, Brief COPE, and FLIC were repeated at weeks 12 and 14.

2.8. Statistical analysis

Data analyses were conducted using the IBM SPSS 23.0 (IBM Corp., Armonk, New York). The Shapiro–Wilk test was utilized for the test of normality. The baseline variables, including categorical data of participants such as age, marital status, educational level, time since diagnosis, and breast cancer stages were compared using the Chi-square test. The age and Hgb value were compared using the one-way ANOVA. The comparisons between the study groups in terms of BFI, Brief COPE, and FLIC scores were made using the Kruskal–Wallis test. Tukey's HSD post-hoc test was performed for defining group differences. The

statistical significance level for the all tests were considered as $p < .05$. The results were analyzed based on the principles of intention-to-treat analysis.

2.9. Ethical considerations

The study was approved by clinical trials ethic committee of the University of Health Sciences, Dr. A.Y. Ankara Oncology Hospital (decision number: 2018–03/70) and was conducted in accordance with the Helsinki Declaration. All participants were asked to submit a written informed consent. Participants could withdraw from the study at any point of time without stating a reason. Patients were informed that they need not to bear any cost for their participation in this study.

3. Results

3.1. Demographic and disease characteristics

The mean ages of the participants were 46.67 ± 10.06, 48.21 ± 10.23, and 52.86 ± 11.70 years in the PMR, MM, and CG groups, respectively. All participants (100.0%) in the three study groups were females. The majority of the participants in all groups were married. Half of the participants in the MM and more than half of them in the PMR (54.8%) and the CG (65.6%) had completed at least primary education. More than half of the participants in all groups were unemployed and had a moderate-income level. With regard to disease characteristics, the length of time since diagnosis of breast cancer was between 1 and 12 months in the PMR (96.7%), in the MM (96.8%), and the CG (96.5%). Participants in the PMR group had stage I (12.9%), stage II (61.3%), and stage III (25.8%) breast cancer diagnose. As for MM group, 12.5% of had stage I, half of them had stage II, and 37.5% of had stage III. With regard to the CG, 3.4% of those were diagnosed with stage I, 55.2% of had stage II, and 41.4% of had stage III breast cancer. The mean values of Hgb were greater than 11 mg/dL in all groups. With regard to group homogeneity findings, PMR, MM, and CG were similar in terms of age (t = 2.698; p = .073), educational level (X^2 = 13.778; p = .315), employment status (X^2 = 1.683; p = .431), income level (X^2 = 2.025; p = .731), time since diagnosis (X^2 = 0.868; p = .929) breast cancer stage X^2 = 3.731; p = .444), and Hgb value (t = 175.026; p = .507) except for marital status (X^2 = 6.492; p = .039). (Table 1).

3.2. Effects of PMR and MM on fatigue severity

The median total BFI severity scores of the participants in the PMR group were 12.0 at baseline, 7.5 in the 12th week, and 7.5 in the 14th week of the study. The corresponding scores for the MM group were 12.0, 6.0, and 8.0, respectively. As for CG, the scores were 11.0 at baseline, 12.0 in the 12th week, and 15.0 in the 14th week. Regarding the comparison of total BFI severity scores between the three groups, while statistical testing showed no significant difference for the baseline assessment, there was a significant reduction in the 12th and 14th weeks of the study in favor of the intervention groups. With regard to the median total BFI interference, the scores of participants in the PMR group were 20.0 at the baseline and 1.5 in 12th and 14th weeks; and the scores of participants in the MM group were 17.0 at baseline and 2.0 in 12th and 14th weeks. The corresponding scores for the CG were 15.0 at baseline, 8.0 in the 12th week, and 7.0 in the 14th week of the study. As for comparisons of fatigue interference scores between the three groups, no significant differences at baseline and at weeks 12 and 14 of assessments were observed. Looking at comparisons between the groups in terms of total BFI scores, there was a significant reduction in the 12th (X^2 = 12.047, p = .002) and 14th weeks (X^2 = 12.189, p = .002) of the study in favor of the intervention groups (Table 2).

3.3. Effects of PMR and MM on coping styles

Regarding Brief COPE scores, at the end of the monitoring period, both the intervention groups, PMR and MM, yielded significantly higher coping style scores compared with the CG in 12th and 14th weeks of the study in terms of the use of instrumental support, active coping, acceptance, positive reframing, use of emotional support, and planning sub-dimensions ($p < 0.05$). Significant differences in the use of instrumental support sub-dimension resulted from MM in the 12th week (KW = 8.222, p = .017) and from PMR in the 14th week (KW = 6.333, p = .042). As for the active coping sub-dimension, differences resulted from the PMR in the 12th week (KW = 9.922, p = .007) and from the MM in the 14th week (KW = 6.013, p = .049). The differences were related to MM in the 12th week (KW = 4.598,

Table 1
Socio-demographics and clinical characteristics of participants (N = 92).

Socio-demographic characteristics	PMR (N = 31)		MM (N = 32)		CG (N = 29)		Test statistics*	p value
Age (X ± SD)	46.67 ± 10.06		48.21 ± 10.23		52.86 ± 11.70		2.698**	.073
Marital status	n	%	n	%	n	%		
Married	29	93.5	22	68.8	25	86.2	6.492	**.039**
Single	2	6.5	10	31.2	4	13.8		
Educational level								
Primary	17	54.8	16	50.0	19	65.6	13.778	.315
High school	9	29.0	7	21.9	5	17.2		
University-+	5	16.2	9	28.1	5	17.2		
Employment status								
Employed	5	16.1	7	21.9	4	13.8	1.683	.431
Nonemployee	26	83.9	25	78.1	25	86.2		
Income level								
Low	13	41.9	9	28.1	10	34.5	2.025	.731
Moderate	17	54.8	21	65.6	17	58.6		
High	1	3.3	2	6.3	2	6.9		
Clinical characteristics								
Time since diagnosis								
1–12 months	30	96.7	31	96.8	28	96.5	.868	.929
13 months-+	1	3.3	1	3.2	1	3.5		
Breast cancer stage								
I	4	12.9	4	12.5	1	3.4	3.731	.444
II	19	61.3	16	50.0	16	55.2		
III	8	25.8	12	37.5	12	41.4		
Hgb value, (mg/dL) (X ± SD)	11.69 ± 1.14		11.75 ± 0.95		11.48 ± 0.92		175.026**	.507

X = Mean, SD: Standard deviation, PMR: Progressive Muscle Relaxation, MM: Mindfulness Meditation, Hgb: Hemoglobin *: Chi-square test, **One-way ANOVA, ***: No Chi-square analysis was done due to the presence of values less than 5.

Table 2
Comparison of median BFI scores in the PMR, MM, and CG groups (N = 92).

Variable	Measurement time	PMR (N = 31) Median (25th – 75th)	MM (N = 32) Median (25th – 75th)	CG (N = 29) Median (25th – 75th)	Test statistic	p-value	Difference (Tukey's test)
Fatigue severity							
Now	Baseline	4.0 (0.0–5.0)	4.0 (2.0–5.0)	2.0 (0.0–6.0)	.549	.760	–
	12th week	2.0 (0.0–4.0)	2.0 (0.0–4.0)	3.0 (2.0–7.0)	6.115	**.047**	3–1,2
	14th week	2.0 (0.0–5.0)	3.0 (0.0–4.5)	5.0 (2.5–5.0)	7.721	**.021**	3–1,2
Usual	Baseline	3.5 (0.0–6.0)	5.0 (2.0–5.0)	4.0 (1.5–6.0)	.675	.714	-
	12th week	3.0 (0.0–5.0)	2.0 (0.0–4.0)	5.0 (3.0–7.5)	13.654	**.001**	3–1,2
	14th week	3.0 (0.0–5.0)	3.0 (0.0–4.5)	5.0 (3.0–6.0)	13.114	**.001**	3–1,2
Worst	Baseline	5.5 (4.0–7.2)	5.0 (2.5–7.5)	5.0 (2.5–8.0)	.153	.926	-
	12th week	3.0 (0.0–5.0)	2.0 (0.0–4.0)	4.0 (3.0–8.0)	12.721	**.002**	3–1,2
	14th week	3.5 (0.0–6.0)	3.0 (0.0–5.0)	5.0 (3.0–7.0)	12.575	**.002**	3–1,2
Total BFI severity	Baseline	12.0 (6.5–18.0)	12.0 (6.0–18.0)	11.0 (6.5–21.5)	.094	.954	–
	12th week	7.5 (2.0–13.0)	6.0 (6.0–11.5)	12.0 (8.5–21.0)	12.047	**.002**	3–1,2
	14th week	7.5 (2.0–15.3)	8.0 (1.5–13.0)	15.0 (9.0–18.0)	12.189	**.002**	3–1,2
Fatigue Interference							
General activity	Baseline	5.0 (0.7–7.0)	4.0 (1.5–7.5)	4.0 (0.0–6.0)	.651	.722	-
	12th week	0.0 (0.0–4.0)	0.0 (0.0–4.0)	2.0 (0.0–5.5)	2.977	.226	-
	14th week	0.0 (0.0–3.0)	0.0 (0.0–3.0)	2.0 (0.0–5.5)	3.535	.171	-
Mood	Baseline	3.0 (0.0–8.0)	4.0 (0.0–7.0)	2.0 (0.0–5.5)	3.110	.211	-
	12th week	0.0 (0.0–0.3)	0.0 (0.0–1.5)	0.0 (0.0–5.0)	2.852	.240	-
	14th week	0.0 (0.0–1.3)	0.0 (0.0–1.5)	0.0 (0.0–3.0)	.753	.686	-
Walking	Baseline	3.0 (0.0–7.0)	4.0 (0.0–7.0)	2.0 (0.0–5.5)	1.394	.498	-
	12th week	0.0 (0.0–2.3)	0.0 (0.0–3.0)	3.0 (0.0–5.5)	5.817	0.55	-
	14th week	0.0 (0.0–2.0)	0.0 (0.0–2.0)	3.0 (0.0–5.0)	8.314	0.16	-
Normal work	Baseline	4.5 (0.0–6.3)	4.0 (0.0–6.5)	2.0 (0.0–5.0)	1.253	.534	-
	12th week	0.0 (0.0–1.3)	0.0 (0.0–1.0)	2.0 (0.0–5.0)	8.497	0.14	–
	14th week	0.0 (0.0–1.3)	0.0 (0.0–1.0)	0.0 (0.0–4.5)	4.706	0.95	-
Relations	Baseline	3.0 (0.0–5.0)	2.0 (0.0–7.5)	0.0 (0.0–3.5)	6.430	.052	-
	12th week	0.0 (0.0–0.3)	0.0 (0.0–0.0)	0.0 (0.0–3.0)	2.359	.307	-
	14th week	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–1.5)	3.178	.204	-
Enjoyment	Baseline	4.0 (1.0–6.3)	2.0 (0.0–7.5)	0.0 (0.0–3.0)	7.198	0.27	-
	12th week	0.0 (0.0–0.3)	0.0 (0.0–4.0)	0.0 (0.0–2.5)	.779	.677	-
	14th week	0.0 (0.0–0.0)	0.0 (0.0–1.0)	0.0 (0.0–2.5)	2.115	.347	-
Total BFI Interference	Baseline	20.0 (7.0–35.3)	17.0 (8.0–39.0)	15.0 (2.0–20.5)	3.404	.182	-
	12th week	1.5 (0.0–7.0)	2.0 (0.0–14.5)	8.0 (0.0–28.5)	4.469	.107	–
	14th week	1.5 (1.5–10.3)	2.0 (0.0–8.0)	7.0 (0.0–23.5)	3.141	.208	–
Total BFI	Baseline	55.5 (40.5–86.0)	62.0 (39.0–77.0)	77.0 (45–104.0)	1.802	.406	–
	12th week	9.5 (3.5–19.0)	9.0 (0.5–24.0)	20.0 (12.5–46.0)	11.036	**.004**	3–1,2
	14th week	13.5 (0.0–22.5)	13.0 (3.–21.5)	20.0 (15.0–37.0)	8.967	**.011**	3–1,2

BFI: Brief Fatigue Inventory, PMR: Progressive Muscle Relaxation, MM: Mindfulness Meditation.
*: Kruskal-Wallis test, 1: PMR, 2: MM, 3: CG.

p = .026), and both PMR and MM in the 14th week (KW = 6.868, p = .050) in terms of acceptance sub-dimension scores. The group differences resulted from both interventions in positive reframing and the use of emotional support sub-dimensions. Significant differences in the planning sub-dimension scores were observed in MM in the 12th week (KW = 9.764, p = .008) and in both the interventions in the 14th week (KW = 20.426, p = .000). Moreover, humor sub-dimension scores were significantly higher in the 14th week in favor of MM (KW = 8.572, p = .014; Table 3).

3.4. Effects of PMR and MM on quality of life

With regard to the QOL, the FLIC median scores for the PMR group were 91.0 points at baseline, 95.5 points in the 12th week, and 92.5 in the 14th week; 98.0 points at baseline, 95.0 points in the 12th and 14th weeks for the MM. Corresponding scores for the CG were 95.0, 94.0, and 95.0 points, respectively. At the end of the monitoring period, there were no significant differences between the three study groups at baseline (KW = 1.600, p = .449) and at weeks 12 (KW = 1.445, p = .486) and 14 (KW = 4.699, p = .095) assessments in terms of QOL scores (Table 4).

3.5. Adherence of participants to PMR and MM interventions

During the weekly adjuvant paclitaxel regimens, five participants dropped out from the study; all of them reported to have practiced PMR or MM intervention in line with the study protocol. Moreover, no participants dropped out owing to unexpected adverse events of PMR or MM, indicating that both interventions were safe and well-tolerated by patients with EBC.

4. Discussion

The current prospective, assessor-blinded, and three-arm randomized controlled trial tested the effects of a well-established 12-week PMR and MM interventions on fatigue, coping styles, and QOL in patients with EBC receiving adjuvant paclitaxel regimen. Although reports exploring the effects of the different mind-body approaches in a variety of treatments or cancer-related symptoms exist in the literature, to the best of our knowledge, there has been no study that compared the effects of PMR and MM, initiated with concurrent adjuvant paclitaxel regimen in patients with EBC.

Following PMR or MM intervention, our data analyses revealed that fatigue severity scores were significantly reduced at the end of interventions, and this beneficial effect continued at the follow-up assessment in the 14th week of the study. These results supported our first hypothesis and coincided with earlier studies focusing on PMR effects (Charalambous et al., 2016; Cohen and Fried, 2007). A prospective randomized controlled study, investigating the effects of combined PMR and guided imagery interventions reported a significant decrease in fatigue severity among breast and prostate cancer patients receiving chemotherapy (Charalambous et al., 2016). Similarly, Cohen and Fried

Table 3
Comparison of median brief COPE scores in the PMR, MM, and CG groups (N = 92).

Brief COPE Sub-dimensions	Measurement time	PMR (N = 31) Median (25th–75th)	MM (N = 32) Median (25th–75th)	CG (N = 29) Median (25th–75th)	Test statistic	P value	Difference (Tukey's test)
Use of instrumental support	Baseline	6.0 (5.0–7.0)	6.0 (5.0–6.5)	6.0 (5.5–7.0)	1.234	.539	–
	12th week	5.0 (3.0–7.25)	6.0 (5.0–7.0)	5.0 (4.0–6.0)	8.222	**.017**	2–3
	14th week	6.0 (4.75–7.25)	6.0 (4.0–8.0)	5.0 (4.0–6.0)	6.333	**.042**	1–3
Humor	Baseline	4.0 (2.0–7.0)	5.0 (3.0–7.5)	3.5 (3.5–4.0)	1.187	.552	–
	12th week	5.0 (4.0–6.25)	4.0 (4.0–4.0)	4.0 (3.0–6.0)	2.183	.336	–
	14th week	5.0 (4.0–6.25)	6.0 (5.0–7.0)	4.0 (3.0–6.0)	8.572	**.014**	2–3
Active coping	Baseline	3.0 (2.0–3.5)	2.5 (2.25–3.25)	2.5 (2.0–3.0)	1.594	.451	–
	12th week	3.0 (2.5–3.5)	3.0 (2.5–3.5)	3.0 (2.5–3.0)	9.922	**.007**	1–3
	14th week	3.0 (2.5–3.5)	2.5 (2.5–3.0)	2.5 (2.25–3.0)	6.013	**.049**	2–3
Substance use	Baseline	2.0 (2.0–2.0)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	.3693	.158	–
	12th week	2.0 (2.0–420)	2.0 (2.0–2.0)	3.5 (2.75–3.5)	3.615	.164	–
	14th week	2.0 (2.0–2.0)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	3.959	.564	–
Acceptance	Baseline	8.0 (6.0–8.0)	7.0 (6.5–8.0)	8.0 (7.5–8.0)	3.383	.184	–
	12th week	8.0 (8.0–8.0)	8.0 (8.0–8.0)	8.0 (8.0–8.0)	4.598	**.026**	2–3
	14th week	8.0 (8.0–8.0)	8.0 (8.0–8.0)	8.0 (7.0–8.0)	6.848	**.050**	3–1,2
Venting	Baseline	6.0 (5.0–7.0)	6.0 (5.0–7.0)	6.0 (5.5–7.0)	2.163	.339	–
	12th week	7.0 (6.0–8.0)	8.0 (7.0–8.0)	6.0 (5.0–8.0)	5.375	.068	–
	14th week	7.5 (6.0–8.0)	7.0 (6.0–8.0)	7.0 (6.0–8.0)	3.524	.172	–
Religion	Baseline	8.0 (7.0–8.0)	8.0 (7.0–8.0)	8.0 (8.0–8.0)	1.038	.595	–
	12th week	8.0 (8.0–8.0)	8.0 (8.0–8.0)	8.0 (7.5–8.0)	1.547	.483	–
	14th week	8.0 (8.0–8.0)	8.0 (8.0–8.0)	8.0 (6.0–8.0)	4.004	.135	–
Denial	Baseline	2.0 (2.0–4.0)	2.0 (2.0–5.0)	3.0 (2.0–2.5)	.950	.622	–
	12th week	2.0 (2.0–2.0)	2.0 (2.0–3.0)	2.0 (2.0–3.0)	1.855	.395	–
	14th week	2.0 (2.0–2.0)	2.0 (2.0–2.5)	2.0 (2.0–3.0)	1.547	.461	–
Behavioral disengagement	Baseline	2.0 (2.0–3.0)	2.0 (2.0–4.5)	3.0 (2.0–4.0)	1.333	.513	–
	12th week	2.0 (2.0–2.25)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	1.788	.409	–
	14th week	2.0 (2.0–2.0)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	.938	.626	–
Self-distraction	Baseline	3.5 (3.0–4.0)	4.0 (3.5–4.0)	3.0 (3.0–3.75)	2.296	.317	–
	12th week	3.75 (3.5–4.0)	3.0 (3.0–4.0)	3.5 (3.0–4.0)	3.923	.141	–
	14th week	3.5 (3.5–4.0)	4.0 (3.5–4.0)	3.5 (3.0–4.0)	2.526	.283	–
Self-blame	Baseline	6.0 (5.0–7.0)	6.0 (5.0–70)	6.0 (5.5–7.0)	3.033	.220	–
	12th week	7.0 (6.0–8.0)	8.0 (6.0–8.0)	7.0 (6.0–8.0)	4.026	.134	–
	14th week	7.5 (6.0–8.0)	7.0 (6.0–8.0)	7.0 (6.0–8.0)	1.947	.378	–
Positive reframing	Baseline	7.0 (6.0–7.0)	7.0 (5.5–8.0)	6.0 (5.5–8.0)	.425	.809	–
	12th week	7.0 (6.75–8.0)	8.0 (7.0–8.0)	7.0 (6.0–7.5)	7.373	**.025**	3–1,2
	14th week	7.0 (7.0–8.0)	8.0 (7.0–8.0)	6.0 (5.0–7.0)	15.968	**.000**	3–1,2
Use of emotional support	Baseline	5.0 (3.75–6.0)	5.0 (3.0–7.0)	5.0 (3.5–7.0)	.013	.994	–
	12th week	5.0 (3.75–7.25)	7.0 (5.0–8.0)	4.0 (3.5–5.0)	17.184	**.000**	3–1,2
	14th week	6.0 (4.75–7.0)	6.0 (5.0–8.0)	5.0 (4.0–6.0)	14.372	**.001**	3–1,2
Planning	Baseline	6.0 (5.0–7.0)	6.0 (4.5–8.0)	6.0 (5.0–8.0)	.061	.970	–
	12th week	7.0 (5.5–8.0)	7.0 (6.0–8.0)	6.0 (4.0–7.0)	9.764	**.008**	2–3
	14th week	6.0 (5.0–8.0)	8.0 (7.0–8.0)	5.0 (4.0–6.5)	20.426	**.000**	3–1,2

PMR: Progressive Muscle Relaxation, MM: Mindfulness Meditation, *: Kruskal-Wallis test, 1: PMR, 2: MM, 3: CG.

Table 4
Comparison of median FLIC scores in the PMR, MM, and CG groups (N = 92).

FLIC Sub-dimension	Measurement time	PMR (N = 31) Median (25th–75th)	MM (N = 32) Median (25th–75th)	CG (N = 29) Median (25th–75th)	Test statistic	p-value
Physical function	Baseline	26.0 (23.0–28.3)	25.0 (22.5–29.0)	25.0 (23.0–26.5)	.740	.691
	12th week	25.0 (22.8–26.0)	25.0 (23.0–26.0)	25.0 (22.5–26.0)	.835	.659
	14th week	25.0 (23.0–26.0)	25.5 (23.0–27.0)	25.0 (24.0–27.0)	1.182	.554
Psychologic function	Baseline	29.5 (25.0–33.0)	30.0 (26.0–34.0)	31.0 (28.0–33.5)	.814	.666
	12th week	34.5 (30.0–36.0)	35.0 (32.5–35.5)	34.0 (29.5–35.0)	1.423	.491
	14th week	31.0 (30.0–35.0)	33.5 (31.0–35.8)	33.0 (31.0–35.0)	2.345	.310
General well-being	Baseline	23.0 (17.0–26.0)	23.0 (20.0–26.0)	21.0 (17.5–25.0)	2.062	.357
	12th week	21.0 (19.0–24.0)	21.0 (18.0–23.0)	21.0 (18.5–23.0)	.319	.852
	14th week	20.0 (18.8–23.0)	20.50 (18.8–23.0)	22.0 (20.0–23.0)	2.333	.311
Social function	Baseline	12.0 (9.75–14.0)	12.0 (8.0–14.0)	14.0 (11.0–14.0)	4.144	.126
	12th week	14.0 (11.8–14.0)	14.0 (14.0–14.0)	14.0 (10.0–14.0)	3.174	.205
	14th week	14.0 (12.0–14.0)	14.0 (11.3–14.0)	14.0 (10.5–14.0)	1.993	.369
Gastrointestinal symptoms	Baseline	5.0 (2.0–9.25)	6.0 (2.0–10.5)	4.0 (2.0–8.0)	.706	.703
	12th week	2.0 (2.0–2.0)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	.215	.898
	14th week	2.0 (2.0–2.0)	2.0 (2.0–2.0)	2.0 (2.0–4.0)	3.818	.147
Total scores	Baseline	91.0 (85.0–103.5)	98.0 (88.5–104.5)	95.0 (89.0–99.5)	1.600	.449
	12th week	95.5 (90.8–98.0)	95.0 (92.0–98.0)	94.0 (87.0–98.0)	1.445	.486
	14th week	92.5 (88.0–96.2)	95.0 (89.8–97.0)	95.0 (92.0–99.0)	4.699	.095

FLIC: Functional Living Index-Cancer, PMR: Progressive Muscle Relaxation, MM: Mindfulness Meditation.
*: Kruskal Wallis test.

(2007) emphasized the positive effect of PMR in alleviating fatigue symptoms in patients with early-stage breast cancer. Similar to PMR, clinical studies using MM intervention also showed considerable positive effects on fatigue severity in cancer patients. For example, Castellar et al. (2014) showed that patients with breast cancer who meditated twice a day for eight weeks observed a considerable decrease in their fatigue severity. Kim et al. (2013) also emphasized that 12 sessions of MM applied during a period of six weeks significantly reduced fatigue scores in patients with breast cancer receiving radiotherapy. When reviewing all study outcomes with a holistic perspective, a significant decrease in fatigue scores in our study sample could be related to the effects of PMR, including relaxation that involves energy restoration in the body and reduction of autonomic arousal (Benson and Klipper, 1975; Davidson et al., 2003). Moreover, the beneficial effects of MM on fatigue scores may result from the increase in the energy level and positive influence on the emotional aspects of patients (Kim et al., 2013; Lengacher et al., 2009). It is believed that regularly practicing PMR and MM interventions and using the diaphragmatic deep-breathing technique during sessions may contribute to an increase in the oxygen level of muscle cells (Bahcivan et al., 2018).

In support of our second hypothesis, PMR and MM interventions significantly improved coping styles in the intervention groups. When looking at our study outcomes, problem-focused coping strategies, such as the use of instrumental support, active coping, and planning, were significantly improved in both PMR and MM groups at the post-intervention and follow-up assessments. With regard to the emotion-focused coping strategies, including acceptance, positive reframing, and use of emotional support, these were significantly used by participants in both intervention groups at weeks 12 and 14. Additionally, humor sub-dimension was significantly higher in MM at week 14. It could be concluded that PMR and MM interventions have similar effects in improving coping styles in patients with EBC who are receiving paclitaxel. These parallel findings in coping style strategies may be partially attributed to the nature of PMR and MM interventions that belong to mind–body-based approaches and have similar therapeutic components. In the literature, problem-focused coping strategies are frequently used to change or modify the fundamental cause of the stress. Moving from this point, the participants in the PMR and MM groups had greater coping scores than those in the CG, and this may help in coping better the daily-life and disease- or treatment-related stresses by a daily practice of PMR or MM along with the adjuvant paclitaxel regimen. Emotion-focused coping strategies also help in controlling an individual's emotions (Contrada and Baum, 2011). Considering the significant improvements in emotion-focused coping strategies in the PMR and MM groups in our study, we believe that participants may gain abilities in terms of self-reflection, expression, and processing their emotions to reappraise unchangeable stressors (Baldacchino and Draper, 2001; Stanton et al., 2000).

Patients with EBC often receive adjuvant paclitaxel chemotherapy as part of their treatment and may experience several symptoms that cause impairment in the QOL. In the present study, the PMR and MM interventions initiated with the first cycle of adjuvant paclitaxel regimen until the completion of the treatment did not result in positive effects on the QOL scores. Similar to our findings, another study examining the effects of cognitive behavioral therapy, relaxation, and health education on improving psychological distress in patients with EBC specified that relaxation did not improve the QOL. In contrast to our outcomes, one recent trial with a pre-post intervention design without a control group combining with PMR and guided imagery, and conducted in cancer patients receiving chemotherapy, reported a significant improvement in the QOL (Parás-Bravo et al., 2017). However, this study was performed with a sample containing patients having different malignancies and combined PMR with guided imagery; therefore, it is not possible to draw a firm conclusion about which intervention is superior than the others in terms of improving the QOL. Several trials of MM in cancer patients have also reported significant effects on the QOL (Bisseling et al., 2017; Bower et al., 2014; Carlson et al., 2013; Crosswell et al., 2014; Castellar et al., 2014). For instance, a pilot study with a pre-post-test design reported a significant improvement in QOL scores following an 8-week mindfulness-based stress reduction program including relaxation, meditation, gentle yoga movements, and daily home practices (Carlson et al., 2003). Castellar et al. (2014) also suggested that the 8-week meditation intervention in cancer patients improved the QOL. A possible explanation for the variations observed in these study outcomes could be that these resulted from participants' characteristics, differences in cancer diagnoses and stages, duration of interventions, and the use of PMR or MM intervention as combined or single. Another explanation for these variations between the study findings, QOL has many varying domains such as physical, emotional, socio-economic, and spiritual. Recent studies also emphasized that MM may improve physical domains of QOL including pain, inflammation, fatigue, sleep quality, and psychological domains such as distress, stress, depression, emotion regulation, and spiritual well-being (Bower et al., 2014; Johns et al., 2015; Kenne Sarenmalm et al., 2017; Ngamkham et al., 2019; Schell et al., 2019; Yun et al., 2017; Würtzen et al., 2015; Zhang et al., 2019). It is important to note that although our study revealed significant reduction in fatigue severity, with improvement in both problem-focused and emotion-focused coping strategies, accompanied side effects of adjuvant paclitaxel, including alopecia, lack of appetite, and peripheral neuropathy, may have detrimental effects on the QOL. Therefore, these uncontrolled common symptoms may be associated with persistent QOL scores, reported by participants in all groups in our study.

4.1. Strengths and limitations

Findings from the present trial must be interpreted in the context of some unique strengths and limitations. One of the strengths of the present study is that this trial utilized an attention-matched control education. Another strength is ensuring the condition of assessor-blinded trial. The main limitation of the study was the inability to perform a double-blind randomized control trial, as it was difficult to mask patients based on the intervention provided. Additionally, the adherence of all the participants in the intervention groups was self-reported. Lastly, we performed only a single time follow-up assessment, two weeks after the last adjuvant paclitaxel infusion. Despite the limitations of the trial, we believe that the rigorous design and implementation allow for the generalizability of the findings in patients with EBC.

4.2. Implications for practice and research

Overall, the results of the present study conclude that PMR and MM interventions are effective in managing fatigue through the implementation of problem-focused and emotion-focused coping strategies in patients with EBC. The PMR and MM interventions appear to be well-tolerated, acceptable, and practical, particularly during a stressful time when patients with EBC are on adjuvant paclitaxel therapy. Moreover, we found a high adherence to the sessions in the present study and no participants reported side effects related to PMR or MM interventions. The current study provides evidence for the benefits of PMR and MM interventions, thereby allowing the nurses to integrate these interventions into the clinical setting after participating in specific training programs. Before initiating the paclitaxel regimen, healthcare providers may inform patients with breast cancer about the benefits of PMR and MM interventions in reducing fatigue and improving coping styles, and providing the volunteering patients with this opportunity along with the chemotherapy regimen. Future studies are warranted that investigating the effects of mind-body interventions such as PMR, and MM in advance stage cancer patients. Additionally, further research with a larger scale and longer duration is recommended that examining effects of PMR and MM on chemotherapy-related side effects like pain,

nausea, vomiting, and sleep disturbances and quality of life, as well.

5. Conclusion

In conclusion, the present randomized control trial provided evidence that PMR and MM interventions applied concurrently with adjuvant paclitaxel regimen, assist in decreasing fatigue severity and improving coping styles among patients with EBC. On the contrary, both PMR and MM interventions do not affect the QOL scores. Based on the study results, we conclude that PMR and MM interventions could be safely integrated into the clinical practice for patients with EBC who scheduled to receive adjuvant paclitaxel therapy.

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Conflicts of interest

The authors declare they have no conflict of interest.

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References

Anagnostopoulos, F., Vaslamatzis, G., Markidis, M., 2004. Coping strategies of women with breast cancer: a comparison of patients with healthy and benign controls. Psychother. Psychosom. 73 (1), 43–52.
Ando, M., Morita, T., Akechi, T., Ito, S., Tanaka, M., Ifuku, Y., Nakayama, T., 2009. The efficacy of mindfulness-based meditation therapy on anxiety, depression, and spirituality in Japanese patients with cancer. J. Palliat. Med. 12 (12), 1091–1094.
Avis, N.E., Crawford, S., Manuel, J., 2004. Psychosocial problems among younger women with breast cancer. Psycho Oncol. 13 (5), 295–308.
Bacanlı, H., Sürücü, M., İlhan, T., 2013. Başa çıkma stilleri ölçeği kısa formunun (BÇSÖ-KF) psikometrik özelliklerinin incelenmesi: geçerlik ve güvenirlik çalışması. Kuram ve Uygulamada Eğitim Bilimler 13 (1), 81–96.
Bahcivan, O., Estape, T., Gutierrez-Maldonado, J., 2018. The swinging effect intervention: CBT based guided imagery and breathing technique integrated with mindfulness therapy for cancer patients. Med. Hypotheses 121, 42.
Baldacchino, D., Draper, P., 2001. Spiritual coping strategies: a review of the nursing research literature. J. Adv. Nurs. 34 (6), 833–841.
Bektas, H.A., Akdemir, N., 2006. Kanserli bireylerin fonksiyonel durumlarının değerlendirilmesi. Turkiye Klinikleri J. Med. Sci. 26 (5), 488–499.
Benson, H., Klipper, M.Z., 1975. The Relaxation Response. Morrow, New York.
Bisseling, E.M., Schellekens, M.P., Jansen, E.T., van Laarhoven, H.W., Prins, J.B., Speckens, A.E., 2017. Mindfulness-based stress reduction for breast cancer patients: a mixed method study on what patients experience as a suitable stage to participate. Support. Care Cancer 25 (10), 3067–3074.
Boon, H.S., Olatunde, F., Zick, S.M., 2007. Trends in complementary/alternative medicine use by breast cancer survivors: comparing survey data from 1998 and 2005. BMC Women's Health 7 (1), 4.
Bower, J.E., Ganz, P.A., Crosswell, A.D., Crespi, C.M., Stanton, A.L., Winston, D., Cole, S.W., 2014. Effects of mindfulness meditation on stress and inflammation in breast cancer survivors: a randomized controlled trial. In: Psychosom Med 76. pp. 19 3.
Bower, J.E., Crosswell, A.D., Stanton, A.L., Crespi, C.M., Winston, D., Arevalo, J., ... Ganz, P.A., 2015. Mindfulness meditation for younger breast cancer survivors: a randomized controlled trial. Cancer 121 (8), 1231–1240.
Boyle, C.C., Stanton, A.L., Ganz, P.A., Crespi, C.M., Bower, J.E., 2017. Improvements in emotion regulation following mindfulness meditation: effects on depressive symptoms and perceived stress in younger breast cancer survivors. J. Consult. Clin. Psychol. 85 (4), 397.
Carlson, L.E., Speca, M., Patel, K.D., Goodey, E., 2003. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. Psychosom. Med. 65 (4), 571–581.
Carlson, L.E., Doll, R., Stephen, J., Faris, P., Tamagawa, R., Drysdale, E., Speca, M., 2013. Randomized controlled trial of mindfulness-based cancer recovery versus supportive expressive group therapy for distressed survivors of breast cancer. J. Clin. Oncol. 31 (25), 3119–3126.
Carver, C.S., 1997. You want to measure coping but your protocol'too long: consider the brief cope. Int. J. Behav. Med. 4 (1), 92.
Castellar, J.I., Fernandes, C.A., Tosta, C.E., 2014. Beneficial effects of pranic meditation on the mental health and quality of life of breast cancer survivors. Integr. Cancer Ther. 13 (4), 341–350.
Charalambous, A., Giannakopoulou, M., Bozas, E., Marcou, Y., Kitsios, P., Paikousis, L., 2016. Guided imagery and progressive muscle relaxation as a cluster of symptoms management intervention in patients receiving chemotherapy: a randomized control trial. PLoS One 11 (6), e0156911.
Cohen, M., Fried, G., 2007. Comparing relaxation training and cognitive-behavioral group therapy for women with breast cancer. Res. Soc. Work. Pract. 17 (3), 313–323.
Complementary, N.C.f., Health, I., 2015. Complementary, alternative, or integrative health: what's in a name? In: US Department of Health and Human Services. National Institutes of Health.
Contrada, R.J., Baum, A.E., 2011. The Handbook of Stress Science: Biology, Psychology, and Health. Springer Publishing Co.
Crosswell, A.D., Boyle, C.C., Moreno, P.I., Ganz, P.A., Stanton, A.L., Motivala, S.J., et al., 2014, April. Impact of mindfulness meditation on acute stress response in breast cancer survivors. Psychosom. Med. 76 (3), 113.
Davidson, R.J., Kabat-Zinn, J., Schumacher, J., Rosenkranz, M., Muller, D., Santorelli, S.F., ... Sheridan, J.F., 2003. Alterations in brain and immune function produced by mindfulness meditation. Psychosom. Med. 65 (4), 564–570.
Gandhi, S., Fletcher, G., Eisen, A., Mates, M., Freedman, O., Dent, S., Trudeau, M., 2015. Adjuvant chemotherapy for early female breast cancer: a systematic review of the evidence for the 2014 Cancer Care Ontario systemic therapy guideline. Curr. Oncol. 22 (Suppl. 1), S82.
Greenlee, H., Kwan, M.L., Ergas, I.J., Sherman, K.J., Krathwohl, S.E., Bonnell, C., ... Kushi, L.H., 2009. Complementary and alternative therapy use before and after breast cancer diagnosis: the Pathways Study. Breast Canc. Res. Treat. 117 (3), 653–665.
Gudenkauf, L.M., Antoni, M.H., Stagl, J.M., Lechner, S.C., Jutagir, D.R., Bouchard, L.C., Giron, G.L., 2015. Brief cognitive–behavioral and relaxation training interventions for breast cancer: a randomized controlled trial. J. Consult. Clin. Psychol. 83 (4), 677.
Haghighat, S., Akbari, M.E., Holakouei, K., Rahimi, A., Montazeri, A., 2003. Factors predicting fatigue in breast cancer patients. Support. Care Cancer 11 (8), 533–538.
Ho, M.Y., Mackey, J.R., 2014. Presentation and management of docetaxel-related adverse effects in patients with breast cancer. Cancer Manag. Res. 6, 253.
İzci, F., İlgün, A.S., Fındıklı, E., Özmen, V., 2016. Psychiatric symptoms and psychosocial problems in patients with breast cancer. J. Breast Health 12 (3), 94.
Jacobson, E., 1938. Progressive muscle relaxation. University of Chiago. Press, Chicago IL.
Jang, S., 2013. Effects of meditation program on power, anxiety, depression and quality of life in women with breast cancer. J. Korean Acad. Psychiatr. Ment. Health Nurs. 22 (3), 205–215.
Johns, S.A., Brown, L.F., Beck-Coon, K., Monahan, P.O., Tong, Y., Kroenke, K., 2015. Randomized controlled pilot study of mindfulness-based stress reduction for persistently fatigued cancer survivors. Psycho Oncol. 24 (8), 885–893.
Kabat-Zinn, J., 2013. Full Catastrophe Living, Revised Edition: How to Cope with Stress, Pain and Illness Using Mindfulness Meditation: Hachette UK.
Kang, G., Oh, S., 2012. Effects of mindfulness meditation program on perceived stress, ways of coping, and stress response in breast cancer patients. J. Korean Acad. Nurs. 42 (2), 161–170.
Kashani, F., Babaee, S., Bahrami, M., Valiani, M., 2012. The effects of relaxation on reducing depression, anxiety and stress in women who underwent mastectomy for breast cancer. Iran. J. Nurs. Midwifery Res. 17 (1), 30.
Kenne Sarenmalm, E., Mårtensson, L.B., Andersson, B.A., Karlsson, P., Bergh, I., 2017. Mindfulness and its efficacy for psychological and biological responses in women with breast cancer. Cancer Med. 6 (5), 1108–1122.
Kershaw, T., Northouse, L., Kritpracha, C., Schafenacker, A., Mood, D., 2004. Coping strategies and quality of life in women with advanced breast cancer and their family caregivers. Psychol. Health 19 (2), 139–155.
Kim, Y.H., Kim, H.J., Do Ahn, S., Seo, Y.J., Kim, S.H., 2013. Effects of meditation on anxiety, depression, fatigue, and quality of life of women undergoing radiation therapy for breast cancer. Complement. Ther. Med. 21 (4), 379–387.
Lake, B., Fuller, H.R., Rastall, S., Usman, T., 2019. Breast reconstruction affects coping mechanisms in breast cancer survivors. Indian J. Surg. 81 (1), 43–50.
Ledesma, D., Kumano, H., 2009. Mindfulness-based stress reduction and cancer: a meta-analysis. Psycho Oncol.: J. Psychol. Soc. Behav. Dimens. Cancer 18 (6), 571–579.
Lengacher, C.A., Johnson-Mallard, V., Post-White, J., Moscoso, M.S., Jacobsen, P.B., Klein, T.W., ... Barta, M., 2009. Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. Psycho Oncol.: J. Psychol. Soc. Behav. Dimens. Cancer 18 (12), 1261–1272.
Lindquist, R., Tracy, M.F., Snyder, M., 2018. Complementary & Alternative Therapies in Nursing. Springer Publishing Company.
Matsuno, R.K., Pagano, I.S., Maskarinec, G., Issell, B.F., Gotay, C.C., 2012. Complementary and alternative medicine use and breast cancer prognosis: a pooled analysis of four population-based studies of breast cancer survivors. J. Women's Health 21 (12), 1252–1258.
Mendoza, T.R., Wang, X.S., Cleeland, C.S., Morrissey, M., Johnson, B.A., Wendt, J.K., Huber, S.L., 1999. The rapid assessment of fatigue severity in cancer patients: use of the Brief Fatigue Inventory. Cancer 85 (5), 1186–1196.
Ngamkham, S., Holden, J.E., Smith, E.L., 2019. A systematic review: mindfulness intervention for cancer-related pain. Asia-Pac. J. Oncol. Nurs. 6 (2), 161.
Parás-Bravo, P., Salvadores-Fuentes, P., Alonso-Blanco, C., Paz-Zulueta, M., Santibañez-

Margüello, M., Palacios-Ceña, D., ... Fernández-de-las-Peñas, C., 2017. The impact of muscle relaxation techniques on the quality of life of cancer patients, as measured by the FACT-G questionnaire. PLoS One 12 (10), e0184147.
Schell, L.K., Monsef, I., Wöckel, A., Skoetz, N., 2019. Mindfulness-based stress reduction for women diagnosed with breast cancer. Cochrane Database Syst. Rev.(3).
Schipper, H., Clinch, J., McMurray, A., Levitt, M., 1984. Measuring the quality of life of cancer patients: the Functional Living Index-Cancer: development and validation. J. Clin. Oncol. 2 (5), 472–483.
Seib, C., Porter-Steele, J., Ng, S.K., Turner, J., McGuire, A., McDonald, N., et al., 2018. Life stress and symptoms of anxiety and depression in women after cancer: the mediating effect of stress appraisal and coping. Psycho Oncol. 27 (7), 1787–1794.
Stanton, A.L., Kirk, S.B., Cameron, C.L., Danoff-Burg, S., 2000. Coping through emotional approach: scale construction and validation. J. Personal. Soc. Psychol. 78 (6), 1150.
Tao, J.J., Visvanathan, K., Wolff, A.C., 2015. Long term side effects of adjuvant chemotherapy in patients with early breast cancer. Breast 24, S149–S153.
Usta Yeşilbalkan, O., Karadakovan, A., 2015. *Kemoterapi uygulanan Hastalarda Eğitimin Yorgunluk Düzeyine Ve Yaşam Kalitesine Olan Etkisinin Incelenmesi.* (PhD thesis). Ege Üniversitesi.
Würtzen, H., Dalton, S.O., Christensen, J., Andersen, K.K., Elsass, P., Flyger, H.L., et al., 2015. Effect of mindfulness-based stress reduction on somatic symptoms, distress, mindfulness and spiritual wellbeing in women with breast cancer: results of a randomized controlled trial. Acta Oncol. 54 (5), 712–719.
Yun, M.R., Song, M., Jung, K.H., Boas, J.Y., Lee, K.J., 2017. The effects of mind subtraction meditation on breast cancer survivors' psychological and spiritual well-being and sleep quality: a randomized controlled trial in South Korea. Cancer Nurs. 40 (5), 377–385.
Zainal, N.Z., Booth, S., Huppert, F.A., 2013. The efficacy of mindfulness-based stress reduction on mental health of breast cancer patients: a meta-analysis. Psycho Oncol. 22 (7), 1457–1465.
Zhang, Q., Zhao, H., Zheng, Y., 2019. Effectiveness of mindfulness-based stress reduction (MBSR) on symptom variables and health-related quality of life in breast cancer patients—a systematic review and meta-analysis. *Support. Care Cancer* 27 (3), 771–781.
Zhou, K., Li, X., Li, J., Liu, M., Dang, S., Wang, D., Xin, X., 2015. A clinical randomized controlled trial of music therapy and progressive muscle relaxation training in female breast cancer patients after radical mastectomy: results on depression, anxiety and length of hospital stay. Eur. J. Oncol. Nurs. 19 (1), 54–59.