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Online Mindfulness-Based Counseling for Cognitive Preoccupation and Future Anxiety in Women with Breast Cancer: A Randomized Controlled Trial

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Abstract

Background: Breast cancer and its treatment with chemotherapy can cause substantial psychological distress, including cognitive preoccupation and future anxiety/fear of recurrence. This study evaluated the association of online mindfulness-based counseling with these outcomes among women with breast cancer receiving chemotherapy, using the eight-item Breast Cancer Psychological Care Questionnaire (BC-PPCS-8).

***Materials and Methods*:** In this two-arm, parallel-group randomized controlled trial conducted in Kerman, Iran, 70 women with stage I–III breast cancer receiving chemotherapy were randomly assigned to an eight-week online mindfulness-based counseling program or usual care. Cancer-related psychological distress was assessed using the eight-item Breast Cancer Psychological Care Questionnaire (BC-PPCS-8) at baseline, post-intervention, and one-month follow-up. Baseline characteristics were compared using t-tests, chi-square tests, or Fisher's exact tests, as appropriate. Post-intervention outcomes were compared using the Mann–Whitney U test.

***Results**:* Of 84 patients assessed for eligibility, 70 were randomized in equal numbers to mindfulness-based counseling or usual care. Post-intervention outcome data were obtained from 34 participants in the counseling group and 35 in the control group. Groups were comparable at baseline regarding demographic and clinical characteristics, including age, marital status, education, income, cancer type, time since diagnosis, and number of chemotherapy sessions (all $p > 0.05$). At post-intervention, participants receiving mindfulness-based counseling reported significantly lower cognitive preoccupation (mean vs. mean), future anxiety/fear of recurrence (mean vs. mean), and total BC-PPCS-8 scores (mean vs. mean) than control participants (all $p < 0.05$).

***Conclusion**:* Online mindfulness-based counseling was associated with lower post-intervention cognitive preoccupation, future anxiety/fear of recurrence, and psychological distress than usual care among women receiving chemotherapy for breast cancer. This accessible intervention may complement psychosocial care; larger longitudinal trials should confirm the magnitude and durability of effects.

***Key Words**:* Anxiety, Breast cancer, Mindfulness, Psychosocial Intervention, Randomized Controlled Trial.

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1- INTRODUCTION

Cancer remains one of the most formidable global public health challenges, ranking as a leading cause of mortality and a critical impediment to increasing life expectancy worldwide (1). Among various malignancies, breast cancer holds a distinct position in women's oncology due to its disproportionate burden, pervasive psychosocial impact, and complex survivorship trajectory (2, 3). According to the latest global cancer statistics (GLOBOCAN), approximately 2.3 million new female breast cancer cases are diagnosed annually, making it the most frequently diagnosed cancer and the foremost cause of cancer-related mortality among women globally (1, 3). In Iran, breast cancer similarly ranks as the most prevalent malignancy among women, presenting at an earlier age of onset compared with Western populations and posing substantial clinical and psychosocial burdens (4, 5).

Advances in early screening and multimodal therapeutic protocols—encompassing surgical resection, cytotoxic chemotherapy, radiotherapy, and targeted endocrine therapies—have substantially improved overall survival rates (3, 6). Nonetheless, this oncological success is frequently shadowed by profound physical and psychological morbidity (6, 7). Systemic chemotherapy, while vital for disease control, invariably induces debilitating adverse effects, including intractable nausea, severe fatigue, alopecia, and systemic toxicities (7, 8). Compounding these somatic symptoms, patients with breast cancer endure profound emotional turbulence, notably clinical anxiety, demoralization, depressive symptomatology, and an altered sense of identity, all of which compromise functional independence, resilience, and treatment adherence (9–11).

In response to the limitations of pharmacological psychotropics, clinical interest in evidence-based integrative oncology and mind–body interventions has expanded substantially (12, 13). Among these modalities, mindfulness-based interventions (MBIs)—such as Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cancer Recovery (MBCR)—have demonstrated notable efficacy in mitigating distress, enhancing emotional regulation, and improving health-related quality of life in cancer survivors (13–15).

Despite these positive findings, two critical clinical and empirical gaps substantiate the necessity of the present investigation:

First, although conventional psycho-oncology studies have predominantly targeted broad psychiatric phenotypes such as non-specific anxiety and depressive affect, they often overlook nuanced cognitive vulnerabilities unique to oncology survivorship—specifically cognitive preoccupation (unproductive rumination and hypervigilance regarding somatic sensations) and future anxiety (existential dread and pervasive fear of cancer recurrence) (10, 16). These unconstructive thought patterns trigger chronic autonomic hyperarousal and neuroendocrine dysregulation via persistent hypothalamic–pituitary–adrenal (HPA) axis activation, ultimately impairing clinical recovery and treatment compliance (13, 16). Mindfulness practices cultivate non-judgmental present-moment awareness and metacognitive decentering, thereby directly interrupting repetitive negative thinking and defusing future-oriented catastrophic appraisals.

Second, from a methodological and ethical perspective, patients undergoing intensive adjuvant chemotherapy experience debilitating physical exhaustion and cognitive fatigue (often referred to as "chemo brain"). Administering lengthy, multi-domain psychological batteries under such clinical states introduces substantial participant burden, leading to

respondent fatigue, increased missing data, and reduced data quality (17, 18). International consensus recommendations emphasize minimizing questionnaire length, reducing assessment frequency, and shortening completion time to mitigate respondent burden in oncology trials (17). In this context, utilizing a concise, brief assessment strategy—such as the 8-item Breast Cancer Psychological Care Questionnaire (BC-PPCS-8) or its subscales targeting cognitive distress—directly minimizes response burden while safeguarding ecological validity and clinical precision in an active clinical trial setting (18).

By targeting these distinct cognitive pathways, empirical evidence from this study can help transition mindfulness counseling from a discretionary supportive luxury to a structured, indispensable component of standard oncology care. Therefore, the present randomized controlled trial was conducted to evaluate the effectiveness of mindfulness-based counseling in alleviating cognitive preoccupation and future anxiety among women diagnosed with breast cancer.

2- MATERIALS AND METHODS

2-1. Study Design and Trial Registration

This study was a two-arm, parallel-group randomized controlled trial conducted at five breast cancer referral centers in Kerman, Iran. Participants were assessed at baseline, immediately after the eight-week intervention, and one month after the post-intervention assessment.

After completion of baseline assessments, eligible participants were randomly allocated in a 1:1 ratio to either an online mindfulness-based counseling program or usual oncological care. The trial was registered with the Iranian Registry of Clinical Trials under the identifier IRCT20201027049164N1. The trial was reported in accordance with the CONSORT 2025 statement (19). Because the intervention was delivered online, relevant recommendations for reporting digital and e-health interventions were also considered (20). The intervention was described according to the Template for Intervention Description and Replication (TIDieR) checklist (21).

2-2. Participants, Eligibility Criteria, and Recruitment

Participants were recruited using convenience sampling from five breast cancer referral centers in Kerman, Iran, including two public oncology centers and three private oncology clinics. Recruitment was conducted between December 2022 and February 2023.

Participants were eligible if they were aged 18 years or older; had histologically confirmed stage I–III breast cancer; had initiated chemotherapy at least one month before enrollment; had weekly access to the internet; were literate in Persian; and provided written informed consent.

Participants were excluded if they had stage IV or metastatic disease; a documented chronic psychiatric disorder, such as major depressive disorder or bipolar disorder; concurrent participation in a structured psychological intervention; psychotropic medication use during the preceding month; complementary medicine use during the preceding two months; or absence from more than two intervention sessions.

2-3. Sample Size and Randomization

The sample size was estimated using G*Power version 3.1. The calculation was informed by effect estimates reported in previous mindfulness-based cancer recovery studies (13, 14). Assuming a two-sided significance level of 0.05, 80% statistical power, and an anticipated standardized effect size of [insert value], the initial required sample was estimated at 30 participants per group. Allowing for

approximately 15% attrition, the recruitment target was increased to 35 participants per group, resulting in a total planned sample of 70 participants.

Following completion of baseline assessments, participants were randomly allocated in a 1:1 ratio to either the mindfulness-based counseling group or the usual-care control group. A computer-generated permuted-block randomization sequence with variable block sizes of four and six was created using the Sealed Envelope randomization service. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes, which were opened only after baseline assessment.

Because of the behavioral nature of the intervention, participants and intervention providers could not be blinded. However, the data analyst remained blinded to group allocation throughout the statistical analysis.

2-4. Intervention: Mindfulness-Based Cancer Recovery

The intervention consisted of an eight-week online mindfulness-based counseling program based on core Mindfulness-Based Cancer Recovery (MBCR) principles (13, 14). Because of COVID-19–related restrictions, all sessions were delivered synchronously through the Skyroom platform.

The program included eight weekly group sessions, each lasting approximately 90 minutes, and a “Day of Silence” retreat conducted between sessions six and seven. The intervention was delivered in accordance with the core structure of MBCR and previous online MBCR protocols (14, 15).

Sessions were facilitated by a certified MBCR instructor and supervised by health psychologists and oncologists. The intervention included body-scan meditation, sitting meditation, walking meditation, mindful Hatha yoga, cognitive processing related to cancer experiences, cancer-related symptom-management strategies, self-compassion practices, and home-based mindfulness exercises.

Participants were encouraged to practice mindfulness at home between sessions. Attendance was recorded for each session. Intervention fidelity was monitored using session recordings and supervision reports.

2-5. Control Condition

Participants assigned to the control group received usual oncological care during the study period. Usual care consisted of routine medical follow-up and cancer treatment provided by the participating oncology centers. Participants in the control group did not receive a structured mindfulness-based or psychological intervention during the intervention period.

After completion of the one-month follow-up assessment, control-group participants were offered access to the recorded mindfulness-based counseling sessions.

2-6. Outcome Measure

2-6-1. Breast Cancer Psychological Care Questionnaire

The primary outcome was cancer-related psychological distress, assessed using the researcher-developed eight-item Breast Cancer Psychological Care Questionnaire (BC-PPCS-8). The questionnaire was developed specifically for patients with breast cancer. Item generation was informed by semi-structured interviews with women with breast cancer and conceptually guided by the Mental Adjustment to Cancer scale and the Fear of Cancer Recurrence Inventory (10, 16).

The BC-PPCS-8 contains two four-item subscales:

- Cognitive preoccupation: persistent and intrusive cancer-related thoughts.

- Future anxiety/fear of recurrence: concerns about disease progression, recurrence, and future health.

Each item is rated on a five-point Likert scale ranging from 1 ("never") to 5 ("always"). Higher scores indicate greater cancer-related psychological distress. Subscale scores range from 4 to 20, and the total score ranges from 8 to 40.

The content validity of the questionnaire was assessed by an expert panel. The content validity index was 0.89, and the content validity ratio was 0.85 (22). Exploratory factor analysis supported a two-factor structure explaining 68% of the total variance. Internal consistency was satisfactory, with a total Cronbach's alpha of 0.82; subscale alpha coefficients were 0.79 for Cognitive Preoccupation and 0.81 for Future Anxiety/Fear of Recurrence. Two-week test–retest reliability was satisfactory, with an intraclass correlation coefficient of 0.87 (95% CI: 0.78–0.93) (23).

The BC-PPCS-8 was completed at baseline, immediately after the eight-week intervention, and one month after the post-intervention assessment.

2-7. Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.0. Continuous variables were summarized using means and standard deviations, whereas categorical variables were summarized using frequencies and percentages. Baseline demographic and clinical characteristics were compared between groups using independent-samples t-tests for continuous variables and chi-square tests or Fisher's exact tests for categorical variables, as appropriate.

Because post-intervention BC-PPCS-8 scores were not normally distributed, between-group comparisons were performed using the Mann–Whitney U test. Outcome analyses were based on participants with available post-intervention data. All statistical tests were two-tailed, and $p < 0.05$ was considered statistically significant.

2-8. Ethical Approval and Informed Consent

The study protocol was reviewed and approved by the Ethics Committee of Kerman University of Medical Sciences, Iran, before participant recruitment commenced (Ethics Code: IR.KMU.REC.1401.246).

Eligible participants received written and verbal information about the study objectives, procedures, potential benefits and risks, voluntary nature of participation, confidentiality protections, and their right to withdraw from the study at any time without affecting their medical care. Written informed consent was obtained from all participants before baseline assessment and randomization.

Participant confidentiality was maintained throughout the study. Each participant was assigned a unique study identification code, and identifying information was stored separately from research data. Access to identifiable information was restricted to authorized members of the research team. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (22) and applicable institutional and national regulations.

3- RESULTS

3-1. Participant Flow and Follow-up

The flow of participants through the trial is shown in **Figure 1**. Between December 2022 and February 2023, 84 patients were assessed for eligibility. Fourteen patients were excluded because they did not meet the eligibility criteria (n = 9), declined to participate (n = 4), or had a technical or device-related barrier (n = 1). The remaining 70 participants

were randomized in a 1:1 ratio to the mindfulness-based counseling group (n = 35) or the treatment-as-usual control group (n = 35).

All participants allocated to the mindfulness-based counseling group received the intervention. Thirty-three participants attended at least six sessions, whereas two attended fewer than six sessions. At the post-intervention assessment, 34 participants in the mindfulness-based counseling group and 35 participants in the control group completed the outcome assessment. One participant in the intervention group was lost to follow-up because of chemotherapy-related fatigue.

At the one-month follow-up, 33 participants in the mindfulness-based counseling group and 34 participants in the control group completed the assessment. One additional participant in the intervention group was lost to follow-up because of relocation or inability to contact the participant, and one participant in the control group was lost to follow-up because of a disconnected telephone number.

3-2. Baseline Characteristics

Baseline demographic and clinical characteristics are summarized in **Table 1**. No statistically significant differences were observed between the mindfulness-based counseling and control groups in age, marital status, breast cancer type, educational level, income level, time since diagnosis, or number of chemotherapy sessions (all $p > 0.05$).

The mean age was 47.40 ± 6.24 years in the mindfulness-based counseling group and 47.23 ± 5.45 years in the control group. An independent-samples t-test showed no statistically significant difference in age between groups ($t(68)=0.12$, $p=0.903$).

3-3. Post-intervention Outcomes

Post-intervention BC-PPCS-8 outcome scores are presented in **Table 2**. Compared with the control group, the mindfulness-based counseling group had significantly lower cognitive preoccupation scores (4.00 ± 0.00 vs. 11.31 ± 3.07, $p < 0.001$), future anxiety/fear of recurrence scores (4.00 ± 0.00 vs. 13.49 ± 2.08, $p < 0.001$), and total BC-PPCS-8 scores (8.00 ± 0.00 vs. 24.80 ± 4.58, $p < 0.001$).

Between-group comparisons were performed using the Mann–Whitney U test. At the post-intervention assessment, participants in the mindfulness-based counseling group reported lower cancer-related cognitive preoccupation, future anxiety/fear of recurrence, and overall psychological distress than participants in the control group.

Table-1: Baseline demographic and clinical characteristics of participants by study group.

Variables	Category/statistic	Mindfulness-based counseling group (n = 35)	Control group (n = 35)	P-value
Age, years	Mean ± SD	47.40 ± 6.24	47.23 ± 5.45	0.903
Marital status	Single	2 (5.7)	2 (5.7)	0.953*
	Married	30 (85.7)	31 (88.6)	
	Divorced/widowed	3 (8.6)	2 (5.7)	

Variables	Category/statistic	Mindfulness-based counseling group (n = 35)	Control group (n = 35)	P-value
Breast cancer type	Ductal	31 (88.6)	31 (88.6)	0.928*
	Lobular	1 (2.9)	1 (2.9)	
	Not specified	3 (8.6)	3 (8.6)	
Educational level	Elementary	8 (22.9)	9 (25.7)	0.799
	Middle school	3 (8.6)	2 (5.7)	
	Diploma	13 (37.1)	10 (28.6)	
	University	11 (31.4)	14 (40.0)	
Income level	Sufficient	5 (14.3)	5 (14.3)	1.000
	Relatively sufficient	24 (68.6)	24 (68.6)	
	Insufficient	6 (17.1)	6 (17.1)	
Time since diagnosis, years	3	9 (25.7)	9 (25.7)	0.716
	4	8 (22.9)	11 (31.4)	
	5	12 (34.3)	8 (22.9)	
	6	6 (17.1)	7 (20.0)	
Number of chemotherapy sessions	3	9 (25.7)	9 (25.7)	0.717
	4	8 (22.9)	11 (31.4)	
	5	12 (34.3)	8 (22.9)	
	6	6 (17.1)	7 (20.0)	

Note: Values are presented as n (%) unless otherwise stated. SD: standard deviation. Age was compared using an independent-samples t-test. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test, as appropriate. *Fisher's exact test.

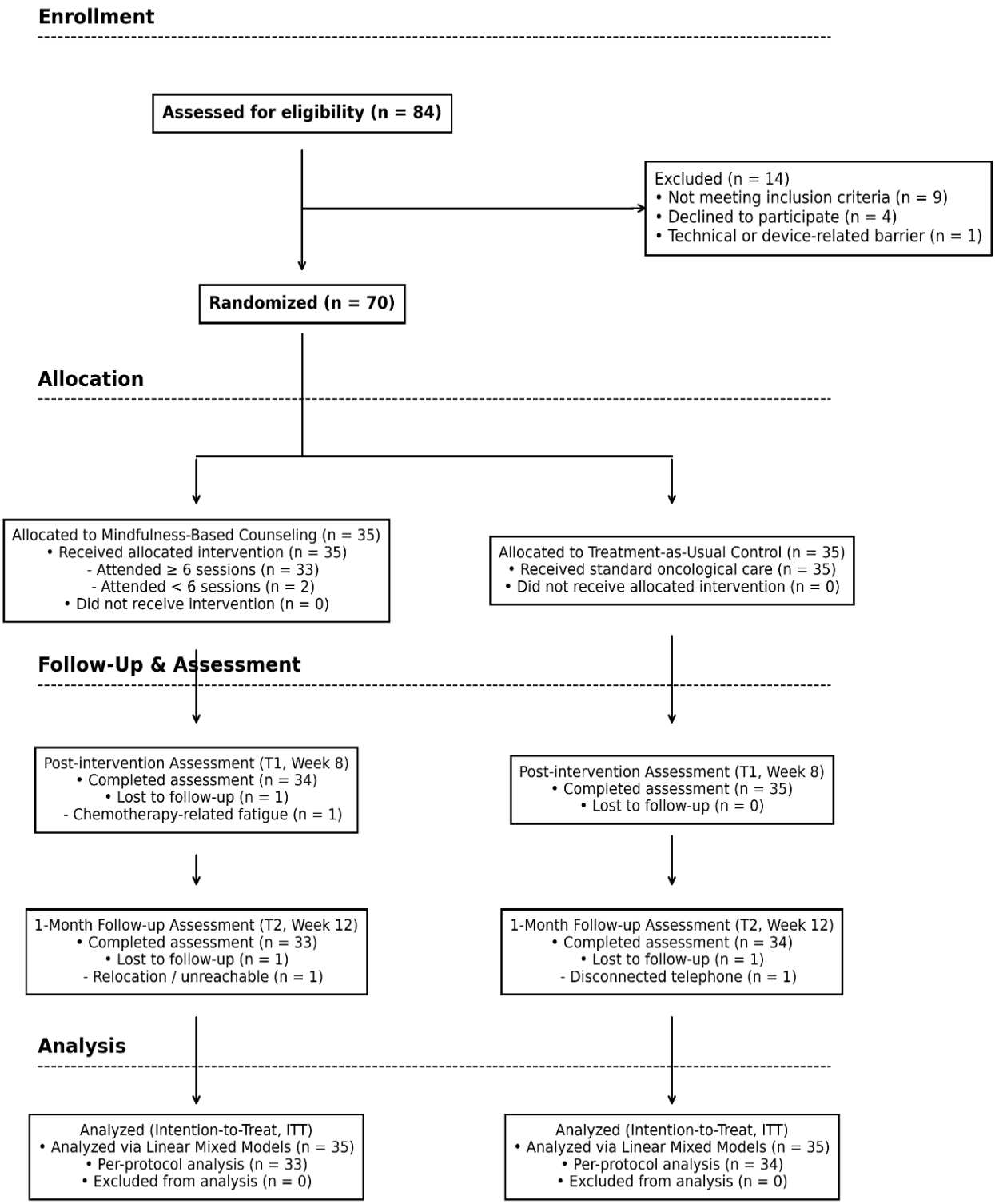

Fig.1. CONSORT flow diagram of participant recruitment, randomization, allocation, follow-up, and analysis. MBCR: Mindfulness-Based Cancer Recovery, TAU: treatment as usual, ITT: intention-to-treat, LMM: linear mixed-effects model.

Table-2: Comparison of post-intervention BC-PPCS-8 scores between the mindfulness-based counseling and control groups.

Outcome	Mindfulness-based counseling group (n = 34), mean ± SD	Control group (n = 35), mean ± SD	Statistical test	P-value
Cognitive preoccupation	4.00 ± 0.00	11.31 ± 3.07	Mann–Whitney U test	< 0.001
Future anxiety/fear of recurrence	4.00 ± 0.00	13.49 ± 2.08	Mann–Whitney U test	< 0.001
Total BC-PPCS-8 score	8.00 ± 0.00	24.80 ± 4.58	Mann–Whitney U test	< 0.001

Note: Values are presented as mean ± SD. Higher scores indicate greater cancer-related psychological distress. Between-group comparisons were performed using the Mann–Whitney U test. The mindfulness-based counseling group included 34 participants with available post-intervention outcome data, whereas the control group included 35 participants. SD: standard deviation.

4- DISCUSSION

This randomized controlled trial examined whether online mindfulness-based counseling was associated with lower cancer-related cognitive preoccupation and future anxiety/fear of recurrence among women with breast cancer receiving chemotherapy. At the post-intervention assessment, participants in the mindfulness-based counseling group reported significantly lower cognitive preoccupation, future anxiety/fear of recurrence, and total BC-PPCS-8 scores than those in the treatment-as-usual control group. Because the groups were comparable on measured demographic and clinical characteristics at baseline, these findings support the potential value of mindfulness-based counseling as an adjunctive psychosocial intervention during chemotherapy.

4-1. Relation to prior evidence

The findings are consistent with evidence that mindfulness-based interventions may improve psychological outcomes among women with breast cancer. Haller et al. reported beneficial effects of mindfulness-based interventions on psychological symptoms in women with breast cancer (15). A systematic review and meta-analysis of mindfulness-based interventions among patients with cancer and survivors similarly found small but statistically significant improvements in psychological distress, anxiety, and depression (25). In addition, trials of MBCR have reported improvements in stress symptoms, quality of life, social support, and mood outcomes among distressed breast cancer survivors (26, 27). Although populations, intervention formats, and outcome measures differ across studies, the direction of findings is consistent with the lower post-intervention distress scores observed in the present study.

The present findings are particularly relevant to future anxiety and fear of recurrence. Cancer-related fear may involve repetitive worry, intrusive illness-related thoughts, heightened attention to

bodily sensations, and uncertainty about the future. A systematic review and meta-analysis found that psychological interventions can produce small but robust improvements in fear of cancer recurrence, with effects largely maintained at follow-up in the included studies (28). Mindfulness-based counseling may be relevant to these processes because it encourages participants to observe distressing thoughts and emotions without automatically engaging in rumination, avoidance, or threat-focused interpretation. Rather than attempting to eliminate cancer-related thoughts, patients may learn to recognize them as transient internal experiences, potentially reducing cognitive preoccupation and future-oriented anxiety.

4-2. Potential mechanisms

Mindfulness-based counseling may operate through attentional regulation, nonjudgmental awareness, acceptance, and cognitive decentering. Mindfulness interventions aim to change an individual's relationship with difficult thoughts and feelings rather than directly disputing their content (12). In the context of breast cancer, this may help patients respond more flexibly to uncertainty about treatment, physical symptoms, recurrence, and future health. Similar findings have been reported in women with breast and gynecological cancers, in whom mindfulness-based cognitive therapy was associated with reduced hopelessness (29). The findings of the present study are therefore conceptually consistent with the theoretical mechanisms underlying mindfulness-based interventions, although these mechanisms were not directly measured and should not be interpreted as demonstrated by the present data.

4-3. Online delivery and feasibility

The online format is clinically relevant because women undergoing chemotherapy may encounter fatigue, nausea, pain, transportation barriers, scheduling difficulties, or concerns regarding exposure to infection. Online MBCR was developed to increase access to mindfulness-based psychosocial support during chemotherapy while maintaining group interaction and structured practice (14). Feasibility research on online MBCR has also suggested that this delivery mode is acceptable to people affected by cancer (30). In the present study, 33 of 35 participants in the intervention group attended at least six sessions, indicating that the online program was feasible within this clinical context.

4-4. Study limitations

The current findings should be interpreted in light of several limitations.

First, the reported primary analysis was based on post-intervention between-group comparisons. Therefore, the results show lower post-intervention scores in the mindfulness-based counseling group but do not independently quantify within-person change from baseline or determine whether effects were maintained at the one-month follow-up.

Second, intervention-group scores at post-intervention reached the lower end of the BC-PPCS-8 scale. These findings should be reported as observed scale scores and should not be interpreted as indicating complete resolution of cancer-related anxiety or psychological distress.

Third, participants and intervention providers could not be blinded, and the outcomes were self-reported; expectancy effects, reporting bias, and social desirability may have influenced results. Fourth, the BC-PPCS-8 was researcher-developed and requires further validation against established measures of fear of cancer recurrence and psychological distress.

Fifth, the sample size was modest and drawn via convenience sampling from breast cancer referral centers in one Iranian

city, which may limit statistical power and the generalizability of the findings to other cultural, healthcare, or treatment contexts.

Finally, we did not collect data on participants' prior mindfulness experience, concurrent use of other psychosocial services, or detailed medication histories (e.g., anxiolytics, antidepressants), any of which could have influenced responsiveness to the intervention.

4-5. Study strengths

The study also has important strengths. It used a randomized controlled design, allocation concealment, a usual-care comparator, a structured eight-week online intervention, and documented participant flow. The intervention was delivered during chemotherapy, when psychological distress and barriers to accessing in-person psychosocial services may be substantial. Furthermore, the study addressed cancer-specific cognitive preoccupation and future anxiety, which are clinically meaningful yet less commonly reported outcomes than general anxiety or depression.

4-6. Clinical implications

Online mindfulness-based counseling may be considered as an adjunct to usual oncology care for women with breast cancer who experience persistent cancer-related worry, intrusive illness-related thoughts, or future anxiety during chemotherapy. Its online delivery may improve access for patients facing travel, physical-symptom, scheduling, or geographic barriers. Clinical implementation should involve trained facilitators, appropriate assessment of psychological needs, and referral pathways for patients requiring more intensive mental-health support. Current integrative-oncology guidelines recognize mindfulness-based interventions as options for managing anxiety and depressive symptoms in adults with cancer and in women undergoing or completing breast cancer treatment (31, 32).

5- CONCLUSION

Online mindfulness-based counseling was associated with lower post-intervention scores for cognitive preoccupation, future anxiety/fear of recurrence, and overall cancer-related psychological distress than treatment as usual among women with breast cancer receiving chemotherapy. These findings suggest that online mindfulness-based counseling may be a feasible adjunct to psychosocial care during chemotherapy. Larger multicenter trials using validated cancer-specific measures, baseline-adjusted longitudinal analyses, and longer follow-up are needed to confirm the magnitude and durability of these findings.

6- CONFLICT OF INTEREST: None.

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