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Comparing the Efficacy of a Quality of Life Enrichment Package and Mindfulness-Based Cancer Recovery Intervention on Pain Self-Efficacy in Mastectomized Women Undergoing Chemotherapy

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1. Round 1

1.1. Reviewer 1

Reviewer:

The sample size of 45 participants, with only 15 individuals in each group, requires an explicit a priori power analysis. The manuscript currently does not indicate whether the study was sufficiently powered to detect the expected group-by-time interaction or differences between the two active interventions. The authors should report the statistical test used for power estimation, assumed effect size, alpha level, desired statistical power, number of repeated measurements, assumed correlation among repeated measures, and any adjustment for expected attrition. Without such information, it is difficult to determine whether statistically nonsignificant comparisons reflect true equivalence or simply inadequate statistical power.

The inclusion criterion stating that participants were required to have “a high score on the cancer-related fatigue measure used during participant screening” appears conceptually disconnected from the primary outcome of pain self-efficacy. The authors should explain why high cancer-related fatigue was required for entry into a trial primarily evaluating pain self-efficacy, identify the fatigue instrument used, provide the threshold defining a “high” score, and clarify whether this criterion was theoretically linked to the development of the Quality of Life Enrichment Package. Otherwise, this criterion may introduce unnecessary sample restriction and may limit the external validity of the findings.

The development of the Quality of Life Enrichment Package requires considerably more methodological detail. The statement that the package "was developed through a systematic review of relevant Iranian and international literature published between 2021 and 2025" is not sufficient to establish reproducibility. The authors should describe the databases searched, search terms, inclusion and exclusion criteria, screening procedure, number and type of sources retained, coding process, thematic extraction procedure, and how the identified themes were translated into intervention components. If the package development was genuinely systematic, the reporting should allow another research team to reconstruct its theoretical and empirical foundations.

The statement that "Attride-Stirling's thematic network analysis framework was used to organize and evaluate the conceptual content of the intervention" requires methodological clarification. Attride-Stirling's thematic network approach is principally a qualitative analytic framework rather than a conventional method for establishing intervention content validity. The authors should clearly distinguish between thematic analysis used to derive intervention themes and quantitative content-validity assessment performed through CVR and CVI. They should also report the exact CVR and CVI values, the criterion used for acceptable values given seven experts, how disagreements were resolved, and whether any sessions or components were revised or deleted following expert evaluation.

The two interventions differ substantially in dose, with the Quality of Life Enrichment Package consisting of 10 sessions and Mindfulness-Based Cancer Recovery consisting of eight sessions. This constitutes an important design issue because greater therapeutic contact itself may contribute to stronger outcomes. The Discussion currently interprets the superior performance of the Quality of Life Enrichment Package primarily in terms of its "broader therapeutic scope," but this interpretation may be confounded by treatment dose. The authors should report session duration, total therapist-contact hours, group size, homework burden, and facilitator contact outside sessions for both interventions and should explicitly consider unequal exposure as an alternative explanation for between-intervention differences.

Authors revised the manuscript and uploaded the document.

1.2. Reviewer 2

Reviewer:

The manuscript states that participants were "between 30 and 50 years of age" and had "received chemotherapy for a period of approximately one to three months," but it does not provide sufficient clinical characterization of the sample. The authors should report relevant oncological variables, including cancer stage, histological diagnosis where available, type and date of mastectomy, chemotherapy regimen, number of chemotherapy cycles completed, current analgesic use, hormone therapy or targeted therapy, recurrence status, presence of metastatic disease, and major comorbid conditions. These variables could materially influence pain, fatigue, functional capacity, and pain self-efficacy and therefore represent potentially important confounders.

The exclusion criterion "any condition associated with impaired consciousness, alertness, or ability to participate adequately" is too vague for reproducible clinical research. The authors should specify how cognitive and consciousness status were assessed, who performed this assessment, and whether neurological disorders, severe psychiatric disorders, substance-related conditions, or medication-related cognitive impairment were formally screened. More importantly, the manuscript should clarify whether major psychiatric disorders or concurrent psychotherapy constituted exclusion criteria, because both could independently affect responsiveness to the psychological interventions.

In the paragraph describing the control condition, the statement that participants "continued to receive routine medical and supportive care" is insufficiently defined. The authors should specify what routine care consisted of, including whether participants had access to psychological counseling, psychiatric medication, oncology social work, pain-management services, educational sessions, or support groups. Because the two experimental conditions involved considerable therapist contact and group support, an untreated or minimally treated control group introduces attention and expectancy effects. This limitation should be acknowledged, and the manuscript should clearly describe any procedures used to prevent contamination between intervention and control participants.

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The description of the Pain Self-Efficacy Questionnaire requires closer attention to construct validity in the present population. The sentence “The questionnaire is designed to assess the extent to which individuals experiencing persistent pain believe that they can continue performing daily activities and functioning effectively despite the presence of pain” accurately reflects the general construct, but the manuscript should explain whether the Persian version used in this study had previously been psychometrically validated specifically among Iranian cancer patients or women with breast cancer. Reliability evidence from chronic pain samples alone is not sufficient to establish measurement validity in oncology. The exact Persian validation source, translation procedure if applicable, factorial validity, and scoring procedure should be reported.

The manuscript reports that “In the present study, the internal consistency of the questionnaire was satisfactory, with a Cronbach's alpha coefficient of .87,” but it does not indicate at which measurement occasion this coefficient was calculated. Cronbach's alpha should ideally be reported for the baseline sample and, where informative, for posttest and follow-up assessments as well. Because there were only 45 participants, the authors should interpret alpha cautiously and consider providing confidence intervals. Moreover, internal consistency does not substitute for test-retest reliability or construct validity, and the manuscript should avoid presenting a single alpha coefficient as comprehensive evidence of measurement quality.

Authors revised the manuscript and uploaded the document.

2. Revised

Editor’s decision: Accepted.
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