

Associative Factors for Quality of Life and Psychological Distress among Women with Breast Cancer: An Evaluative Study on the Impact of Psycho-Social Interventions

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Abstract

Globally, breast cancer accounts for one in four cancer diagnoses; in India, over 100,000 new cases are reported annually. Women with breast cancer often experience high levels of psychological distress, which can diminish their Quality of Life (QoL) and adversely affect clinical outcomes. This study aimed to evaluate the effects of a nurse-led, individualised psychosocial support and nursing care programme on women with breast cancer in India, hypothesising that such an approach could enhance QoL and alleviate psychological distress. The study employed a systematic review and meta-analysis in Phase I to determine the effectiveness of psychosocial interventions, culminating in the development of a tailored PIP. In Phase II, an experimental time-series design was used to assess the effect of the PIP on QoL and psychological distress among 176 women with breast cancer. Using purposive sampling, subjects were assigned to intervention (n=88) and control groups (n=88). The intervention group received PIP, comprising three in-person psycho-education sessions, telephonic follow-ups over three months, and an informational booklet. Pre- and post-test data collection involved the Hospital Anxiety and Depression Scale (HADS), Distress Thermometer, and WHO QoL BREF. Of the 248 identified articles, six studies met the inclusion criteria for qualitative analysis, and four studies qualified for meta-analysis in Phase I. The interventions, particularly psycho-education, demonstrated positive effects on reducing psychological distress at both short-term (6 weeks) and long-term (6 months) follow-ups, with statistical significance in some cases. While the results indicated modest improvements in QoL, especially with cancer-specific QoL measures, the overall clinical impact remained inconclusive. In Phase II, data analysis revealed a significant reduction in psychological distress and improvement in QoL among the intervention group. Key findings included a statistically significant reduction in psychological distress scores in within-group analysis, which further confirmed the intervention's effectiveness (Anxiety: $F=871.63$, $p<0.001$; Depression: $F=1098.33$, $p<0.001$; Distress Thermometer: $F=1872.45$, $p<0.001$). QoL scores improved significantly, with within-group $F = 472.63$, $p<0.0001$. This study underscores the value of psychosocial interventions tailored to breast cancer patients, demonstrating that PIP effectively reduces psychological distress and enhances QoL, and advocates for developing nurse-led, individualised psychosocial support framework within oncology care in developing regions.

Key words: Quality of life, Psychological distress, Breast cancer

As per the global statistics, cancer ranks as a leading cause of death and an important barrier to increasing life expectancy in every country of the world (Bray et al, 2021). According to estimates from the World Health Organisation (WHO, 2019), cancer is the first or second leading cause of death before the age of 70 years in 112 of 183 countries and ranks third or fourth in a further

23 countries. The Indian scenario too is similar. The Indian Council of Medical Research (ICMR) report (2020) indicates that more than 100,000 cases of breast cancer are diagnosed newly each year. Further, cancer of breast is most common in women, revealing the highest disease burden in metropolitan cities. Population-based cancer registries including the new studies noticed the steady hike in the breast cancer cases in the country posing a great health challenge for the women (Grassi et al, 1996). Based on the 2012-2014 report of 27 population-based cancer registries (PBCRs), highest incidence of breast cancer was reported in

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Delhi (41.0), followed by Bengaluru (34.4), Chennai (37.9), and Thiruvananthapuram (33.7) (Sung et al, 2021). The diagnosis of breast cancer, its subsequent management by various therapies and long-term follow-up cause physical dysfunction in most of the women. Many studies have reported that most of the breast cancer patients have increased levels of psychological distress (WHO, 2016).

Need for the study: The global burden of cancer is rapidly escalating and is projected to vividly affect low- and middle-income countries (LMICs) in the coming years (Grassi et al, 1996). Detection of psychological distress in patients with breast cancer is a significant aspect of cancer care. Unrecognised and untreated psychological distress negatively affects several areas of functioning (Dastan & Buzlu, 2012).

A nurse-led psycho-social intervention programme that guides the breast cancer patients throughout the trajectory of treatment and survival life, would be a promising step in the field of oncology nursing care which will bring a quality nursing care that ensures complete satisfaction among the patients.

Objectives

Phase I

1. To identify various psychosocial interventions for psychological distress and QoL among women with breast cancer by doing a systematic review.
2. To compare the effectiveness of various psychosocial interventions to develop a psychosocial intervention package

Phase II

3. To evaluate the effect of psychosocial intervention package on the QoL and psychological distress of women with breast cancer in intervention group.
4. To determine association of QoL and psychological distress with the selected demographic variables of women with breast cancer.

Review of Literature

A study carried in 2022 investigated the relationship between psychological distress and HRQoL and related factors among women with breast cancer in Sweden. In this descriptive cross-sectional study, a total of 481 women with breast cancer answered voluntarily a questionnaire about sociodemographic and support factors, psychological distress, and HRQoL. Data were subjected to Pearson's correlation and linear regression analyses. Psychological distress was

related to HRQoL in terms of body image, future perspective, side effects of systemic therapy, breast symptoms, arm symptoms, and hair loss. Women with lower age were associated with increased symptoms of anxiety, while those having undergone breast reconstruction were associated with increased symptoms of depression. Breast reconstruction and chemotherapy worsened body image, low support from partner decreased sexual functioning and enjoyment, and low support from physicians and nurses worsened future perspective, side effects of systemic therapy, breast symptoms, and indignation about hair loss. Psychological distress was correlated with the HRQoL. Increased support from physicians, nurses, and husband/partner may increase the HRQoL among women with breast cancer. Breast cancer treatments such as breast reconstruction and chemotherapy were factors that decreased the psychological distress and increased the HRQoL.

Methodology

Phase I- Systematic Review

The search retrieved 248 articles. After the duplicates were eliminated, 233 publications were separated for initial screening. Then, the abstracts of the remaining 82 potential studies were retrieved. From these, 62 papers were excluded which left 20 publications to be included in the current review. From these, 14 publications were excluded with relevant justifications stated in the 'Excluded studies' section. Finally, six studies were considered for the qualitative analysis and in that only four studies were included for the quantitative or meta-analysis.

Design: This review included RCTs only. Therefore, all the included studies (6) reported at least a baseline assessment and one post-intervention assessment. However, the number of post-intervention assessments varied in each study. Only results of 3 studies gave the required statistical data for doing the meta-analysis.

Sample sizes: The sample size of the 6 included studies ranging between 76 and 558, with a total number of 1404 participants. The average number of subjects was 234.

Phase II

An experimental time-series design was used to assess the effect of the PIP on QoL and psychological distress among 176 women with breast cancer. In this study population refers to adult women aged between 18 and 65 years, diagnosed with breast cancer (stage 1-3) and got admitted for surgery in Father Muller Medical College Hospital, Mangalore. Ethical clearance and permission from the setting

were obtained. Using purposive sampling, subjects were assigned to intervention (n=88) and control groups (n=88).

Sampling technique: The selected subjects were randomly allotted to experimental group (88) and control group (88) by simple random sampling technique (lottery method- Opaque envelopes). By following the principles of probability and equipoise the subjects were randomised into experimental and control group with a 1:1 allocation ratio. Allocation was concealed by using sequentially numbered, opaque sealed envelopes (SNOSE). Concealment was ensured by numbering the envelopes in advance and during intervention assignment, it was opened sequentially only after writing participant details on appropriate envelope. This helped to prevent deciphering of treatment assignment.

Blinding: Due to the nature of the present study, it was not possible to blind the researcher or participants and the outcome assessors as mentioned in the study limitation. **Manipulation:** In this study manipulation means introduction of PIP (Psycho-social Intervention Package) for women with breast cancer who are undergoing surgery. PIP refers to a psycho-education support intervention, a printed informative material and telephonic calls provided to women with breast cancer to deal with psychological distress and enhance their QoL. This included three face-to-face educational supportive contact programmes of minimum 60 minutes (PIP - Part I, II and III) with a specific and unique format. In each session the first 30 minutes was common to all subjects and would contain the same instructions, and the remaining 30 minutes will be tailored to the unique problems and concerns facing each individual subjects. The intervention group subjects received telephonic follow-up (minimum one call per week) for 3 months

and an information booklet on breast cancer was given on their 2 weeks follow-up visit.

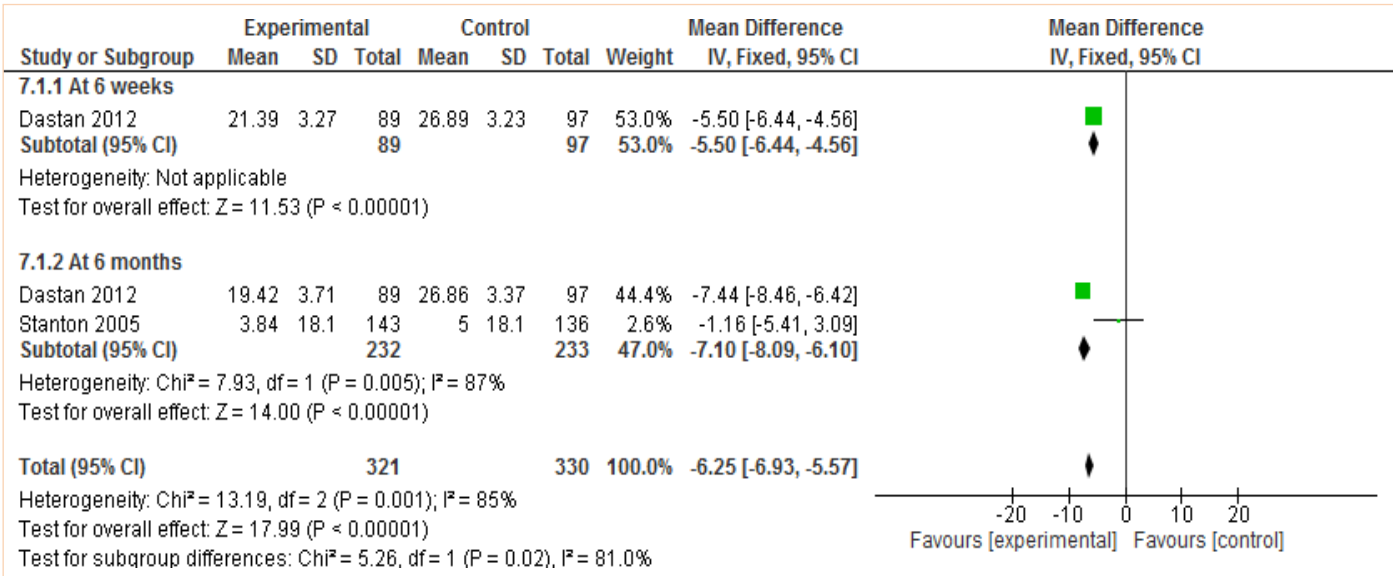
Control: Many control measures were employed to achieve the desired outcomes. Control measures included in the present study were: involvement of a control group who received a routine care from doctors, nurses and other paramedical professionals, a clearly defined sampling criteria, controlling the intervention through a well-developed intervention protocol along with strategies used to ensure consistency in implementing treatment, use of valid and reliable instruments for data collection and control of extraneous variables through randomisation, and statistical control measures like homogeneity tests. The schematic representation of research design and CONSORT Flow diagram on progress of participants through the phases of this study are shown below.

Pre-and post-test data collection involved the Hospital Anxiety and Depression Scale (HADS), Distress Thermometer, and WHO QoL BREF.

Results

Phase I

Figure 1 shows the effect of psych-education against control group with no interventions. Both the observation points (6 weeks and 6 months) the interventions proved its effectiveness (Dastan & Buzlu, 2012). Two studies contributed for 6 months observation which was found to be effective (SMD: -7.10, 95% CI:-8.09: -6.10), whereas only one study contributed for 6 weeks analysis with a strong significance (SMD: -5.50, 95% CI -6.44 -4.56). However, the percentage variability in effect estimates that was due to heterogeneity rather than sampling error (chance) was high (p <



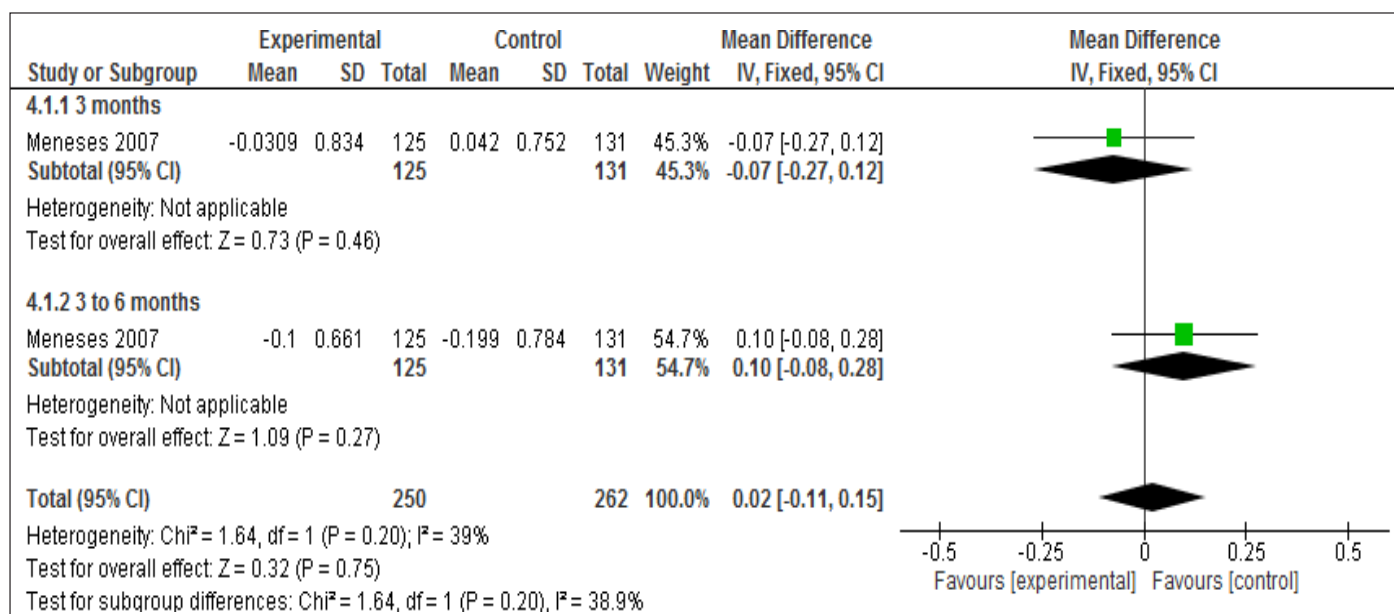


Fig 1 : Effect of intervention on Experimental and Control Groups.

0.00001, I² = 81%). The heterogeneity found was likely to reflect differences in size and character of the patient populations examined, possible differences in the contents of the intervention, the mode of delivery or the discipline of the ‘trained helper’, as well as differences in the methodological quality of the different trials.

There is only one study which was classified as primarily psycho-educational although many others were designed with an educational component (Meneses et al, 2007). Although it could not be prove significant difference may be due to a less well-known validated measure of QoL was used. The RCT involved 250 breast cancer participants in an adequately randomised design with no indication of other methodological concerns (SMD: 0.02, 95% CI -0.11 to 0.15).

Phase II: Effect of PIP on Psychological Distress among Women with Breast Cancer

The intervention group showed a significant reduction in both anxiety and depression levels over time. For anxiety, the mean score dropped from 20.20 ± 1.08 before surgery to 6.15 ± 4.25 after three months, with a large effect size (R ANOVA = 871.63, effect size = 0.91, p = 0.0001). Similarly, depression scores decreased from 20.39 ± 0.81 to 5.95 ± 4.03 (R ANOVA = 1098.33, effect size = 0.93, p = 0.0001). In contrast, the control group showed minimal changes in both parameters, confirming the psycho-social intervention’s effectiveness in reducing psychological distress among women with breast cancer.

Effect of PIP on Psychological Distress among women with Breast Cancer as measured by Distress Thermometer

The intervention (Int) group demonstrated a significant decrease in mean scores over time, from 8.45 ± 0.54 before surgery to 2.93 ± 0.71 after three months, with a high effect size (R ANOVA = 1872.45, effect size = 0.96, p = 0.001), indicating the intervention’s strong impact. Conversely, the control (Con) group showed minor changes, with mean scores remaining relatively stable, from 8.57 ± 0.58 before surgery to 7.57 ± 0.67 after three months, and a lower effect size (R ANOVA = 83.41, effect size = 0.49, p = 0.001). This suggests the psycho-social intervention significantly improved outcomes in the intervention group compared to the control.

Effect of PIP on QoL measured by WHO QOL- BREF

The intervention (Int) group showed a significant improvement in mean scores over time, rising from 63.28 ± 1.79 before surgery to 89.90 ± 9.47 after three months, with a substantial effect size (R ANOVA = 472.63, effect size = 0.85, p = 0.0001), indicating a highly significant (HS) positive effect of the intervention. In contrast, the control (Con) group demonstrated a decrease in mean scores from 61.92 ± 1.95 before surgery to 53.57 ± 0.67 after three months, with an even higher effect size (R ANOVA = 1054.711, effect size = 0.92, p = 0.0001). This suggests that while the intervention group benefited significantly, the control group experienced a decline over time, highlighting the intervention’s effectiveness.

This study found that urban residence and higher family income are significantly associated with better quality of life (QoL) among women with breast cancer, as evidenced by F values of 8.27 (p = 0.01) and 6.43 (p = 0.00), respectively. Higher education level also correlates positively with QoL,

with graduates reporting the highest mean score ($F = 4.12$, $p = 0.02$). These findings suggest that socioeconomic and environmental factors, such as urban living, income, and education, may influence QoL outcomes. Other demographic and clinical variables did not show significant associations with QoL in this sample.

Discussion

Among 176 subjects 33 (37.5%) in the intervention group and 43 (48.9%) in control group were in the age group of 51-60 and only 7 (8%) in intervention group and 5 (5.7%) in control group were in the age below 30. The average age of the sample was 49 ($\chi^2 = 49 \pm 10.31$). The findings are found to be consistent with the Indian scenario as the breast cancer population in India reports the occurrence of breast cancer a decade earlier in comparison to their western counter parts. While most of the breast cancer is reported after menopause (>60 years) in western countries, in India the picture is quite different as more than 80 percent of them are below 60 years (National Cancer Registry 2001). The average age of patients in six hospital-based cancer registries reported a range from 44.2 years in Dibrugarh, 46.8 years in Delhi, 47 years in Jaipur, to 49.6 years in Bengaluru and Chennai (Agarwal & Ramakant, 2008).

Breast cancer affects both literate and illiterate population; however, their educational status and socio-economic status may have an impact on the awareness about breast cancer that may lead to early diagnosis and the treatment options they choose. In the present study around 42 (47.7%) in the intervention group and 65 (73.9%) in the control group were educated up to high school.

Subjects who were illiterate were only 5 (5.7%). At the same time North Indian picture is quite different as the findings reveals that 34 percent of the subjects were illiterate and 29.5 percent had only primary education (Wagner et al, 2014).

Nursing Implications

Nursing services should focus on providing structured pre-operative psychological support and incorporating mental health assessments and interventions as part of routine care. Training in psycho-social interventions, such as stress management and coping techniques, should be included in nursing education programmes, equipping nurses with the skills to address the emotional needs of breast cancer patients.

Recommendation

Future research should explore several areas to deepen our understanding of psycho-social

interventions for women with breast cancer. Studies could examine the long-term effects of these interventions on quality of life and psychological resilience beyond three months, providing insights into sustained benefits.

Conclusion

This study underscores the value of psychosocial interventions tailored to breast cancer patients, demonstrating that PIP effectively reduces psychological distress and enhances QoL. The findings advocate for developing nurse-led, individualised psychosocial support frameworks within oncology care in developing regions.

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