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**A Randomized Controlled Trial to Evaluate the Impact of Nurse Navigator Programme (NNP) on Anxiety, Psychological Distress and Quality of Life of Breast Cancer Patients in a Tertiary Care Hospital, Karnataka”**

Shejila C H

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**Title:** A randomized controlled trial to evaluate the impact of Nurse Navigator Programme (NNP) on anxiety, psychological distress and quality of life of breast cancer patients in a tertiary care hospital, Karnataka

## **ABSTRACT**

Cancer of breast is the most commonly detected malignancy and a main cause of death from cancer among women around the world. The prolonged course of illness from initial diagnosis through its treatment and subsequent follow-up causes physical, psychological, social and financial burden among patients. Nurses have a major role in cancer care.

A research study titled “A randomized controlled trial to evaluate the impact of Nurse Navigator Programme (NNP) on anxiety, psychological distress and quality of life of breast cancer patients in a tertiary care hospital, Karnataka” was conducted by Ms. Shejila C H as a requirement for the award of Degree of Doctor of Philosophy at Manipal University, Manipal, Karnataka.

The objectives of the study were to: (i) assess the anxiety, psychological distress and quality of life of breast cancer patients undergoing surgery followed by adjuvant chemo/radiation therapy or both, (ii) evaluate the effectiveness of a nurse navigator programme on anxiety, psychological distress and quality of life of breast cancer patients undergoing surgery followed by adjuvant chemo/radiation therapy or both.

The conceptual framework used was based on synergy model developed by Curley (1998) and navigation process framework developed by Doll *et al.* (2007). The review of literature was conducted as four traditional reviews and two systematic reviews. The result of the review showed that there were no nurse navigator programmes conducted in India for the care of cancer patients.

An evaluative approach was considered for the study, since the aim of the study was to test the effectiveness of Nurse Navigator programme. A randomized controlled trial design was used with stratified randomization based on age and stage of cancer. Participants were randomly allocated to the intervention (n=60) and control group (n=60). The intervention group after pretest received Nurse Navigator Programme which consisted of an informal interview with patient, preoperative teaching, progressive muscle relaxation technique, and information booklets on care after surgery, chemotherapy and radiotherapy, telephonic follow up and nurse navigator visit. Whereas control group received routine care from all health professionals. The intervention programme was developed by the researcher after discussion with experts and validity of the programme was established. Post test assessments were done at discharge, at the beginning of adjuvant therapy, middle of adjuvant therapy and at the end of adjuvant therapy in both the intervention as well as the control group.

Data were collected using various instruments like: Baseline Proforma, Spielberger State Trait Anxiety Inventory, Impact of Event Scale, Functional Assessment of Cancer Therapy-Breast and Hook Patient Satisfaction Tool. The validity and reliability of the tools were established before administration.

The data was coded, tabulated and analyzed using SPSS package version 16. Inferential as well as descriptive statistics were used for analysis.

The results of the study showed that the mean age of the experimental group was  $50.42 \pm 09.47$  years and that of control group was  $50.33 \pm 10.22$  years. Majority of the samples in the experimental group (96.67%) and control group (98.33%) were married, maximum participants in experimental group (51.70%) had education upto secondary level (8-10), whereas many of them (53.30%) in the control group had education only upto primary level

(1-7). Majority of women in experimental and control group were housewives (85% and 83.33% respectively), with a monthly income between Rs 5000-10,000.

The present study showed that half of the samples in experimental and control group were in stage 3 of cancer (50% each). Eighty percentage of experimental group women and 88.30% of control group women had undergone modified radical mastectomy. Eighty five percentage of people from experimental group and 83.34% people from control group received both chemo & radiation therapy. It is also noticeable that 26.67% of experimental group and 21.67% of control group were suffering from various co-morbidities like diabetes, hypertension, thyroid or renal disorders.

The results of the effect of the intervention on outcome variables revealed that there was a positive statistically significant change in anxiety, psychological distress and quality of life in experimental group. The significant findings were- reduction in anxiety scores in between group analysis  $F(1,118) = 19.49, p = .000$  and within the group analysis  $F(3.42, 402.92) = 131.63, p = .002$ , reduction in psychological distress scores- between groups  $F(1,118) = 4.36, p = .039$  and within group  $F(3.65, 430.78) = 5.08, p = .001$ , improvement in quality of life scores- between the groups  $F(1,107) = 10.29, p = .002$  and within group  $F(3.39, 362.26) = 22.28, p = .000$ .

The study found that there is no association between anxiety, psychological distress and quality of life with selected demographic and clinical variables. The study also revealed that there is a weak positive correlation between anxiety and psychological distress ( $r = .34, p = .009$ ), and a weak negative correlation exists between psychological distress and quality of life ( $r = -.49, p = .000$ ). The responses for overall satisfaction of the programme showed that 93.33% of women expressed that Navigation services are necessary, 88.33% reported

navigation service improved their cancer experience and 95.00% strongly agreed that they would recommend navigation services for other patients.

Hence it was concluded that Nurse Navigator Programme was effective in reducing anxiety and psychological distress and improving quality of life in breast cancer patients.

**Key words:** Anxiety, Adjuvant therapy, Breast cancer, Nurse navigator programme, Nursing intervention, Psychological distress, Quality of life, Supportive care.

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