STM JOURNALS

International Journal of
Oncological Nursing and Practices

Volume 2, Issue 1, 2024
January—June
DOI (Journal): 10.37591/IJONNP

https://journals.stmjournals.com/ijonnp

Research IJONNP

Examining the Impact of a Nurse Navigator Program on Anxiety, Psychological Well-being, and Quality of Life in Breast Cancer Patients at a Tertiary Care Hospital in Haryana: A Randomized Controlled Trial

Kavita Choudhary[1,*], Nityasha Dalal[2]

Abstract

Background of study: *Breast cancer stands as the leading cancer type affecting women and remains a significant contributor to female mortality. It is a complex ailment influenced by multiple factors. Globally, in 2020, approximately 2.3 million women received diagnoses of breast cancer, resulting in 685,000 fatalities. This condition can profoundly impact various aspects of a person's existence, encompassing physical, psychological, emotional, social, and familial spheres. A notable observation is the heightened psychological distress experienced by a majority of women afflicted with breast cancer.* ***Objectives:*** *(i) The primary objective was to gauge the levels of anxiety, psychological distress, and quality of life among breast cancer patients who have undergone surgery and subsequent adjuvant chemotherapy. (ii) Additionally, the aim was to assess the impact of a nurse navigator program on anxiety, psychological distress, and quality of life experienced by breast cancer patients.* ***Methodology:*** *The research employed a randomized controlled trial methodology, wherein individuals were assigned randomly to either the intervention or control group, each consisting of 60 participants. Various assessment instruments were utilized for data gathering, such as a baseline proforma, Depression, Anxiety and Stress Scale–21 (DASS 21), and the Functional Assessment of Cancer Therapy–Breast (FACT-B) instrument.* ***Results:*** *The results revealed that the average age of participants in the intervention group was 46.222 ± 8.47 years, whereas in the control group, it averaged at 45.22 ± 9.22 years. Analysis of the intervention's impact on outcome variables demonstrated statistically significant reductions in mean anxiety scores, as evidenced by repeated analysis of variance (F (df 1,118) = 12984.191, p = .000) and within-group analysis (F (df 4, 1.314) = 408,964, p = .000), as well as decreases in depression scores (between groups F (df 1, 118) = 8920.942, p = .000; within-group F (df 4, 1.644) = 109.247, p = .000), and stress scores (between groups F (df 1, 118) = 1158.535, p = .000; within-group F (df 4, 1.214) = 36.244, p = .000). Moreover, there was a significant improvement in quality-of-life scores, particularly in the Physical Well-Being domain, compared to the control group (between the groups F (df 1, 118) = 6847, p = .000; within-group F (df 4, 2,037) = 1321, p = .000). Consequently, it was concluded that the Nurse Navigator Program effectively reduced anxiety and psychological distress while enhancing the quality of life among breast cancer patients.* ***Conclusion:*** *The analysis findings show that the Nurse Navigator Program was effective in relieving anxiety, psychological distress and improving quality of life among breast cancer patients undergoing surgery followed by chemotherapy.*

Keywords: Anxiety, adjuvant therapy, breast cancer, Nurse Navigator Program, nursing intervention, psychological distress, quality of life

***Author for Correspondence**
Kavita Choudhary
E-mail: kavitachoudhary2003@gmail.com

[1]Lecturer (Jr.), College of Nursing, Pt. B.D. Sharma University of Health Sciences, Rohtak, Haryana, India
[2]Professor, Department of General Surgery, Pt. B.D. Sharma University of Health Sciences, Rohtak, Haryana, India

Received Date: March 25, 2024
Accepted Date: May 01, 2024
Published Date: May 11, 2024

Citation: Kavita Choudhary, Nityasha Dalal. Examining the Impact of a Nurse Navigator Program on Anxiety, Psychological Well-being, and Quality of Life in Breast Cancer Patients at a Tertiary Care Hospital in Haryana: A Randomized Controlled Trial. International Journal of Oncological Nursing and Practices. 2024; 2(1): 31–39p.

INTRODUCTION

Cancer ranks among the leading causes of illness and death globally, affecting a significant portion of the population. According to GLOBOCAN, about one in six women and one in five men received a cancer diagnosis in 2018, with projections indicating that cancer-related deaths may reach 13 million by 2030. In India, breast cancer holds the top position as the most common cancer among women, with an age-adjusted incidence rate of 25.8 per 100,000 women and a mortality rate of 12.7 per 100,000 women. Recent statistics from the National Cancer Registry Programme (NCRP) indicate a notable rise in cancer occurrences, projected to increase from 13.9 lakh in 2020 to 15.7 lakh by 2025, especially prevalent among women aged 50 to 64 years. With a concerning statistic of one woman diagnosed with breast cancer every 4 minutes and one succumbing to it every 13 minutes in India, breast cancer poses a significant health challenge for Indian women. The diagnosis and treatment of breast cancer often lead to various psychological struggles, including anxiety, depression, anger, uncertainty about the future, and fear of recurrence, among others. Oncology navigation has shown to be beneficial for individuals who are at risk or have been diagnosed with cancer, offering advantages such as reduced delays in diagnosis and treatment, enhanced knowledge among patients and their caregivers, improved compliance with treatment protocols, and better overall quality of life [1–5].

OBJECTIVES OF THE STUDY

The objectives of the study were the following:

1. To assess anxiety, depression, stress levels, and quality of life in breast cancer patients undergoing surgery followed by chemotherapy.
2. To assess the impact of a nurse navigator program on anxiety, psychological distress, and quality of life among breast cancer patients undergoing surgery followed by chemotherapy.

Hypotheses

All the hypotheses are tested at 0.05 level of significance:

1. *H_1:* There will be a significant difference in mean pretest and post test scores of anxiety, depression, and stress among breast cancer patients who received care from a nurse navigator with that of routine care group.
2. *H_2:* There will be a significant difference in mean pretest and post-test scores of quality of life among breast cancer patients who received care from a nurse navigator with that of routine care group.

MATERIAL AND METHODS

Research Design

Randomized controlled trial.

Research Approach

Quantitative research approach (evaluative research approaches).

Sample Size

The sample size was 120 women, with 60 in each group, namely experimental and control.

Research Setting

The settings chosen for the study were general surgery wards (4, 5, 6, and 8) of Pt. B.D. Sharma Post Graduate Institute of Medical Sciences (PGIMS).

Sample

Women diagnosed with breast cancer undergoing surgery followed by adjuvant chemotherapy admitted in general surgery ward and radiotherapy ward for chemotherapy Pt. B.D. Sharma PGIMS.

Sampling Technique

The sampling is done by a random assignment of subjects into experimental and control group with 1:1 allocation ratio. Allocation concealment was maintained by employing sequentially numbered,

opaque, sealed envelopes (SNOSE). Concealment was ensured by numbering the envelopes in advanced and during intervention assignment, it was opened sequentially only after writing participant details on the envelope [6, 7].

Data Collection Instruments

The following tools were used to collect data:

- *Tool 1:* Baseline Performa and clinical profile
- *Tool 2:* Depression, Anxiety, and Stress Scale – 21 (DASS-21) was used to assess anxiety, depression and stress
- *Tool 3:* Functional Assessment of Cancer Therapy – Breast (FACT-B) was used to measure the quality of life.

RESULT

Section 1: Description of Sample Characteristics Between the Experimental and Control Group

This section deals with characteristics of breast cancer patients undergoing surgery (N = 120) in both experimental (n = 60) and control groups (n = 60) in terms of demographic and clinical variables.

Table 1. Frequency and percentage distribution of demographic variables between groups (N= 120).

Demographic variables	**Experimental group (n = 60)**		**Control group (n = 60)**	
Mean age (years)	46.22 ± 8.47		45.22 ± 9.22	
Age group years	*Frequency (f)*	*Percentage (%)*	*Frequency (f)*	*Percentage (%)*
25–35	7	12%	7	12%
36–45	14	23%	12	20%
46–55	22	37%	19	32%
56–65	11	18%	14	23%
>66	6	10%	8	13%
Education				
Illiterate	30	50%	32	54%
Primary	13	22%	10	17%
Middle	5	8%	8	13%
Secondary	4	7%	5	8%
Graduate and above	8	13%	5	8%
Occupation				
Government job	3	5%	3	5%
Non-government job	1	2%	3	5%
Self-business	7	12%	6	10%
Housewife	49	81%	48	80%
Monthly income (in Rs.)				
10000–20000	22	37%	23	38%
20001–30000	22	37%	26	43%
30001–40000	9	15%	7	12%
≥40001	7	12%	4	7%
Marital status				
Single	0	0%	0	0%
Married	49	82%	50	83%
Divorced	2	3%	0	0%
Widowed	9	15%	10	17%

Session 1.1: Description of Demographic Variables Between Groups

Data presented in Table 1 reveals that the mean age of breast cancer patients in the experimental group was 46.22 and of those in the control group was 45.22. Most of the women in experimental and control groups, 22 (37%) and 19 (32%), respectively, were in the age group of 46–55 years. Most of the breast cancer women in the experimental group, 30 (50%), and in the control group, 32 (54%) were illiterate.

In both the experimental and control groups, a significant portion of the participants were homemakers, accounting for 49 (81%) and 48 (80%), respectively. Majority of women 22 (37%) in the experimental and 26 (43%) in control group had monthly income between Rs. 20001 and 30000.

Section 1.2: Description of Clinical Variables Between Groups

Table 2 depicts that majority of 53 (88%) sample in the experimental group and 56 (93%) sample in the control group had invasive ductal carcinoma. Majority 44 (74%) of women in the experimental group and and the control group 41 (68%) had carcinoma in upper outer quadrant.

Table 2 depicts that majority 28 (47%) in the experimental group and 24 (40%) in the control group had menarche at the age of 12 to 13 years. A total of 28 (47%) and 24 (40%) had premenopausal stage in the experimental and control groups, respectively. Overall, 32 (53%) and 36 (60%) had postmenopausal stage in the experimental and control groups, respectively. Majority, 31 (52%), of women in the experimental group and the control group 28 (47%) had lump without pain.

Section 2: Description of DASS-21 Score Among Experimental Group and Control Group Across Over Group

Table 3 depicts the mean and standard deviation (SD) of DASS-21 scores among experimental group and control groups across over group.

Section 3: Description of Quality-of-Life Scores Between Experimental and Control Groups

Table 4 depicts the mean and SD of FACT-B scale among experimental group and control groups.

Section 4: Effectiveness of Nurse Navigator Program on Anxiety

Tables 5 and 6 depict the measures of analysis of variance (ANOVA) on anxiety scores between experimental and control groups and paired *t* test on anxiety scores at two different time points in the experimental group, respectively.

Section 5: Effectiveness of Nurse Navigator Program on Depression

Tables 7 and 8 depict the measures of ANOVA on depression scores between experimental and control group and paired *t* test on depression scores at two different time points in experimental group, respectively.

Section 6: Effectiveness of Nurse Navigator Program on Stress

Tables 9 and 10 depict the repeated measures of ANOVA on stress scores between experimental and control group and paired *t* test on stress scores at two different time points in experimental group, respectively.

Section 7: Effectiveness of Nurse Navigator Program on Quality of Life

Tables 11 and 12 depict the repeated measures of ANOVA on quality-of-life scores between experimental and control group and paired *t* test on quality-of-life scores at two different time points in experimental group, respectively.

Table 13 depicts the paired *t* test on quality-of-life scores at two different time points in experimental group (overall).

Table 2. Frequency and percentage distribution of clinical variables.

Clinical variables	Experimental group (*n* = 60)		Control group (*n* = 60)	
	f	%	*f*	%
Type of breast cancer				
Inflammatory breast cancer	00	00%	01	02%
Ductal carcinoma in situ	00	00%	00	00%
Invasive ductal carcinoma	53	88%	56	93%
Invasive lobular carcinoma	01	02%	00	00%
Others	06	10%	03	05%
Breast quadrant involved				
Upper outer quadrant	44	74%	41	68%
Upper inner quadrant	04	07%	05	08%
Lower outer quadrant	03	05%	04	07%
Lower inner quadrant	05	08%	06	10%
Retroareolar region	02	03%	03	05%
Infraareolar region	02	03%	01	02%
Age of menarche				
10–11 years	20	33%	18	30%
12–13 years	28	47%	24	40%
14–15 years	12	20%	18	30%
Menstrual status				
Premenopausal	28	47%	24	40%
Postmenopausal	32	53%	36	60%
Presenting complains				
Lump with pain	10	17%	13	22%
Lump without pain	31	52%	28	47%
Skin ulceration	06	10%	07	12%
Nipple retraction	02	03%	01	02%
Nipple discharge	05	08%	06	10%
Axillary swelling	06	10%	05	08%
Estrogen receptor status				
Positive	33	55%	34	57%
Negative	27	45%	26	43%
Progesterone receptor status				
Positive	29	48%	31	52%
Negative	31	52%	29	48%
HER2 receptor status				
Positive	07	12%	06	10%
Negative	53	88%	54	90%
Comorbidities				
Yes	21	35%	17	28%
No	39	65%	43	72%
Type of co morbidities				
Diabetes mellitus (DM)	03	05%	02	03%
Hypertension (HTN)	05	08%	04	07%
Both DM and HTN	04	07%	01	02%
Thyroid disorders	06	10%	05	08%
Other disorders	03	05%	05	08%
No	39	65%	43	72%

Table 3. Mean and SD of DASS -21 scale among experimental group and control group across over group.

Outcome variable	Group	At the time of admission (Mean ± SD)	At the time of discharge (Mean ± SD)	At the time of first chemotherapy (Mean ± SD)	At the time of middle of chemotherapy (Mean ± SD)	At the time of last chemotherapy (Mean ± SD)
Depression	Experimental	18.70 ± 3.376	12.20 ± 2.291	13.70 ± 1.566	13.00 ± 1.626	10.80 ± 1.848
	Control	20.60 ± 7.814	14.20 ± 1.675	17.00 ± 2.067	15.80 ± 1.412	14.60 ± 1.575
Anxiety	Experimental	19.70 ± 2.854	7.90 ± 0.709	15.60 ± 1.210	12.20 ± 1.080	8.00 ± 0.000
	Control	22.90 ± 6.876	14.20 ± 1.675	15.80 ± .605	14.40 ± 1.758	12.40 ± 0.807
Stress	Experimental	29.80 ± 5.807	15.90 ± 3.506	26.80 ± 2.420	19.10 ± 2.230	14.00 ± 2.209
	Control	31.40 ± 6.813	23.60 ± 2.519	27.40 ± 1.291	23.80 ± 2.916	22.20 ± 2.773

Table 4. Mean and SD of FACT-B scale among experimental group and control groups.

Outcome variable quality of life (QoL)	Group	At the time of admission (Mean ± SD)	At the time of discharge (Mean ± SD)	At the time of first chemotherapy (Mean ± SD)	At the time of middle of chemotherapy (Mean ± SD)	At the time of last chemotherapy (Mean ± SD)
Physical well-being	Experimental	14.50 ± 0.676	22.10 ± 1.311	15.60 ± 0.807	17.10 ± 1.311	23.20 ± 1.848
	Control	13.80 ± 0.755	16.20 ± 0.988	13.80 ± 0.403	14.20 ± 0.605	17.40 ± 0.669
Social/family well-being	Experimental	16.20 ± 2.246	21.30 ± 1.109	16.60 ± 0.494	17.40 ± 0.807	23.50 ± 1.214
	Control	16.10 ± 1.773	17.70 ± 0.908	16.20 ± 1.549	16.20 ± 1.482	18.50 ± 1.033
Emotional well-being	Experimental	10.80 ± 1.955	19.80 ± 0.879	16.50 ± 0.813	17.70 ± 1.357	20.40 ± 0.924
	Control	11.20 ± 1.735	15.10 ± 1.458	11.60 ± 1.509	12.50 ± 1.578	16.90 ± 0.706
Functional well-being	Experimental	12.70 ± 0.788	20.00 ± 0.638	16.50 ± 0.676	17.00 ± 0.902	22.10 ± 3.266
	Control	12.80 ± 0.879	16.30 ± 1.357	13.20 ± 1.176	14.30 ± 1.197	17.30 ± 0.646
Additional concern	Experimental	19.70 ± 0.908	30.70 ± 1.357	21.80 ± 0.605	23.80 ± 0.988	29.20 ± 2.057
	Control	19.70 ± 0.908	24.00 ± 1.687	19.40 ± 0.807	20.00 ± 0.451	23.70 ± 1.013

Table 5. Repeated measures of ANOVA on anxiety scores between experimental and control groups.

Anxiety score	Mean square	*F* value	*df*	*p* value
Between group *N* = 120	122865.660	12984.191	1, 118	.000
Within group *n* = 60	2379.960	408.964	4, 1.314	.000

Table 6. Paired *t* test on anxiety scores at two different time points in experimental group.

Anxiety score	Mean	SD	Mean difference	95% CI		*t* value	*df*	*p* value
				LL	*UL*			
Baseline–1 month (post-test 2)	19.70 15.60	2.854 1.210	4.100	3.225	4.975	9.373	59	0.00
Baseline–last follow-up (post-test 4)	19.70 8.00	2.854 .000	11.700	10.963	12.437	31.754	59	0.00

Table 7. Repeated measures of ANOVA on depression scores between experimental and control groups.

Depression score	Mean square	*F* value	*df*	*p* value
Between group *N* = 120	136082.160	8920.942	1, 118	.000
Within group *n* = 60	918.510	109.247	4, 1.644	.000

Table 8. Paired *t* test on depression scores at two different time points in experimental group.

Depression score	Mean	SD	Mean difference	95% CI		*t* value	*df*	*p* value
				LL	*UL*			
Baseline–1 month (post-test 2)	18.70 13.70	3.376 1.566	5.000	4.321	5.679	14.728	59	0.00
Baseline–last follow-up (post-test 4)	18.70 10.80	3.376 1.848	7.900	7.073	8.727	19.103	59	0.00

Table 9. Repeated Measures of ANOVA on stress scores between experimental and control groups.

Stress score	Mean square	*F* value	*df*	*p* value
Between group *N* = 120	6514.680	418.153	1, 118	.000
Within group *n* = 60	13289.400	283.088	4, 2.468	.000

Table 10. Paired *t* test on stress scores at two different time points in experimental group.

Stress score	Mean	SD	Mean difference	95% CI		*t* value	*df*	*p* value
				LL	*UL*			
Baseline–1 month (post-test 2)	29.80 26.80	5.807 2.420	3	1.521	4.478	4.061	59	0.00
Baseline–last follow-up (post-test 4)	29.80 14.00	5.807 2.209	15.8	14.412	17.187	22.789	59	0.00

Table 11. Repeated measures of ANOVA on quality-of-life (QoL) scores between experimental and control groups.

QoL score	Mean square	*F* value	*df*	*p* value
Between group *N* = 120	169142.460	68474.030	1, 118	.000
Within group *n* = 60	915.810	1321.418	4, 2.037	.000

Table 12. Paired t test on quality-of-life (QOL) scores at two different time points in experimental group.

Quality of life scores	Mean	SD	Mean difference	95% CI		*t* value	*df*	*p* value
				LL	*UL*			
Baseline–1 month (Post-test 2)	14.50 15.60	0.676 0.807	-1.100	-1.240	-.960	-15.690	59	.000
Baseline–last follow-up (Post-test 4)	14.50 23.20	0.676 1.848	-8.700	-9.208	-8.192	-34.236	59	.000

Table 13. Paired *t* test on quality-of-life (QoL) scores at two different time points in experimental group (overall).

Quality of life scores (overall)	Mean	SD	Mean difference	95% CI		*t* value	*df*	*p* value
				LL	*UL*			
Baseline–1 month (post-test 2)	73.90 87.00	5.420 1.747	-13.100	-14.441	-11.759	-19.550	59	.000
Baseline–last follow-up (post-test 4)	73.90 118.40	5.420 7.275	-44.5	-46.845	-42.155	-37.967	59	.000

DISCUSSION AND CONCLUSION

The results show that the mean anxiety score among experimental group was 19.70 ± 2.854, depression score 18.70 ± 3.376, stress score 29.80 ± 5.807 and in the control group anxiety score was 22.90 ± 6.876, depression score 20.60 ± 7.814 and stress score 31.40 ± 6.813 at the time of admission. DASS-21 score was less in experimental group as compared to control group at the time of last

chemotherapy. The various domain areas of quality of life are physical well-being, social well-being, emotional well-being, functional well-being, and breast subscale domain. The higher the score, better is the quality of life. The mean score was higher in the domain of breast subscale (29.20 ± 2.057) in both experimental group and (23.70 ± 1.013) in control group. Similarly for physical well-being subscale experimental group and control group scored a mean of 23.20 ± 1.848 and 17.40±0.669, respectively. Social wellbeing was the next domain where both groups showed a higher score, 23.50 ± 1.214 for experimental group and 18.50±1.033 for control group. The tables clearly indicates that both groups exhibited relatively low scores in emotional well-being, with the experimental group averaging 20.40 ± 0.924 and the control group averaging 16.90 ± 0.706, as well as in functional well-being, with the experimental group averaging 22.10 ± 3.266) and the control group averaging 17.30 ± 0.646.

The significant findings show the repeated measures ANOVA calculated for anxiety scores in between group showing a statistical significance at $df(1, 118)$ $F = 12984.191$, $p = .000$ and within the group analysis $df(4, 1.314)$ $F = 408{,}964$, $p = .000$, and the paired t test comparison with baseline–1 month (post-test 2) ($t(df\ 59) = 9.373$, $p < .05$with mean difference of 4.1. The last follow-up baseline–1month (post-test 4) ($t(df\ 59) = 12.437$, $p < .05$ with mean difference of 11.7. Noticeable differences in average anxiety scores were observed both among the groups and within each individual group. Hence the null hypothesis H0 was rejected, and it is interpreted that the Nurse Navigator Program was an effective intervention to reduce anxiety among breast cancer patients.

The repeated measures ANOVA was computed for depression score and the result reveled that reduction in depression scores between groups F (df 1, 118) = 8920.942, $p = .000$ and within-group F (4, 1.644) = 109.247 $p = .000$, and the paired t test comparison with baseline–1 month (post-test 2) ($t(df$ 59) = 14.728, $p < .05$with mean difference of 5. During the last follow-up baseline–1 month (post-test 4) ($t(df$ 59) = 19.103, $p < .05$ with mean difference of 7.9. Consequently, the null hypothesis H0 was disproved, affirming the research hypothesis. This indicates that the Nurse Navigator Program proved effective in alleviating depression [8–10].

A one-way repeated measures ANOVA was calculated for stress score and finding shows a significant difference between groups F (df 1, 118) = 1158.535, $p = .000$ and within-group F (df 4, 1.214) = 36.244, $p = .000$, and the paired t test comparison with baseline–1month (post-test 2) ($t(df$ 59) = 4.061, $p < .05$ with mean difference of 3. During the last follow-up baseline–1 month (post-test 4) ($t(df$ 59) = 22.78, $p < .05$with mean difference of 15.8. This outcome indicates that the Nurse Navigator Program successfully reduced the stress levels in the experimental group.

The effectiveness of the program on quality-of-life scores repeated measures ANOVA was computed and result revealed significant difference between the groups F (df 1, 118) = 6847, $p = .000$ and within-group F (df 4, 2.037) = 1321, $p = .000$. and the paired t test comparison with baseline–1month (post-test 2) ($t(df59) = -15.69$, $p < .05$ with mean difference of -1.100. during the last follow-up baseline–1 month (post-test 4) ($t(df$ 59) = -34.236, $p < .05$ with mean difference of -8.700. Therefore, the null hypothesis was dismissed, and the research hypotheses were validated. As a result, it was deduced that the Nurse Navigator Program effectively diminished anxiety and psychological distress while enhancing the quality of life among breast cancer patients.

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