

Original Research Article

Effect of a nurse-led pre-chemotherapy education programme on quality of life and psychological distress of patients with breast cancer; a pilot based randomized controlled trial

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ABSTRACT

Background: Breast cancer has seized the whole world and affecting almost one in four women, globally. Many patients receive chemotherapy as treatment regimen. Oncology nurses are responsible to meet the educational needs of newly diagnosed patients and alleviate their anxiety. Objectives of the study were to assess the effects of Nurse-led pre-chemotherapy education programme on quality of life and psychological distress among breast cancer patients receiving chemotherapy.

Methods: A randomized controlled trial was conducted on newly diagnosed breast cancer patients receiving chemotherapy for the first time at AIIMS, Rishikesh India. Data was obtained from thirty patients (16 in experimental and 14 in control group) by using standardized scale i.e., European organization for research and treatment of cancer quality of life questionnaire C-30 (EORTC QLQ C-30)-version-3 and hospital anxiety and distress scale (HADS) to assess quality of life and psychological distress among patients at baseline (before first cycle of chemotherapy) and at chemotherapy cycle 4.

Results: The mean scores of qualities of life significantly enhanced in experimental group as compared to control group, in terms of global health status ($p=0.00$), functional scores ($p=0.00$) and symptom scores. Similarly, the mean HADS score was significantly less in experimental group as compared to control group ($p=0.05$).

Conclusions: It is concluded that the nurse-led pre-chemotherapy education programme is effective to improve quality of life and reduce psychological distress among patients receiving chemotherapy.

Keywords: Breast cancer, Nurse-led, Pre-chemotherapy education, Psychological distress, Quality of life

INTRODUCTION

Breast cancer, succeeding lung cancer, occupying second rank among the most common malignancies around the globe. The age standardized rate (ASR) of the breast cancer is highest in the Australia and New Zealand (94.2 cases per 100,000 population) and lowest ASR is seen in

the South-Central Asia 26 cases per 100,000).¹ The lifetime risk of developing breast cancer is three times higher in developed countries than low-income countries. In India, the breast cancer accounts for 14% of cancers in women. The highest numbers of breast cancer are recorded in state of Kerala, Mizoram, Haryana, Delhi and Karnataka.²

Quality of life is a comprehensive term used to assess life in multiple spheres of life, including physical functioning, psychosocial status, and role functioning. Over the past 30 years, nurse scientists have viewed and kept quality of life as an important indicator for evaluating health care outcomes, because state of well-being matter for quality of life, not quantity of life lived in years.³

Most of the breast cancer patients receive chemotherapy as treatment protocol. Patients receiving chemotherapy experience multiple symptoms that can be very distressing to them. This is why cancer patients' symptoms are taken as 'symptom burden'.⁴ Patients get afraid because of some unauthentic information or advice from lay persons. It causes more stress and anxiety about treatment. Furthermore, educated people explore knowledge on internet, as they are not well aware about authentic official sites of cancer and jeopardised themselves.

Lack of awareness about disease and its treatment especially chemotherapy create worry and fear of altered physiological functions and disturbed body image. Moreover, it is difficult for the health care professionals in OPD to pay enough consideration to the patients' concerns and queries because of high patient burden. Currently, the Indian medical system is lacking standard practice of nurse-led pre-chemotherapy education programme. Its' existence is functioning at infancy level. Pre-chemotherapy education actually prepare breast cancer patients for the long journey where they have to fight with many side effects and learn early identification and tackle them at home with altered dietary practices.⁵

The current study is an attempt to address the issues regarding preparedness of patients with breast cancer before chemotherapy by educating them to self-manage at home and reducing psychological distress. Further, the findings of this study can also support the need to develop structured nurse led cancer clinics in all settings to enhance quality of life among patients with breast cancer.

Hypothesize that nurse-led pre-chemotherapy education programme can improve quality of life and reduce psychological distress among breast cancer patients receiving chemotherapy at 0.05 level of significance.

METHODS

The study was conducted in the Medical oncology wards and Day care centre of all India institute of medical sciences, Rishikesh, Uttarakhand from August 2019 to December 2019. It is a tertiary care autonomous institute with a capacity of 1060 beds provides comprehensive, high-quality care to patients with advanced technologies.

Trial design

The study was a prospective, randomized controlled, parallel group design and single centric study conducted

with 1:1 per allocation regimen. The study was registered with clinical trial registry of India, with registration number: REF/2019/05/025755.

Ethical considerations

The study was approved by institutional ethical committee. Written informed consent was obtained from all the participants. The confidentiality of information was ensured to the participants.

Participants

Eligibility criteria for participants: Female patients, newly diagnosed with breast cancer and receiving chemotherapy for the first time, having normal hematopoietic, hepatic, renal, cardiac and lung functions at the time of patient enrolment, with 0-2 performance status (ECOG), patients who can read and understand Hindi or English and between 18 years and 70 years of age. The participants with clinically diagnosed mental illness, and had already received chemotherapy or receiving concurrent chemo-radiotherapy were excluded from the trial.

Instruments

European organization of research treatment of cancer quality of life questionnaire (EORTC QLQ-C30): The primary outcome of the study was quality of life among patients with breast cancer receiving chemotherapy. European organization of research treatment of cancer quality of life questionnaire and with breast cancer supplementary module version 3.0 (EORTC QLQ-C30) was used to assess the quality of life of the participants.

It is a standardized tool for evaluating the quality of life (physical, psychological and social functions) of patients participating in clinical trials. It consists of 30 questions regarding activities of the past week. It is divided into three domains: global health (n=2), functional scales (n=15), and symptom scales (n=13). A high score for a functional scales and global health status represents a high or healthy level of functioning whereas high score for a symptom scales represents a high level of symptomatology or problems.⁶ The content validity of the tool was established by a panel of ten experts from the field of medical oncology, surgical oncology, gynaecology, oncology nursing and medicine. The permission was obtained to use the standardised tool in Hindi and English language. The reliability of the tool was calculated due to different research setting, with Cronbach's alpha coefficient and tool was found reliable with $r=0.91$

Hospital anxiety and depression scale (HADS): This tool was used to assess the psychological distress amongst the participants. The HADS is a self-reported, 14 items measure with two sub scales (anxiety HADS-A and depression HADS-D), which may be scored by the scale

or as a total score representing overall distress. Total scores can range between 0 and 21 for either anxiety or depression. The level of anxiety and depression was classified as normal (0-7), borderline abnormal (8-10) and abnormal (11-21).⁷ The reliability of the tool was calculated due to different research setting with Cronbach's alpha coefficient and tool was found reliable with $r=0.8$. The tool was translated in Hindi and then re-translated in English language by language experts.

Sample size

The sample size was calculated by taking the reference of parameters of previous study by using G*power software.⁸ With 90% power (5% significance) to identify differences of at least 12% in quality of life using the European organization for research and treatment of cancer quality of life questionnaire (EORTC QLQ-C30), the sample size resulted 72 participants and after adding 10% drop out rate, it comes with 80 participants. (40 in each group). However, 30 participants have been selected to conduct pilot study to estimate a parameter.⁹ Purposive sampling technique was used to draw sample from the target population.

Random allocation

The random allocation sequence was produced online by sealedenvelope.com. Allocation to each group was conducted in a block randomization manner with a block size of four. The allocation concealment mechanism was developed with predetermined sequences written on paper slips and kept in a sealed opaque envelope. Each envelope had a unique code written and arranged sequentially as per the randomized list. An assigned person, who was not involved in the study, managed the random allocation sequence and it was kept concealed from the researcher. The participants were enrolled after meeting eligibility criteria and written informed consent. Baseline information on primary and secondary outcomes of eligible participants was obtained before allocation. The researcher opened the sealed envelope, and at the same time, participants received their information on allocation to the ChemoED group and control group.

Blinding

It was an open trial study. Patients and researcher allocated to an experimental and control group were aware of the allocated arm.

Intervention

The extensive review of literature on PubMed, Mendeley, Google scholar and Embase, and expert's opinion, focused group interview with patients led the development of intervention. An educational booklet to be given to the participants was prepared. It consisted of 9 chapters including introduction to breast cancer, breast self-examination, post-mastectomy exercises and

prevention of lymphedema, chemotherapy, pre-chemotherapy preparation, management of various side-effects at home, thoughts and feelings, information for relatives and friends, day to day living. Validation of the booklet was done by giving it to experts in oncology, gynaecology, dietician, nursing and psychiatry. Necessary modifications were done by incorporating their valuable suggestions after discussion with the guide.

Data collection procedure

Baseline information related to demographic profile, clinical, and obstetric profile was obtained from both groups. Pre-interventional quality of life and psychosocial distress was measured with EORTC QLQ C-30 and HADS for both experimental and control groups.

Following this, the nurse Led pre-chemotherapy education (ChemoED) Programme was administered to the participants included in experimental group. It consisted of two steps: a) Twenty minutes of pre-chemotherapy education programme was implemented to the patients enrolled in the experimental group. It was conducted in a separate room before the administration of first cycle of chemotherapy to the patients. The educational booklet was provided to the patients after clarifying their doubts. b) Telephonically follow up was done with each participant, after one week of the chemotherapy cycle to motivate them to get adhere to the information given in booklet. Participants in the control group were given standard nursing care including nursing assessment and basic care while providing chemotherapy and routine information related to side-effects and follow-up treatment. At 4th cycle of chemotherapy, quality of life and psychological distress was assessed for the participants of both the groups.

Statistical analysis

Data was coded and analysed by SPSS version 23.0 through descriptive statistics (frequency, percentage, Mean, SD) and inferential statistics (independent t test, paired t test and Chi square).

RESULTS

Table 1 illustrates characteristics of the patients in terms of socio-demographic and clinical variables: Mean age of patients in experimental group was 46.2 ± 9.2 and in control group was 45.8 ± 10.4 . Both the groups were comparable in terms of homogeneity except working status and staging of cancer at $p < 0.05$.

Table 2 depicts the mean difference in global health status among experimental and control group at baseline and chemotherapy cycle four. The mean scores (at baseline) in both groups were comparable ($p=0.45$). After the intervention (at cycle four), there was statistically significant difference in the global health status in both groups with mean difference 23.4 at $p=0.00$.

Table 1: Characteristics of patients with breast cancer, n=30.

Characteristic	Experiment, n=16		Control, n=14		P value
	Mean, (n)	SD (%)	Mean, (n)	SD (%)	
Age (years)	46.2	9.2	45.8	10.4	0.364 ^ψ
BMI (kg/m ²)	27.1	4.3	25.3	4.4	0.112 ^ψ
No. of family members, Median (Range)	5	2-12	5	2-11	0.644 ^ζ
Marital status					
Married/Widow	15	97.5	40	100	---
Unmarried	1	2.5	0	0	
Working status					
Working	04	25	01	5	0.025 [#]
Not working	12	75	13	95	
Smoking history					
Yes	01	06.3	03	7.2	0.999 [#]
No	15	93.7	13	92.8	
Alcohol history					
Yes	01	2.5	0	0	0.317 [#]
No	15	97.5	40	100	
Staging of cancer					
Stage 1	02	12.5	06	42.8	0.036 [#]
Stage 2	04	25.0	04	28.5	
Stage 3	10	62.5	04	28.5	
Duration of cancer (months), Median (Range)	4.5	1-36	6	0.5-72	0.149 ^ζ
Hormonal status					
ER/PR+ve/HER2 neu negative	06	37.5	06	42.9	0.585 [#]
Triple Negative	05	31.3	06	42.9	
ER/PR-ve/HER2 neu positive	01	06.2	01	07.1	
ER /HER2 neu positive/PR-ve	04	25.0	01	07.1	
Chemotherapy regimen					
AC	14	87.5	13	92.8	0.166 [#]
Others (ACF, ACT, CAF, CDT)	02	12.5	01	07.1	

^ψ T-test of two independent samples; [#]Chi-square/Fisher's exact test; ^ζMann-Whitney U test; bold numbers represent statistical significance at 5% level

Table 2: Global health status (quality of life) amongst the participants at baseline and chemotherapy cycle four in both the groups, n=30.

GHS	Experimental group, (n=16)	Control group, (n=14)	Mean difference	P value
Baseline	60.4±16.8	65.5±19.8	-5.1	0.45
Cycle four	69.3±14.8	45.8±20.3	23.4	0.00 ^{**}
P value	0.07	0.03		

^{**}significant p<0.05 Higher score depicts good quality of life (global health status)

The functional scores (Table 3) represent that in experimental group at chemotherapy cycle four, the mean difference has increased from baseline values reflecting higher quality of life but results were not statistically significant except Role functioning (p=0.03). However, in control group, a significant reduction in functional scores was observed at chemotherapy cycle four from baseline values, indicating poor quality of life in control group. Mean scores has significantly reduced from baseline in domains of physical functioning (p=0.03), cognitive functioning (p=0.04) and social functioning (p=0.03).

The symptoms scores (Table 4) depict that after intervention, mean symptom scores at chemotherapy cycle four, has increased from baseline scores, but this difference in mean score is statistically non-significant except Fatigue (p=0.03). In contrast, control group has exhibited a highly significant change in terms of increased mean scores at chemotherapy cycle four as compared to baseline values. Thus, indicating poor quality of life in terms of increased fatigue (p=0.01), nausea and vomiting (p=0.00), constipation (p=0.00), diarrhoea (p=0.00) and financial difficulties (p=0.00).

Table 3: Functional scores (quality of life) amongst the participants at baseline and chemotherapy cycle four in both the groups, n=30.

Functional scores	Experimental group, (n=16)		P value	Control group, (n=14)		P value
	Baseline Mean±SD	Cycle four Mean±SD		Baseline Mean±SD	Cycle four Mean±SD	
Physical functioning	81.2±17.1	80.8±15.7	0.94	81.9±26.3	60.0±23.4	0.03*
Role functioning	68.7±32.1	87.5±16.7	0.03*	69.0±33.8	58.3±31.8	0.39
Emotional functioning	60.4±28.1	71.3±21.7	0.19	64.3±32.7	60.7±30.6	0.69
Cognitive functioning	78.1±21.7	84.4±15.5	0.18	79.7±19.8	59.5±25.1	0.04*
Social functioning	78.1±25.6	75.0±25.1	0.68	86.9±20.8	60.7±31.7	0.03*

*Significant, Higher functioning scores depicts good quality of life

Table 4: Symptom scores (quality of life) amongst the participants at baseline and chemotherapy cycle four in both the groups, n=30.

Symptom scores	Experimental group, (n=16)		P value	Control group, (n=14)		P value
	Baseline Mean ±SD	Cycle four Mean ±SD		Baseline Mean ±SD	Cycle four Mean ±SD	
Fatigue	27.1±24.6	41.7±19.2	0.03*	24.6±31.5	55.5±23.8	0.01
Nausea and vomiting	5.21±10.0	16.7±25.8	0.13	4.76±13.7	35.7±25.2	0.00*
Pain	19.8±31.8	14.6±20.1	0.54	29.8±28.6	39.3±25.8	0.43
Dyspnoea	12.5±26.8	12.5±26.8	1	14.3±25.2	26.2±32.5	0.26
Insomnia	10.4±23.5	10.4±20.1	1	16.7±25.3	42.8±44.2	0.09
Appetite loss	6.2±25.0	12.5±20.6	0.48	26.2±37.4	33.3±29.2	0.55
Constipation	18.7±40.3	20.8±34.1	0.84	11.9±21.1	52.3±33.8	0.00*
Diarrhoea	4.2±11.4	6.25±18.1	0.71	0	28.6±34.2	0.00*
Financial difficulties	45.8±38.2	29.2±31.9	0.08	30.9±27.6	57.1±35.6	0.00*

*Significant p<0.05 higher symptom scores depict high level of symptomatology

Table 5: Post interventional quality of life score amongst participants at chemotherapy cycle four in both the groups, n=30.

Cycle four, QoL C-30	Experimental group (n=16)	Control group (n=14)	Mean difference	P value
Global health status	69.3±14.8	45.8±20.3	23.4	0.00**
Physical functioning	80.8±15.7	60.0±23.4	20.8	0.00**
Role functioning	87.5±16.7	58.3±31.8	29.1	0.00**
Emotional functioning	71.3±21.7	60.7±30.6	10.6	0.27
Cognitive functioning	84.4±15.5	59.5±25.1	24.8	0.00**
Social functioning	75.0±25.1	60.7±31.7	14.2	0.18
Fatigue	41.7±19.2	55.5±23.8	-13.8	0.08
Nausea and vomiting	16.7±25.8	35.7±25.2	-19.0	0.05*
Pain	14.6±20.1	39.3±25.8	-24.7	0.00**
Dyspnoea	12.5±26.8	26.2±32.5	-13.6	0.21
Insomnia	10.4±20.1	42.8±44.2	-32.4	0.01*
Appetite loss	12.5±20.6	33.3±29.2	-20.8	0.03*
Constipation	20.8±34.1	52.3±33.8	-31.5	0.01*
Diarrhoea	6.25±18.1	28.6±34.2	-22.3	0.03*
Financial difficulties	29.2±31.9	57.1±35.6	-27.9	0.03*

*Significant p<0.05

Table 5 showed the effect of intervention on quality of life in experimental and control group. At chemotherapy cycle four, mean differences in both the groups indicating significant improvement in quality of life among experimental group as compared to control group in terms of global health status GHS ($p=0.00$), physical functioning ($p=0.00$), role functioning ($p=0.00$) and cognitive functioning ($p=0.00$). The symptom score was significantly reduced in experimental group as compared to control group. The minus sign in mean differences indicates reduction of symptoms in experimental group. There was statistically significant reduction in following

symptoms: nausea and vomiting ($p=0.05$), pain ($p=0.05$), sleep disturbances (0.01), appetite loss (0.03), constipation (0.01), diarrhoea (0.03) and financial difficulties ($p=0.03$).

Table 6 represents changes in mean HADS score from baseline to chemotherapy cycle four in experimental group. The mean HADS scores (anxiety and depression) at chemotherapy cycle four (10.3 ± 7.5) has reduced from baseline scores (15.1 ± 8.6) after intervention. However, this reduction in scores was statistically non-significant ($p=0.11$).

Table 6: Psychological distress amongst participants at baseline and chemotherapy cycle four in experimental group, n=16.

HADS		Baseline, f (%)	Cycle four, f (%)	P value
Anxiety	No anxiety (0-7)	9 (56.2)	14 (87.5)	0.11
	Mild (8-10)	3 (18.7)	1 (6.2)	
	Moderate (11-14)	2 (12.5)	0	
	Severe (15-21)	2 (12.5)	1 (6.2)	
Depression	No depression (0-7)	9 (56.2)	12 (75.0)	
	Mild (8-10)	3 (18.7)	1 (6.2)	
	Moderate (11-14)	2 (12.5)	1 (6.2)	
	Severe (15-21)	2 (12.5)	2 (12.5)	
Mean \pmSD		15.1 \pm 8.6	10.3 \pm 7.5	

Table 7: Psychological distress amongst participants at baseline and chemotherapy cycle four in the control group, n=14.

HADS		Baseline, f (%)	Cycle four, f (%)	P value
Anxiety	No anxiety (0-7)	10 (71.4)	8 (57.1)	0.72
	Mild (8-10)	0	2 (14.3)	
	Moderate (11-14)	2 (14.3)	2 (14.3)	
	Severe (15-21)	2 (14.3)	2 (14.3)	
Depression	No depression (0-7)	8 (57.1)	8 (57.1)	
	Mild (8-10)	3 (21.4)	2 (14.3)	
	Moderate (11-14)	2 (14.3)	4 (28.6)	
	Severe (15-21)	1 (7.1)	0	
Mean \pmSD		13.8 \pm 11.0	15.0 \pm 7.5	

Table 8: Comparison of mean values of psychological distress among participants at baseline and chemotherapy cycle four in both groups, n=30.

HADS	Baseline, Mean \pm SD	P value	Cycle four, Mean \pm SD	P value
Experimental group	15.1 \pm 8.6	0.72 ^{NS}	10.8 \pm 15.0	0.05*
Control group	13.8 \pm 11		15 \pm 7.5	

*Significant $p<0.05$

On the contrary, in control group, (Table 7) mean HADS scores has increased from baseline scores (13.8 ± 11) and at chemotherapy cycle four (15 ± 7.5) with mean difference (-1.2). However, this difference was statistically non-significant ($p=0.72$).

Table 8 depicts that effect of intervention on HADS score among experimental group and compare it with control group at chemotherapy cycle four. The mean HADS score at baseline in experimental and control group was non-significant ($p=0.72$). However, after intervention, mean

HADS score were significantly less among experimental group (10.8 ± 15) as compared to control group (15 ± 7.5) with mean difference 4.2 ($p=0.05$).

DISCUSSION

The newly diagnosed patients with cancer feel stress and worry of being diagnosed and on the top of that, chemotherapy treatment and its various side-effects lead to anxiety among the patients. Moreover, if patients lack adequate knowledge about the disease and treatment and

how to self-manage at home, fear of commencing chemotherapy affect quality of life and create psychological distress in the patients. Quality of life is a comprehensive and subjective phenomenon about ways of living of a patient with cancer. The diagnosis of breast cancer itself develops burden among patients and their family members in terms of physical sufferings, psychological distress and economic burden.

Psychological distress is an unpleasant and emotional suffering experienced by person that may interfere with his ability to cope with disease or symptoms effectively.¹⁰ The current study was carried out on newly diagnosed females with breast cancer receiving chemotherapy for the first time in life. The results showed that Nurse-led pre-chemotherapy education programme has not only enhanced the global health status, but also quality of life pertaining to various domains of health. After the intervention, the global health status ($p=0.00$), physical functioning ($p=0.00$), role functioning (0.00), and cognitive functioning (0.00) has shown significant improvement in quality of life as compared to control group. Nonetheless, social functioning and emotional functioning has not improved significantly. The educational intervention has heightened their awareness about disease, treatment and also made patients psychologically strong enough to accept themselves as they are and combat with illness.

However, the symptomatology scores have statistically significantly reduced after the intervention at cycle four as compared to control group in terms of nausea and vomiting ($p=0.05$), pain ($p=0.00$), sleep disturbances ($p=0.01$), appetite (0.03), constipation ($p=0.01$), diarrhoea ($p=0.03$) and financial difficulties ($p=0.03$). Loh et al stated that the quality of life, including all domains significantly increased in intervention group after implementing one month self-management programme compared to control group ($p<0.001$).¹¹ Similar findings have also been reported by Park et al, Sharif et al and Matsuda et al wherein educational intervention has significantly improved quality of life among patients receiving chemotherapy.¹²⁻¹⁴ Results of the current study regarding HADS at baseline were well balanced between the two groups ($p=0.72$). After the intervention, the psychological distress has significantly reduced at cycle four in experimental group compared to control group ($p=0.05$). The results are supported by the findings of study conducted by Cox et al, Zhu and Aranda et al wherein there was significant reduction in psychological distress with education intervention ($p=0.027$).¹⁵⁻¹⁷ Despite of technological advancement in treatment and survival, cancer remains a dreaded diagnosis and produced distress along the continuum of cancer. This distress is a combination of multidimensional stressors that strain the patients' and family coping capabilities.

Pre-chemotherapy education sessions significantly increased the global health status and functioning of patients and similarly there was significant reduction in

symptom burden and psychological distress as compared to control group in the present study. With better understanding of diagnosis, goals of treatment, potential side-effects and management strategies, patients have reported reduced anxiety and depression associated with chemotherapy and further have better quality of life and better clinical outcomes. This knowledge can be well enhanced by oncology nurses by providing individual educational sessions either by giving written material for educated people or some animated videos for other ignorant patients.¹⁸

The findings of the current study have depicted the importance of pre-chemotherapy education for the patients with breast cancer undergoing chemotherapy. Thus, the oncology nurses can meet the educational and psychosocial needs of newly diagnosed patients with cancer and are going to be started with chemotherapy.

Limitations

The current study was limited to thirty patients from one hospital only. So, selection bias could not be completely omitted. The weakness of study is that we have to rely on patient's responses on adherence to guidelines provided in educational booklet. However, telephonically follow up was done to remind them to read booklet and follow the content of booklet.

CONCLUSION

Newly diagnosed patients with cancer usually suffers with psychological distress, which can trouble their quality of life. Embedding authentic information along with treatment modalities may improve quality of life and psychological distress among patients. Nurse-led pre-chemotherapy education programme can be cost-effective and practical method to improve patients' preparedness to get chemotherapy. It will also empower the specialised nurses to provide utmost quality patient-centred care.

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