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The Effects of the Continuous Care Model on Sleep Quality, Pain, Fatigue and Nausea among Breast Cancer Patients Receiving Chemotherapy: A Clinical Trial

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ABSTRACT

Background: Patients with breast cancer (BC) suffer from sleep disorders, pain, fatigue, and nausea after receiving chemotherapy. **Objectives:** The objective of this study was to assess the effects of the continuous care model (CCM) on sleep quality, pain, fatigue, and nausea among patients with BC who were receiving chemotherapy. **Methods:** This randomized clinical trial was conducted on 78 patients with BC who referred in April–June 2013 to the chemotherapy clinic of Ahvaz University of Medical Sciences, Ahvaz, Iran. Initially, patients were paired with each other respecting their age, type of surgery, and educational level, and then through tossing a coin, one patient in each pair was randomly allocated to the intervention and the other to the control group. The CCM was used for care provision to patients in the intervention group, while care services were provided to patients in the control group through routine methods. Data were collected 4 days after chemotherapy onset and 2 months after the intervention using a demographic questionnaire, a visual analog scale for nausea assessment, the Pittsburgh Sleep Quality Index, the Brief Fatigue Inventory, and a 10-cm ruler for pain assessment. For data analysis, the independent-sample t and the Chi-square tests were used. **Results:** Before the intervention, the groups did not significantly differ from each other concerning the scores of sleep quality, fatigue, pain, and nausea ($P > 0.05$). However, after the intervention, between-group differences of the intervention group and the controls were statistically significant for sleep quality (7.81 ± 4.50 vs. 16.80 ± 4.32, $P < 0.0001$), fatigue (36.23 ± 15.60 vs. 61.00 ± 12.32, $P < 0.0001$), pain (2.90 ± 2.82 vs. 6.81 ± 2.31, $P < 0.0001$), and nausea (2.16 ± 2.90 vs. 5.2 ± 2.93, $P < 0.0001$). **Conclusion:** This study proves the positive effects of the CCM on sleep quality, pain, fatigue, and nausea among patients with BC. Nurses can use this model to improve the patient outcomes.

KEYWORDS: *Breast cancer, Chemotherapy, Fatigue, Long-term care, Models, Nausea, Nursing, Pain, Sleep*

INTRODUCTION

*B*reast cancer (BC) is the most prevalent type of cancer among women worldwide.[1] Around 25% of all diagnosed cancers and 15% of all deaths among women are attributed to BC.[2] According to the National Cancer Registry Report, BC accounts for 23% of all cancers diagnosed among Iranian women.[3] Although the rate of BC is different according to the life expectancy and lifestyle in different region,[4,5] the age of BC onset in Iran is one decade earlier than developed countries.[6]

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Patients with BC often suffer from problems such as sleep disorders, fatigue, pain, and nausea.[7-9] Fatigue and sleep disorders can increase pain sensitivity.[10] These symptoms can negatively affect functioning and quality of life.[11] On the other hand, effective pain management can improve sleep quality and reduce fatigue.[12]

Chemotherapy, which is a common treatment for cancer, can aggravate fatigue, pain, and nausea in patients with cancer. Therefore, they may decide to postpone or avoid receiving chemotherapy due to the fear over its unpleasant complications.[12] Nurses, as members of health-care teams, are responsible for the prevention and management of chemotherapy complications. Various pharmacological therapies such as hypnotics,[13] opioids,[14] antiemetics,[15] and some types of complementary therapies[16] are used to manage chemotherapy complications. However, these therapies not only are not effective for some patients but also may exacerbate complications.[17] Therefore, nurses need to use nonpharmacological therapies for the effective management of the complications.[8]

Nursing models help organize professional nursing activities and improve patient outcomes. As one of the nursing models, the continuous care model (CCM) facilitates a dynamic, interactive, and reciprocal cooperation among nurses, patients, and family members. It is compatible with chronically ill patients' needs and significantly contributes to the improvement of patient health.[18] However, this model has not yet been used for patients with cancer who receive chemotherapy.

Objectives

The objective of this study was to assess the effects of CCM on sleep quality, pain, fatigue, and nausea among patients with BC who were receiving chemotherapy.

METHODS

Study design and participants

This randomized controlled trial was conducted on patients with BC who referred in April–June 2013 to the chemotherapy clinic of Ahvaz University of Medical Sciences, Ahvaz, Iran. Inclusion criteria were an age of 25–65 years, ability to fill out the study questionnaires, no history of psychiatric disorders or amnesia, suffering from Stages 2–4 of BC, having received 1–5 doses of chemotherapy, and agreement for partaking in the study. Patients who were hospitalized or opted for voluntary withdrawal from the study were excluded from the study.

The sample size was calculated based on the results of a pilot study conducted on 20 patients in intervention and a control group. The means of sleep quality in the groups were 13.20 ± 3.40 and 15.70 ± 3.80, respectively. Then, with a Type I error of 0.05, a Type II error of 0.20, S_1 of 3.40, S_2 of 3.80, a μ_1 of 13.20, and a μ_2 of 15.70, it was estimated that 32 patients were necessary for each group. However, considering probable withdrawals from the study, the sample size was increased to 39.

More than 100 eligible patients were approached. They were initially paired respecting their age, type of surgery, and education level, and then, one patient in each pair was randomly allocated to the intervention and the other to the control group through tossing a coin [Figure 1].

Study instruments

Data were collected using five instruments. The first was a demographic questionnaire with items on age, education level, marital status, employment status, and medical history. The second was a visual analog scale. It
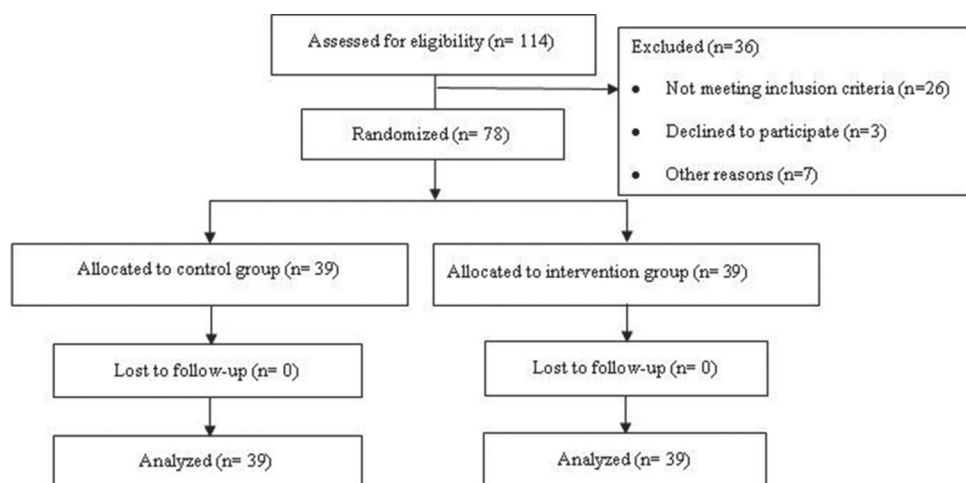

Figure 1: Flow diagram of the study

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was a 10 cm line to assess nausea severity. Scores 1–3, 4–6, and 7–9 on the scale stood for mild, moderate, and severe nausea, respectively. The third instrument was the Pittsburgh Sleep Quality Index. This index was used to assess sleep quality and sleep disturbances in the last month. It contains 19 items with a total score of 0–21. Higher scores indicate lower sleep quality. The cutoff score of the index is 5 so that scores >5 are interpreted as low sleep quality and scores <5 are interpreted as good sleep quality.[19] The fourth instrument was the Brief Fatigue Inventory which contains nine items on unusual fatigue felt during the last week. Three items are about the severity of fatigue during the last 24 h and six items measure how fatigue interferes with different aspects of life during the last 24 h. The interference items are scored 0–10, with 0 standing for "Does not interfere" and 10 for "Completely interferes." The inventory has great internal consistency with a Cronbach's alpha of 0.96.[20] The score zero was considered as no fatigue, then, scores 1–3.9, 4–6.9, and 7–10 were considered as mild, moderate, and severe fatigue, respectively. The fifth instrument was a 10 cm ruler for pain assessment. The left end showed no pain and scored 0, while the right end showed very severe pain and scored 10. Scores 1–3, 4–6, and 7–9 are interpreted as mild, moderate, and severe pain, respectively.

Intervention

At least 4 days later chemotherapy onset, patients were asked to complete study instruments. Then, patients in the control group received care services routinely provided to all patients in the study setting, while care services were provided to patients in the intervention group using CCM in 8 successive weeks (or 2 months) in the following four stages.

Orientation

The first stage of CCM dealt with orienting patients to the goal of nurse–patient relationship, fostering their participation in the study, and enhancing their knowledge about the necessity and the importance of continuous care.

Sensitization

This stage was gone through concurrently with the orientation stage. In this stage, we focused on encouraging patients to accept their responsibilities toward their own care and health. Accordingly, we held a 45–60 min session to evaluate patients' educational needs and provide them with explanations about BC and its complications, necessity of continuous care, and lifestyle modification. Family members were also instructed and encouraged to engage in patient care and support. Besides, patients were provided with an educational pamphlet which contained information about chemotherapy and its complications, self-care activities,

dietary regimen, and relaxation therapy. The first and the second stages lasted two whole weeks.

Control

In this 6-week stage, patients were divided into three ten-person and one nine-person groups and were provided with personal and group consultation services in 2–3 sessions. The number of sessions depended on patients' level of knowledge and intensity of their problems. Sessions lasted 1–2 h and were held in the clinic of Shafa Hospital, Ahvaz, Iran. Then, based on the type of patients' needs, daily and weekly continuous care counseling services were provided to patients. Patients were provided with the opportunity to call the authors over the phone in case of any question.

Evaluation

The evaluation was performed throughout all stages and aimed to monitor the care delivery process and supervise patients' activities.

Two months after the intervention, all patients were requested to recomplete the study questionnaires. Blinding was not applied in this study.

Ethical considerations

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran (approval code: AJUMS.REC.1392.36) and registered in the Iranian Registry of Clinical Trials (registration number: IRCT2013070613802N2). All participants signed the consent form of the study and were ensured of the confidentiality of their personal data.

Table 1: Patients' demographic characteristics

Characteristics	Group[a]		P^b
	Intervention	Control	
Type of surgery			
Unilateral mastectomy	32 (82.1)	26 (66.6)	0.194
Breast-conserving surgery	7 (17.9)	13 (33.4)	
Educational level			
Primary	12 (30.8)	20 (51.3)	0.165
Secondary	24 (61.5)	16 (41.0)	
University	3 (7.7)	3 (7.7)	
Marital status			
Married	33 (84.6)	27 (69.2)	0.118
Single	1 (2.6)	6 (15.4)	
Divorced or widowed	5 (12.8)	6 (15.4)	
Number of chemotherapy sessions			
1-3	23 (58.9)	18 (46.2)	0.364
4-5	16 (41.1)	21 (53.8)	
Age	43.90±10.10	48.20±10	0.70[c]

[a]Values are presented as n (%) or mean±SD, [b]Chi-square or Fisher's exact test, [c]t-test. SD: Standard deviation

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Data analysis

Statistical data analysis was carried out using the SPSS software version 13.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was conducted to test the assumption of normality. Descriptive statistic measures (such as frequencies, percentage, mean, and standard deviation) were calculated. The Chi-square or Fisher's exact tests were run to compare the groups concerning categorical demographic variables, while the independent samples t-test was used to compare the groups concerning the mean scores of sleep quality, fatigue, pain, and nausea. $P < 0.05$ was considered statistically significant.

Table 2: Between- and within-group comparisons concerning the mean scores of sleep quality, pain, fatigue, and nausea

Variables	Group	Time[a]		P[b]
		Before	After	
Sleep quality	Intervention	16.71±5.12	7.81±4.50	<0.0001
	Control	16.01±4.70	16.80±4.32	0.23
	P[c]	0.5	<0.0001	-
Pain	Intervention	6.05±3.05	2.90±2.82	<0.0001
	Control	6.38±3.16	6.81±2.31	0.09
	P[c]	0.6	<0.0001	-
Fatigue	Intervention	56.51±18.33	36.23±15.60	<0.0001
	Control	53.42±15.92	61.00±12.32	0.12
	P[c]	0.4	<0.0001	-
Nausea	Intervention	7.08±2.28	2.16±2.90	<0.0001
	Control	5.97±3.19	5.20±2.93	0.40
	P[c]	0.11	<0.0001	-

[a]Values are presented as mean±SD, [b]Paired t-test, [c]Independent-sample t-test. SD: Standard deviation

RESULTS

There were no significant differences between the groups regarding their demographic characteristics such as education level, marital status, age, number of chemotherapy sessions, and type of surgery [$P > 0.05$; Table 1].

The independent samples t and the Chi-square tests showed no significant between-group differences concerning the scores of sleep quality, pain, fatigue, and nausea ($P > 0.05$). However, after the intervention, there were significant between-group differences concerning the scores of sleep quality, pain, fatigue, and nausea [$P < 0.0001$; Tables 2 and 3].

The independent samples t and the Chi-square tests showed that, before the intervention, the number of sleeping hours and the use of sedative medications in the intervention group were not significantly different from the control group ($P > 0.05$); however, after the intervention, the between-group differences were statistically significant ($P < 0.01$).

DISCUSSION

The present study showed significant between-group differences concerning the posttest values of sleep quality, fatigue, pain, and nausea, denoting the effectiveness of CCM in improving sleep quality and reducing fatigue, pain, and nausea among patients with BC receiving chemotherapy. Earlier studies also showed that the CCM use can improve sleep quality

Table 3: Frequency distribution of fatigue, pain, and nausea in both groups[a]

Variable	Before		P[b]	After		P[b]
	Intervention group	Control group		Intervention group	Control group	
Fatigue						
Mild	7 (17.9)	7 (17.9)	0.457	19 (48.7)	1 (2.6)	<0.001
Moderate	14 (35. 9)	19 (48.7)		18 (46.2)	21 (53.8)	
Severe	18 (46.2)	13 (33.4)		2 (5.1)	17 (43.6)	
Pain						
Normal	0	2 (5.1)	0.603	11 (28.2)	0	<0.001
Mild	8 (20.5)	5 (12.8)		13 (33.3)	5 (12.8)	
Moderate	12 (30.8)	13 (33.3)		6 (15.4)	9 (23.1)	
Severe	10 (25.6)	10 (25.6)		9 (23.1)	22 (56.4)	
Extremely severe	9 (23.1)	9 (23.2)		0	3 (7.7)	
Nausea						
Normal	1 (2.6)	3 (7.7)	0.307	18 (46.2)	4 (10.3)	<0.001
Mild	4 (10.2)	6 (15.4)		12 (30.7)	7 (17.9)	
Moderate	7 (17.9)	10 (25.6)		3 (7.7)	13 (33.3)	
Severe	15 (38.5)	15 (38.5)		6 (15.4)	12 (30.8)	
Extremely severe	12 (30.8)	5 (12.8)		0	3 (7.7)	

[a]Values are presented as n (%), [b]Chi-square or Fisher's exact test

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among hemodialysis patients,[21] patients undergoing coronary artery bypass graft surgery,[22] and those with diabetes mellitus.[23] Sleep problems among patients can impair their cognitive function.[24] CCM improves care providers' cognitive function in the process of care delivery,[25] promotes patients' awareness, and improves their ability to control and manage their health-related problems.[23] Moreover, educating patients and their families through CCM can improve their mental status.

Study findings revealed that the CCM use significantly reduced fatigue among patients with BC who were receiving chemotherapy. Similarly, another study indicated that the CCM use can alleviate fatigue in patients with BC.[26] Fatigue reduction following the CCM use may also be attributed to the effectiveness of CCM in improving sleep quality. Low-sleep quality is associated with physical, behavioral, and psychological problems as well as impairments in psychological, social, and interpersonal interactions.[27]

We also found the effectiveness of CCM use in reducing pain. This is in line with the findings of a study which showed that the CCM use reduced chest pain among patients with myocardial infarction.[28] Another study also showed that the great focus of CCM on health behavior observation helps prevent and manage complications and symptoms such as pain.[29] Based on these findings, following up the client's behavior at home by telephone helped better controlling the chemotherapy side effects. Usually, patients forget the therapeutic recommendations gradually after discharge from the hospital; therefore, it is necessary to recall and strengthen or provide them such information.

CCM use in the present study also significantly reduced BC patients' nausea. A study also reported that the implementation of a self-care education program was effective in reducing the intensity of nausea and vomiting among patients with colorectal cancer who received chemotherapy.[30] Two other studies also showed that improving patients' awareness helps alleviate gastrointestinal problems among patients with chronic illnesses.[31,32] Hence, it can be concluded that the use of CCM can increase the patient's self-care ability to control nausea, which can be considered as a complementary approach to the antiemetic medications.

Most of the participants were from different cities and towns near Ahvaz, and hence, they might have differed from each other respecting their personal, psychological, and cultural characteristics.

Moreover, this study was conducted on a limited number of patients, and thus findings may have limited generalizability. Further studies with blinded designs and long follow-up periods on larger samples of patients recruited from more homogenous populations are needed to evaluate the pure effects of CCM.

CONCLUSION

CCM use has positive effects on sleep quality, pain, fatigue, and nausea among patients with BC. Therefore, it can be incorporated into nursing rehabilitation programs for BC patients. In-service training courses on CCM are recommended for nursing staff. Further studies are needed to determine the effects of CCM on patients with other types of cancer.

Conflicts of interest

There are no conflicts of interest.

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