

Psychoeducational Nursing Intervention for Symptom Management in Cancer Patients: A Randomized Clinical Trial

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ABSTRACT

Objective: The objective of this study was to assess the effects of a psychoeducational intervention upon symptom control and quality of life (QoL) among cancer patients. **Methods:** This was an open randomized clinical trial (RCT) conducted at the Cancer Institute of the State of São Paulo. The RCT comprised 107 outpatients in chemotherapy or radiation for malignant neoplasms. Participants were randomized to control group (usual treatment) or intervention group (IG) (psychoeducational intervention) with assessments at baseline and upon completion of the intervention. Sociodemographic information, clinical data, QoL, functionality, and symptoms were assessed. This trial is registered with the Brazilian Clinical Trials Registry number RBR-9337nv. A mixed-effects model was applied to compare the effects of the intervention between the groups.

Results: The most frequent symptoms were fatigue (76.6%), insomnia (47.7%), pain (42.1%), and loss of appetite (37.4%). The symptom intensity analysis suggests that insomnia was the strongest symptom, followed by fatigue, loss of appetite, and pain. The IG experienced a significant improvement in terms of loss of appetite ($P = 0.002$) and a tendency toward less insomnia ($P = 0.053$). **Conclusions:** The intervention significantly reduced appetite loss in cancer patients. Despite no effects observed in global QoL or functionality, the intervention yielded a tendency to improve insomnia, and this outcome should be investigated in future studies.

Key words: Neoplasms, nursing, oncology nursing, quality of life, signs and symptoms

Introduction

Cancer patients face multiple symptoms that often persist after treatment cessation, impacting functionality and quality of life (QoL).^[1-4] Fatigue is present in 7%–55% who are undergoing chemotherapy or radiation therapy,^[5,6] pain affects 55%–67% of cancer patients,^[4,7] while nausea,

constipation, and diarrhea are reported in 5%–17% of cases.^[5] Poor sleep quality affects roughly 57% of patients and can be exacerbated by the presence of other symptoms, such as pain and nausea.^[8,9]

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Further, symptoms such as anxiety occur in 20%–30%,^[10] and depression affects 10%–47% of cancer patients.^[8,10,11] The stress related to diagnosis, treatment, and fear of relapse also causes substantial psychological impact, and some patients reported emotional symptoms as the most burdensome.^[12-14]

Throughout cancer treatment, the nursing team focuses mainly on treatment safety, which is essential, but there is a lack of attention to symptom management and psychosocial aspects.^[15]

On the other hand, psychoeducational interventions can be used by nurses to address symptoms and prevent complications associated with treatment.^[16-22] These interventions focus on patients' educational needs and include education strategies in a cooperation environment, with skills training to cope with stress and symptoms.^[22]

Psychoeducational interventions on symptom management in cancer patients were analyzed in a systematic review.^[23] The authors concluded that although it was possible to observe significant improvement in functional performance, the evidence that these interventions could alleviate cancer symptoms is inconclusive and future well-designed investigations are warranted.^[23]

This study aims to assess the effects of a psychoeducational nursing intervention on symptom management and QoL among cancer patients undergoing chemotherapy or radiation treatment. The underlying hypothesis is that a psychoeducational intervention based on educational strategies and relaxation techniques can contribute to symptom management and consequently improve QoL in cancer patients.

Methods

Study design

This was an open, randomized clinical trial (RCT) conducted with outpatients receiving chemotherapy or radiation at the Cancer Institute of the State of São Paulo (ICESP). The nature of the on-site intervention meant that it was not to blind the individuals who were participating or professionals who carried out the intervention. However, the final assessment was blinded, and it was performed by a team member with no previous contact with the patients.

Inclusion criteria include the following characteristics: cancer patients undergoing treatment at the ICESP, receiving modality of treatment chemotherapy (weekly application protocols) or radiation therapy, over 18 years of age, at least 4 years of formal education, without communication dysfunctions, and aware of time and space. The exclusion criteria were illiterate patients or those with cognitive disabilities such as dementia and patients with

high care needs (Karnofsky Score <40). Eligible patients received information regarding the study objectives and data collection procedures and were then invited to participate in the study. Those who agreed signed informed consent forms before the study taking place.

A preliminary pilot study analysis was conducted to determine the sample size. Thirty patients were randomly assigned to intervention group (IG) or control group (CG). In the pilot study, patients varied by up to eight points in their reported global QoL score. To obtain a significant time × group interaction effect on a repeated measures ANOVA model at least as big as the one found in the pilot sample in global QoL score, a minimum of 60 patients were necessary, 30 in each group.^[24] Type I and II errors were each set at 5% in the computations. Whereas approximately 30% of patients failing to complete the treatment in the pilot study, the same noncompletion rate is assumed for the main sample, resulting in the requirement of at least 90 participants, 45 in each group. This analysis was conducted on R 3.5.0 Statistical Software.

The study complied with the principles of the Declaration of Helsinki and had been approved by the Research Ethics Committee of the School of Nursing at São Paulo University, CAAE 43461315.8.0000.5392, and registered on the Brazilian Clinical Trials Registry (ReBec), number RBR-9337nv, available on <http://www.ensaiosclinicos.gov.br/>, titled as Multimodal nursing intervention to reduce cancer treatment related symptoms.

Randomization

Random assignment to IG or CG was performed by a computer program at a proportion of 1:1. Generated codes were placed in an opaque, sealed, and sequentially number envelope. Each participant received a numbered envelope after finishing the initial assessment. The corresponding envelope was opened by the researcher conducting the recruitment in the presence of the patient, and it determined their allocation in the groups.

Psychoeducational intervention

The theoretical framework used to develop this psychoeducational intervention was Symptom Management Model, which is based on the principal that effective management of symptoms demands that three dimensions must be considered: symptom experience, management strategies, and outcomes.^[25,26] The model was developed by the Center for Symptom Management faculty of the University of California, San Francisco, and it is applicable to symptoms and patient populations in a variety of settings.^[25,26]

The three dimensions of the Symptom Management Model were operationalized through the following

elements: (1) symptom experience – to promote a welcoming environment with emphasis on support, in order to understand the patient’s experience regarding symptoms, (2) management strategies – to teach strategies to cope with symptoms, and (3) outcomes – to establish the patient personal goals related to the management of symptoms and QoL.^[25,26]

In this study, the symptom management strategies included psychoeducation on managing common symptoms in cancer patients and relaxation techniques. The relaxation technique occurred over 15 min in each intervention session and included training in deep breathing, progressive muscle relaxation, and guided imagery. Progressive muscle relaxation technique was adapted from: Jacobson,^[27] and the guided imagery used images from nature, to encourage a sensation of peace and well-being.^[28,29]

Patients from the IG were encouraged to practice the relaxation technique at home, although their compliance with these recommendations was not assessed. Patients also received a folder containing a CD with relaxing songs and a symptom diary to write the occurrence of symptoms between sessions. The organization of the psychoeducational intervention is placed in Table 1.

The psychoeducational intervention was delivered by a research team comprising two nurses and a psychologist. Four undergraduate nursing students were trained to recruit and select patients and also to perform initial and final patient assessments. One of the nurses was the principal investigator, who is specialized in cognitive behavioral therapy, and the other nurse was a master student. The psychologist also had expertise in cognitive behavioral therapy.

Both nurses and the psychologist who delivered the intervention sessions received training and followed a protocol developed by the principal researcher and designed to standardize the activities. The intervention was organized into six sequential weekly sessions. Each session averaged 45 min in length and was applied individually in units

where outpatients were receiving their chemotherapy or radiation therapies.

The CG received the standard treatment given to cancer patients at ICESP, which included information provided in the institution’s health-care routine regarding the patients’ disease such as side effects and symptoms, the recommended forms of treatment, and methods commonly employed to control various symptoms. In addition, information regarding psychosocial support was subsequently provided to patients via telephone. In cases where symptoms of anxiety or depression were reported, patients were encouraged to speak with the physician attending for a proper referral. In cases of social issues, patients were referred to as the institution’s social service for an assessment.

Outcomes measures

This study had primary outcome symptoms such as pain, fatigue, nausea, constipation, diarrhea, insomnia, and loss of appetite which were assessed by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire “Core” 30 (EORTC-QLQ-C30).^[30] The secondary outcome was QoL, which was measured by two global questions of EORTC-QLQ-C30 which were QoL and overall health. Patients were assessed via a sociodemographic and clinical data survey, also by EORTC-QLQ-C30. The participants were recruited from January through March of 2016. The information was collected on two occasions: before starts the intervention and, in the last session, after 6 weeks.

The EORTC-QLQ-C30 questionnaire, which assesses health-related QoL in cancer patients, was already validated for the use with Brazilians.^[31] The psychometric properties were tested, and Cronbach’s alpha coefficients varied from 0.78 to 0.84, except for cognitive functioning, social functioning, and nausea/vomiting that were lower than 0.70.^[31]

Items of EORTC-QLQ-C30 are rated on a Likert scale from 1 (not at all) to 4 (very much), except for two

Table 1: Description of the general content of the psychoeducational nursing intervention

Psychoeducational nursing intervention	1 st week	2 nd week	3 rd week	4 th week	5 th week	6 th week
Personal introduction, expectations, and goals	X					
Expression of feelings, perceptions, and fears	X	X	X	X	X	X
Information about the disease and treatment	X					
Pain control education		X				
Nausea/vomiting and fatigue control education			X			
Constipation and diarrhea control education				X		
Sleep hygiene education					X	
Coping improvement strategies					X	X
Problem-solving technique			X	X	X	
Relaxation technique	X	X	X	X	X	X
Review of learning, skills acquired, and progress made						X

global QoL items, which are rated from 1 (very poor) to 7 (excellent).^[30,31] It is composed of 30 questions that encompass five functional scales, three symptom scales, one overall health/QoL scale, five items related to symptoms, and one item that assesses the financial disease's treatment impact. All items are linearly transformed to a 0–100 scale. For the functioning and global QoL scales, a higher score represents a better QoL. In contrast, a higher score for a symptom scale represents a greater symptom's intensity.^[30,31]

Statistical analysis

Data are presented as absolute and relative frequencies, mean, standard deviation (SD), and medians. Sociodemographic and clinical data baseline traits from both the groups were compared using Chi-square test, or Fisher's exact test and Student's *t*-test were used for categorical and numerical variables, respectively. Longitudinal analysis of the main outcomes was run with a linear mixed-effects model on all available information; interaction plot group × time was constructed to find out results which presumed as relevant. All analyses were conducted on the Statistical Software R 3.5.0, intention-to-treat analysis was used, and $P < 0.05$ was considered statistically significant.

Results

Characteristics of the sample

A total of 162 patients were assessed for eligibility: 23 did not meet the inclusion study's criteria and 32 declined participation. The major reasons for declining to participate were lack of time, lack of interest, and discomfort. Therefore, the study's sample included 107 participants: 52 allocated to IG and 55 allocated to the CG. Three patients originally allocated to IG did not receive the intervention (due to lack of time or changes in treatment scheme) and migrated to the CG. Thereby, 49 patients received the intervention (IG) and 58 were CG [Figure 1]. The final number of participants after considering the dropout rate was 67.

Table 1 displays a summary statistic of participants in the total sample, as well as by IG. The following characteristics were women (56.1%), having a partner (61.7%), mean of 55.1 years of age, 10 years of study's education, and household income mean of U\$ 87,200 by month.

The most frequent cancer was gastrointestinal (50.0%), followed by breast (24.5%), prostate (8.5%), and other types (17%). The diagnosis mean time was 13.1 months (SD = 16.5), and 67.6% were currently undergoing chemotherapy. In the comparison characteristics to two groups (IG and CG), there was no significant difference for any of the variables examined ($P > 0.05$), indicating similar characteristics between the groups [Table 2].

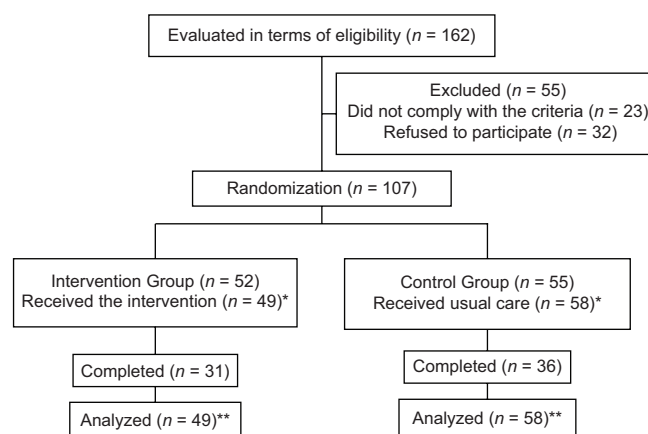


Figure 1: Flowchart of patients in the study. *Three patients originally allocated to the intervention group did not receive the intervention (due to lack of time or change in treatment scheme) and migrated to the control group. **Follow-up losses were included in the analysis since intention-to-treat analysis was used (intervention group = 18; control group = 22)

Prevalence and intensity of symptoms

The prevalence of symptoms occurring the most was as follows: fatigue (76.6%), insomnia (47.7%), and pain (42.1%), followed by loss of appetite (37.4%), nausea/vomiting (33.6%), constipation (27.1%), diarrhea (26.2%), and dyspnea (18.7%). An analysis of symptom intensity by EORTC-QLQ-C30 scores showed that insomnia was the most harmful symptom (30.5%), followed by fatigue (29.2%), loss of appetite (25.6%), and pain (22.0%). There were no statistically significant differences in the evolution of QoL or functionality scores between the treatment group and CG [Table 3]. However, there was a significant improvement in loss of appetite ($P = 0.002$) and a tendency toward the improvement of insomnia ($P = 0.053$) in the IG. On the other hand, there was a significant deterioration in dyspnea ($P = 0.007$) which was not expected [Table 4].

Discussion

The present clinical trial tested the effects of a psychoeducational nursing intervention which included educational strategies and relaxation techniques to improve symptom management and QoL in patients undergoing treatment for various cancers.

The intervention was designed to improve patients coping mechanisms with common cancer treatment symptoms by promoting a welcoming environment and emphasizing support and understanding of the difficulties they were facing. Results indicated that the intervention had significantly improved appetite which is one of the most frequent symptoms in the study sample.

The multitude of symptoms experienced by cancer patients in this study includes a high prevalence of fatigue, insomnia,

Table 2: Characteristics of the total sample, intervention group and control group

Variables	Total sample (n=107)	IG (n=49)	CG (n=58)	P
Gender				
Male	47 (43.9)	20 (40.8)	31 (53.4)	0.551
Female	60 (56.1)	29 (59.2)	27 (46.6)	
Age (year)				
Mean (SD)	55.2 (11.1)	55.6 (11.3)	54.8 (10.8)	0.692
Median	57.0	57.0	56.5	
Education (year)				
Mean (SD)	10.20 (4.5)	10.8 (3.8)	9.7 (4.9)	0.203
Median	11.0	11.0	10.0	
Household income				
Mean (SD)	R\$ 3408.1 (R\$ 3174.3)	R\$ 3809.5 (R\$ 3939.9)	R\$ 3069.6 (R\$ 2288.0)	0.262
Diagnosis				
Breast cancer	26 (24.5)	10 (20.4)	16 (28.1)	0.462
Prostate cancer	9 (8.5)	06 (12.2)	03 (5.3)	
Colorectal cancer	53 (50.0)	26 (53.1)	27 (47.4)	
Other	18 (17.0)	07 (14.3)	11 (19.3)	
Diagnosis time (month)				
Mean (SD)	13.1 (9.0)	10.9 (11.9)	14.9 (19.4)	0.262
Current treatment				
Chemotherapy	71 (67.6)	31 (66.0)	40 (69.0)	0.743
Radiation therapy	34 (32.4)	16 (43.0)	18 (31.0)	
Metastasis				
Yes	33 (37.5)	16 (38.1)	17 (37.0)	0.912
No	55 (62.5)	26 (61.9)	29 (63.0)	

IG: Intervention group; CG: Control group; SD: Standard deviation

Table 3: Comparison of quality of life and functionality between the two groups before and after the psychoeducational intervention

Variables	Mean (SD)		P ^a
	Intervention group	Control group	
Quality of life (global)			
Baseline	69.1 (23.4)	72.7 (24.0)	0.365
Postintervention	76.3 (18.0)	74.1 (21.2)	
Difference	7.2	1.4	
Physical function			
Baseline	71.4 (27.0)	71.4 (23.8)	0.348
Postintervention	79.6 (19.5)	72.0 (24.8)	
Difference	8.2	0.6	
Role function			
Baseline	74.2 (35.0)	77.0 (27.4)	0.243
Postintervention	81.7 (28.0)	72.7 (31.9)	
Difference	7.5	- 4.3	
Emotional function			
Baseline	65.5 (29.2)	70.3 (23.0)	0.601
Postintervention	69.4 (26.7)	73.5 (25.7)	
Difference	3.9	3.2	
Cognitive function			
Baseline	77.9 (24.4)	78.7 (27.5)	0.687
Postintervention	77.4 (27.7)	76.9 (29.1)	
Difference	-0.5	-1.8	
Social function			
Baseline	66.7 (34.0)	79.6 (29.3)	0.904
Postintervention	68.8 (34.4)	77.8 (28.7)	
Difference	2.1	-1.8	

^aGroup × time interaction effect from a linear mixed-effects model. SD: Standard deviation

pain, and loss of appetite. These findings corroborated with previous research that identified similar rates.^[1,2,32,33]

Nursing interventions with psychoeducational strategies have yielded good results in controlling symptoms such as pain and fatigue.^[34-36] However, psychoeducational or multimodal interventions have been tested less frequently.^[37,38] Monitoring of symptoms has also been beneficial to cancer patients in terms of improved QoL and increased survival rates. This is partially due to the rapid response of nurses to patients' symptoms, which mitigates adverse complications.^[39,40]

Loss of appetite in cancer patients is a serious clinical problem and can be related to nausea, changes in the way how food tastes, and metabolic changes associated with the disease and treatment.^[41] Over time, specifically in mid and long terms, loss of appetite can lead to malnutrition, anemia, loss of physical functionality, and lower treatment response.^[42] Therefore, improved appetite has a significant impact on the overall state of patients and treatment results.

The improvement observed in patient appetite among the IG cannot be explained clearly by the educative strategies, but this effect may be related to the relaxation technique that has had positive effects on symptom control in patients with cancer.^[43]

Insomnia affects a significant portion of cancer patients, and it is tied to various emotional symptoms and physical repercussions of the disease. It may exacerbate fatigue and

Table 4: Comparison of the evolution of symptoms between the two groups

Variables	Mean (SD)		P*
	Intervention group	Control group	
Fatigue			
Baseline	32.6 (32.3)	26.2 (23.2)	0.391
Postintervention	28.3 (25.1)	29.0 (25.9)	
Difference	-4.3	2.8	
Nausea and vomiting			
Baseline	11.9 (25.2)	14.1 (24.1)	0.882
Postintervention	11.8 (18.4)	9.7 (18.0)	
Difference	-0.1	-4.4	
Pain			
Baseline	24.8 (34.5)	19.5 (31.1)	0.220
Postintervention	16.1 (21.7)	20.4 (32.4)	
Difference	-8.7	0.9	
Dyspnea			
Baseline	2.7 (9.2)	12.1 (22.3)	0.007
Postintervention	11.8 (26.6)	6.5 (15.6)	
Difference	9.1	-5.6	
Insomnia			
Baseline	34.7 (37.2)	27.0 (37.2)	0.053
Postintervention	21.5 (33.9)	32.4 (38.6)	
Difference	-13.2	5.4	
Loss of appetite			
Baseline	34.7 (41.9)	17.8 (32.0)	0.002
Postintervention	14.0 (28.3)	20.4 (34.1)	
Difference	-20.7	2.6	
Constipation			
Baseline	23.1 (36.1)	12.1 (27.0)	0.344
Postintervention	23.6 (35.7)	17.6 (33.3)	
Difference	0.5	5.5	
Diarrhea			
Baseline	12.9 (24.4)	12.6 (24.8)	0.658
Postintervention	16.1 (30.9)	17.6 (29.3)	
Difference	3.2	5.0	

*Group × time interaction effect from a linear mixed-effects model. SD: Standard deviation

pain and can reduce functionality and increase infection risk.^[9,44,45] A tendency of sleep disturbances improvement was observed in the IG. Those findings could be enhanced to patients' mood, auto perception of well-being and functionality, and in the case of this study it might was a result of relaxation techniques which allows better sleep levels.

Dyspnea scores had increased significantly in the IG, and it was not expected. This finding can be explained by the disease progression, or the fact of the relaxation technique includes deep breathing training, and it may change the patient's perception of this symptom. The prevalence and intensity of dyspnea in this study were lower than in previous research. This finding may be further investigated in future studies.

This psychoeducational intervention did not improve QoL significantly, which may be a result of the scope of the intervention, which was designed primarily to minimize

symptoms and perhaps impact QoL, as a secondary outcome. Unfortunately, the intervention only improved appetite which was not enough to impact QoL.

In addition, diverse patient characteristics, including various types of cancer and different symptom manifestations found in this study, may have played a role in the findings. Future research examining psychoeducational interventions for managing symptoms may focus on a specific type of cancer, one symptom cluster, and must also consider the intensity of symptoms when establishing inclusion criteria.

Limitations and implication for practice

This RCT has limitations, which are going to be pointed out. The relatively small sample size and the fact that the study was conducted in a single cancer treatment institution potentially limit the generalizability of the findings. Furthermore, no minimum criteria were established for the occurrence of symptoms, resulting in the inclusion of patients with different clinical manifestations and diverse care needs. This may impact findings since a patient's response to intervention treatments may vary by disease progression or symptom intensity.

Despite the limitations of this study, it had a potential benefit based on the psychoeducational nursing intervention which affected positively appetite issues make that intervention applicable to other contexts faced for cancer patients. The application of this intervention in future research may contribute to refine this kind of intervention and perhaps contribute to improving symptom management and QoL of these patients.

Conclusions

The psychoeducational intervention focused on education about symptom management and relaxation techniques significantly reduced appetite loss in cancer patients undergoing chemotherapy and radiation therapy. Despite no effects observed in global QoL or functionality, the intervention yielded a tendency to improve insomnia, and this outcome should be investigated in future studies.

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Conflicts of interest

There are no conflicts of interest.

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