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# Effect of Education and Telephone Counseling on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors in Patients with Cancer: A Randomized Clinical Trial

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## Abstract

**Background:** Cancer treatment has been increasingly fulfilled on an outpatient basis by family caregivers. The variety and severity of caregivers' responsibilities expose them to physical and mental risks. Investigating the effect of education and telephone counseling on patient and family outcomes requires performing further studies.

**Aim:** This study aimed to determine the effect of education and telephone counseling on caregiver strain and unmet needs in family caregivers and self-care behaviors in cancer patients.

**Method:** The present randomized controlled trial was conducted on 60 caregivers-cancer patients referred to urban health education clinics in northeastern Iran within 2018-2019. A 20-minute face-to-face training session was held for the caregivers of cancer patients, and seven training pamphlets were given to the caregivers. Moreover, the intervention group received four telephone counseling sessions during three courses of chemotherapy. The strain and unmet needs of caregivers were measured by the Zarit Burden Interview and Supportive Care Needs Survey-Partners and Caregivers questionnaires, respectively. The patient self-care was assessed by the Nail Self-care Diary questionnaire. The data were analyzed by SPSS software (version 16) using an independent t-test and paired t-test.

**Results:** The mean values of caregivers' age were  $38.9 \pm 12.7$  and  $37.7 \pm 8.6$  years in the intervention and control groups, respectively. The results of the independent t-test showed no statistically significant difference between the two groups ( $P=0.42$ ). The results also revealed that the mean scores of caregiver strain and unmet needs decreased following the intervention, and the mean scores of self-care behaviors increased in the intervention group after the intervention ( $P=0.001$ ).

**Implications for Practice:** Education and telephone counseling can simultaneously help to follow up problems, improve self-care behaviors in cancer patients, alleviate the caregiver strain, and meet the needs of family caregivers.

**Keywords:** Caregiver strain, Family caregivers, Telephone counseling, Self-care, Supportive care needs

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## Introduction

There have been reported about 18.1 million new cases of cancer and 9.6 million cancer deaths in 2018. Cancer is predicted to be the leading cause of mortality and most important barrier to increasing life expectancy in any country in the 21<sup>st</sup> century (1). Cancer treatment is mostly fulfilled on an outpatient basis and relies on informal caregivers, especially families. Caregiver activities include bathing, transporting, dressing, therapeutic drug monitoring, and managing the side effects (2,3). These responsibilities impose a huge burden and strain on caregivers; however, they are not sufficiently trained for this role (2).

Helping a cancer patient to cope with illness and provide emotional supports are among the most difficult responsibilities of caregivers (4,5). The results of studies showed that the caregivers are at high risk of physical, mental, and social problems, as well as prone to change in social roles (2,6). Unmet needs are defined as the difference between the deemed support necessary to face a challenge and received actual support. Failure to recognize information and support needs can affect the health of caregivers and cause caregiver strain (7). The unmet needs endanger the life quality of patients and caregivers (8).

The evidence showed that there is a need to expand services for caregivers, who are typically deprived of support services (6,9). Learning to manage the side effects of chemotherapy can help alleviate patients' anxiety and improve self-care behaviors (10). Since cancer treatment is currently performed in outpatient centers and the duration of treatment is short, most patients have difficulty learning and remembering due to strain and anxiety; therefore, it is necessary to follow up on the given training (11).

The telephone counseling can prevent patients from wasting time and rehospitalizing and increase the cost-effectiveness, quality, and availability of services (12). The use of telephone counseling reduces costs, facilitates access to patients, improves communication between the patient and caregivers, and removes barriers to time and space (13). Kouchakinejad et al. (2016) showed that telephone follow-up decreases caregiver strain (14). In addition, Bastani et al. (2012) reported that group discussion and telephone counseling reduced perceived stress in caregivers (15). Fong et al. (2014) demonstrated that the smartphone psychoeducation program reduced caregivers' strain and increased their quality of life (16). Nevertheless, Heckel et al. (2018) reported that the telephone outcall program reduced the unmet needs of caregivers, but not the caregivers' burden (17).

The data obtained from health education clinics suggest that attending face-to-face training sessions is often difficult due to the unhealthy condition of the patient and busy caregivers, and subsequent visits to counseling centers are irregular despite the patient's needs. Therefore, education and telephone counseling can be effective in following up given training according to the literature.

Based on the evidence, a limited number of studies have been performed on cancer patient caregivers in Iran. In addition, the available articles have often considered outcomes for a group of caregivers or patients; however, the present study examined the outcomes of both groups simultaneously. Emotional support was also provided during telephone counseling, as a gap in most previous studies. With this background in mind, the current study aimed to determine the effect of education and telephone counseling on caregiver strain and unmet needs in family caregivers and self-care behaviors in patients with cancer.

## Methods

The present randomized controlled trial was carried out on 60 caregivers-patients with esophageal, stomach, and colorectal cancers referred to urban health education clinics in northeastern Iran within 2018-2019. The participants were randomly assigned to two intervention and control groups using a randomized complete block design. As a result, the list of four blocks was determined by someone other than the researcher through a simple draw. Given that all dependent variables in this study were quantitative, the sample size was estimated using the formula of determining the sample size based on the comparison of the mean values of two-population dependent variables. Furthermore, a 95% confidence interval and 80% test power were considered.

The sample sizes were estimated to be 17 and 24.5 based on the variables of caregiver strain and unmet needs, respectively, using mean parameters and standard deviation according to the findings of a study by Heckel et al. in 2018 (17). In addition, the results of a study performed by Behboudifar et al. in 2018 (18) were used to calculate the sample size based on the self-care variable, which was

estimated to be 23.45 in each group.

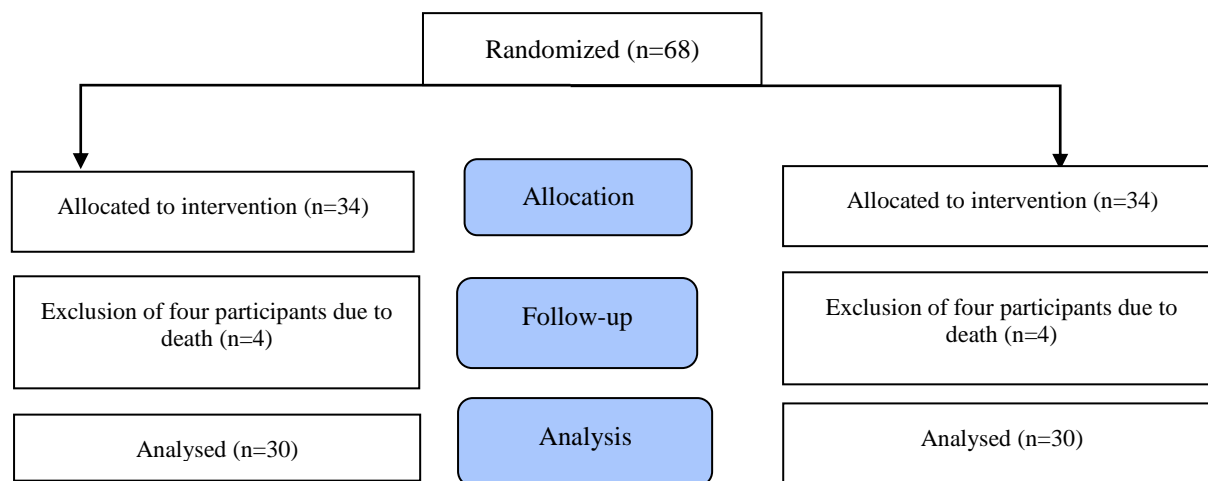
The sample size was considered to be 25 patients-caregivers per group. Finally, 34 patients-caregivers enrolled in the study with the consideration of sample attrition. In both intervention and control groups, four patients were excluded from the study due to patient death. Eventually, the sample size in each group reached 30, and a total of 60 patients-caregivers were statistically analyzed (Figure 1).

Sampling began on January 21<sup>st</sup> in 2019 and lasted for 5 months. The inclusion criteria for the patients were willingness to participate in the study, signing informed consent, definitive diagnosis of esophageal, stomach, and colorectal cancers, candidate for the treatment of three courses of chemotherapy, age range within 18-65 years, ability to read and write in Persian, no speech and hearing problems, and access to a telephone. The inclusion criteria for the caregivers were willingness to participate in the study, signing informed consent, primary caregiver of the patient, ability to read and write in Persian, no speech and hearing problems, access to a telephone, and no history of mental illness. The informed written consent to participate in the study was obtained from the participants who met the inclusion criteria after explaining the objectives and methodology of the research in the training session. The exclusion criteria included nonresponse to phone calls after three calls, stressful events for caregivers and patients, three incomplete questionnaires, inappropriate general condition of the patient, and caregiver participation in support groups.

Prior to the intervention, demographic profile and caregiver strain and unmet needs questionnaires were completed by the caregivers. In addition, demographic profile and self-care behavior questionnaires were filled out by the researcher in the interviews with patients. The caregiver strain and caregiver unmet needs were measured using the Zarit Burden Interview (ZBI) and Supportive Care Needs Survey-Partners and Caregivers (SCNS-P&C45) questionnaires, respectively. The questionnaires were completed by the caregivers in both intervention and control groups at the baseline.

After the intervention, the questionnaires were completed by visiting the clinic in person or during the fourth course of chemotherapy after entering the study or visiting the doctor 7 to 10 days after the last phone call. In the 22-item ZBI questionnaire, primary caregivers were asked to report their feelings about caring for someone else. The severity of caregiver strain was determined by a 5-point Likert scale, scoring from 0 to 4. The ZBI questionnaire is a standard tool for the measurement of caregiver strain, whose validity was confirmed by Gonçalves-Pereira (19). The instrument reliability was reported to be 0.9 by internal consistency and 0.94 by the test-retest method according to studies by Jennifer et al. in 2013 (20) and Navidian et al. in 2008 (21), respectively.

In the 45-item SCNS-P&C45 questionnaire, the primary caregivers asked to identify the items that needed help as a result of caring for a person with cancer last month. The levels of needs were determined based on a 5-point Likert scale scoring from 1 to 5. This questionnaire is a standard tool for the measurement of the unmet needs of caregivers, whose validity was confirmed by Girgis et al. in 2011 using construct validity (22). Because the Persian version of this tool was not available, the questionnaire was translated and translated back by three professors from the Department of Foreign Languages at Mashhad University of Medical Sciences and then presented to seven faculty members



**Figure 1. Flow chart of research process**

of Mashhad University of Medical Sciences, Mashhad, Iran.

The accuracy of the translation and its validity were confirmed by content validity. The reliability of this questionnaire was corroborated by Girgis et al. (2011) with Cronbach's alpha coefficient of 0.88 to 0.94 (8, 22). This tool was completed in this study by 15 people at the same session, and the reliability of the questionnaire was confirmed by Cronbach's alpha coefficient of 0.75. The questionnaire was filled out by the caregivers in both intervention and control groups at the baseline in the face-to-face training session.

After the intervention, the questionnaire was completed by visiting the clinic in person or during the fourth course of chemotherapy after enrolling in the study or visiting the doctor 7 to 10 days after the last phone call. The Nail Self-care Diary questionnaire was completed for the patients before and after the intervention through a telephone interview.

In the present study, the procedure was holding a face-to-face and individual 20-minute training session only for the caregivers of cancer patients at Ghaem (n=4), Omid (n=40), and Imam Reza (n=16) teaching health clinics in both intervention and control groups. Before the training, according to the American Cancer Society, the patient training requirements included demographic characteristics, cancer symptoms, treatment side effects (e.g., nausea, vomiting, fever and chills, fatigue, canker sores, diarrhea, and constipation), educational needs, and problems of the patient through a primary caregiver. Then, the caregivers were briefly explained how to care for the patient, nutrition, activity and rest, infection prevention, drug management, and side effects of chemotherapy.

At the end of the session, seven education and training pamphlets were provided to the caregivers of both groups. The educational content was the same in both groups. In the intervention group, the intervention method was that in addition to face-to-face training and educational pamphlets, they received four telephone counseling sessions during the three courses of chemotherapy (two calls in the first course of chemotherapy after enrolling in the study and one call in the second and third courses of chemotherapy).

The first phone call was made to the patient a week after receiving the chemotherapy drug from a trained researcher. The approximate time and date of the first call were coordinated with the patient caregiver at the end of the individual training session. The second call was a week after the first call. The third and fourth phone calls were made a week after undergoing chemotherapy during the second and third courses of chemotherapy. In the second to fourth phone calls, education and counseling were given only to caregivers based on the needs. Each telephone counseling session lasted for 15 to 20 min. If the participants needed, it was possible to extend the call time to 30-40 min.

In the first telephone counseling session with the patient, the educational content on the patient problems was reviewed, and the patient was trained about self-care. Since the second session of telephone counseling, which was conducted with the caregiver, the caregiver was trained for the signs and symptoms of nursing detection of caregiver role strain and needs, derived from Sparks and Taylor's Nursing Diagnosis Reference Manual. If the caregiver strain and unmet needs are present or possible, interventions will be performed according to standard measures (23). The educational content of telephone counseling for the caregivers included the management of symptoms in the second session, reduction of ambiguities and formation of optimistic attitudes in the third session, and effective coping skills in the fourth session.

The present study was approved by the Ethics Committee of Mashhad University of Medical Sciences (1397, 056IR.MUMS.REC). The ethical considerations observed in this study included providing information about study objectives, having the right to choose the time of intervention, obtaining written consent, being free to withdraw at any stage of the intervention, ensuring the confidentiality of the obtained information, and reporting the research results to participants and officials.

The collected data were analyzed by SPSS software (version 16). Frequency, percentage, as well as mean and standard deviation, were determined using descriptive statistics. A p-value less than 0.05 was considered statistically significant. The normal distribution of quantitative and qualitative data was determined by the relevant tests, namely the Kolmogorov-Smirnov and Shapiro-Wilk tests. The two groups were homogeneous in terms of all intervention and background variables using an independent t-test, Mann-Whitney U, Chi-square, Chi-square exact, and Fisher's exact tests.

## Results

The mean values of caregivers' age were  $38.9 \pm 12.7$  and  $37.7 \pm 8.6$  years in the intervention and control groups, respectively. The mean scores of patients' age were  $53.2 \pm 10.3$  and  $56.6 \pm 9.4$  years in the intervention and control groups, respectively. The results of the independent t-test showed no significant statistical difference in the mean age of the caregivers and patients between the two groups ( $P= 0.42$  and  $P=0.19$ , respectively). Therefore, the results of statistical tests revealed that the two groups were homogeneous in terms of age and other variables. In addition, there was no significant statistical difference between the two groups in this regard (Table 1).

**Table 1. Demographic profiles of study participants**

Variable	Intervention group n (%) or mean±standard deviation	Control group n (%) or mean±standard deviation	P-value
Age of caregivers (year)	$38.9 \pm 12.7$	$37.7 \pm 8.6$	0.42*
Gender of caregivers			
Female	21 (70)	19 (63.3)	0.35**
Male	9 (30)	11 (36.7)	
Marital status of caregivers			
Single	2 (6.7)	4 (13.3)	
Married	27 (90.0)	24 (80.0)	0.30***
Divorced	0 (0.0)	2 (6.7)	
Deceased spouse	1 (3.3)	0 (0.0)	
Educational level of caregivers			
Primary school	4 (13.3)	9 (30.0)	
Secondary school	7 (23.4)	4 (13.3)	0.15**
High school	10 (33.3)	11 (36.7)	
Academic degree	9 (30.0)	6 (20.0)	
Duration of patient care (month)	$16.2 \pm 13.9$	$17.5 \pm 13.4$	0.65****
Age of patients	$53.2 \pm 10.3$	$56.6 \pm 9.4$	0.19*
Gender of patients			
Female	19 (63.3)	19 (63.3)	0.75**
Male	11 (36.7)	11 (36.7)	
Marital status of patients			
Single	23 (76.7)	25 (83.3)	
Married	1 (3.3)	0 (0.0)	0.75**
Divorced	0 (0.0)	0 (0.0)	
Deceased spouse	6 (20)	5 (16.7)	
Educational level of patients			
Primary school	13 (43.3)	24 (80.0)	
Secondary school	5 (16.7)	3 (10.0)	0.32**
High school	4 (13.3)	1 (3.3)	
Academic degree	7 (26.7)	2 (6.7)	
Type of disease			
Esophageal cancer	3 (10.0)	4 (13.3)	
Colorectal cancer	22 (73.3)	18 (60.0)	0.63**
Stomach cancer	5 (16.7)	8 (26.7)	
Disease metastasis			
Metastatic	16 (53.3)	14 (46.7)	0.61**
Nonmetastatic	14 (46.7)	16 (53.3)	
Disease stage			
Stage 2	9 (30)	12 (40)	0.02**
Stage 3	21 (70)	18 (60)	
Duration of disease (month)	$14.0 \pm 16.2$	$11.8 \pm 14.2$	0.53****

\* Independent t-test

\*\* Chi-square test

\*\*\* Fisher's exact test

\*\*\*\* Mann-Whitney U test

**Table 2. Comparison of mean values of strain and unmet needs of caregivers and self-care of patients in two intervention and control groups**

Variable	Dimension		Intervention group (mean±standard deviation)	Control group (mean±standard deviation)	Intergroup test results (difference between before and after intervention) (P-value)	Intragroup test results (P-value)		Variable
						Control group	Intervention group	
Caregiver strain								
Personal	Before intervention		22.8±3.2	21.3±3.4	0.001*	0.06**		0.001**
	After intervention		11.9±2.9	22.2±3.0				
Emotional	Before intervention		12.6±3.1	11.7±3.2	0.001*	0.54**		0.001**
	After intervention		8.3±1.9	11.9±2.9				
Social	Before intervention		10.0±1.9	9.0±2.3	0.001*	0.19**		0.001**
	After intervention		5.4±1.9	9.4±2.2				
Economic	Before intervention		3.7±1.9	4.1±1.3	0.06*	0.83***		0.09***
	After intervention		3.3±1.6	4.1±1.2				
Total	Before intervention		49.1±7.9	46.2±7.0	0.001*	0.01**		0.001**
	After intervention		28.9±5.1	47.6±6.3				
Unmet needs								
Information needs	Before intervention		27.6±4.2	26.6±3.8	0.001*	0.004**		0.001**
	After intervention		17.9±3.6	24.3±3.8				
Psychoemotional needs	Before intervention		48.9±7.2	46.9±6.5	0.001*	0.01**		0.001**
	After intervention		38.5±6.8	48.0±5.4				
Daily life needs	Before intervention		11.8±2.7	11.7±3.5	0.003*	0.31**		0.001**
	After intervention		9.4±2.4	11.3±2.4				
Financial-legal needs	Before intervention		13.0±2.4	12.7±2.0	0.74*	0.89**		0.51**
	After intervention		12.8±2.6	12.6±2.0				
Healthcare service needs	Before intervention		48.6±6.0	48.8±5.7	0.001*	0.65**		0.001**
	After intervention		44.3±7.2	49.1±5.2				
Communication and interpersonal needs	Before intervention		11.2±2.9	10.5±2.8	0.001*	0.06**		0.001**
	After intervention		9.4±3.0	11.6±2.8				
Total	Before intervention		161.9±14.6	157.1±11.7	0.001*	0.89**		0.001**
	After intervention		131.4±14.9	157.0±9.3				
Self-care								
	Before intervention		1.6±0.4	1.5±0.3	0.001*	0.001*		0.001*
	After intervention		3.8±0.3	1.7±0.3				

\* Independent t-test

\*\* Paired sample t-test

\*\*\* Wilcoxon test

There was no statistically significant difference in the mean total scores of caregiver strain between the intervention (49.1±7.9) and control (46.2±7.0) groups before the intervention (P=0.13). However, the results of the independent t-test showed a significant difference in the mean total score of caregiver strain between the intervention (28.9±5.1) and control (47.6±6.3) groups after the intervention (P=0.001). Regarding the intragroup comparisons, the results of the paired t-test indicated that the intervention group had a significant decrease in the total score of all dimensions (P<0.001); however, no significant difference was observed in the control group (P=0.01; Table 2).

There was no statistically significant difference in the mean total score of unmet needs between the intervention (161.0±14.6) and control (157.1± 1.7) groups before the intervention (P=0.17). Nevertheless, there was a significant difference in the mean total scores of unmet needs between the intervention (131.4±14.9) and control (157.0±9.3) groups after the intervention (P=0.001). Considering the intragroup comparisons, the results of the paired t-test revealed that the intervention

group had a significant decrease in the total scores of all dimensions ( $P=0.001$ ); nonetheless, there was no significant difference in the control group ( $P=0.89$ ; Table 2).

There was no statistically significant difference in the mean scores of self-care behaviors between the intervention ( $1.6\pm 0.4$ ) and control ( $1.5\pm 0.3$ ) groups before the intervention ( $P=0.30$ ); nevertheless, the results of the paired t-test suggested a significant difference in the mean scores of self-care behaviors between the intervention ( $3.8\pm 0.3$ ) and control ( $1.7\pm 0.3$ ) groups after the intervention ( $P=0.001$ ). In terms of the intragroup comparisons, the results of the paired t-test showed a significant decrease in the scores of self-care behaviors in both the intervention ( $P=0.001$ ) and control ( $P=0.001$ ) groups (Table 2).

## Discussion

The results of the present study showed that the education and telephone counseling could reduce caregiver strain among the family caregivers of patients with cancer in terms of overall dimensions, other than economic dimension, significantly in the intervention group. However, the caregiver strain did not make a significant difference in the control group.

Torabi et al. (2017) examined the caregivers of patients undergoing hemodialysis and demonstrated that the mean total score of caregiver strain, except for the economic dimension, decreased after the intervention (24). In the aforementioned study, six group discussion sessions were held for the intervention group, and the posttest results showed that the group discussion could reduce the total score of caregiver strain by 7.54 points.

In the present study, education and telephone counseling also significantly decreased the total score of caregiver strain by 20.2 in the three courses of chemotherapy. In the current study, the caregiver strain reduced to a greater extent because the patient and caregiver were taken into consideration at the same time and each caregiver's problems with their family and patient were considered. In the current study, no difference was observed in the economic dimension of caregiver strain. This result might be due to lack of financial support for the present study, high costs of treatment and cancer drugs, as well as lack of health insurance coverage.

Kouchakinejad et al. (2016) indicated that education and telephone counseling for patients and caregivers cause to significantly reduce caregiver strain in the intervention group (14). In the aforementioned study, the intervention consisted of two training sessions and four phone calls. According to the results, the mean score of caregiver strain significantly changed up to 3.5 points in the intervention group. In the present study, the total score of caregiver strain decreased by 20.2 points in the intervention group which could be due to the purposeful telephone counseling simultaneous with the patient chemotherapy courses.

The caregiver and patient require this purposeful telephone counseling to a great extent to solve cancer problems, with support needs and emotional support. During the intervention, if severe emotional involvement overshadowed the caregivers' ability, they would be advised to seek help from family members, friends, community volunteers, home health agencies, or day-care centers to increase adaptability and care.

In a study carried out by Heckel et al. (2018), with three telephone calls in the intervention group, the results showed that the phone calls had no effect on the strain of the cancer patient caregiver (17). They argued that the reason for this could be the enrollment of caregivers with low levels of strain and newly diagnosed cancer patients in their study that limited changes in caregivers. The differences in the results of the present study might be due to the fact that the intervention was performed for cancer patients with a previous history of chemotherapy, but not in the end-stage, whose caregivers experienced strain so that the effect of the intervention can be followed up on the caregiver strain.

The results of the present study demonstrated that education and telephone counseling for caregivers significantly reduced the unmet needs in the caregivers of cancer patients in all dimensions, other than the financial-legal needs, in the intervention group. Heckel et al. (2018) reported that the telephone call program could decrease the unmet needs of caregivers. Failure to identify information and support needs can affect the health of caregivers and cause caregiver strain (17). In the aforementioned study, the telephone calls fulfilled the information needs of caregivers. The information was provided to caregivers about community resources and support services, and the patients and caregivers were trained for self-care strategies.

In addition, the caregivers were asked to communicate effectively with the patient and other family



members, seek help from children, relatives, as well as close friends, and share the work. The attempts were made to advise caregivers about the patient problems and complaints at each phone call, and the caregivers were encouraged to adopt a healthy lifestyle. These measures were related to the questions and needs of the caregivers and may reduce the unmet needs of the caregivers. There has been no decrease in the financial-legal needs due to a lack of financial support for the results of the aforementioned study, as well as the high costs of medication and cancer treatment.

The results of the present study showed that education and telephone counseling significantly improved cancer patient self-care behaviors in the intervention group and slightly enhanced the self-care behaviors of patients in the control group. Therefore, education on side effects and self-care behaviors can reduce the side effects of cancer therapies and ultimately improve self-care behaviors. Piamjariyakul et al. (2010) examined cancer therapy-related symptoms and self-care in Thailand. They indicated that people with higher levels of self-care attitudes experienced more limited side effects (25).

In a study conducted by Behboudifar et al. (2018), it was shown that teaching self-care behaviors to the intervention group significantly improved self-care behaviors in patients with cancer, compared to those reported for the control group (26). In the present study, education and telephone counseling could improve patient self-care behaviors in both the intervention and control groups. In this regard, the mean self-care score increased up to 2.2 and 0.2 points in the intervention and control groups, respectively.

The improvement in both groups was due to the fact that the control group, similar to the intervention group, received a face-to-face training session and educational pamphlets. In addition, further improvement in the intervention group might be due to one more telephone counseling session. One of the limitations of the present study was the impossibility to limit the sample size to a specific type of cancer and delayed follow-up due to a lack of time and sufficient participants.

### **Implications for Practice**

Given the effectiveness of education and telephone counseling in reducing the strain and unmet needs of caregivers, as well as increasing the self-care behaviors of patients regarding the side effects of chemotherapy, this method can be included in the educational curriculum. Since the use of the telephone as a tele-education tool was confirmed in the present study, it is recommended to nursing managers to use telephone counseling, along with the conventional method, in cancer health treatment centers. In addition, the results of this study can provide an opportunity to familiarize and empower nurses to follow this method. It is suggested to carry out further studies to investigate the long-term effects of education and telephone counseling on patients and care givers.

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### **Conflicts of Interest**

The authors declare that there is no conflict of interest.

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