## **Original Article**

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# The Effects of Nurse-Led Telephone-Based Support on Supportive Care Needs Among Women with Breast Cancer: A Randomized Clinical Trial

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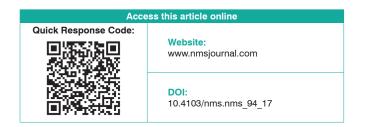
Background: Patients with breast cancer (BC) need to be supported in all aspects of their lives. Objectives: This study aimed to evaluate the impacts of nurse-led telephone-based support on supportive care needs (SCNs) in women with BC. Methods: This two-group randomized clinical trial was conducted on 62 women with BC who were randomly assigned to two groups to either receive telephone-based support (n = 31) or conventional care routinely provided to patients with BC (n = 31). Patients' SCNs were assessed before, 2 weeks, and 1 month after the intervention onset using the SCNs Survey -Short Form 34 The data were analyzed through the repeated-measures analysis of variance and the Bonferroni's, Chi-square, Fisher's exact, independent-sample t, and Mann-Whitney U-tests. Results: Significant decreases were observed in the mean scores of SCNs in both groups (P < 0.001), though the decrease in the intervention group was much greater than the control group (39.08 vs. 2.87). Baseline mean score of SCNs in the intervention group was significantly greater than the control group (P = 0.008); however, 2 weeks and 1 month after the intervention onset, the mean score in the intervention group was significantly lower than the control group (P < 0.05). Conclusion: Telephone-based support is effective in addressing and reducing SCNs among patients with BC.

**KEYWORDS:** Breast cancer, Supportive care needs, Telephone support

#### Introduction

Breast cancer (BC) is the most common cancer among women and has the highest mortality rate among patients with cancer in Iran. Its prevalence and mortality rates in Iran are 24.5% and 14.2%, respectively. The peak incidence age of BC in Iran is in the fourth and the fifth decades of life, which is 10 years earlier than the global peak incidence age.

BC and its treatment-associated complications cause patients many difficulties, affect one or several systems of the body,<sup>[3]</sup> and impair patients' physical, psychological, social, and spiritual well-being.<sup>[4]</sup> Therefore, patients with BC need serious care and support<sup>[5]</sup> to fulfill their informational, emotional, psychological, social, and spiritual needs throughout the courses of cancer diagnosis and treatment.<sup>[6]</sup> These needs are called supportive care needs (SCNs).



Standard supportive care requires effective teamwork among health-care providers, chiefly nurses, and effective use of the available resources and technologies. Telephone-based support is one of the methods for nurses to provide low-cost supportive care and fulfill patients' caring needs. [7,8] Studies show that patients with cancer welcome nurses' telephone-based support. [8-10] This method can be potentially useful for improving patient outcomes because other types of communication necessitate special skills, require access to certain facilities (such as internet) and impose financial burdens on patients due to frequent traveling for visiting

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health-care professionals.<sup>[11]</sup> In addition, telephone-based support can help patients contact health-care providers as needed throughout day and night.

Despite the benefits of telephone-based nursing support, [8,10,12] this system is not broadly established for patients with cancer in Iran. Moreover, due to cultural differences, the findings of studies in Western settings cannot be generalized to the Iranian context. Thus, this study was done to narrow these gaps.

### **Objectives**

This study aimed to evaluate the impacts of nurse-led telephone-based support on SCNs among women with BC.

#### **Methods**

## **Design and participants**

This was a two-group randomized controlled trial. The study population comprised women with BC who were receiving cancer treatments (including chemotherapy, radiotherapy, and surgery) in teaching hospitals affiliated to Kashan University of Medical Sciences, Kashan, Iran. They were included in the study if they had received a definite diagnosis of BC from an oncologist, were aware of the diagnosis, aged 18 or more years, were receiving the first course of cancer treatments, suffered from no metastasis according to oncologist's diagnosis, were literate, had no speech or hearing impairments, had access to home phone, and were living in Kashan, Iran. Exclusion criteria were death during the study or reluctance to stay in the study.

Using the sample size formula for the comparison of two means [Figure 1] and with a type I error of 0.05, a power of 0.80, an  $\rm S_1$  of 0.49, an  $\rm S_2$  of 0.52, and a mean difference of 0.36, [13] sample size for each study group was estimated to be 31, that is, 62 in total.

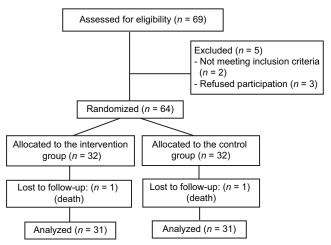


Figure 1: Consort diagram of the study

Participants were randomly assigned to either an intervention (A) or a control (B) group through block randomization with a block size of four. Accordingly, a randomization computer program generated 16 blocks of six possible block arrangements as follows: AABB, BBAA, ABAB, BABA, ABBA, BAAB, and so on. These blocks were randomly sorted and used for allocation of participants to either the intervention (A) or the control (B) group. Sampling and block randomization was continued until 31 patients were allocated to each group.

#### **Instruments**

Data collection instruments were a demographic questionnaire and the SCN Survey Short Form 34 (SCNS-SF34). The demographic questionnaire had items on participants' personal characteristics such as age, education level, employment status, marital status, home address, and telephone number as well as items on BC-related characteristics such as the type of treatment (chemotherapy, radiotherapy, or surgery), time passed from BC diagnosis, and family history of cancer. The SCNS-SF34 contained 34 items on patients' needs in the following five domains: psychological (10 items), health system and information (11 items), patient care and support (five items), physical and daily living (five items), and sexuality (three items). For each item, participants were asked to rate the level of their postcancer need for help over the last month on a five-point Likert-type scale as follows: (1) "Not applicable" (i.e., "This was not a problem for me as a result of having cancer"); (2) "Satisfied" (i.e., "I did need help with this, but my need for help was satisfied at the time"); (3) "Low need" (i.e., "This item caused me little concern or discomfort. I had little need for additional help"); (4) "Moderate need" (i.e., "This item caused me some concern or discomfort. I had some need for additional help"); and (5) "High need" (i.e., "This item caused me a lot of concern or discomfort. I had a strong need for additional help"). The first two responses are interpreted as "no need." while the last three responses are interpreted as "some need."[14] The total score of SCNS-SF34 varies from 34 to 170, with higher scores representing greater need for help. Previous studies reported that the Persian version of SCNS-SF34 has acceptable validity and reliability, with a Cronbach's alpha of 0.9.[15,16]

#### Intervention

Patients in the intervention group were provided with 1-month telephone-based support services. Initially, their telephone numbers and home addresses were obtained and the first author's telephone number was given to them. The first author called each patient twice weekly

at predetermined time points based on the patient's preferences. The duration of each telephone call was 15-20 min, on average. The content of the telephone calls was developed as a protocol based on the results of the latest researchers and textbooks on cancer nursing[17] and supportive care[18] and was approved by the oncology department of the Kashan university of Medical Sciences, in which the present study was conducted. The protocol included explanations about cancer treatments (such as chemotherapy, radiotherapy, and surgery), their side effects, management of treatment side effects (such as nausea, vomiting, diarrhea, constipation, lymphedema, oral mucositis, and fatigue), and self-care in cancer in the areas of nutrition, physical activity, and sleeping. The first telephone call to each patient was made in the 1st week after recruitment to the study. During the calls, patients' problems were addressed and their questions, if any, were answered. When necessary, patients' questions were answered after consulting an oncologist. Moreover, in case of any problem or question, patients could call the first author throughout the study at predetermined time intervals (i.e., 09:00-12:00 am and 16:00–21:00 pm). Patients in the control group merely received conventional care routinely provided to BC patients, which included some explanations by nurses or physicians about cancer and its treatments. All patients in both groups completed SCNS-SF34 at three time points, that is, at the beginning of the study as well as 2 weeks and 1 month afterward.

#### **Ethical considerations**

This study was approved by the Institutional Review Board and the Ethics Committee of Arak University of Medical Sciences, Arak, Iran (with the approval code of IR. ARAKMU. REC.1395.229) and was registered in the Iranian Registry of Clinical Trials (with the code of IRCT2016102430465N1). We adhered throughout the study to the Declaration of Helsinki and the ethical principles issued by the Iranian Ministry of Health and Medical Education. At the beginning of the study, the aims of the study were explained for participants and they were ensured that participation in or withdrawal from the study would have no effect on the process of their treatment and all of their information would remain confidential. Then, written informed consents were obtained from patients who agreed to participate in the study.

#### **Data analysis**

The data were analyzed using the Statistical Package for the Social Sciences (SPSS) software version 16.0 (SPSS Inc., Chicago, IL, USA). Normality of numerical data was tested using the Kolmogorov–Smirnov test. Categorical data were described through frequency

and percentage, while numerical data were described through mean and standard deviation. Between-group comparisons respecting categorical data were made through the Chi-square or Fisher's exact tests, while the same comparisons respecting numerical data were made through the independent-sample t or the Mann–Whitney U-tests. The repeated-measures analysis of variance (RM ANOVA) was also carried out to evaluate the variations of the mean scores of SCNs across the three measurement time points. *Post hoc* analyses were also carried out through the Bonferroni's test.

## **RESULTS**

In total, 62 patients completed the study -31 in each group [Figure 1]. There were no statistically significant differences between the groups with respect to participants' demographic and BC-related characteristics (P > 0.05) [Table 1].

Before the intervention, the mean score of SCNs in the intervention group was significantly greater than the control group (P = 0.008), while 2 weeks and 1 month after the beginning of the intervention, SCNs mean scores in the control group were significantly greater than the intervention group (P < 0.001) and 0.0001, respectively) [Table 2]. RM ANOVA indicated significant decreases in the mean scores of SCNs in both groups across the three measurement time points. Of course, the amount of decrease in the intervention group was much greater than the control group (39.08 vs. 2.87); [Tables 2 and 3]. Subsequently, the Bonferroni's post hoc test was used for pairwise comparisons in each group. Results revealed that all pairwise comparisons in the intervention group were statistically significant (P < 0.0001), while in the control group, only the difference between the baseline and the 1-month mean scores of SCNs was statistically significant (P = 0.028); [Table 3].

RM ANOVA also indicated that the interaction of time and group was statistically significant with respect to the variations in the mean scores of SCNs and all its domains. Moreover, the results of RM ANOVA for the between-subject factor of group illustrated significant difference between the groups regarding the variations of the mean score of SCNs (P < 0.0001) [Table 2]. The adjusted total mean scores of SCNs were calculated in both groups after controlling the effects of confounding variables. Subsequently, the results of RM ANOVA illustrated that the adjusted total mean score of SCNs in the intervention group was significantly lower than the control group (P < 0.0001) [Table 2].

Moreover, there were statistically significant differences between the groups regarding the pretest-posttest mean differences of the mean scores of all domains

Table 1: Comparison of the groups with respect to participants' demographic and breast cancer-related characteristics

Characteristics	Group	$P^{\mathrm{a}}$		
	Intervention, n (%)	Control, n (%)		
Age (years)				
<45	7 (22.58)	12 (38.70)	0.336	
45-59	17 (54.83)	12 (38.70)		
60 and more	7 (22.58)	7 (22.58)		
Marital status				
Single	2 (6.5)	5 (16.1)	0.134	
Married	25 (80.6)	24 (77.4)		
Widowed and divorced	4 (12.9)	2 (6.5)		
Education level				
Primary school completed	21 (67.7)	19 (61.3)	0.729	
High school graduate	3 (9.67)	6 (19.4)		
Undergraduate	3 (9.67)	2 (6.5)		
Postgraduate	4 (12.90)	4 (12.9)		
Employment status				
Homemakers	27 (87.1)	27 (87.1)	0.988	
Laborer	2 (6.5)	0		
Employee	2 (6.5)	4 (12.9)		
Type of treatment				
Chemotherapy	9 (29.3)	13 (41.9)	0.624	
Surgery	19 (16.3)	16 (51.6)		
Radiotherapy	2 (6.45)	3 (9.67)		
Time passed from BC diagnosis (months)				
<12	9 (29.3)	8 (25.80)	0.861	
12-24	13 (41.9)	12 (38.70)		
>24	9 (29.3)	11 (35.4)		
Type of insurance				
Health	5 (61.1)	9 (29)	0.397	
Social security	24 (77.4)	21 (67.7)		
Other	2 (6.5)	1 (3.2)		
Family history of cancer		` ,		
Yes	18 (58.1)	20 (64.5)	0.434	
No	13 (41.9)	11 (35.5)		

<sup>&</sup>lt;sup>a</sup>The results of the Chi-square or the Fisher's exact tests. BC: Breast cancer

of SCNs (P < 0.05), except for the sexuality domain (P = 0.069). In other words, the mean scores of the four domains of SCNs (i.e., physical and daily living, psychological, patient care and support, and health system and information) in the intervention group were significantly less than the control group. The results of RM ANOVA illustrated that after controlling the effects of confounding variables, the adjusted total mean scores of the psychological and the health system and information domains in the intervention group were significantly less than the control group (P < 0.0001) [Table 2], while there were no statistically significant differences between the groups with respect to the mean scores of the other domains of SCNs.

## **DISCUSSION**

The results of this study illustrated that patients with BC who were receiving cancer treatments had many

different SCNs. Similarly, previous studies on Iranian patients with BC reported that these patients had SCNs in different domains.<sup>[5,14,19]</sup> Moreover, studies have revealed that women with cancer have more unmet SCNs than men.<sup>[20,21]</sup> All these findings imply the commonness of SCNs among BC patients. This commonness can be mainly due to the life-threatening nature of cancer. Therefore, comprehensive supportive care programs and services are needed to fulfill BC patients' SCNs.

The study findings showed that telephone-based nursing support for patients with BC significantly reduced their total SCNs as well as SCNs in the psychological and the health system and information domains. Consistently, studies in other countries reported the effectiveness of telephone-based interventions in reducing cancer patients' SCNs, [8,10,12] overcoming their knowledge deficit, giving them reassurance, providing them with the opportunity to talk to doctors, increasing their

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Table 2: Within- and between-group comparisons with respect to the mean scores of supportive care needs and its domains

SCNS subscales/group <sup>a</sup>	Time			$oldsymbol{P}^{\mathrm{b}}$		
	Before	2 weeks after	1 month after	Time	Time* group	Group
Physical and daily living domain						
Intervention	$17.53\pm3.98$	$15.38\pm3.60$	$12.12\pm3.05$	< 0.0001	< 0.001	0.067
Control	$16.83\pm3.97$	$16.83\pm3.97$	16.51±4.06			
$P^{\mathrm{c}}$	0.526	0.137	< 0.0001			
Psychological domain						
Intervention	$37.73\pm7.01$	$32.29\pm5.76$	$24.13\pm4.09$	< 0.0001	< 0.0001	< 0.0001
Control	34.51±4.38	$34.22\pm4.32$	33.16±4.64			
$P^{\mathrm{c}}$	0.002	0.142	< 0.0001			
Patient care and support domain						
Intervention	$12.06\pm3.59$	$10.64\pm2.36$	$9.38\pm2.09$	< 0.0001	< 0.0001	0.233
Control	11.41±2.20	11.54±2.47	11.3±5 2.57			
$P^{\mathrm{c}}$	0.414	0.147	0.002			
Health system and information domain						
Intervention	$37.48\pm5.48$	$28.54\pm2.96$	21.13±1.69	< 0.0001	< 0.0001	< 0.0001
Control	33.67±4.43	33.43±4.39	$32.60\pm4.83$			
$P^{c}$	< 0.001	< 0.0001	< 0.0001			
Sexuality domain						
Intervention	$7.83\pm2.84$	$7.09\pm2.41$	5.93±1.84	< 0.0001	< 0.0001	0.779
Control	$7.19\pm3.56$	$7.06\pm3.49$	7.23±3.41			
$P^{c}$	0.620	0.863	0.069			
Total						
Intervention	112.4±14.61	93.96±11.21	73.31±8.91	< 0.0001	< 0.0001	< 0.0001
Control	103.64±13.05	103.03±12.77	100.77±13.25			
$P^{c}$	0.008	< 0.001	< 0.0001			

<sup>a</sup>Data presented as Mean±SD, <sup>b</sup>The results of RM ANOVA, <sup>c</sup>The results of the independent-sample *t*-test. SD: Standard deviation, RM ANOVA: Repeated-measures analysis of variance, SCNS: Supportive care needs survey

Table 3: Within-group pairwise comparisons in both groups with respect to the mean score of supportive care needs

Time (i)	Time (j)	Group					
		Intervention			Control		
		Mean difference (i-j)	SD	Pa	Mean difference (i-j)	SD	Pa
Before	2 weeks after	18.439	2.04	< 0.0001	0.607	0.607	0.604
	1 month after	39.088	2.16	< 0.0001	2.872	2.872	0.028
2 weeks after	1 month after	20.649	1.13	< 0.0001	2.265	1.103	0.147

<sup>&</sup>lt;sup>a</sup>The results of the Bonferroni's post hoc test. SD: Standard deviation

self-confidence in making treatment-related decisions,<sup>[11]</sup> reducing their BC-related psychological problems,<sup>[22]</sup> alleviating their anxiety,<sup>[7,23]</sup> and improving their self-efficiency.<sup>[22]</sup> These interventions also help provide patients with emotional and informational support, improve their quality of life,<sup>[24]</sup> and facilitate maintaining the continuity of supportive care delivery.<sup>[23]</sup>

To the best of our knowledge, there was no study on Iranian cancer patients' SCNs. However, studies on other patient populations showed the positive effects of telephone-based interventions on patient outcomes. For instance, a study found that telephone-based interventions by nurses improved quality of life after pacemaker implantation for patients with

problems.<sup>[25]</sup> Similarly, cardiovascular nurse-led telephone-based intervention was reported to improve metabolic indices (such as glycosylated hemoglobin and postprandial glucose) among patients with Type II diabetes mellitus.[26] In contrast to our findings, some studies reported that telephone-based interventions had no significant effects on SCNs among patients with colorectal cancer<sup>[7,27]</sup> and had no psychological effects on patients with prostate and colorectal cancers.[7,11] Therefore, the effects of these interventions seem to be largely dependent on the sociocultural background of patients<sup>[19]</sup> and the type of cancer.<sup>[7,11,27]</sup> For instance, as women have greater SCNs[20] and breast is of special importance for them as a sexual organ, [28] they are more interested in speaking about their problems

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over the phone and may receive greater benefits from telephone-based interventions. These findings highlight the need for developing telephone-based interventions according to the immediate sociocultural context, the available facilities, patients' gender, and type of cancer.

Our findings also showed significant decrease in the mean scores of all domains of SCNs, except for the sexuality domain in the intervention group. The insignificant decrease in the mean score of the sexuality domain maybe because talking about sexual issues is a taboo in Iran, [29] and hence, our participants might have been reluctant to speak about their sexual needs in spite of suffering from some sexual problems. With the same reason, nurses may simply ignore patients' sexual needs and problems despite their knowledge about the importance of sexual health. Therefore, specialized educational programs are needed to manage sexual problems in patients with BC and help them fulfill their sexual needs.[28] It is noteworthy that telephone-based interventions can protect patients' privacy and help them more freely talk about their sexual problems and needs.

Based on the findings of this study, telephone-based support can be considered as one of the effective methods for providing supportive care to cancer patients. However, despite the release of a draft plan for palliative and supportive care in Iran in 2012, [30] there is no approved comprehensive clinical guideline and action plan for supportive care delivery in Iran. Thus, there is an urgent need for developing cancer-related supportive care programs and services in the country<sup>[5]</sup> to address all needs of cancer patients and their family members. Furthermore, supportive care education should be incorporated into the curriculums of the health-care professions. Moreover, given the cultural diversity in Iran, more comprehensive studies are needed to evaluate the effects of telephone-based interventions on SCNs among patients from different sociocultural context and with different types of cancer.

This study was conducted in only one city, and hence, its findings may have limited generalizability. Moreover, the study sample only consisted of patients with BC who were receiving cancer treatments. However, patients with different types of cancer have a wide variety of SCNs depending on their treatments, treatment side effects, prognoses, and likelihood of recurrence. Therefore, findings may not be generalizable to patients with other types of cancer or patients in other phases of cancer. Further studies are needed to evaluate the effects of telephone-based support on SCNs among patients with different types of cancer in different societies. Moreover, studies need to be conducted to assess changes over time in SCNs of patients with BC and to assess the

effects of telephone-based support on cancer patients' SCNs at different phases of cancer, including diagnosis, treatment, and rehabilitation.

#### **CONCLUSION**

Telephone-based support can significantly reduce SCNs among patients with BC. Accordingly, health-care policymakers and providers need to develop holistic supportive care programs to fulfill and reduce cancer patients' SCNs, and thereby improve their quality of life. Given the positive effects of telephone-based support on BC patients' SCNs, it can be considered as a good alternative for providing supportive care services by nurses and extending their roles in supporting cancer patients.

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#### **Conflicts of interest**

There are no conflicts of interest.

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