The effect of a support program on the burden of spouses caring for their partners with breast cancer: a randomized controlled trial

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Objective

This study aimed to determine the effect of a support program on burden of spouses caring for their partners with breast cancer.

Methods

This randomized controlled trial was conducted among spouses of women with breast cancer undergoing chemotherapy at a referral chemotherapy center in Iran. They were assigned to intervention (n=40) and control (n=40) groups using permuted block randomization. Three small group sessions lasted 45-60 minutes, followed by three telephone-based sessions, lasting 15-20 minutes (twice a week). The intervention sessions included defining stress management strategies in different situations: strengthening creativity, optimism, and management in planning, and defining the role of the caregiver. Primary outcome was care burden, and secondary outcomes were spouses' stress, satisfaction with intervention, and partners' quality of life (QOL). The caregiver burden inventory, depression anxiety stress questionnaire, World Health Organization QOL brief version, and client satisfaction questionnaire were completed before and after the intervention and at a 6-week follow-up.

Results

Thirty-eight participants in each group with a mean age of 44.24±9.01 years completed the study. Repeated measures analysis of variance showed a significant difference in the care burden (*P*<0.05; effect size, 0.70), stress (*P*<0.05; effect size, 0.64), and women's QOL (*P*<0.05; effect size, 0.67) before and after the intervention.

Conclusion

The results of this study can be used to develop interventions, targeting the care burden and stress of spouses of women with breast cancer undergoing chemotherapy.

Keywords: Caregiver bnurden; Psychological stresses; Breast cancer; Chemotherapy

Introduction

Breast cancer accounts for approximately one-third of all cancers in women, and it is the leading cause of cancer-related mortality [1]. Cancer is currently the third leading cause of death in Iran after cardiovascular diseases and traffic accidents [2]. Care burden and stress for caregivers of cancer patients are among the critical issues addressed in recent years [3]. Caregiver burden refers to stress a person feels from caring for a patient [4], which in addition to stress caused

by changes in life due to presence of a cancer patient, can affect a person's ability to adapt, thereby causing depression [4,5]. It has been found that spouses and children of breast cancer patients care for these patients the most, and the care burden and stress is highest on the spouse due to more complex emotional relationship between the spouses [6]. Psychological issues that may be perceived by caregivers, especially the spouses of patients, include the burden of caregiving and stress caused by the treatment process of the cancer patients. As the disease progresses, the frequency of psychological problems [7], quality of sexual life [8], and professional performance [9,10] of husbands of women with breast cancer undergo undesirable changes. These long-term negative effects can lead to impaired physical health, including a weakened immune system and increased risk of cardiovascular diseases [11]. In some qualitative studies, despair and uncertainty about the future, as well as fear of loneliness, have been cited as major problems experienced by spouses of women with breast cancer [12]. All these problems mean that special attention needs to be paid to support the needs of caregivers of breast cancer patients, and the importance of managing caregivers'stress is highlighted in educational and psychological interventions [13].

Despite the high prevalence of breast cancer in women and the prominent role of husbands in their caregiving, and the need for special attention to psychological problems, such as stress and caregiving burden in the husbands of women with breast cancer, this issue has attracted limited attention in developing countries like Iran [2,14]. It is now recommended that support and intervention programs should be designed and implemented based on the culture of the community [15]. Therefore, this study aimed to determine the effect of a support program on the burden of spouses caring for their partners with breast cancer.

Materials and methods

1. Study design
This was a non-masked, randomized controlled trial that applied the consolidated standards of reporting trials (CONSORT) statement. The study was registered in the Iranian registry of clinical trials with the reference code IRCT20150608022609N7 (https://www.irct.ir/).

2. Participants and recruitment
We recruited spouses of women with breast cancer undergoing chemotherapy at the chemotherapy ward of the Shahid Rajaee Referral-chemotherapy Center in Babolsar city, Mazandaran province, Iran from May 2020 to August 2020.

3. Inclusion and exclusion criteria
Participants were spouses of women with stage 1-3 breast cancer and a history of at least 1 session of chemotherapy. Other inclusion criteria were age 25-60 years, Iranian nationality, and education level higher than primary school. Exclusion criteria were studies in the medical or paramedical field, use of any counseling services on stress management 6 months prior to the start of the study, presence of psychiatric disorders, use of psychotropic drugs, drug and alcohol addiction, severe anxiety (score above 12), and severe depression (score above 13) based on the depression anxiety stress scale (DASS-21). Women with recurrent breast cancer also were excluded from the study.

4. Sample size
Based on the study by Gabriel and Mayers [16], and considering α=0.05, β=0.20, P1=0.18, and P2=0.02, the sample size was calculated to be 33 per group. Forty participants in each group (a total of 80 participants) were selected, considering a 20% attrition rate.

5. Randomization
Sampling was established by attending the outpatient chemotherapy ward of the Shahid Rajaee Hospital to recruit spouses of women diagnosed with breast cancer. These women usually attended the hospital clinics with their relatives, such as their husbands, to receive pre-planned chemotherapy sessions. Using the permuted block randomization method, spouses were allocated to intervention (n=40) and control (n=40) groups. The intervention group comprised 20 blocks of 3-5 participants, such that in each block, the number of intervention and control groups were equal. Further, to adhere to the allocation concealment, 80 envelopes were prepared, and the indicated groups were placed in groups I (intervention) and C (control). The first eligible participant received the first envelope, and if it was written on the envelope of group I, he or she would be in the intervention group; thus, the participants would be in the control and intervention groups.

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6. Outcomes

Primary outcome was care burden, and secondary outcomes were spouses' stress, satisfaction with intervention, and partners' quality of life (QOL).

7. Measurements

1) Demographic and clinical checklist

The participants' demographic information included their age, education, job, place of residence, family history of cancer, underlying disease, adequacy of monthly income, and satisfaction with socioeconomic class. Additionally, their partners' age, stage of disease, type of treatment received, type of surgery, number of chemotherapy sessions, and information about marriage, such as the duration of marriage and number of children were recorded.

2) Caregiver burden inventory (CBI)

The care burden questionnaire for caregivers with 24 items and five subscales was developed by novak and guest to measure objective and mental care burden [17]. This questionnaire was translated into Persian, and its validity was confirmed using content validity. The Cronbach's alpha of 0.93 and intra-cluster correlation of 0.96 at 2-week intervals were satisfactory [18]. It was also used in a study of cancer patients in an Iranian setting [19].

3) Depression anxiety stress scale (DASS-21)

This 21-item scale was developed by Lovibond to assess depression, anxiety, and stress during the last week [20].

Table 1. Content provided in each session in the intervention group based on the COPE model

Session	Major topic	Content of each session
Session 1	Introducing	Initially, the goals and rules of the sessions were expressed and introduced. Then, we introduced breast cancer, treatment steps, side effects of medications, the impact of cancer on the patient's quality of life, the role of the spouse in the lives of sick women, and possible events.
Session 2	Creativity	The role of the caregiver in the treatment process and the importance of the presence of the spouse with the women during the treatment process were explained. Then the content about the COPE model was presented. The first item of this model was creativity, which motivated the participants by defining its benefits and techniques. At the end of this session, the researcher described the scenario of creativity and increased the learning of the group members in the field of creativity. The researcher then performed relaxation exercises using diaphragmatic breathing. At the end of the session, we gave them homework on relaxation exercises.
Session 3	Optimism	Control to do homework the participants' questions were answered, then the content about optimism was presented. In this session, the researcher defined the techniques of using optimism and correcting misconceptions about optimism. Participants were encouraged to use the techniques. Then, planning was explained and techniques for using it were discussed in groups. In this session, the researcher used the brainstorming method to discuss the field of planning and use its techniques in order to improve class performance by involving group members and using their experiences.
Session 4	Problem-solving	In this session, the researcher first explained the needs of a caregiver. Defining needs, and explaining the needs that a caregiver can have and are often ignored were some of the things that the researcher addressed and then explained self-care techniques to them so that they could try to meet their needs. He then ended the session by giving homework and making the next appointment for a phone call.
Session 5	Expert information	Defining the role of the caregiver, the importance and impact of the caregiver's presence in patients' lives, how to take care of themselves (increase physical activity, proper nutrition to improve the condition), improve communication skills (acquire new skills to use in new situations) and information on social support was provided and its related components were explained. In this session, the researcher reminded the participants of relaxation exercises and asked them to use them to manage stress during the week.
Session 6	Final review	In the sixth session, while answering the questions of the participants, the contents were reviewed and summarized.

COPE, creativity, optimism, problem-solving, and expert information.

The Cronbach's alpha coefficient was reported as 0.70 for depression, 0.66 for anxiety, and 0.76 for stress in a study among Iranian population [21].

4) Client satisfaction questionnaire

This 8-item scale was developed by Larsen et al. [22] to measure client satisfaction with counseling and treatment services [23].

5) World Health Organization QOL brief version (WHOQOL-BREF)

This questionnaire was used to measure QOL over the past 2 weeks. It was developed in 1989 by the World Health Organization in collaboration with 15 international centers. It includes 24 questions in four domains, where the first two questions do not belong to any of the domains and assess health status and QOL in general [24]. In Iran, a Cronbach's alpha of 0.84 was reported to be satisfactory [25].

8. Intervention group

After evaluating the eligibility criteria and explaining the objectives of the study, written informed consent was obtained from participants who were willing to participate in the study. The sessions were held by a pre-trained researcher under the supervision of the research team, including a reproductive health professor, psychiatrist, and psychologist. The intervention was conducted twice a week for six sessions. The first three sessions were small group sessions (3-5 partici-
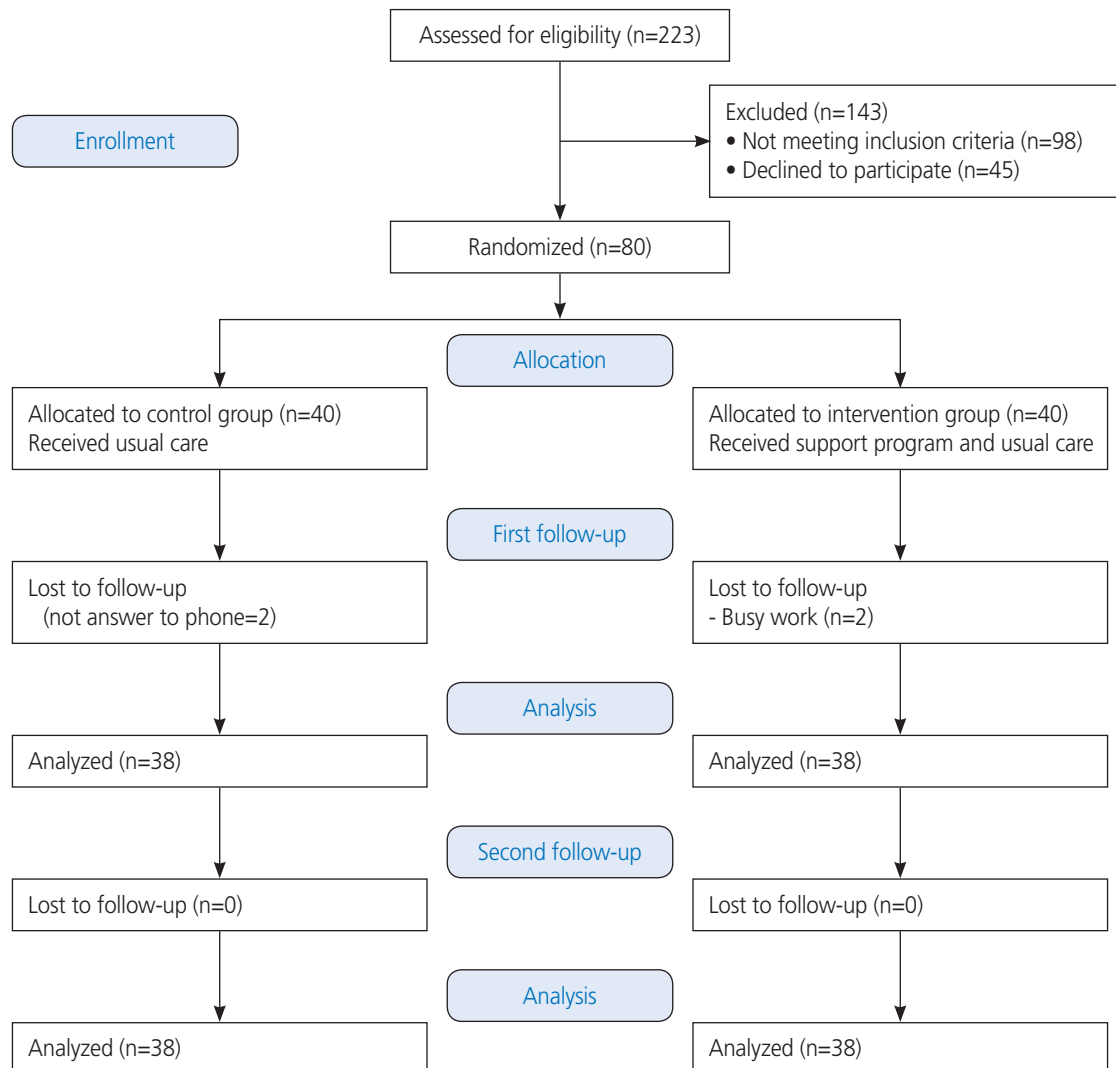

Fig. 1. Consort flow diagram.

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pants in each group), and the next three sessions were held by telephone with each individual. The small group sessions lasted 45-60 minutes, followed by telephone sessions lasting 15-20 minutes.

The intervention sessions included information about breast cancer and its complications, defining stress management strategies in different situations, teaching different levels of problem-solving skills, strengthening creativity, optimism, and management in planning, and defining the role of the caregiver, self-care, strengthening communication skills, relaxation techniques, and related home work (Table 1). Creativity, optimism, problem-solving, and expert information (COPE) models were adopted to develop an intervention protocol [26]. The content validity of the sessions was de-veloped by the research team and evaluated by the opinion of two experts in the field of mental health (psychiatrist and clinical psychologist) and a professor in the field of reproductive health. The experts' comments were applied in the final version of the intervention protocol. During each session, the participants were given the opportunity to ask questions and any concerns about caring for their partners were addressed. The demographic and clinical checklist, DASS-21, CBI, and WHOQOL-BREF (only for women with breast cancer) were completed at recruitment, immediately after the intervention, and at 6-week follow-up by both groups. The client satisfaction questionnaire was completed by the intervention group at the aforementioned times.

Table 2. Demographic and clinical information of the participants and their spouses

Variable	Intervention	Control	P-value
Age (yr)	42.82±10.38	45.66±7.65	0.179[a]
Age of partner (yr)	39.21±9.99	41.71±7.21	0.215[a]
Educational level			0.436[b]
Primary	7 (18.4)	10 (26.3)	
Secondary	19 (50.0)	24 (63.2)	
Bachelor's degree and higher	12 (31.6)	4 (10.5)	
Job			0.642[b]
With fixed salary	17 (44.7)	15 (39.5)	
Without fixed salary	21 (55.3)	23 (60.5)	
Family history of cancer	14 (36.8)	16 (42.1)	0.639[b]
Residency			0.348[b]
Urban	25 (65.8)	21 (43.1)	
Rural	13 (34.2)	17 (57.9)	
Number of chemotherapy sessions	3.18±1.2	3.39±0.79	0.089[c]
Stage of breast cancer			0.069[b]
I	10 (26.1)	10 (26.1)	
II	20 (52.6)	21 (55.2)	
III	8 (21.3)	7 (18.7)	
Type of surgery			0.135[b]
Mastectomy	6 (15.8)	2 (5.3)	
Lumpectomy	32 (84.2)	36 (94.7)	
Satisfaction with socio-economic level			0.205[b]
Low	8 (21.1)	14 (36.8)	
Medium	20 (52.6)	13 (34.2)	
High	10 (26.3)	11 (28.9)	

Values are presented as mean±standard deviation or number (%).
[a]Independent T-test; [b]Chi-square; [c]Mann-Whitney U test.

9. Control group

Both groups received usual care from the study setting, which focused on caregivers of women with breast cancer at a 45-minute counseling session on the side effects of chemotherapy before the first session. To comply with ethical issues, at the end of the study, a brief version of the intervention protocol was provided to the control group as a booklet, and their questions were answered in case of questions regarding care and stress management.

Table 3. Comparison of the mean and SD of care burden, stress, and QOL in both groups at recruitment and over time

Variable	Intervention	Control	P-value[a]
Care burden			
Before intervention	89.79±8.80	68.90±6.00	0.606
After intervention	54.53±10.30	91.76±6.65	0.001
Six-week follow-up	55.13±9.77	95.58±5.77	0.001
Stress			
Before intervention	15.74±1.88	15.47±1.46	0.499
After intervention	8.18±2.70	15.50±1.53	<0.001
Six-week follow-up	7.42±2.22	16.24±1.77	<0.001
Quality of life			
Before intervention	20.61±6.06	21.39±6.94	0.112
After intervention	46.38±11.59	22.14±7.84	0.001
Six-week follow-up	49.97±11.43	21.02±6.53	0.001

Values are presented as mean±standard deviation.
QOL, quality of life.
[a]Independent t-test.

10. Statistical analysis

Mean and standard deviation were used to describe numerical data. Frequencies and percentages were used for categorical data. The Shapiro-Wilk normality test was used to evaluate the normality of the numerical variables. The chi-square test was used to evaluate categorical variables. Repeated measures analysis of variance evaluated the mean difference in outcomes between the intervention and control groups with the Bonferroni *post-hoc* test to control for increased risk of type I error due to multiple comparisons. If the data were not normal, appropriate non-parametric tests were performed. A *P*-value of <0.05 was considered statistically significant with a per-protocol approach. The data were analyzed using SPSS version 26 (IBM Corp., Armonk, NY, USA).

Results

1. Flow of participants through the intervention and recruitment

A total of 223 participants met the eligibility criteria. Finally, 80 people were recruited, four of whom withdrew from the study, and 38 completed the study in each group (Fig. 1).

2. Participant characteristics

The mean age of the participants was 44.24±9.01 years, and most of them had secondary education. The demographic

Table 4. Repeated measure analysis to compare the care burden, stress, and quality of life score in the intervention and control groups

Variable	Sum of squares	Degree of freedom	Mean of squares	F	P-value	Effect size (Cohen's d)
Care burden					0.001	
Groups	39,106.12	1	39,106.12	432.29		0.854
Time	13,135.02	1.71	7,682.64	123.94		0.626
Groups×time	18,337.95	1.71	10,725.82	173.03		0.700
Stress					0.001	
Groups	1,594.77	1	1,549.77	319.28		0.812
Time	720.02	2	360.01	106.87		0.591
Groups×time	900.07	2	450.03	133.59		0.644
Quality of life					0.001	
Groups	16,050.74	1	1,600.74	98.59		0.571
Time	12,194.55	1.47	8,296.02	137.60		0.650
Groups×time	13,715.32	1.47	9,330.61	154.76		0.677

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and clinical information of the participants and their partners are shown in Table 2.

3. Outcomes

At baseline, there were no significant differences between the two groups in terms of care burden, stress, and partners' QOL; however, after the intervention and at 6 weeks of follow-up, they were significant (Table 3).

As shown in Table 4, repeated measures analysis of variance showed a significant difference in the care burden ($P<0.05$; effect size, 0.70), stress ($P<0.05$; effect size, 0.64), and women's QOL ($P<0.05$; effect size, 0.67) before and after the intervention. The Bonferroni *post-hoc* test results for care burden pairwise comparisons between the groups are presented in Fig. 2.

The mean score for the satisfaction intervention was also assessed. The lowest score was 18, highest score was 29, and mean score was 24.82±2.42, which indicates acceptable satisfaction among the intervention group.

Discussion

The experience of having breast cancer, its treatment, and consequences cause numerous psychological problems for the patient and caregivers. Because of the complex emotional relationships and dependencies that develop over time, the spouses of these patients are more affected than other caregivers [24-28]. The present study is one of the few interventional studies on the care burden of spouses (specifi-

Extimated marginal means of MEASURE_1

Fig. 2. Results of the Bonferroni *post hoc* test for care burden pairwise comparisons between the groups. CBI, caregiver burden inventory.

cally dealt with) of women with breast cancer undergoing chemotherapy. In this study, a COPE-based support program was provided to the spouses of women with breast cancer. The results of the upcoming study suggest that the support program in the form of information about breast cancer, its consequences and treatment, social support, communication skills, and description of the COPE model will help increase creativity, optimism, and planning. Providing specific information about healthy lifestyles and caregivers' needs was also found to be effective. The results showed that caregiver burden and caregiver-induced stress differed significantly between intervention and control groups.

The results of the present study were consistent with studies that showed that training and providing support packages based on the COPE model to caregivers of patients with cancer was effective in reducing stress [16,29]. The above studies focused on providing information about cancer stages and complications of treatment, assessing the needs of caregivers [29], and providing information based on the COPE model to reduce the burden of caregiving, stress, anxiety, and depression [29,30], and improving patients' QOL. However, the results of the present study differ from that of a study that assessed the burden and stress in caregivers of advanced cancer patients who received palliative care [31]. One of the reasons for this controversy may be the result of the patients' condition at the end of their lives, and the patients and their caregivers had little hope, which in turn affected their QOL. In another contradictory result, the QOL of patients and their caregivers was assessed after five sessions of intervention [32]. In that study, the rate of change was not stable when the results were reported at two time points: 3 and 6 months after the intervention. One of the reasons for this discrepancy is the inclusion criterion of this study. Participants in that study were at different stages of treatment, which may have affected the results.

The QOL of women with breast cancer was another issue addressed as a secondary outcome in this study. The QOL of patients with breast cancer depend on various factors, and managing the emotions of family members, especially spouses, may be one of the most significant factors in improving the QOL of these patients. It seems that providing a support program for spouses may improve patients' QOL. Based on our findings, a support program based on the COPE model in their caregivers can be recommended for breast cancer patients as an option for part of their rehabilitation to help
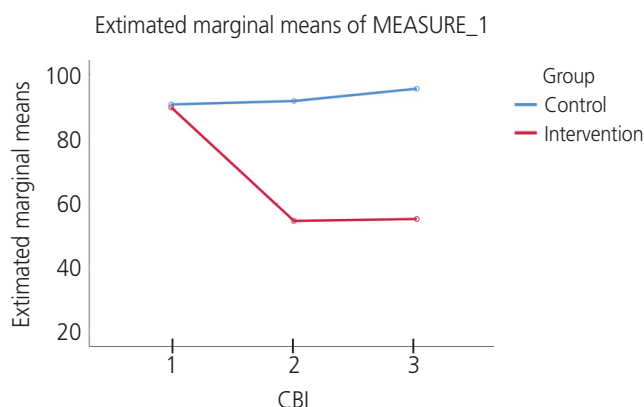
maintain a better QOL [33,34]. Evaluating the QOL of women with breast cancer was our secondary outcomes that are suggested in future studies, and it can be considered as a primary outcome to assess the psychological status of these women in more detail.

1. Limitations

The results of this study should be interpreted in light of some limitations. Since several factors, such as the size of the mass, individual perception of the disease, and social culture are critical in determining the extent of the burden of care, it was not possible to examine them in this study. The timing and completion of chemotherapy sessions during the intervention sessions, number of chemotherapy sessions completed, and family history of cancer (due to earlier preparation in individuals and their greater adjustment to the disease) may increase caregiver burden and stress after the intervention. As all questionnaires were completed by the participants as self-reports, their burden, stress, and QOL may differ from reality. However, it should be noted that the research team tried to control this limitation by assuring the participants that their information was confidential; however, myths about non-emotional men are still widespread, and this affects people's experiences and behaviors. This issue is more prominent in conservative societies, such as Iran, where cultural restrictions prevent caregiver spouses from honestly revealing their real thoughts and feelings, and the results may be prone to information bias. However, the researcher provided the necessary explanations regarding confidentiality of the data. The results of this study could be generalized to spouses caring for their partners with recurrent breast cancer, while not undergoing chemotherapy cautiously, as chemotherapy is a complex stage in the management of women with breast cancer. Notably, 6 weeks follow-up is a fairly short follow-up time after the intervention, and by considering this limitation, it is impossible to evaluate women with breast cancer progression. To understand whether these effects are sustained over a longer term, a long-term follow-up should be considered in future research. The nature of the interventional support program and lack of blinding of the participants' allocation to the intervention or control groups may have increased the performance bias. Since a researcher implemented and evaluated the intervention, there might have been some detection bias as well. However, the data were collected using self-administered questionnaires, and it

seems that this type of bias was inconsiderable. Despite the fact that the patients were administered chemotherapy on different days, there was a possibility that patients in the intervention and control groups might have met and may have been prone to contamination bias. However, the probability of this was very low, owing to the presence of two separate rooms in the chemotherapy ward, number of different chemotherapy sessions, and referral of patients for chemotherapy on different days.

2. Conclusion

A support program reduces the care burden and stress levels of the spouses of women with breast cancer undergoing chemotherapy, as well as increases their partners' QOL, suggesting that informing oncologists, surgeons, and patients about non-pharmacological methods, including support programs along with empowering healthcare providers, can help to promote the health of spouses of women with breast cancer. The results of this study can be used to develop interventions, targeting the care burden and stress experienced by spouses of women with breast cancer undergoing chemotherapy. Further investigation with a blind control group may have implications for the integration of support program interventions into the usual care of women with breast cancer and their relatives. Additionally, as there is a possibility that not only the spouse of breast cancer patients but also the patient's mental health status affected the outcome, an evaluation of the patient's stress level or mental health will be investigated in future studies.

Conflicts of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

We received approval from the deputy for research and technology of Mazandaran University of Medical Sciences (MAZUMS) and Biomedical Research Ethics Committee (ethical code: IR.MAZUMS.REC.1399.6862).

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