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**THE EFFECT OF FAMILY-BASED INTERVENTION PROGRAM ON
MANAGERIAL SELF-EFFICACY RELATED TO CHEMOTHERAPY
SYMPTOMS IN IRANIAN PATIENTS WITH BREAST CANCER; A
RANDOMIZED CONTROL TRIAL**

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ABSTRACT

Introduction: Family plays an important role in the health of breast cancer patients and improves their self-efficacy. The aim of this study was to determine the effectiveness of a family-based intervention program on the managerial self-efficacy associated with chemotherapy symptoms in women with breast cancer referred to the educational centers of Urmia in 2016.

Methods: In this clinical trial study conducted on 60 patients, convenience sampling was done and all patients were randomly assigned into two intervention and control groups. The intervention included implementing family-based intervention on the managerial self-efficacy associated with chemotherapy symptoms in breast cancer patients. The data collection instruments were demographic questionnaire and SMSES-BC questionnaire.

Results: The results indicated a significant difference between the mean score of problem-solving subscale, management of symptoms related to chemotherapy, management of emotional and interpersonal disturbance and total score of the managerial self-efficacy associated with chemotherapy symptoms in the post-test intervention group ($P < 0.001$). However, no significant difference was found in the control group.

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Conclusion: The results showed that intervention program based on family support led to an increase in the managerial self-efficacy associated with chemotherapy symptoms in patients with breast cancer.

INTRODUCTION

Breast cancer is the most common cancer among women worldwide. In the developed countries, breast cancer is the most prevalent, as in North America, the prevalence of it in terms of age is up to 99.4 per 100,000 population. Its annual prevalence is rising by 5% per year (1-3) Studies in Iran indicated an increase in its incidence and prevalence over recent years (4).

Cancer diagnosis is an extremely unpleasant and unbelievable experience for any person. In addition to disrupting the status of the occupation, the socio-economic status and life of the patients, the range of symptoms including pain and physical or psychological disorders (5). All these problems affect the individual's ability to control illness and life, and ultimately affects the patient's self-efficacy (6).

According to Bandura, self-efficacy is the individual's confidence in his ability to perform self-care activities in a regular manner, so that the individual achieves the desired results (7). Studies have shown that self-efficacy and self-care behaviors play a vital role in controlling the complications and management of breast cancer. In the process of treating any disease, the patient's participation in treatment is emphasized, but the fact that the patient is confident about herself or himself ability to make this change of behavior is underestimated. In this regard, patients need constant support for the effectiveness and sustainability of self-care and self-efficacy behaviors (8, 9). Several studies have shown that families play an important role in health and promote self-efficacy. Getting supportive behaviors from the environment leads to a feeling of competence for the patient with any cancer, which leads to the development of mental and emotional tendencies and ultimately increases self-efficacy (12-10).

Family members' support leads to appropriate behavior in the patient, and it is a behavior that helps the patient to communicate clearly with his/her family members and to state his/her needs, desires and feelings for others without violating human rights. They raise them (13, 14). Having a family that is involved in all aspects of breast cancer is one of the key factors in the process of treatment and subsequent recovery. Most family caregivers feel very frustrated sooner, so helping them change the belief of caregiver leads to overcome problems (15).

Intervention through family support is a method for planning and implementation that is controlled by the beneficial contributions of patients and families. Family members of breast cancer patients need constant counseling and training in order to help them more effectively due to their physical, mental and psychological complications (16). The purpose of the interventions is to enhance family members' abilities to overcome barriers to health and well-being, otherwise the patient with breast cancer will not be able to control the disease.

Considering the importance of the family and the chronic nature of breast cancer, it is necessary to design family-based educational and interventional programs. Given that many studies have been done on family support in patients with breast cancer in our country, Iran, but it seems that what these patients suffer more are how to adapt and use effective methods and lack of knowledge about the effect of family support on self-efficacy in different dimensions, so investigating the effect of interventions based on family support are needed. Therefore, the aim of this study was to determine the effectiveness of a family-based intervention program on the managerial self-efficacy associated with chemotherapy symptoms in women with breast cancer referred to the educational and therapeutic centers of Urmia in 2016.

METHOD AND MATERIALS

This is a clinical trial study with the IRCT2016052820778N16 registration code, which was conducted in 2016 for patients with breast cancer under chemotherapy. Inclusion criteria were included: aged 20-60 years, familiarity with Persian language, having diagnosed breast cancer, having chemotherapy and having a mastectomy experience. Exclusion criteria included the occurrence of any stressful incident for a patient or first-degree family member during the study and absence more than 2 sessions of intervention.

The applied questionnaires in this study included a demographic questionnaire including personal and disease information of the samples consisting of age, type of surgery, stage of illness, marital status, educational level, economic status and lifestyle, which was designed by the researcher, as well as the symptom-management self-efficacy scale-breast cancer (SMSES-BC) questionnaire; this questionnaire has 27 questions and 3 subscales, which includes: Acquiring problem-solving including 7 questions (questions 9-11-18-20-22-25-26), second subscale was managing chemotherapy-related symptoms including 15 questions (questions 3-4-

6-7-10-12-13-14-15-16-17- 19-21-23-27) and third, managing emotional and interpersonal disturbance subscale including 5 questions (questions 1-2-5-8-24). The range of scores were from 0-10. A zero score indicates a lack of self-esteem and a score of 10 represents the maximum score of self-esteem. The higher scores obtained in the questionnaire indicate a high level of managerial self-efficacy in these patients (17). SMSES-BC questionnaire was developed by Liang et al. in 2015. In their study, internal consistency was calculated 0.96 among 3 subscales of the questionnaire and Cronbach's alpha was calculated 0.88 to 0.95 among the components of the subscales (17). In the study of Tabriz et al., the reliability of questionnaire using the Cronbach's alpha coefficient was estimated 0.93 and for each aspect of the problem-solving approach, the management of symptoms related to chemotherapy and the management of emotional and interpersonal disturbance was 0.88, 0.86 and 0.92, respectively. Content validity ratio (CVR) and content validity index (CVI) for the entire questionnaire were 89.33 and 96.66, respectively (18).

Sample size was calculated based on the results of a study conducted by Behzadipour et al. which was estimated 26 subjects in each group and 20 percent attrition was added to the sample (n=30).(19). As illustrated in the CONSORT flowchart (Figure 1) 120 breast cancer patients and their families were invited for the study, 60 participants were excluded because of not meeting inclusion criteria (n=39), declining to participate (n=13) and other reasons (n=7). Finally, 60 participants were included in the study and randomized, 30 allocated to the intervention and 30 to the control group. Finally there were 3 lost cases in the intervention group and 2 lost in the control group.

After obtaining the necessary permissions, the researcher referred to the educational and therapeutic centers of Urmia to find patients with breast cancer. According to the inclusion criteria, 60 patients with active family members were included in the study by convenience sampling method. After selecting 60 patients, based on odds or even numbers, 30 patients were randomly assigned to the control group and 30 patients were assigned to the intervention group. The researcher received written informed consent after introducing them and expressing the goals and method of the study. The intervention included a group counseling and, if needed, a focus discussion group based on family support using some tools such as flash card, PowerPoint, and pamphlet, which consisted of 4 sessions with 5-6 patients and one active member of the

family. The duration of each session was about 1.5-2 hours and was performed weekly.

A diary notepad was also provided to the participants for recording their thoughts and feelings and the adopted strategies. Patients were encouraged to perform practical exercises at home between two sessions in practice, and to report the process of previous practice in each session. It should be noted that due to the ethical observance of those who were in the control group, after the intervention, one session was also held for them. In the last 20 minutes, the researcher summarized and presented the content of the discussion. The completion of the questionnaires was done by the samples before the intervention and immediately after the intervention in the last session.

The aim of these interventions was to increase the knowledge of the patient and the family about the process of treatment and treatment, the familiarity with breast anatomy and physiology, therapeutic methods of breast cancer, especially surgery and chemotherapy, post-mastectomy care and chemotherapy. Solutions to improve the ability to manage symptoms in the disease and the impact of family support in this regard were presented such as: strategies to control the common side effects of routine treatments (for example, coping with pain, fatigue, digestive and nutritional problems, and nausea, vomiting, changes in skin, hair and nails). Strategies to support the patient's tangible and personal support from family members were presented including how to make physical assistance and the importance of group work such as services and grants, and other tools, or strategies for emotional support in order to emotional support of family members such as positive family members' interaction and time sharing with each other, and recommendations for changing previous relationships, striving for sustainability and increasing the relationship of family members with each other, the effective communication of family members with each other and sharing concerns, gaining trust in the person affected by the lack of family members' complaints of a person's illness. As well as strategies to support the family awareness of the affected person, such as consulting family members in important decision-making situations and helping the patient to cope with his or her illness and giving information about breast cancer was provided to how other patients control their illness. Descriptive and analytical statistics were used to analyze the observations. For analyzing the hypotheses, parametric tests including t test were used. Data analysis was performed using SPSS20 software.

RESULTS

The results of this study showed that women with breast cancer were homogeneous in terms of mean age in both intervention and control groups. The mean age of women with breast cancer in the intervention group was 47.03 ± 7.73 and 46.16 ± 7.59 years in the control group ($t = 0.45$, p -value = 0.65). Table 1 shows the comparison of the research units according to the

qualitative demographic characteristics of women with breast cancer in two intervention and control groups. The results of Chi-square and Fisher tests showed no significant difference between the two groups in the control and intervention groups. In other words, the two groups were identical in terms of the variables of interest. ($P > 0.05$).

Table 1. Qualitative demographic characteristics of patients with breast cancer in the intervention and control group.

Variable		Intervention		Control		Statistics
		N	%	N	%	
Educational Status	Under Diploma	18	60	19	63.3	$X^2=0.5$ df=2 $P^*=0.77$
	Diploma	6	20	7	23.3	
	Collegiate	6	20	4	13.3	
Marital Status	Married	29	96.7	26	86.7	Fisher=0.41
	Divorced	1	3.3	2	6.7	
	Widow	0	0	2	6.7	
Economic Status	No money problem	10	33.3	8	26.7	Fisher=0.92
	Fair	17	56.7	19	63.3	
	Not enough	3	10	3	10	
Type Of Surgery	Total Mastectomy	24	80	26	86.7	$X^2=0.48$ df=1 $P=0.48$
	Partial Mastectomy	6	20	4	13.3	
Life Status	With Husband And Children	29	96.7	27	90	Fisher= 0.74
	Parent	1	3.3	1	3.3	
	Alone	0	0	1	3.3	
Stage	I	6	20	4	13.3	$X^2=0.78$ df=2 $P=0.48$
	II	15	50	16	53.3	
	II	9	30	10	33.3	

According to table 2, the results of independent t-test showed a significant difference in the rate of acquiring problem-solving, management of symptoms related to chemotherapy, managing emotional and interpersonal disturbance, and total score of management of symptom related to chemotherapy in the after intervention group. This means that family-based intervention has been able to increase the total rate of self-efficacy in women with cancer in the intervention group. The results of paired t-

test in table 3 showed that there was a significant difference between the two groups regarding the mean score of each dimension of the questionnaire before and after the intervention in the two intervention and control groups ($P < 0.001$). This means that the use of intervention has been able to increase the managerial self-efficacy symptoms associated with chemotherapy in the intervention group.

Table 2. Comparison of the mean score of each aspect of managerial self-efficacy associated with chemotherapy symptoms after intervention between two intervention and control groups using independent t test

Managerial self-efficacy		Mean	SD	P value	Statistics
Acquiring problem-solving	Intervention	59.40	9.69	0.00	6.82
	Control	40.84	10.44		
Management of symptoms related to chemotherapy	Intervention	113.50	14.18	0.03	2.14
	Control	102.80	22.43		
Management of emotional and interpersonal disturbance	Intervention	38.76	6.23	0.00	3.93
	Control	31.32	7.81		
Total self-efficacy score associated with chemotherapy symptoms	Intervention	206.06	23.86	0.00	4.50
	Control	171.16	33.44		

Table 3. Comparison of the mean score of each dimension of the managerial self-efficacy of symptoms related to chemotherapy before and after intervention in two intervention and control groups using paired t test.

Managerial self-efficacy			Mean	SD	P value	Statistics
Acquiring problem-solving	Intervention	Before intervention	47.16	16.85	0.002	-3.44
		After intervention	59.40	9.69		
	Control	Before intervention	45.44	9.92	0.09	1.75
		After intervention	40.84	10.44		
Management of symptoms related to chemotherapy	Intervention	Before intervention	100.73	15.45	0.00	-4.33
		After intervention	113.50	14.18		
	Control	Before intervention	96.60	16.41	0.26	-1.13
		After intervention	102.80	22.43		
Management of emotional and interpersonal disturbance	Intervention	Before intervention	31.23	7.45	0.00	-4.11
		After intervention	38.76	23.6		
	Control	Before intervention	29.76	8.07	0.46	-0.75
		After intervention	31.32	7.81		
Total self-efficacy score associated with chemotherapy symptoms	Intervention	Before intervention	171.83	25.13	0.00	-5.76
		After intervention	2.6.06	23.86		
	Control	Before intervention	164.68	28.03	0.41	-0.82
		After intervention	171.16	33.44		

DISCUSSION

The purpose of this study was to investigate the effectiveness of a family-based intervention program on the managerial self-efficacy of symptoms associated with chemotherapy in women with breast cancer. Results and analysis of data showed that this method increases the managerial self-efficacy of symptoms associated with chemotherapy in these patients. Given that no similar research has been done in this area, only a few studies in this area can be mentioned.

In patients with breast cancer, when people lose a member of their body that is valuable to them, they lose the source of social support and fall into seclusion, so the mental and physical image change that leads to decrease in self-esteem. As a result, this decrease in self-esteem is effective in the level of their social interactions and reduces the level of self-efficacy (9, 10). The study of Rasouli et al. showed that there is a positive and significant correlation between prognosis and self-efficacy in patients with cancer. This means that patients with negative prognosis of their disease have lower self-efficacy (20).

Rahmani also showed that one of the important factors in incubating cancer treatment in cancer patients, is family members of their patients and their families (21). Self-efficacy in cancer patients leads to better reconciliation with cancer diagnosis and improved quality of life. And reduces the symptoms of cancer in patients. A high level of self-efficacy improves the mental image of cancer patients and improves their communication with health care staff (22). In a study

conducted by Akin et al., the quality of life and self-efficacy of women with breast cancer under chemotherapy in Turkey evaluated, the self-efficacy score of patients generally decreased compared with pre-chemotherapy (23).

Cancer due to some reasons can decrease self-efficacy including reduction in physical strength, reduction in ability to perform daily activities, frequent and long-term hospitalization, reduction in life expectancy, and eventually depression (24). The results of study performed by lev et al. showed that any intervention for increasing self-efficacy leads to improved quality of life and reduced symptoms of psychosis in women with breast cancer (25). The study of lee et al. showed that Meaning-making intervention in patients with breast cancer or colorectal can lead to increased self-efficacy (26).

In explaining the findings of this study, it can be said that research suggests that some supportive programs in women with breast cancer can prevent complications. In this regard, it can be said that women who benefit from the support of their close relatives, especially their spouse during their illness and treatment, are more likely to tolerate their own stress and hardship. Family support plays an important role in restoring function after cancer. In fact, spouse, children, and family are supportive factors which are importance for patients. These individuals are less or more dependent on others and are not able to support others, so their individual interactions are limited to others and may be isolated in the community, and therefore their need for family support is increased.

Therefore, one of the most important factors in the self-efficacy of women in coping with the psychological pressures due to disease is family support. The lack of attachment to the family and generally disruption in the relationship with family members can increase the level of stress and consequently reduce mental health as well as inability to cope with the disease. Family members of patients can increase their ability to cope with their supportive behaviors.

CONCLUSION

Factors such as improving information and awareness about physical and psychological aspects, increase of motivation, support and counseling improve the physical condition, reduce anxiety and mood disorders, enhance one's perception of life goals, improve adaptability with the behaviors of patients, in a such way that lead to symptom management and ultimately lead to a better quality of life.

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Conflict of interest

The authors declare that there is no conflict of interest in this study.

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