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The effect of Lymphedema self-management group-based education on fear of cancer recurrence in women with breast cancer: A clinical trial

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ABSTRACT

Background: Breast cancer-related lymphedema is a chronic problem after breast cancer surgery, which cause physical symptoms and are, therefore, considered as signs of cancer recurrence by patients and triggers fear of cancer recurrence. Fear of cancer recurrence, as one of the most common problems of cancer survivors, is associated with reduced adherence to lymphedema self-management behaviors. This study aims to investigate the effect of lymphedema self-management group-based education on fear of cancer recurrence in women with breast cancer. *Methods:* This research is a clinical trial with two groups conducted on 70 patients with breast cancer-related lymphedema in the past one year in Seyed-Khandan rehabilitation center. The women participating in the study were assigned to one of the two groups group-based education (GE) (n=35) and the control group (CO) (n=35) using a random block method with a size of two-people. In addition to the routine lymphedema treatment that done for all patients, the group-based education group also received self-management education in five sessions in groups of five. Fear of cancer recurrence was assessed in the two groups before, immediately after, and three months after the intervention using the short form of the fear of disease progression questionnaire. *Results:* During three months, the mean score of fear of cancer recurrence from 34.4 to 31.8 (p=0.112) in the group-based education group, and from 36.6 to 35 (p=0.242) in the control group. Although mean score of fear of cancer recurrence reduced more in the intervention group than in the control group, changes in score of fear showed no statistically significant difference immediately (p=0.287) and three months (p=0.099) after the intervention. *Conclusion:* Lymphedema self-management education was associated with reduced score of fear of cancer recurrence. Lack of observe a meaningful relationship in the difference in fear scores between the two groups may indicate the impact of other related factors or the use of other educational methods, which emphasizes the need for further research in this regard. *Trial registration:* This study was registered in the Iranian Center for the Registration of Clinical Trials under the number (IRCT2017052834176N1).

Keywords: Self-Management, Lymphedema, Fear of cancer recurrence, Breast Cancer.

1. INTRODUCTION

Breast cancer-related lymphedema (BCRL) is one of the most important side effects of breast cancer treatments and is considered as a stressful incident in the lives of the survivors of this type of cancer (Wanchai et al., 2016). BCRL, with a prevalence of 70 percent, is considered a common type of secondary lymphedema (Borman et al., 2017). Lymphedema are chronic swelling which can progress and increase the risk of wound and infection in the affected limb and has negative effects on personal economy (due to increased treatment expenses) and the quality of life of the patients. Lymphedema can trigger fear of cancer recurrence (FCR) by causing swelling, pain, physical dysfunction, anxiety, depression, social isolation, and disturbing thoughts (Alcorso et al., 2016, Chachaj et al., 2010, Fu and Rosedale, 2009). FCR is one of the most prevalent complications reported by cancer survivors, which is defined as the fear and anxiety of the return or progression of cancer in the same organ or into other organs (Lebel et al., 2017). The prevalence of FCR among people with a history of breast cancer is reported to be 82 percent (Koch et al., 2014). FCR can range from normal fear to clinical level of fear (Lebel et al., 2017). High levels of fear are associated with inefficiency, stress, reduced quality of life, and social, emotional, and cognitive dysfunction (Mehnert et al., 2013, Simonelli et al., 2016). Promoting the survivors' self-efficacy increases their belief in controlling symptoms related to the disease (Alcorso et al., 2016). Self-management helps the patients promote their self-efficacy by enabling the patients to take an active role in taking care of themselves (Lorig and Holman, 2003). The increase in the number of cancer survivors, treatment expenses, lack of trained personnel, and the progressive and costly nature of lymphedema causes the patients to show willingness to take an active role in taking care of themselves (Akechi et al., 2014, Jansen et al., 2015). Therefore, self-management has turned into a common term in health education (Lorig and Holman, 2003). Self-management education can be used at any time during the cancer care chain (McCorkle et al., 2011). Self-management is often taught in group (Calzone et al., 2005). The group aspect of this type of programs is related to the principles of social cognitive theory which emphasize learning through participation and peer support. Different studies have shown the psychosocial advantages and improvement in treating the side effects of the disease by using this method among patients with cancer (Smith-Turchyn et al., 2016). Although self-management is the second phase of standard lymphedema treatment or Complete Decongestive Therapy (CDT) (Ridner et al., 2012), but the level of awareness and the rate of adherence to self-management behaviors among patients with

lymphedema in less than optimal (Alcorso et al., 2016). On the other hand, FCR is one of the factors that reduce adherence to self-management behaviors (Fu et al., 2013, Fu and Rosedale, 2009). Given the fact that there is no agreed-upon approach to treating FCR and that the interventions used to treat lymphedema are also symptomatic and only control the swelling of lymphedema and also the scarcity of studies investigating the role of teaching self-management to women with lymphedema, the present study was conducted to explore the effect of lymphedema self-management group-based education on fear of cancer recurrence. Proving the effectiveness of this intervention can be useful in promoting the quality of life and reducing fear of recurrence among patients with lymphedema by offering appropriate solutions in health policy making.

2. METHODS

Trial Design

This research is a two-arm clinical trial which was conducted on 70 women with BCRL. Sampling was done using a random block method with a size of two, assigning one person to each group. Thirty-five women were studies in each group. The control group only received the routine lymphedema treatments and the intervention group received self-management education in five sessions in groups of five as well as the routine treatments. The study was approved by the Ethics Committee of the Iran University of Medical Sciences (IR.IUMS.REC1395.9411173002).

Participants

The participants in the study were women with lymphedema who had referred to Seyed-Khandan rehabilitation center for treatment in the past one year. The inclusion criteria were a history of confirmed breast cancer (stages 0 to IV), lymphedema confirmed by a physician in the past year, aged 18-65 years old, completion of primary cancer treatments, ability to read and write, no post-cancer psychiatric disorders requiring drug therapy. The exclusion criteria were failure to attend in the third and fourth sessions of in-person education as the key sessions, detection of cancer recurrence during the study, and unwillingness to continue the intervention.

Intervention

Interested eligible patients were registered by the researchers after obtaining written consent from late September 2017 to late June 2018. The patients were randomly assigned to one of the following groups: group-based education (GE) and control (CO). All the patients received the routine treatment for lymphedema, which included 20 sessions of CDT. The treatment was offered in two phases of acute and preservative. The acute phase treatment was offered for 2-3 weeks in the clinic, and the preservative phase was done by the patients at home. FCR was measured in both groups before starting the study (T0), immediately after the study (T1), and three months later (T3). The researcher's phone number was given to the patients so that the participants could ask any potential questions during the three months. During this time, to avoid potential bias and providing additional information for some of the participants, the patients were not contacted. The participants were reminded of reviewing the contents by SMS every week. Due to the design of the study, blinding was not possible, and it was not done. In order to prevent the contamination of information, the staff of the clinic was ordered to arrange appointments for the GE group in the morning and arrange appointments for the CO group in the afternoon. Having been informed about the design of the study, the participants were asked not to share information with other people.

The educational content of the program was designed after library studies, being approved by three faculty members of the faculty of nursing and midwifery, and based on lymphedema self-management behaviors as well as one session of stress management strategies. The group training included five sessions of 60 to 90 minutes, held twice a week in the form of lectures, group discussions in groups of five in one of the quiet rooms of the clinic, presented by the researchers. The educational content included preventing the stress, fear, and anxiety caused by breast cancer with an emphasis on lymphedema, principles of self-management skills, problem-solving skills in lymphedema for preventing its complications, lymphedema management methods (second phase of standard lymphedema treatment), decision making, using resources, explaining the use of each self-management process appropriate to the patient's condition, cooperating with the treatment team and employing the learned skills at home. The CD of the educational materials was provided to the participants. The control group received the CD of the educational materials after the completion of the study, too (Fig. 1).

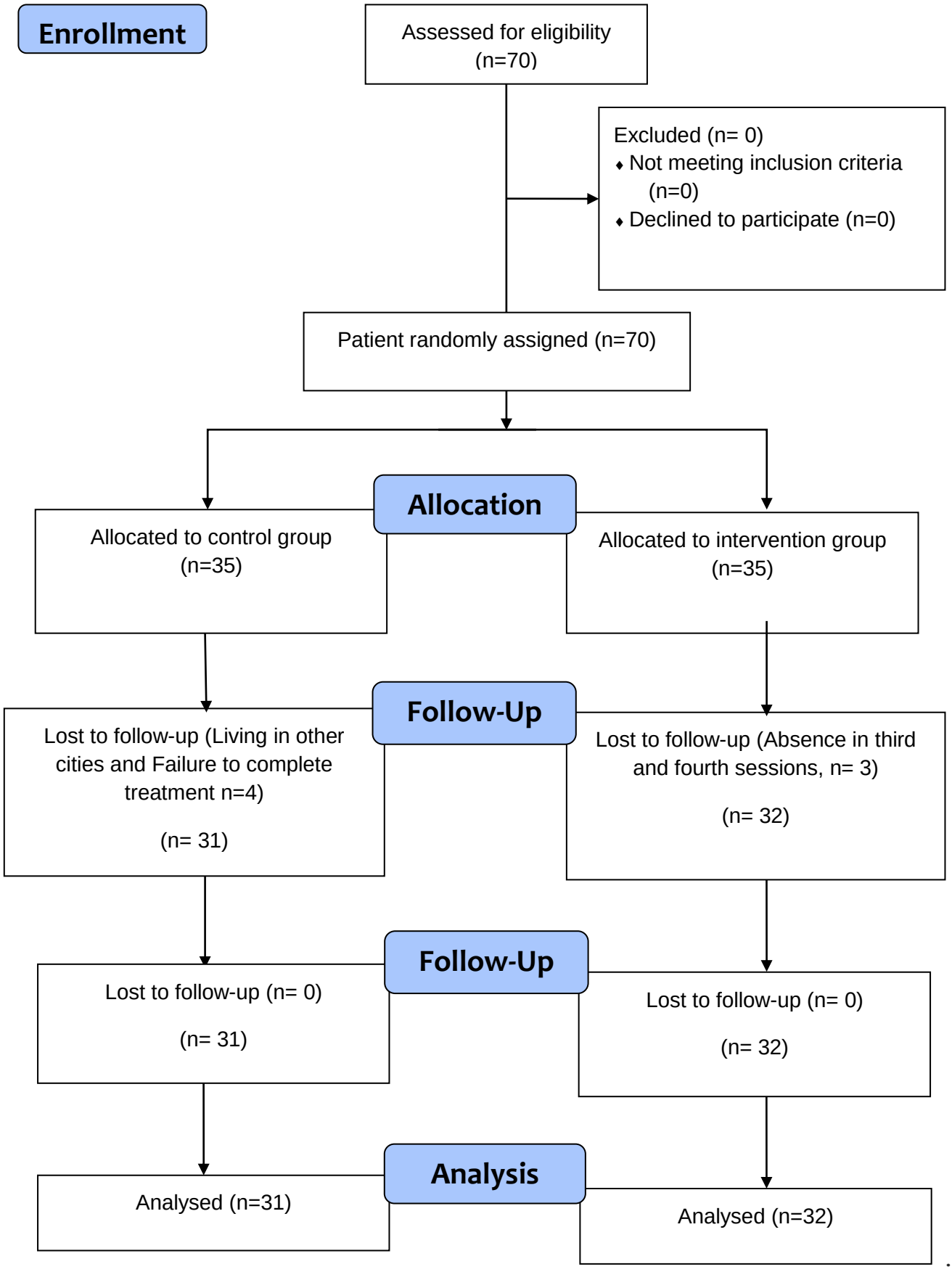

Figure 1 Recruitment and eligibility screening, randomization, follow-up, and analysis

Outcomes

1. The demographic characteristics and the information related to the disease were completed using a researcher-made demographic from before the study started. The form included questions about age, educational level, marital status, employment status, BMI, type of surgery, the duration of the lymphedema, the severity of the lymphedema, and the stage of cancer.
2. Fear of cancer recurrence was assessed using the Persian version of Fear of Progression Questionnaire - Short Form (FoPQ-SF) which was completed by the participants before the intervention (T0), immediately after the intervention (T1), and three months after the intervention (T2). It is a 12-item questionnaire based on the fear of cancer recurrence questionnaire, scored by a 5-point Likert scale. The total score is the obtained by adding up the responses to each of the questions, with the maximum possible score being 60. The score 46.5 is considered as a cut-off point for high FCR. The reliability and validity of the Persian version of the questionnaire have been investigated by Mohajjel-Aghdam and colleagues (Aghdam et al., 2014).

Sample size

The sample size was estimated by α = 0.05, β = 0.2 and based on a previous similar study (Ghavam-Nasiri et al., 2012) and by considering a 15 percent drop out of participants, was obtained to be 35 people for each group. The total sample size was 70 people.

$$n = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{\left(\mu_1 - \mu_2\right)^2} = \frac{(1.96 + 0.84)^2 16.81^2}{(8.62)^2} \sim 30$$

Randomization

Using a random block method with the ratio of 2:2, 35 sets of AB, BA modes with numbers from 1 to 35 were randomly prepared by a statistics expert using the Excel software. Both of the two participants who entered the study had to be assigned to one of the sets. The letters A and B were chosen as symbols for one of the two groups of GE group or CO group. The participants were assigned to one of the two groups in the study based on the determined letters. This way, each five people who entered GE group received the intervention.

Statistical methods

The statistical analyses were performed using SPSS version 16 software. The difference between demographic and clinical variables was investigated using Chi-square and Independent-Samples t-Test. Kolmogorov-Smirnov test confirmed normal distribution of FCR variable, so parametric tests were used. The mean scores of FCR between the two groups was compared using a t-test, the changes in the score of FCR from immediately after the intervention and three months after the intervention were analyzed using an ANCOVA tests, and the effects of intervention over time was examined using repeated measures tests. $P<0.05$ was considered statistically significant for analyses.

3. RESULT

Of the 70 patients who entered the study, four people in the control group (due to living in cities far from the clinic) and three people in the intervention group (due to absenteeism the third and fourth sessions of training) dropped out of the study. Totally, 63 people were assigned to the two groups of group training (n=32) and the control (n=31). Most of the women were married, educated, with grade II- cancer, and stage II of lymphedema. There was no statistically significant difference between the two groups in terms of the demographic characteristics (Table 1).

The difference between the mean scores of FCR in the two groups was analyzed at each stage of the study using Independent Samples t-Tests. The mean scores of FCR decreased in both groups, but there difference between the intervention group and the control group was not significant neither immediately after the intervention (p=0.099) nor three months after the intervention (p=0.287) (Table 2). Based on the repeated measures test, the changes in the scores of FCR showed a declining trend in the intervention group and the control group (p=0.112 and p=0242, respectively) (Fig. 2). Based on the ANCOVA test, the changes in the scores of FCR in the two groups were not statistically significant immediately after the intervention (p=0.139) or three months after the intervention (p=0.243) at the level of 5% error (Table 2).

Table 1 Demographic and disease-related characteristics of participants and comparison among groups.

Variable	Group training (n=32) N (%)	Control (n=31) N (%)	P-value
Marital status			
Single/Divorced/Widowed	5(15.6)	5(16.1)	0.956
Married	27(84.4)	26(83.9)	
Educational level			
Diploma/Under Diploma	19(59.4)	16(51.6)	0.535
University	13(40.6)	15(48.4)	
Occupation			
Employed	6(18.8)	5(16.1)	
Housekeeping	19(59.4)	20(64.5)	0.915
Retirement	7(21.9)	6(19.4)	
Type of surgery			
Modified Radical Mastectomy	18(56.2)	16(43.8)	0.712
Breast Preservation	14(51.6)	15(48.4)	
Grading of breast cancer			
I	2(6.2)	2(6.5)	
II	15(46.9)	19(61.3)	0.236
III/ IV	15(46.9)	10(32.3)	
Severity of lymphedema			
I	4(12.5)	8(25.8)	0.179
II/ III	28(87.5)	23(74.2)	
	Mean (SD)	Mean (SD)	
Age	52.47 (±10.62)	50.23(±8.90)	0.368
BMI (kg/m2)	28.04 (±5.07)	28.35(±4.52)	0.798
Duration of lymphedema (month)	6.22(±3.86)	7.26(±3.34)	0.259

4. DISCUSSION

To the best of our knowledge, the present study is one of the first studies investigating the effect of group training of self-management on FCR in women with lymphedema. According to the results of the study, although the mean score of FCR decreased more in the intervention group than in the control group, the different between the two groups was not statically significant in any of the three stages of the study.

The present study was conducted on a population of women in which 55.6% had high school education, 85.7 % were married, their mean age was 51 years old, and their mean BMI was 28. In the study by Melam which was also conducted on women with breast cancer-related lymphedema, most of the participants were educated, married, and with a mean age of 56 years old (Melam et al., 2016).

Evidence from the present study showed that the mean score of fear immediately and three months after the intervention decreased in both groups, with the reduction being more for the intervention group than the control group (p=0.099, p=0.287, respectively). In the study by Visser which was done on 109 women with breast cancer, group medical counseling and online group back-up support sessions based on tablets had no effect on the level of FCR and the quality of life one week, three months, and six months later, and there was not a significant difference between the scores for the intervention and control groups (Visser et al., 2018). Given the fact that only one session was devoted to teaching stress management, it can be concluded that more reduction in stress scores could have been achieved by devoting more sessions to teaching stress management or by using cognitive-behavioral treatments in a more specific way.

Table 2 Comparison fear of cancer recurrence among groups on T0, T1, T2

Fear of cancer recurrence	Groups Mean (SD)		P*
	GE (n=32)	CO (n=31)	
T0	34.37(12.27)	36.60(11.12)	0.452
T1	31.78(11.00)	36.29(10.31)	0.099
T2	31.81(11.91)	35.03(11.88)	0.287
P**	0.112	0.242	
P*** T1/T0	0.139; Adjusted R Squared = 0.839		
P*** T2/T0	0.243; Adjusted R Squared = 0.592		

P*Indicates Independent-Samples T-Test.
P**Indicates repeated measure test in each group.
P***Indicates ANCOVA test

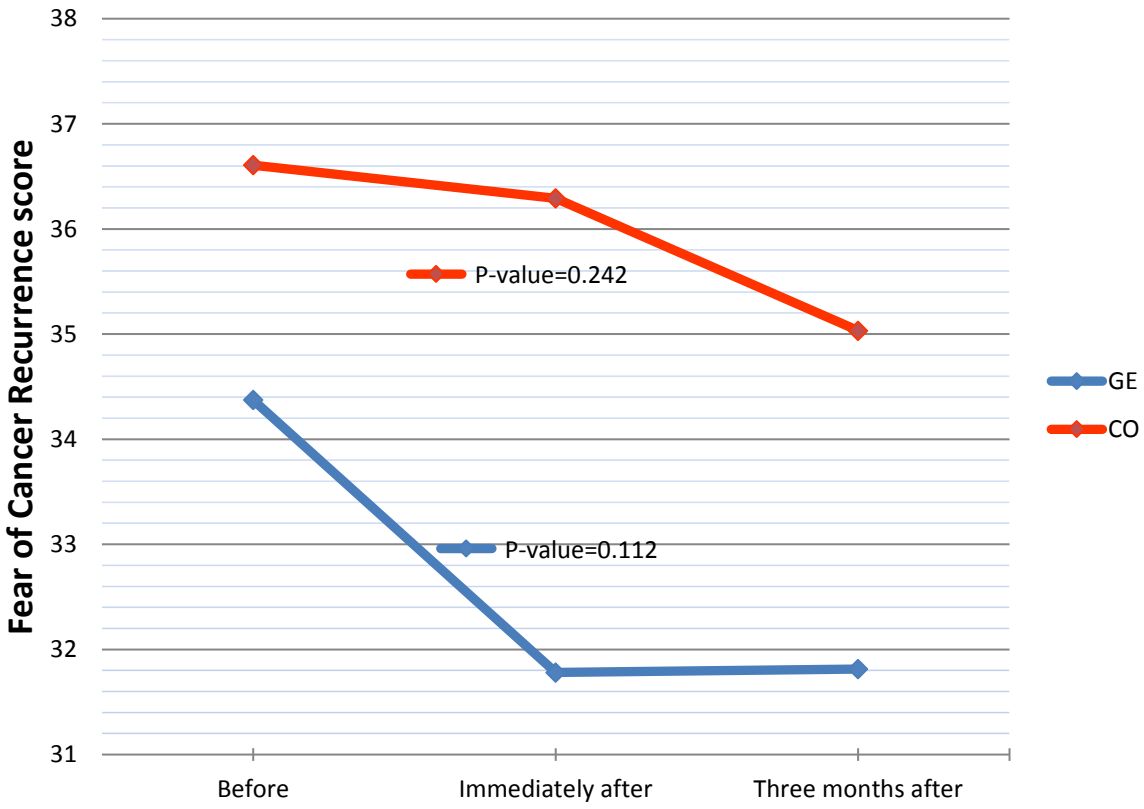

Figure 2 Effect of the intervention on FCR

As shown in Figure 2, the reduction in fear scores from before the intervention to immediately after the intervention has been higher in the intervention group. In another study which investigated the effectiveness of cognitive-existential group therapy on fear of cancer recurrence in 56 women with breast and ovarian cancer, considerable improvement was shown in fear of cancer recurrence, cancer-related stress, and quality of life immediately and three months after the intervention (Lebel et al., 2014). Given that the population of the participants in the present study consists of women with lymphedema, it seems that other factors such as swelling and chronic pain may act like barriers for accepting and using stress management strategies, in such a way that the changes in the mean scores of FCR was not significant in either groups after three months. Although other studies have mentioned lymphedema as triggers for FCR (Fu and Rosedale, 2009), but in the population studied in our research the score of FCR was not very high. Perhaps comparison the fear score between populations with and without lymphedema can shed light on the current situation and help offer solutions for dealing with fear in these patients.

Since there is not agreed-upon approach to controlling FCR (Akechi et al., 2014), in most studies cognitive-behavior therapy or psychological counseling have been used to control FCR. In our study, it was first supposed that adding stress management skills to lymphedema self-management skills can not only enable the patients to control their lymphedema, as the trigger for fear, but also to reduce stress and anxiety and on the other hand, the patient's participation in groups and benefiting from peer support and education can facilitate people's belief in being able to control the disease. The results of the study by Compen, which compared the effect of mindfulness-based cognitive therapy in a face-to-face way and in group sessions and based on the Internet in patients suffering from cancer, showed improvements in FCR, rumination, mental functioning, mental health, and quality of life in the participants (Compen et al., 2018). Therefore, it may be claimed that FCR in women with lymphedema requires education and group sessions with short intervals, since factors triggering fear in these people will diminish with the passage of time. In the present study, the CD of the taught subjects was given to the patients, and reviewing the content was reminded by text messages, but it was impossible to hold sessions during the follow-up stage because some participants resided in other cities. It is suggested that future studies consider holding review sessions in short intervals.

It seems that most aspects of the lives of women with lymphedema can be improved by education of them, or even to start teaching the patients how to deal with lymphedema before the lymphedema happen and during primary cancer treatments to prevent or reduce FCR in patients, since 40 percent of breast cancer survivors never receive any information about lymphedema, hence they take them as a sign of cancer recurrence (Fu et al., 2016). Also, there is scarcity of knowledge in the area of FCR (van Helmondt et al., 2016), in a way that only five studies dealing with FCRwere found in a systematic review (Simard et al., 2013). Considering that most of the interventions on the fear of cancer recurrence of survivors were in the early stages of cancer treatment as well as the number of people with lymphedema and that there are few clinic for treating lymphedema in Iran, in the present study a more reduction in FCR was witnessed in the intervention group than the control group by using group-base education as a method in which more people can be taught simultaneously and in which group support makes the participants more interested in achieving their goals. Since the difference in scores between the two groups was not statistically significant, more studied are needed to investigate the effects of different methods of teaching among patients with lymphedema. The present study offered the grounds for answering many questions regarding how to use the group method. Although the present study was conducted in a clinic, the results of this study are largely applicable to women with lymphedema in general, since patients who are referred to this clinic are from different parts of the country.

5. CONCLUSION

Teaching lymphedema self-management in a group way decreased FCR immediately and three months after the intervention, but the difference between the intervention and the control groups was not significant. Our study highlighted FCR and its complications in women with lymphedema because these patients face the less responded to need such as FCR in addition to their lymphedema, which is itself a barrier to managing the symptoms of lymphedema. It seems that these people need a wide range of psychological measures in addition to educational support to enable them control their fear.

Ethics approval and consent to participate

The study was approved by the university ethics committee (Iran University of Medical Sciences, Tehran, Iran).

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