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Does Exercise Change Quality of life in Patients with Breast Cancer Undergoing Chemotherapy? A Randomized Controlled Trial

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ABSTRACT

Chemotherapy is used as the most common therapeutic method in breast cancer. Despite of some therapeutic effects, this approach can create potentially some side effects that can decline the quality of life of patients. This research was conducted to describe the effects of exercise on quality of life (On various aspects) of patients with breast cancer undergoing chemotherapy. This is a clinical trial study in which 60 patients undergoing chemotherapy due to breast cancer at Imam Reza Chemotherapy clinic in Seyyed Alshohada Hospital of Isfahan were selected and assigned to intervention and control groups (group A & B). At the start, the questionnaire including demographic information and quality of life were filled in by the participants. The A group adopted a 6 weeks exercise intervention whereas no intervention for the other group. Then after completion of exercise program, both of the groups filled up the quality of life questionnaire again. Data were compared statistically. The mean score comparison of the participants' quality of life pre& post study indicated a significant difference between the groups in aspect of physical ($p = 0.001$), psychological ($p = 0.005$), social ($p = 0.006$) and total score of quality of life ($p = 0.001$). The finding also indicated lack of significant difference in mean score of spiritual aspect of QOL between A&B groups. Adopting exercise activities in patients with breast cancer is a beneficial intervention that brought change in emotional, social, spiritual and physical aspects of QoL in these patients.

Keywords: *Breast Cancer, Chemotherapy, Quality of life, Exercise, Intervention, psychological Declaration of interest: There is no conflict of interest among authors and ethical committee has approved this study.*

1. INTRODUCTION

Breast cancer is usually known as a cancerous tissue in the inner layer of breast ducts or lobules wich may be derived from environment and genetic interaction [1].Breast cancer is the most prevalent cancer in females which represents sixteen percent of all women cancers. The long-term impact of breast cancer and its curative planning have been recognized to have favorable and adverse effects on various dimensions of quality of life (QOL)[2].More than two-hundred types of cancer have been recognized so far. Evidences have shown that cancer is the second etiology of mortality in some countries [3]. It is responsible for 32% of women's mortality in range of 20 -59 years and also second cause of mortality among women in all ages [4].

Breast cancer is the most common malignancy among Iranian women that its prevalence is about24.41% [5].Treatment of Cancer depends on the staging of the cancer and is usually a combination of surgery, chemotherapy, hormone therapy, radiotherapy and pharmacotherapy [6]. Chemotherapy has important role in managing and controlling of breast cancer [7] but it has many side effects like mucosit is, bone marrow suppression, alopecia, nausea, vomiting, diarrhea, and lack of appetite [8]. These side effects increase emotional disturbances in patients, impairment in physical, social and occupational activities, and specially decline quality of life (QOL).It has been showed that stress management plays an important role in improving the patient's access to psychosocial intervention after chemotherapy[9].

More than50% of patients who suffered from breast cancer, mentioned weakness during chemotherapy. There are some interventions for decreasing feeling of fatigue via somatic and psychological mechanisms [10, 11].

A study evaluated 63,949 patients being treated with chemotherapy and reported 80 %fatigue, 48% pain, and 8% nausea/vomiting as side effects of chemotherapy. Also it showed that anxiety and depression can elevate the risk of fatigue. Furthermore, missed work days were higher in patients who have more side effects [12]. Some interventions are necessary for improving the QOL in patients undergoing chemotherapy [13].Physical exercise is an acceptable intervention to decrease fatigue, to improve physical functioning and QOL and to increase survival in patients with breast cancer [13].

Exercise is considered as one of the effective interventions which account for a in part of rehabilitation and follow-up care in chronic illness [14]. Also it is successful intervention for improving the QO Land decline of the mortality rate [13, 15, 16]. Exercise has a supportive effect on physical and psychological well-being. Exercise is known to have positive impacts on

accelerated physical function, muscular power; emotional and spiritual ability, increased self confidence and declined fatigue, anxiety, depression [17, 18].The mechanism(s) of exercise in cancer is unclear until now but there is some probable mechanisms such as change the steroid hormones or insulin/insulin-like growth factors, effect on free radical production and also effect on immunomodulatory system. How exactly the exercise helps improve cancer is still not established, there are some probable explanations such as the change in the steroid hormones [19].

Exercise is known as an intervention for rehabilitation of patients who suffered from cancer[20] and also patients who were advised complete bed rest [21,22].Several studies revealed that this intervention resolve weakness and the ability of patients against the problems of disease. Unfortunately, there is no exercise intervention to improve the Iranian patients' QOL and the studies on this field are all from those countries with different demographic and socio-cultural characteristics. The purpose of this study is assessing the effects of exercise on QOL (in various dimensions) in Iranian patients with breast cancer undergoing chemotherapy as a population with different demographic and socio-cultural characteristics. Our study compared to previous studies has same distinctive properties:

a. In contrast to many studies, It designed a for the role of exercise on multiple dimensions of health.
b. There are very few studies conducted in this field in Iran.
c. Finally, Item phases more on role of exercise on health.

2. MATERIAL AND METHODS

2.1 Subjects

In this clinical trial study, 60 breast cancer patients undergoing chemotherapy at the Seyed Alshohad Hospitalin Isfahan, Iran from Sep 2007 till Feb2008 were selected via convenient method and randomly assigned into 2 groups of intervention and control. There is a registry in Imam Reza Chemotherapy Clinic that all breast cancer patient undergoing chemotherapy register at. We have used that registry for convenient selection.

Inclusion criteria was include: Age 30 -55 years (Because breast cancer in younger patients is nearly rare and risk of co morbidity is really high in patients older than 55 years old age)breast cancer diagnosis more than1 month before the survey, undergoing modified radical mastectomy in stage I and II, having chemotherapeutic regimens (AC, CAF, CEF) for at least one session, and lying-in the functional level of 0-1. Exclusion criteria was include: metastasis, treatment with anti-coagulant , and diagnosis of other cancers, dementia, psychiatric disorders, undergoing radiotherapy, cardiovascular diseases such as myocardial infarction(MI) in past 3 months and congestive heart failure (CHF),medications for arrhythmia and constant exercise in past 2 months for 2 to 3 times weekly.

2.2 Instruments

To assess the participants' QOL, the standard tool of the National Medical Center and Beckman Research Institute was used which assess the patients' QOL in four aspects: physical, psychological, spiritual and social. Instrument was translated to Persian version. The internal consistency(IC) and Content validity (CV) of questionnaire were used to assure the validity and reliability of the instrument respectively. The Cronbach's alpha was 0.80 before the intervention for the 10 patients undergoing chemotherapy. These were excluded from the survey. Before the intervention, the QOL questionnaire was completed for both groups. The Consent form was obtained from all of the participants in intervention group. We have gotten informed consent from all participants in intervention group but we didn’t so in control group because doing this in control group could make some bias in our study because having information about the study could make some problem. In addition we didn’t want to do any intervention could may have some difficulties for control group.

Although we explain in the head of questionnaire that “we need to know about your QoL” and also we had explained about security of their responses so we suppose that answering to questionnaire could substitute to informed consent.

2.3 Intervention

The intervention group undergoes 6 weeks of exercise while the control received usual care. According to the declaration of the Journal of American College of Sport Medicine, at least 6-7 weeks of exercise is needed for intervention to get significant results Likewise, the other declaration of this journal suggests that 3 to 4 exercise sessions per week are enough for men and women(23)Kornia et al recommend specifically 20 to 30 minutes continuous exercise, 3 to 5 days per week for patients(24) A review of various studies revealed that exercise interventions with low to moderate intensity (55% to 85% of the maximum heart beat) are appropriate for cancer patients (25)In this study, the exercise interventions included 3 sessions in 30 minutes per week for 6 weeks. Also, according to the style of American College of Sport Medicine, the researcher designed a structured supervised exercise protocol including warm up, aerobic exercise and cool down. The Mode of designed exercise protocol was Aerobic. The exercise sessions were done one by one. In the first 7 minutes, a nurse guided the patient for stretching and ballistic movements to warm up. This part included a series of dynamic moves to activate big groups of muscles. In the next stage, the aerobic moves were done for seven minutes, calm and jogging on electronic treadmill which showed the heart rate and the used calories. Then for another 7 minutes, the patients cycled on a fixed magnet bicycle with heart beat monitoring. The intensity of exercise activities was controlled by pulse rate; it was

planned as 55% of intensity in the 1th, 2th weeks, 65% in the third and fourth weeks and 75% in the fifth and sixth weeks. In the stage3 and to cool down, patients did stretching and ballistic movements like those of the stage 1. This stage was also 7 minutes. All of the exercise items were done under supervision of research assistants. Before intervention and at the end of 6 weeks exercise intervention, the questionnaire of quality of life was completed by the patients in both groups.

In addition to independent variables(exercise intervention) and dependent variables(QOL scores), other variables such as age, education, history of regular exercise before and after disease diagnosis, duration of diagnosis, body mass index (BMI), and chemotherapy regimen were considered as well.

2.4 Statistical Analysis

Data were analyzed using SPSS. To compare the QOL means score within groups, paired t-test, and to compare QOL means score between groups, independent t-test was used. Also to compare the relationship between the QOL means score and background variables, Pearson and Spearmen statistical methods were applied. Moreover Chi-Square, Man Whitney and Fisher test were used to study homogeneity of the background variables in the both groups.

3. RESULTS

The results showed that the two groups compared for their background variables were not statistically different (Table 1). There was also no significant relationship between the two groups in Baseline QOL means score. Table 2 (T-Student, P=0.33).

The mean score of the physical aspects of QOL in intervention group before the intervention was 57.25±15.04 while after the intervention, it reached to 64.12±14.52 showing no significant relationship (p = 0.107).

The mean score of the physical aspects of QOL in the control group before the intervention was 53.66±13.23after which it reached 49.04±10.95. The difference, however was not significant (p = 0.187) although the mean score reduced after the intervention. Although the difference between the means score of physical aspect of QOL in each group was not significant, but after the intervention, the difference between the score of physical aspect of QOL between group, was significant (p = 0.001).

In terms of the psychological views, no significant relationship was found between the groups before the intervention (p= 0.844). The mean scores of the psychological aspect after intervention were 47.75±14.10 and 37.96±11.80 in the intervention group and control group respectively thus being statistically significant (T-Student, P = 0.005). Although no significant relationship was detected between the pre and post means score of the intervention group (T-Paired, P = 0.171). This was the case with the other group (control group) although the mean score reduced (p = 0.227).

Given the social aspect, the mean scores after the intervention in the intervention group and control group turned out to be 46.95±15.41 and 37.42±9.91 respectively and the difference was significant (p = 0.006).No significant relationship was found between the mean score of the intervention group before and after the intervention (44.14±15.28 and 46.95±15.41 respectively). The reduction of mean score, however, in the control group after the intervention compared with that of before (42.76±13.01 and 37.42±9.91) respectively, which was statistically significant, indicated low quality of life in this group at the end of the study (T-Paired, P = 0.021).

In terms of the spiritual aspects of QOL, there was no significant relationship between the mean score of the two groups before (p = 0.711) and after the intervention (p = 0.896). Moreover, no significant relationship was detected between the mean score of the intervention group before and after the intervention (65.19±12.14 and 68.95±12.08 respectively, p = 0.151) as well as the scores of the control group before and after the intervention. (64.14±9.47 and 69.33±10.30 respectively, p = 0.078)

With regard to the overall score of QOL before the intervention in Intervention group (48.50±11.70) and control group (48.02±9.54), no significant relationship was detected (p = 0.862) However after the intervention it was significant (intervention group, 53.97±10.77; and control group, 44.88±7.88) indicating remarkably higher overall quality of life with the intervention group (p = 0.001).

The results also indicated that although there was an increase in the overall score of quality of life in intervention group after the intervention compared with that of before, the different was not significant (p = 0.113).

This was the case with the other group, i.e. the difference was not significant although the score reduced in the end (p = 0.163).

4. DISCUSSION

We aimed this study to examine the alteration in quality of life in patients with breast cancer undergoing chemotherapy because of exercise. To assess the participants' QOL, the standard tool of the National Medical Center and Beckman Research Institute was used which assess the patients' QOL in four aspects: physical, psychological, spiritual and social.

The mean score of two groups compared after the intervention for physical domain indicated a significant difference. In a study conducted by Thorsen et al as title “Effectiveness of Physical Activity on Cardio respiratory Fitness and Health-Related QOL in Young and Middle-Aged Cancer Patients Shortly After

Chemotherapy" it was shown that the maximum consumption of oxygen increased while exhaustion score reduced in intervention group compared with control group[26].

Kim found that only cardiovascular responses (deceleration of heart rate and systolic blood pressure at rest; maximum the systolic blood pressure; and maximum O_2 consumption) improved in control group [27]. However the results of Headly's research in US on the breast cancer patients at stage IV undergoing chemotherapy demonstrated exercise intervention reducing physical aspect of QOL in the intervention group [28].

The subjects who enjoy of a regular physical activity have a favorable physical views of QOL compared with sedentary life style subjects [29].

In a survey on patients with breast cancer survivors undergoing a combined exercise program of resistance and aerobic type suggested that the exhaustion score of participant in delay exercise group enjoyed an increasing process before exercise intervention while in continuation of the program and during the future weeks, this score reduced. Supervised exercise post breast cancer approaches may aid to positive reinforcement of exercise motivational profile among these patients [30].It seems that exercise could have very benefit for help to oncologists for better treatment of their patients. Over all the results of this study like as similar studies have revealed the improvement of multiple aspects of quality of life for subjects who undergoing a regular exercise planning. Probably the reason for a reduction of physical aspect of quality of life in the control group in this study can be attributed to the treatments methods and related side effects as well as lack of an appropriate program to acceleration of QOL.

5. CONCLUSION

Although the results of this survey shows significant difference between the beginning and end of the study within both group (in terms of physical aspect), the improvement of physical aspect in the intervention group and the reduction of it in control group can be attributed to the positive results of the exercise intervention.

The study of literature reveals that an exercise planning , even though not statistically significant, can enhance the physical aspect of quality of life among all other aspects and this is the reason that most of nurses and other clinicians have already attention more on these aspects. The physicians and nurses should be protecting to integrate physical activity recommendations into practice, tailored to the individual's health status.

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Table 1: Baseline demographic and medical variables of study participants

Demographic Profile	Overall	Intervention Group	Control Group	P
Age (±SD)	45.86(±6.58)	45.66 (±6.72)	46.06 (±6.54)	Independent t-test (0.816)
Educational Status				Man Whitney Test (0.445)
Elementary	24(40%)	13(43.4%)	11(36.7%)	
Guidance School	19(31.7%)	10(33.3%)	9(30%)	
High School	17(28.3%)	7(23.3%)	10(33.3)	
Marital Status				
Single	4(6.7%)	2(6.7%)	2(6.7%)	χ2 (1.000)
Married	25(83.3%)	25(83.3)	50(83.3%)	
Widowed	3(10%)	3(10%)	6(10%)	
Occupational Status				
Employed	4(6.7%)	1(3.3%)	3(10%)	χ2 (0.459)
Householder	53(88.3%)	28(93.4%)	25(83.3%)	
Retired	3(5%)	1(3.3%)	2(6.7%)	
Breast Cancer Familial History				
First Degree Family	1(1.7%)	1(3.4%)	0(0%)	χ2 (0.804)
2nd Degree Family	10(16.6%)	5(16.6%)	5(16.7%)	
3rd Degree Family	7(11.7%)	4(13.3%)	3(10%)	

Negative FH	42(70%)	20(66.7%)	22(73.3%)	
Exercise History (Before Cancer Diagnosis)				
Irregular Exercise	15(25%)	7(23.3%)	8(26.7%)	$\chi 2$ (0.776)
No History of Exercise	45(75%)	23(76.7%)	22(73.3%)	
BMI(±SD)	26.25(±5.32)	26.92(±6.27)	25.58(±4.1)	Independent t-test (0.335)
Chemotherapy Regimens				
AC	39(65%)	19(63.3%)	20(66.7%)	$\chi 2$ (0.520)
CAF	15(25%)	9(30%)	6(20%)	
CEF	6(10%)	2(6.7%)	4(13.3%)	

Table 2: Changes in patient-rated outcomes over the 6-week study

		Baseline	**After Intervention**	**P**
Physical Domain of QoL	Intervention group	57.25(±15.04)	64.12(±14.52)	0.107
	Control Group	53.66(±13.23)	49.04(±10.95)	0.187
P		0.33	0.001	
Psychological Domain of QoL	Intervention group	41.40(±16.98)	47.75(±14.10)	0.171
	Control Group	42.19(±13.74)	37.96(±11.80)	0.227
P		0.884	0.005	
Social Domain of QoL	Intervention group	41.14(±15.28)	46.95(±15.41)	0.500
	Control Group	43.76(±13.01)	37.42(±9.91)	0.021
P		0.918	0.006	
Spiritual Domain of QoL	Intervention group	65.19(±12.14)	68.95(±12.08)	0.151
	Control Group	64.14(±9.47)	69.33(±10.33)	0.078
P		0.711	0.896	
Total Score of QoL	Intervention group	48.50(±11.77)	53.97(±10.77)	0.113
	Control Group	48.02(±9.54)	44.88(±7.88)	0.163
P		0.862	0.001	

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