



The Impact of Lifestyle Interventions in Breast Cancer Women after Completion of Primary Therapy: A Randomized Study

Haleh Ghavami^{1,2}, Neriman Akyolcu¹

¹Department of Surgical Nursing, Florence Nightingale, İstanbul University School of Nursing, İstanbul, Turkey

²Department of Medical Surgical Nursing, Urmia University of Medical Sciences School of Nursing and Midwifery, Urmia, Iran

ABSTRACT

Objective: Many breast cancer survivors have unmet physical and psychological needs. Therefore, current study aimed to evaluate the impact of a lifestyle interventions program on fatigue, quality of sleep, quality of life (QoL), and body mass index (BMI) in women with breast cancer.

Materials and Methods: This randomized controlled trial study (RCT) was carried between 2012 and 2015, and included 80 women with breast cancer. They were divided into two groups via a random allocation process: 40 women were allocated to the lifestyle interventions group, and 40 to the control group. Women in the lifestyle group received dietary energy-restriction training and practiced supervised aerobic exercises for 45-60 minutes three times per week throughout 24 weeks and the control group continued their routine life.

Results: Differences between the two groups were significantly high for those who participated in the intervention group; this group reported significantly less fatigue, less BMI, improved QoL and better quality of sleep as compared to the control group ($p < 0.05$).

Conclusion: Breast cancer survivors may physically and psychologically benefit from participating in a healthy lifestyle interventions program. This program can help relieve fatigue, maintain healthy BMI, improve QoL and enhance the quality of sleep in women with breast cancer. Lifestyle interventions program may provide a non-pharmacologic adjunctive therapy for symptom management in breast cancer survivors.

Keywords: Breast cancer, fatigue, lifestyle, physical activity, quality of life, quality of sleep.

Introduction

A number of risk factors have been identified in the pathogenesis of breast tumors. Among these, a great number of factors are attributed to the lifestyle (1). Reduced physical activity during cancer treatment can decrease the capacity for physical conditioning. The late effects of cancer and its treatment may consequently reduce physical activity in survivors. Breast cancer survivors with sedentary lifestyle have a higher risk for early mortality (2).

About 20%–70% of breast cancer survivors may have sleep disturbance, which is twice of the general population. Sleep disturbance is more prevalent in women with breast cancer as compared to those with other cancers. They report new or worsening sleep disturbances with frequent nocturnal awakening. These problems are attributed to chemotherapy or endocrine treatments induced by early menopause (3, 4).

Obesity and severe or extreme obesity is becoming a complex health problem that healthcare providers must begin to address within the oncology community (5). Studies have shown that obese women constitute a high-risk population for developing post-menopause breast cancer, and it is estimated that up to half of breast cancers that develop after menopause are attributed to obesity (6).

One third of breast cancer patients report that Cancer-Related Fatigue (CRF) has an adverse impact on their daily living activities (7).

Quality of Life is a concept that receives a lot of interest from healthcare providers. QoL measures have been used to help identify problems associated with cancer, medical management, and effectiveness of rehabilitative interventions, and to set healthcare policy (8).

Accordingly, current research assessed the impact of a healthy lifestyle interventions program on QoL, quality of sleep, BMI and fatigue, i.e., our primary outcomes. We hypothesized that healthy lifestyle interventions program would decrease fatigue and BMI and would enhance quality of life and quality of sleep.

Materials and Methods

Sample and Setting

The sample of this randomized controlled trial was composed of 80 women in total who had undergone surgery for breast cancer and completed their radiation therapy or chemotherapy between three and eighteen months ago. Samples were allocated in two groups using the random allocation process: control group and healthy lifestyle interventions program group. For randomization in this study, an independent researcher made random allocation cards using computer-generated random numbers. The allocator kept the original random allocation sequences in an inaccessible third place and worked with a copy. Instead of the letters A and B, she used the codes I and C (I for intervention group and C for control group) to avoid further confusion. Then, she continued randomization until 40 samples were allocated to the intervention group and 40 to the control group.

Sample Size and Power

The body weight was chosen for sample size calculation in this study. In the study by Utter et al. (1998), body weight had decreased to 81.8 ± 10.8 kg, from a baseline \pm SD level of 89.9 ± 11.7 after the lifestyle intervention and this amount of weight loss is related to better physical and mental health status in obese women (9). Utter et al. (1998) reported 8.1 kg reduction in body weight following a 12-week lifestyle intervention (moderate dietary energy restriction in conjunction with exercise) among obese women (9). Considering these data and accounting for an estimated patient drop-out of up to 10% (9), allocation of 40 patients for each group could give 90% power to detect a difference in body weight of 8 kg at α level of 0.05 (9). For this reason, we registered 80 patients (40 for each group) in this study.

Inclusion Criteria: a) breast cancer (stage I-III) women with a BMI > 25; b) samples must have completed their primary treatment (surgery, chemotherapy, radiotherapy) between 3 and 18 months ago; c) having received the permission from a cardiologist to participate in exercise sessions; d) patients on (Nolvadex; Tamoxifen) or other endocrine treatments will be included, but they should not receive hormone replacement therapy; e) patients must be 18 years old and above; f) patients must be able to read and write in Persian; g) samples must be able to continue their participation for a period of 24 weeks (at least 3 times per week) .

Exclusion Criteria: a) patients with terminal disease or metastatic breast cancer; b) patients who have severe anorexia, nausea, or other diseases that affect health; c) use of oral contraceptives (OCP) or hormone replacement therapy during the last 4 months; d) patients that receive high-dose antioxidant supplements or follow alternative/complementary diets; e) having a physical/psychiatric problem that could limit their participation in exercise sessions; f) survivors that were unable for other reasons to continue participating in this research; g) patients who were engaged in exercise at the beginning of study .

Data Collection and Instruments

Data were collected using BMI form, Patient Information Form, Cancer Fatigue Scale (CFS), Pittsburgh Sleep Quality Index (PSQI), EORTC QLQ-C30 and QLQ-BR23 (version 3.0) questionnaires. All

the patients in the case and control groups were asked to complete these questionnaires before and after the intervention. The patient information form and BMI form were researcher-made forms.

The EORTC QLQ-BR23 is a breast cancer-specific questionnaire including 23-items about the common adverse effects of treatment, outlook for the future, body image, and sexuality (10, 11). All of these items were scored on 4-point Likert scales ranging from 1 (not at all) to 4 (very much). The Persian version of the QLQ-BR23 that was developed by Montazeri et al. (11) was used in this study. According to the EORTC scoring manual (10); scoring of the EORTC QLQ-BR23 was performed. In our study of the EORTC QLQ-BR23 scale, the Cronbach's alpha reliability coefficient (α) in the first measurement was 0.790, and it was calculated as 0.796 in the last measurement.

The CFS measures the current fatigue status (12). The Persian Version of the CFS was used in this study. The reliability of the Persian Version of CFS was examined by Haghigat et al. in 2003 (13), and its reliability was found acceptable. (Cronbach's alpha coefficients for physical, emotional, cognitive, and total exhaustion were 0.92, 0.89, 0.85, and 0.94, respectively). In our study, Cronbach's alpha coefficient (α) reliability of CFS was calculated as 0.789 in the first measurement and 0.800 in the final measurement.

The Persian version of PSQI, which was developed by Afkham Ebrahimi et al. in 2008 (14), was used in this study. In our study, Cronbach's alpha reliability coefficient of PSQI scale (α) in the first measurement was calculated as 0.746. It was 0.783 in the last measurement.

Procedures

Ethics committee approval for human studies and informed consent were provided at first. After that, 80 women in total (according to the Sample Inclusion and Exclusion Criteria of study) were randomized to the lifestyle intervention and control groups. Patients in the control group continued their routine care. Patients in the healthy lifestyle interventions group followed these manipulations.

Supervised Strength Exercise: Strength exercise can improve health variables in cancer survivors such as body mass, muscular strength and endurance, quality of life, and fatigue (15). Patients who were randomized to the lifestyle interventions program in this study attended moderate-intensity aerobic exercise sessions under the supervision of a researcher and an exercise coach for 3-5 days per week throughout 24 weeks. Patients were encouraged to attend five supervised exercise sessions each week and had to try to attend at least three of them. Supervised exercises were performed in groups of 15 to 20 participants in an exercise room that contained a variety of aerobic exercise equipment. Each session comprised a 10-minute light aerobic exercise and a gentle range of motion exercises (warm-up period), followed by 30 minutes of aerobic exercise at an intensity of 70%–85% heart rate reserve, and a final ten minute lower intensity aerobic exercise (cool-down period). Also, exercise sessions used a variety of positive attitudes and experiences for promoting adherence to the exercises.

Dietary Energy Restriction: Patients who were randomized to the intervention group received healthy eating dietary advice that was individualized just for them. Counseling and advice were focused on reducing the patient's total daily calorie intake (to 600 kcal below their calculated energy requirements). Energy requirements were calculated using the basal metabolic rate formulae and caregivers' physical activity level for each participant. We aimed to apply this strategy to ensure

Table 1. Socio-demographic characteristics by group (n=80)

Characteristics	Total (n=80)		Lifestyle intervention (n=40)		Control (n=40)		X ² /z	p
	n	%	n	%	n	%		
Age (Mean ±SD)	48.99±9.42		48.75±9.49		49.23±9.46		-0.236	0.813
Marital status							-	1.000
Single	3	3.8	2	5.0	1	2.5		
Married	77	96.2	38	95.0	39	97.5		
Level of education							0.195	0.978
Primary school	19	23.7	9	22.5	10	25.0		
Secondary school	7	8.8	4	10.0	3	7.5		
High school	40	50.0	20	50.0	20	50.0		
Above high school	14	17.5	7	17.5	7	17.5		
Employment Status							0.063	0.802
Housewife	58	72.5	30	75.0	28	70.0		
Employee	22	27.5	10	25.0	12	30.0		
Having children							-	0.675
Yes	74	92.5	36	90.0	38	95.0		
No	6	7.5	4	10.0	2	5.0		
Number of children (mean±SD)	2.57±1.40		2.58±1.34		2.55±1.46		-0.192	0.848
Lactation (n=74)							-	1.000
Yes	68	91.9	33	91.7	35	92.1		
No	6	8.1	3	8.3	3	7.9		
Lact. Period (mean±SD)	39.92±28.71		42.11±30.91		37.84±26.72		-0.440	0.660
Comorbidity							0.000	1.000
Yes (HTN)	27	33.8	14	35.0	13	32.5		
NO	53	66.3	26	65.0	27	67.5		

p>0.05
X² = Chi-square test
z = Mann Whitney U test

that the participants have a steady (up to 0.5 kg/week) weight loss. Once a week, patients met with the researcher and received counseling on their individualized healthy diet.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) software for Windows 17.0 was used for statistical analysis in this lifestyle interventions study. Numbers are shown as a percentage and average for identifying the patient characteristics; Mann-Whitney U, and chi-square tests were used for evaluating the statistical significance in socio-demographic data, disease characteristics and differences in QLQ-BR23 scores between the experimental and control groups before and after the study. The results were accepted as having a confidence interval of 95% and a statistical significance level of p<0.05.

Results

Demographic or Medical Characteristics

Patients included in the study were compared to each other in terms of variables such as age, marital status, education level, employment status, number of children, number of lactations, duration of breastfeeding, comorbidities, use of other medications, surgical procedures applied to the breast, chemotherapy, radiotherapy, use of (Nolvadex; Tamoxifen) and duration of (Nolvadex; Tamoxifen) use that might af-

fect the results of the research. No baseline differences existed between the two groups in terms of either demographic or medical characteristic before the start of this study, and the groups were similar to one another (p>0.05, Table 1, 2).

BMI

The mean BMI in the lifestyle intervention group decreased to 25.12±2.86 after the application of the program, while it increased to 30.42±6.89 in the control group. There were no baseline differences between the two groups for the mean BMI (p=0.366) before the start of this study, but differences found in the mean BMI between the two groups after the application of lifestyle interventions program was statistically high (p<0.001) (Table 3) (16) .

CFS

The mean CFS score in the lifestyle interventions program group decreased to 8.15±6.12 after the application of the program, while it increased to 22.30±7.73 in the control group. There were not any baseline differences between the two groups for the mean CFS scores (p=0.957) before the start of this study; however, differences in the mean CFS scores between the two groups after the application of the lifestyle interventions program were statistically high (p<0.001) (Table 4) (17).

Table 2. Medical characteristics by group (n=80)

Characteristics	Total (n=80)		Lifestyle intervention (n=40)		Control (n=40)		X ² /z	p ²
	n	%	n	%	n	%		
Surgery type							-	0.241
Mastectomy	77	96.3	37	92.5	40	100.0		
Breast-conserving surgery	3	3.8	3	7.5	0	0.0		
Chemotherapy								
Yes	80	100.0	40	100.0	40	100.0	-	-
Radiotherapy								
Yes	80	100.0	40	100.0	40	100.0	-	-
Tamoxifen use							0.000	1.000
Yes	46	57.5	23	57.5	23	57.5		
No	34	42.5	17	42.5	17	42.5		

p>0,05
X² = Chi-square test

Table 3. Comparison before and after lifestyle intervention by body mass index (BMI) (n=80)

Before intervention	Group	n	Mean	SD	z ^a	p*
BMI	Intervention	40	29.37	2.59	-0.905	0.366
	Control	40	28.89	2.18		
After intervention	Group	n	Mean	SD	z ^a	p*
BMI	Intervention	40	25.12	2.86	-6.072	<0.001*
	Control	40	30.42	6.89		

BMI: Body mass index
^a= Mann Whitney U test
*=p<0.001

Table 4. Comparison before and after lifestyle intervention by Cancer Fatigue Scale (CFS) (n=80)

Before intervention	Group	n	Mean	SD	z ^a	p*
CFS	Intervention	40	22.98	8.15	-0.053	0.957
	Control	40	22.88	7.90		
After intervention	Group	n	Mean	SD	z ^a	p
CFS	Intervention	40	8.15	6.12	-6.615	<0.001
	Control	40	22.30	7.73		

CFS =Cancer Fatigue Scale
^a= Mann Whitney U test
*=p<0.001

Table 5. Comparison before and after lifestyle intervention by Pittsburgh Sleep Quality Index (PSQI) (n=80)

Before intervention	Group	n	Mean	SD	z ^a	p
PSQI	Intervention	40	9.83	3.90	-0.533	0.594
	Control	40	10.20	3.69		
After intervention	Group	n	Mean	SD	z ^a	p
PSQI	Intervention	40	2.40	1.39	-7.335	<0.001
	Control	40	9.45	3.95		

Sleep Quality Index (PSQI)
^a= Mann Whitney U test
*=p<0.001

Table 6. Comparison before and after lifestyle intervention by quality of life score EORTC -QoL BR23 (n=80)

Functional scales	Group	Before intervention				After intervention			
		Mean	SD	z ^a	p	Mean	SD	z ^a	p
Body image	intervention (n=40)	63.54	24.80	-0.262	0.793	88.96	11.69	-5.326	<0.001*
	Control (n=40)	63.12	22.40			64.16	22.02		
Sexual functioning	intervention (n=40)	84.16	18.08	-0.320	0.749	43.71	17.64	-5.942	<0.001*
	Control (n=40)	85.41	18.56			80.83	23.13		
Sexual enjoyment	intervention (n=40)	83.33	18.49	-0.219	0.826	44.16	19.08	-5.947	<0.001*
	Control (n=40)	83.33	21.35			82.50	23.86		
Future perspective	intervention (n=40)	30.00	24.80	-1.172	0.241	77.50	23.13	-5.590	<0.001*
	Control (n=40)	36.66	25.93			37.50	28.43		
Symptom scales / items	Group	Mean	SD	z ^a	p	Mean	SD	z ^a	p
Systemic therapy side effects	intervention (n=40)	35.35	23.48	-0.455	0.649	4.02	5.59	-7.076	<0.001*
	Control (n=40)	38.33	25.59			34.80	22.40		
Breast symptoms	intervention (n=40)	34.51	25.60	-0.492	0.623	6.92	10.26	-4.928	<0.001*
	Control (n=40)	32.65	27.09			30.00	27.28		
Arm symptoms	intervention (n=40)	43.05	29.58	-0.493	0.622	8.89	11.85	-5.620	<0.001*
	Control (n=40)	38.61	26.98			33.33	21.35		
Upset by hair loss	intervention (n=40)	68.33	39.19	-0.477	0.633	16.67	22.64	-4.581	<0.001*
	Control (n=40)	64.17	40.22			59.16	40.99		

Quality of life score = EORTC -QoL BR23
 a= Mann Whitney U test
 *=p<0.001

PSQI

The Mean PSQI score in the lifestyle interventions program group decreased to 2.4±1.39 after the application of the program, while it decreased to 9.45±3.95 in the control group. There were no baseline difference between the two groups in terms of the mean PSQI score (p=0.594) before the start of this study, but the difference between the mean PSQI scores in the two groups was statistically high after the application of the lifestyle interventions program (p<0.001) (Table 5) (18).

Quality of Life (QLQ-BR 23)

The differences in “body image,” “sexual function,” “sexual enjoyment,” “future perspective,” “systemic therapy side effects,” “breast symptoms,” “hair loss upset”, and “arm-related symptoms” subscale scores between the two groups of this study were statistically significant (p<0.001) after the lifestyle interventions program (Table 6), but there was no baseline difference between the two groups in terms of the mean QLQ-BR23 subscale scores (p>0.05) before the start of this study. Also, the average scores for “future perspective” and “body image” subscales in the lifestyle interventions group were higher than in the control group after the application of interventions. The average score for “sexual enjoyment” and “sexual functioning” in this group were lower than in the control group of study. On the other hand, the average scores for “systemic therapy side effects,” “breast symptoms,” “upset by hair loss”, and “arm-related symptoms” subscales in the lifestyle interventions program group were lower than in the control group after the intervention (p<0.001) (Table 6) (19).

Discussion

The current study findings support our hypothesis that lifestyle interventions in women with breast cancer can relieve fatigue, maintain a healthy BMI, improve their quality of life and enhance their quality of sleep.

According to the previous studies, lifestyle interventions such as increasing physical activity or eating healthy benefit a wide variety of bio-psycho-social factors such as cardiovascular fitness, body composition, emotional and cognitive functions, self-esteem, mood states, fatigue, sleep quality, and quality of life in breast cancer patients (20-24).

Today, there is a growing interest in the non-traditional care options for breast cancer patients. The current study has shown that lifestyle interventions can help relieve fatigue, maintain healthy BMI, improve quality of life and enhance sleep quality among breast cancer survivors. Furthermore, these low-cost, effective, simple, and non-invasive lifestyle interventions program for breast cancer survivors may apply to other cancer patients.

Conclusion

The results of this lifestyle interventions study may contribute to the growing body of knowledge supporting the feasibility and effectiveness of lifestyle interventions as a non-pharmacologic option for enhancing the physical and psychological health status among the breast cancer survivors. The authors of this study feel that the involvement of clini-

cians, who are the closest to the patients, is valuable in identifying possible interventions to optimize patient care. To provide the best evidence-based care for patients with breast cancer, healthcare providers might be trained on the potential benefits of a lifestyle interventions program such as relieving cancer-related fatigue, improving quality of life, lowering body mass index, and enhancing quality of sleep in breast cancer survivors.

Ethics Committee Approval: Ethics committee approval was received for this study.

Informed Consent: Informed consent was obtained from all of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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