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Effects of Exercise Intervention on Pain, Shoulder Movement, and Functional Status in Women after Breast Cancer Surgery: A Randomized Controlled Trial

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Abstract

Background: Breast cancer is the most important types of cancer among women and the incidence is increasing worldwide. It is a significant stressor in women's life that may affect functional health status. **Aim:** To examine effects of exercise intervention on pain, shoulder movement, and functional status in women after breast cancer surgery.

Methods: A Quasi experimental design. A convenience sample of 60 female with breast cancer surgery was recruited from Oncology Department at Mansoura University Hospital(MUH). Data were collected utilizing the following tools: 1) Inventory Functional Status-Cancer (IFS-CA) questionnaire; 2) Numerical rating scale: to measure pain intensity; 3) Universal goniometer: to measure shoulder ROM; 4) A structured questionnaire to collect data related to socio-demographic data.

Results: A statistically significant differences between the study and control group in level pain intensity, shoulder movement and functional status ($p < 0.05$). A significant improved in patients' pain, shoulder movement and functional status after exercise program application($p < 0.05$).

Conclusions: application of exercise program was useful in improving women shoulder movement and decrease pain level which leading to positive effect on functional status. **Recommendations:** Utilization of exercise program should be routine care for women suffering from breast cancer surgery.

Keywords: Breast cancer, Pain, Shoulder disability, Functional status.

1. Introduction

Breast cancer is the most common malignancy that affect women. It is a leading cause of death from cancer among female globally and leading cause of death among United States. It estimated over three million US women have a history of invasive BC, and there are about 232, 000 new breast cancer diagnoses were expected in 2014[1,2] and ranks second overall (10.9% of all cancers).[3] Breast cancer and its treatments often correlated with declined upper extremity (UE) function and mobility can lead to debilitate patient's functional and negatively affect the quality of life. [4,5]

Breast cancer therapy can experience impairment can result from lymphedema, wound infections, sensory and motor dysfunction and pain. Pain is more likely when axillary lymph node dissection, Shoulder or arm pain can be present in thirty to seventy percentage of BC following axillary surgery.[6] Postoperative pain control remains a common problem for patients undergoing breast cancer surgery[7]. Uncontrolled, postoperative pain result in increased surgical stress lead to impaired pulmonary function and peripheral[8], increase length of hospital stays, decreased patient satisfaction and diminished quality of life (QoL).[9-13] In Cohort study, Gartner et al[14] revealed that over one third of women (n=3754) have post-surgical pain and endorsed negative impact of pain on psychological and behavioral status. So, Appropriate interventions lead to improved postoperative outcomes and minimize that risk.[9,10]

Most common problems patients experience after breast cancer treatment is pain, tightness, lymphadenoma, and loss of mobility.[15] Shoulder pain is commonly experienced on the side and/or front of the shoulder area and often increases when the arm is raised.[16-18] Women with lymphedema can also exposured to functional impairment as well as reduce psychological

well-being.[19-20] In cross-sectional study by *Nascimento de* Carvalho colleagues.[21] revealed that women who had BC surgery and long-term follow-up define greater disability. However, physical, psychological, and functional impairments after treatment, which leads to poor activity of daily living and low quality of life.[19]

A systematic literature review look the prevalence of upper shoulder and arm impairment following breast cancer treatment, found wide variation, but demonstrated that upper-limb dysfunction is a long-term problem following breast cancer therapy.[22-24] In cross sectional study, Ahmed and colleagues[25] who studied 1,287 women, found that one third to three quarters suffered at least impacting after breast treatment has been found a negative impact on quality of life. Thus, it is important to develop methods to reduce acute pain after breast cancer surgery and to reduce chronic pain for breast cancer survivors. Thus, it is important to develop methods to reduce pain symptoms and lymphedema after breast cancer surgery.

Functional status(FS) has been used as is a significant predictor of resource utilization for measuring patients' outcomes. FS is a complex multi-dimensional assessing physical ability to perform activities of daily living , ability to work, emotional and social relationship as well as health well-being related limitations.[26,27] Rozema, and colleagues[28] reported that disease and its treatment has been associated with worse functional outcome and quality of life. Previous study show that a diagnosis of breast cancer and its treatment are stressful events that affect the long-term functioning of patients.[29] Also there are some results revealed that declines of functional status and overall QOL after cancer treatment.[30-32]

Exercise can decrease the side effects of treatment, aid in recovery and enhancing survival following surgery, radiation and chemotherapy. Many studies concluded the exercise intervention with upper limb dysfunction.[33,34] In arandomized controlled trials of 2132 participants in McNeely et al.[35] found reducing lymphoma, shoulder pain and improving shoulder mobility. Other study by Torres Lacomba and colleagues[36] studies of 116 women had breast surgery with follow-up at one years conducted in In Madrid, Spain, found improving patients outcomes after physiotherapy program. Milne and colleagues reported the relationship between exercise and overall quality of life (QoL) in group of West Australia breast cancer survivor. The results showed improved quality of life in breast cancer survivors.[37] This attributed that physical activity and exercises is an effective methods to prevent upper limb dysfunction and better QoL. This attributed that physical activity and exercises is an effective methods to prevent upper limb dysfunction and better QoL.

1.1 Operational definition

For the purposes of this study, pain and functional status are defined as:

1.1.1 Pain: It is a physiological response that occurs from cancer, the treatment of cancer, or the blend of illness and treatment.[38]

1.1.2 Functional status: It is ability to perform daily living tasks these can be reflect on many aspects of life including physical, intellectual, psychological, social, spiritual wellbeing.[39]

1.2 Significance of the Study

With breast cancer survivors living longer there is a need for making life more pleasant and manageable. Pain and other symptoms such as disability of shoulder function are bound to occur from not only breast cancer itself, but the medical treatment associated with this particular illness.[40] The data achieved by this study could provide an in-depth understanding of associates of functional status of this category of patients. Consequently, this could assist nurses and allied health care personnel in planning and implementing strategies for relevant effective care and ultimately assist breast cancer patients on treatment to lead quality life through improving their functional capabilities. In addition, It is important to assess non-pharmacological options such as exercise intervention that can be helpful in treating symptoms such as pain and disability of shoulder function in breast cancer patients and improves functional abilities and the ability to fight breast cancer more effectively, because regular practice of exercise, as soon as possible after surgery and during treatment, may reduce secondary effects.

1.3 Aim of the Study

To evaluate effect of exercise intervention on pain, shoulder movement, and functional status in women post breast cancer surgery

1.4 Research hypothesis

H1: BC patients receiving exercise program post-surgery will have less pain than those who do not receive.
H2: BC patients receiving exercise program post-surgery will have improve function of shoulder mobility than those who do not receive.
H3: There is improvement of functional outcomes among breast cancer surgery patients receiving therapeutic exercises than

who do not **receive**.

2. Subjects and methods

2.1 Research design

A Quasi experimental research design was used in this study.

2.2 Study Setting

This study conducted at inpatient ward and outpatient clinic of the Oncology department at Main Mansoura University Hospital(MMUH).

2.3 Study Subjects

A convenience sample of sixty patients at admitted to oncology department. The sample randomly selected and divided into two equal groups: (30) study group and (30) control group. Study group received the exercise intervention and control group received the routine care from hospital. The inclusion criteria were as follows: breast cancer with age between 18 years to 60 years, and accepted to participate in the study. Exclusion criteria were as follows: secondary breast cancer, other type of cancer, presence of chronic illness such as respiratory, heart disease; mental disability, and previous information about exercise intervention for breast cancer. (**Figure1:** flow of participants through study)

2.4 Tools for data collection

Three tools were utilized in this study. It is developed by researcher after reviewing the literatures.

Tool I : Functional status questionnaire

The Inventory of Functional Status Cancer (IFS-CA) adopted by Tulman et al. [41] and adapted by El sayed [42] to measure functional status of breast cancer women. It consists of 39 items, designed to measure functional status according to its four subscales items that tap functional status relevant to cancer patients :(a) Personal care activities (10 items); (b) Household and family activities (15 items); (c) Occupation activities (8items) and; (d) Social and community activities (6items). It is numerical scale with ranging from1 (never) to 4 (all of the time). While household and family activities, social and community activities subscale in numerical range of 1 (not at all) to 4(full time) . total scores with range of 39 to156, higher score indicates better function status.[43] This tools were translated into Arabic with Cronbach's coefficient for IFS-CA was 89.5. IFS-CA requires approximately 10 -15 minutes to complete.

Tool II: Pain Assessment Scale

Numerical Pain Rating scale(NPRS) was adopted from (McAffery & Beebeg),[44] used to measure pain intensity. It consists of 15 questions in numerical (0-10) and taking 10 minutes to administer.

Scoring system:

0 indicates no pain, (1-3) mild pain, (4- 6) moderate pain, (7-9) severe pain and (10) worst pain. The pain intensity level was measured and recorded before and repeated 2 hours after exercise intervention and follow up after 2 month for studies **groups**.

Tool III: Range of motion of the shoulder (ROM)

The measurement of shoulder ROM was demonstrated by using a universal goniometer was developed by Riddle, Rothstein & Lamb[45] to assess shoulder mobility as active and passive . ROM includes flexion, abduction and external rotation. The final score was recorded in degrees as the best of three attempts. The higher scores indicated the greater range of **motion**.

Tool IV: Socio-demographic and Medical data

Socio-demographic data was gathered from existing self-report and medical record review information collected during enrollment of the subjects. Data extracted for this study included age, sex, educational level, residence, employment status, household income and marital status. Clinical data: It includes hemoglobin level (Hb) of the patient, history of chronic diseases, treatment measures taken, family history of breast cancer, site and types of surgery.

2.5 Ethical considerations

Approval to carry research was obtained and the purpose and nature of study was obtained informed consent, Confidentiality, privacy , participation in the study was voluntary and right to withdrawal from study must be considered in this study.

2.6 Validity and reliability

Content validity of the utilized tools was done by (7) senior in medical surgical nursing and surgical oncology field to clarity and relevance . The reliability was done for tool at 0.86 respectively by using Cronbach’s alpha coefficient.

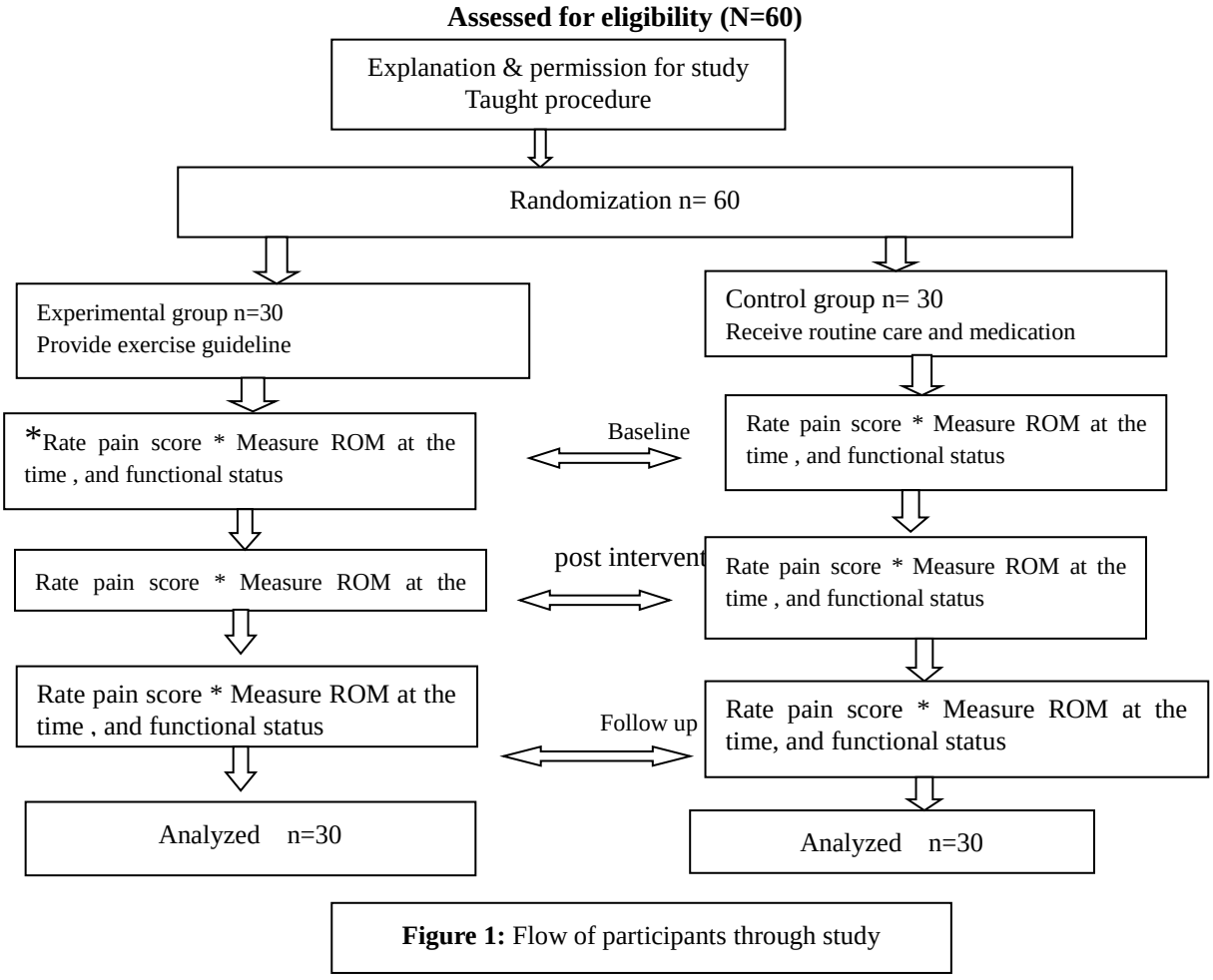

Figure 1: Flow of participants through study

2.7 Pilot study

A pilot study was carried out to test the clarity, feasibility and applicability of the tools on 10% of sample then excluded from the total of sample.

2.8 Procedure

- Permissions to conduct this study were obtained from the authorized person. Researchers recruited patients with breast cancer according to the criteria and then allocated them studies group. The objective and process of the research were explained to the women and informed consent taking from them.
- Developing tools and the program to be implemented after review literature regarding breast cancer surgery and exercise intervention program. The researcher explained to the patients also how to fill the tools before baseline assessed. Furthermore, the sample put in study and control group each equal 30 patients and given guidelines according program.
- Study tools were tested for content validity and reliability to ensure content comprehensiveness and applicability.
- The researcher were collected data about 6 months range from April 2014 to Sept. 2015,using socio-demographic sheet, pain assessment questionnaire, ROM questionnaire, and Inventory of Functional Status Cancer were assessed for participants before exposed to the exercise intervention.
- The study sample selected according criteria and randomly assigned them to two groups (intervention & control group). Meanwhile, exercise group was divided into small group from three to five patients.
- The outcome measure was assessed through the changes in physical components between pretest, **posttest** and follow up (3 months), for both intervention (study) and control groups.

2.8.1 Intervention group

The researcher taught exercise therapy (intervention practice) to the patients in the study group and demonstrated with them, Participants in the intervention group received exercise therapy bi-day for three mouth, at 30 minutes per intervention and the control group received nothing more than the routine healthcare, the researcher gave a handbook of guidelines for exercise technique to the subjects and encouraged to assume a comfortable position while performing the practice and researcher were available to ensure that the patient was not stressed. The practice of intervention group was started for 10 minutes for exercise

therapy and the researchers assisted patients in reading and demonstrated exercise therapy every day. Also evaluating the patients through assessed pain and shoulder mobility and functional status at three times pretest, 2 hours after the intervention from exercise, and follow up after 3 month using pain assessment tool, ROM to assess the shoulder mobility and functional status profile scores in ordered to show effect of exercise intervention self-management on pain, shoulder movement and functional status condition.

2.8.2 Control group

Patients assigned to the control group received routine care according to hospital policy(no exercise intervention). The data collection procedure was the same for both groups. This study did not interfere with patients' medication regimens. Analgesics were given to patients in accordance with physician orders, ward routines.

2.9 Statistical analysis

Data entry and analytical statistics was performed using Statistical Software Package(SPSS) version 18.0. The mean and standard deviations, numbers, percentages, Chi-square and t-test for variables are used for study and control group. Level of significant was thresholds at $p<0.05$

3. Results

Table 1: Socio demographic and medical characteristics of women with breast cancer surgery (N=60)

Variables	Intervention G. Frequency (%)	Control G. Frequency (%)	p- value
Age: Mean ± SD	43.1±2.5	45.5±3.6	0.230
Marital status			
- Married	25(83.3)	26(86.6)	
- Divorced/widow	3(10.0)	3(10.0)	0.254
- Single	2(6.6)	1(3.3.)	
Employment status:			
- Do not work	5(16.6)	3(10.0)	
- Worker	7(23.3)	9(30.0)	0.412
- Housewife	18(60.0)	18(60.0)	
Education			
- Illiterate	20(66.6)	19(63.3)	
- Read and write	3(10.0)	2(6.6)	0.154
- Secondary	6(20.0)	6(20.0)	
- University	1(3.3)	3(10.0)	
Residence:			
- Rural	23(76.6)	22(73.3)	.1070
- Urban	7(23.3)	8(26.6)	
Side of surgery			
- Left	19 (63.3)	16 (53.3)	0.718
- Right	11(36.6)	14 (46.6)	
Breast cancer Surgery			
- Lumpectomy	13(43.3)	11 (36.6)	0.398
- Mastectomy	17(56.6)	19 (63.3)	

Table (1) shows that socio demographic and medical characteristic of the participants. The mean age of patients was 43.1±2.5 years in experimental group, 45.5±3.6 years in control group. The most of participants were (66.6.0% and 63.3) had illiterate in both group, were housewives (60.0%) and nearly two third were married (83.3 and 86.6 % in both groups). Regards sites of surgery, more than half of participants (63.3%and 53. 3%) were in left side. In addition to, most of both group (65. 6 % and 63. 3%) were mastectomy.

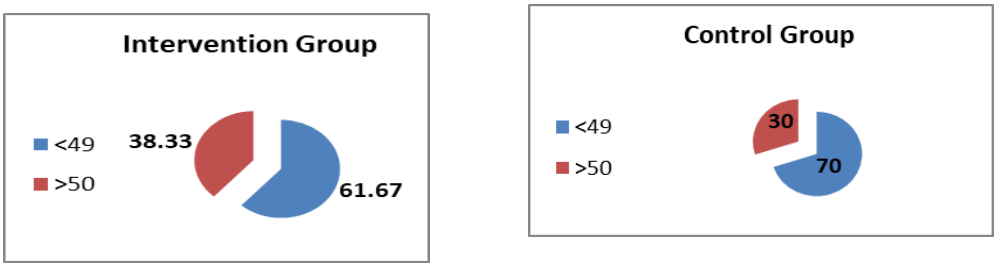

Figure2. Age of both groups

Figure 2. This figure revealed that most of patients (61.67% and 70%) were more than 50 years in study groups.

Table (2) Mean and standard deviation of pain severity before and after exercise program in the intervention and control groups (N =60)

Items	Intervention Group (n=30)	Control Group (n=30)	t-test	P value
Pain	Mean(SD)	Mean(SD)		
- Before	3.85(.366)	3.68(.598)	1.594	.1190
- After	2.43(.605)	2.99(.224)	3.568	0.001*
- Follow up	2.95(.587)	3.55(.639)	2.062	0.046*

Table (3) Measurement of central tendency and distribution of ROM among patients over three times of treatment (N =60)

Items	Intervention Group			Control Group			P- value
	Baseline	Post	Follow up	Baseline	Post	Follow up	
Abduction :							
Affected	91.8±19.46	93.6±17.72	105.0±14.01	88.17±16.45	88.50±12.2	95.92±15.7	
Non – affected	101.6±17.75	96.3±11.47	97.58±16.19	00.0±18.4	101.50±10.6	110.7±14.3	<0.001
Flexion :							
Affected	103.7±12.4	109.2±13.5	115.6±12. 49	101.82±17.3	112.8±14.7	121.2±16.8	
Non – affected	101.6±17.75	96.3±11.47	97.58±16.19	106.10±13.8	116.90±14.4	126.6±13.37	<0.001
Internal rotation							
Affected	45.83±14.5	53.75±7.81	58.33±11.5	47.18±20.13	48.09±17.7	52.82±18.7	
Non – affected	47.40±10.43	54.90±14.72	58.75±14.73	53.10±17.4	52.83±9.81	59.30±13.12	0.002
Extension :							
Affected	35.42±11.4	38.33±11.1	44.92±11.65	38.36±9.29	42.45±8.93	48.27±8.92	
Non – affected	37.42±12.1	41.17±9.9	49.25±11.6	39.50±9.25	45.10±6.15	48.30±4.45	.0950
External rotation :							
Affected	63.33±20.2	62.17±12.4	68.25±9.9	65.54±11.89	69.09±5.75	71.00±6.29	
Non – affected	69.08±12.3	68.25±9.9	67.83±12.1	70.50±14.3	70.50±11.9	71.60±14.2	0.010

Table (2) shows the difference of the pain mean scores between intervention and control groups pre and post implementation of exercise therapy. Statistical significant differences in the pain level assessment at three time in the intervention (3.86; 2.45, and 2.95 respectively) when compared with control group (3.68, 2.99 , and 3.55 respectively at the $p<0.05$).

Table (3) reveals that measurement of central tendency and distribution of ROM among patients over three times of treatment. A significant difference was found between groups result in relation to abduction, flexion , internal rotation for the affected arm in the whole group (p<0. 05). While no significant differences was found between intervention and control group in external rotation (p>0.05).

Table (4) Measurement of central tendency and distribution of functional status among patients over three times of treatment(N =60)

Items	Intervention			Control			p-value
	Pre M±SD	Post M±SD	Follow up M±SD	Pre M±SD	Post M±SD	Follow up M±SD	
Personal care							
-Mean ± SD	23.62±2.36	25.92±2.04	26.44±2.19	22.04±3.24	24.62±2.36	23.62±2.36	<0.001
-Range	19-28	23-29	19-31	21–30	19-28	20-28	
Household activities							
-Mean ± SD	17.18±3.72	21.35±5.36	25.55±6.18	20.86±10.17	21.35±5.36	19.18±3.72	<0.001
-Range	15-30	15-34	15-33	15-48	15-36	15-34	
Social activities							
-Mean ±SD	10.80±1.39	11.10±1.43	12.22±1.49	11.50±1.66	11.89±1.39	10.77±1.39	0.002
-Range	8-14	8-15	9–15	8-14	8-16	8-15	
Occupation activities							
-Mean + SD	10.33±4.62	14.67±5.98	14.33±5.84	10.47±7.01	11.88±3.62	11.33±3.67	0.095
-Range	8-21	8-24	8-24	8-21	8-23	8-22	
TIFSCA	63.19±9.86	72.67±10.05	73.87±10.21	63.93±15.54	64.19±9.86	63.99±9.86	0.010
-Mean±SD	54-85	57-91	53-93	54–85	54-87	54-86	
-Range							

Table (4) Shows that function status dimensions improvement over time from beginning of week 0 to 12 weeks after exercise therapy. As regard personal care (mean=23.62 to 26.04, at p<0.001). Moreover, an improvement in social activities was detected from (10.80 to 11.50, at p=0.002). Greatest changes occurred in mean score household activities from (17.18 to 24.86,at p<0.001 and TIFS-CA (63.19 to 72.93, at p =0.010).These difference indicated improvement over time.

Table (5) shows that correlation found between the exercise program with pain level, shoulder movement and functional status pre , post and follow up after participations in the program (p <0 .05).

4. Discussion

Breast cancer and its treatment sequelae results in adverse side effects, such as upper extremity restricted, fatigue, body image concerns and pain.[46] These symptoms accompanied with breast cancer treatments could be affect patients' quality of life and functional status as well as self-esteem, psychological reactions after treatment.[47,48] Research indicates that exercise interventions after cancer diagnosis and its treatment is linked with improvements in fatigue, functional capacity, prolonged survival and improved quality of life.[49,50] The major finding of literature revealed that exercise intervention had a profitable effect on shoulder pain and ROM. It is evidenced that improve upper-limb strength and endurance without pain. The results are proportionate with the hypothesis of study.

In current study, the demographic characteristics of the study and control groups revealed that, that majority mean age 44.5

years in intervention group compared by 45.5 in control group, with no statistically significant differences between both groups. which is agreement to the study in Iraq in which age range 40-49 years. [51]

Table (5). Correlation between patients exercise program and outcome variables preprogram, post program, and follow up after three month for the intervention group.

Research variables	***Exercise program***	
Preprogram	***R***	***P***
- Pain intensity	0.237	0.140
- Shoulder movement	-0.234	0.147
- Functional status	-0.108	0.509
Post program:		
- Pain intensity	-0.491	0.005*
- Shoulder movement	-0.628	<0.01*
- Functional status	-0.568	0.004*
Follow up program :		
- Pain intensity	0.372	0.014*
- Shoulder movement	-0.323	0.035*
- Functional status	-0.477	<0.01*

Regarding to marital status, almost over half of study groups were married. The finding in contrast with Alwan[51] who carried studied on 721 breast cancer women, found that 75% were married. In relation to rural area, most patients in studied groups were rural area. This findings are also consistent with Alwan, who revealed that most of sample coming from urban areas. Our results inconsistent with Ngowa and colleagues[52] showed that 92% came from urban as Residential area

According to the current study finding, there was the marked and constant statistical significant difference in pain severity before and after exercise intervention. This result supported by Wong et al.[53] established that exercise program reducing breast and chest wall pain breast cancer women. In this regard, Visovsky & Dvorak [54] shows that improved QOL scores amenable to deceased level of pain, improved self-esteem and mood as well as higher level of functioning was observed following home-based exercise programs.

The current study revealed that the improvements in the shoulder ROM in the actions of internal rotation, abduction, flexion and external rotation and in the strength actions of flexion, internal rotation, extension and horizontal adduction. This is congruent with McNeely and colleagues[55] who stated that ROM may be improved to a greater degree after exercise program.

In randomized control trail, Box et al. [56] established physiotherapeutic program to minimize that postoperative lymphedema. They found that effectively facilitating and improved in shoulder movement and decrease pain. Which agree with Thomas and Shaw [57] evaluated that impact of exercise intervention(yoga) among 10 women breast cancer between the ages of 26 and 70 related arm morbidity. They found improved in physical activities and relief from symptoms related to breast cancer treatment. With agree with previous study, reported that physiotherapy can significant improve shoulder function as long as six months post-operatively[58].

Findings of the present study exhibited significant improvement in the total functional status scores among patients over study phase. This improvement were demonstrated by personal care activities, and household activities ($p < 0.001$), as well as social activities ($p = 0.002$) which may be attributed to breast cancer control, response for nursing intervention, and rehabilitation.

Previous literature concluded that exercise in breast cancer survivors or post treatment can be improve the functioning of the cardiorespiratory system, physical function, and muscular strength.[59,60] Many studies have revealed the effectiveness of regular exercise after breast cancer surgery. The resulted showed that positive impact in mortality, morbidity, survivors

outcomes and overall QOL. In randomized control trail, Eyigor et al.[61] conduct study among 52 female with breast cancer, found significant effect on functional capacity, fatigue, flexibility, and quality of life in intervention group compared to the control group.

Further, supported by Cruickshank et al.[62] stated the effects of breast cancer on women physically, mentally, emotionally and socially aspects in life . On the same line, Vadiraja, Raghavendra, et al.[63] investigated that the participants reported improvement in their QOL after exercise program. Dodd et al.[64] studied the effect of home-based exercise at least 90 min per week for three or more days in women with breast cancer who reported significantly less fatigue and emotional distress as well as higher functional ability and QOL than the women who were less active during treatment.

The study suggests that there is strong evidence for reduced risk of some cancers with increasing physical activity. The strongest evidence exists for breast cancer's patients to increase physical activity in a consistent way during treatment, because regular practice of exercise, as soon as possible after surgery and during treatment, may reduce secondary effects and improvements in physical functioning, , muscle strength and endurance.[65] The findings agreement with Oliveira,[66] shows the physical function, emotional function, role function, cognitive function and global quality-of-life scales, a higher score indicates better level of functioning. Finally, it was obvious that the findings revealed significant improvements in pain level and functional of shoulders and functional status findings through study phases, which lead to all women being controlled by the end of program. Thus the main study hypothesis was achieved.

5. Conclusion and recommendations

The exercise intervention can be effective in the management of breast cancer symptoms through improving level of pain and shoulder movements. In addition, improvement in physical and psychological functioning and overall quality of life. It is recommended that apply this intervention as a routine care in the study setting and similar ones. The illustrative booklet should be distributed to breast cancer patients. Further research should be conducted in different geographical areas to better assess the impact of exercise therapy on people's upper limb mobility, daily activities and quality of live .

Conflicts of interest

None declared.

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