

Effect of Home-Based and Early Institutional Physiotherapy Program for Breast Cancer Women Following Surgery: A Pilot Clinical Trial

Noura BinSaad^{1*}, Farah Alabdulkarim PT², Ayman Babiker³ and Isamme AlFayyad, RN, MA⁴

¹Surgical Oncology Department, King Fahad Medical City, Riyadh Second Health Cluster P.O. Box. 59046, Riyadh 11525

²Physical Therapy Department, King Fahad Medical City, Riyadh Second Health Cluster P.O. Box. 59046, Riyadh 11525

³Surgical Oncology Department, King Fahad Medical City, Riyadh Second Health Cluster

P.O. Box. 59046, Riyadh 11525

⁴Research Center, King Fahad Medical City, Riyadh Second Health Cluster P.O. Box. 59046, Riyadh 11525

*Corresponding author:

Noura BinSaad,
Surgical Oncology, King Fahad Medical City,
Riyadh Second Health Cluster P.O. Box. 59046,
Riyadh 11525

Received: 26 Feb 2024

Accepted: 06 Apr 2024

Published: 12 Apr 2024

J Short Name: COO

Copyright:

©2024 Noura BinSaad, This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and build upon your work non-commercially.

Citation:

Noura BinSaad, Effect of Home-Based and Early Institutional Physiotherapy Program for Breast Cancer Women Following Surgery: A Pilot Clinical Trial. Clin Onco. 2024; 7(10): 1-9

Keywords:

Breast Cancer; Physiotherapy; Home-Based Exercise; Pain; Shoulder Disabilities; Surgery; Pilot trial

1. Abstract

1.1. Background: Many patients suffer from musculoskeletal shoulder problems after breast cancer (BC) surgery. Early postoperative and home-based physiotherapy has been proven clinically to improve shoulder function.

1.2. Objective: This pilot study aims to investigate the effect of an individually tailored, three-month combined program of home-based and institutional physiotherapy interventions in improving shoulder functions for women who have undergone BC surgery.

1.3. Methods: A pilot, single-arm non-randomized clinical trial was conducted between the period of September 2018 and June 2019 on a convenient sample of BC women. The primary study outcome was regaining shoulder mobility following the surgery. Secondary outcomes were a decrease in self-reported pain, disabilities of the Arm, Shoulder, and Hand (DASH), handgrip strength, quality of life (QoL), and feasibility assessment of this pilot study. All outcomes were recorded at three time-intervals (T0=day 1 post-surgery), (T1=day 30), and (T2=day 90). The interventions were delivered by the physiotherapist early within 24 hours post-operatively, T1, and T2. In addition, home-based exercise was provided with written instructions during hospitalization with rehearsal sessions to ensure the patient's understanding and compliance.

United Prime Publications.LLC., <https://clinicsofoncology.org/>

1.4. Results: A total of 23 participants completed the pilot study with a mean age of 43.70±11.53 and free of postoperative complications. The study interventions showed a significant reduction in pain score (effect size (ES): -3.39±2.50), DASH (ES: -20.35±14.66), increase in shoulder flexion and abduction (ES: 61.32±44.84 and 84.83±28.52, respectively), improvement in handgrip strength (ES: 4.26±3.16) and QoL (ES: 13.39±6.46).

Conclusions: This individually tailored, three-month combined program of home-based and institutional physiotherapy interventions is effective in improving shoulder functions during the immediate 3-months period following surgery.

2. Introduction

Breast cancer (BC) is the most common cancer in women worldwide and ranked first among Saudi women [1, 2]. Breast cancer accounts for 29% of all reported cancers among females with an approximate increase of more than

10-fold in incidence since the 1990's [2, 3]. Recent advances in BC screening and treatment resulted in significant improvement in the survival rate [4]. However, the quality of life (QoL) of BC patients is challenged and reduced due to upper body extremity impairments following aggressive BC regimens, particularly, surgery to the breast and axilla as a mainstay treatment. Following breast surgery and Axillary Lymph Node Dissection (ALND), women

presented with upper limb problems within three months of surgery and may persist for up to 6 years [5]. Persistent upper limb problems after surgery therapy had varied debilitating negative impacts on quality of life, physical functioning, social, and emotional well-being [6]. Decreased shoulder range of motion (ROM), impaired strength and post-operative pain are common adverse effects in the acute treatment phase due to scar tissue formation, fibrosis and shortening of soft tissues [7, 8]. In further stages, breast lymphedema, adhesive capsulitis, myofascial dysfunctions, or and/or nerve dysfunctions may induce pain and impairs shoulders ROM. These impairments have been shown to have restrictions in daily life activities, work, sports, and relaxation activities [9]. Persistent pain following BC surgery occurs in 25% to 60% of patients [10]. Pain is associated with mood disturbance, decrements in functional status, and decreases in QOL [11, 12]. A systematic review study concluded that mastectomy and ALND are risk factors for pain, reduced muscle strength, and decreased degree of daily activities [13]. Percentages of patients with reduced shoulder ROM varied from 6%–31% after 12 months and reduced to 0%–9% after 24 months [5]. Several studies have described a reduction in the shoulder ROM in different directions: abduction, flexion/abduction, and external rotation [12, 14-17]. Breast cancer-related lymphedema of the arm is considered one of the most common sequelae with mastectomy and ALND that can lead to a negative impact on patients' QoL. Therefore, an adequate rehabilitation plan is a prerequisite for optimal treatment [18-20]. Many studies have highlighted the effectiveness of various postoperative physiotherapy and exercise programs following breast cancer surgery to reduce pain, lymphedema management and improve shoulder function, and restore independence and self-sufficiency while focusing on QOL [5, 21-23]. Some studies have investigated the effectiveness of rehabilitation programs in a clinical setting under clinical supervision while other studies involved a self-administered, home-based program [5]. A recent systematic review has reported several postoperative rehabilitation strategies including, stretching exercises, resistance training, mobilization exercises, and a combination of endurance and resistance training. Additionally, other rehabilitative interventions involved Kinesio tape, compression bandages and intermittent pneumatic compression, compression garments, aqua lymphatic therapy, and moist heat applied to the axilla and inner arm [24]. Prehabilitation prior to BC surgery may facilitate postoperative recovery, improve health behavior and, improve physical activity levels, and functional capacity [19]. Furthermore, several inflammatory and metabolic biomarkers could play a significant role in rehabilitation treatment effectiveness, thus, opening a new paradigm of future research on individualized rehabilitation interventions tailored to patients' needs and characteristics [25]. However, there is inconsistency and uncertainty on the effect of physiotherapy programs that have been developed and implemented in terms of content, omitting patients' reported QoL,

frequency and timing, making it difficult for adopting standardised physiotherapy interventions [5]. Moreover, as far as this, there is a scarcity in the literature investigating the effect of physiotherapy programs to manage complications post-BC surgery and restores normal shoulder functions among Saudi BC patients.

3. Materials and Methods

3.1. Study Aim

The primary study outcome of this study was to gain insight into the impact of an individually tailored, three-month combined program of home-based and institutional physiotherapy interventions in improving shoulder mobility after surgery. The primary study outcome was the restoration of shoulder mobility after the surgery. The secondary outcomes were a decrease in pain level, disabilities of the Arm, Shoulder, and Hand (DASH), handgrip strength, and quality of life (QoL), and feasibility assessment of this pilot study. The feasibility assessment included the data collection instrument, sample recruitment strategy, timelines, cost, adverse events, and compliance with the treatment.

3.2. Design and Participants

A nonrandomized uncontrolled pilot clinical trial was conducted at the surgical oncology and rehabilitation departments of King Fahad Medical City, Riyadh, Saudi Arabia between September 2018 and June 2019. Women were considered eligible for the study and asked to take part in the study if they were: diagnosed with histologically confirmed primary BC and scheduled for surgery; aged 18 years and above; showed a willingness to provide written informed consent and comply with the study protocol; at risk of developing postoperative shoulder problems (such pain and moderate shoulder disabilities). Patients with a previous contra-lateral BC surgery were excluded. A convenient sampling technique over 6 months period was utilized to recruit the study participants. One day before surgery, patients were approached by the primary investigator and provided with study information and asked to participate in this study. The institutional review board of King Fahad Medical City has approved the study (IRB Log No. 18-115). Written informed consent was obtained from each patient who fulfilled the inclusion criteria and was willing to participate in the trial. Patients who did not agree to participate were offered the standard institutional treatment.

3.3. Intervention

A full-time physiotherapist at the study site has agreed to adhere to and comply with the physiotherapy treatment guidelines recommended for upper extremity rehabilitation for post-operative BC women. The physiotherapy guidelines were based on the Clinical Practice Guidelines for BC Rehabilitation and modern treatment for lymphedema adopted elsewhere [26, 27] and have shown significant improvements in shoulder impairments, pain control and improving QoL [26].

The interventions guidelines included the following:

- Advice and exercises for upper extremity, coordination exercises, exercises for muscular strength, posture correction, and improvement of physical condition.
- Exercises for lymphedema prevention.
- Massage for the soft tissue of the surgical scar if needed.
- Patients' self-management approaches towards lifestyle redesign, and incorporating health promotion aspects.

Institutional physiotherapy exercise: on the first postoperative day, patients received a low-intensity physiotherapy exercise session, subsequently tailored on a daily basis by the physiotherapist till they were discharged. Other physiotherapy exercise sessions were provided on day 30 and day 90 post-operative in the outpatient physiotherapy clinic. The exercises were scheduled 3-5 times per week for 30–40 min per session at the patient's convenient time and when the pain is absent over three months. The exercises for lymphedema prevention intervention included the lymph drainage technique used for the prevention of postoperative edema (thorax, breast, axilla, and upper arm of affected side). Massage of the scar along with stretching exercises for levator scapulae, upper trapezius, pectoralis major, and medial and lateral rotators muscles of the shoulder [28]. For upper extremity coordination exercises and muscular strength and posture correction, the below exercises were gently provided to the patients as well:

- Deep breathing.
- Pumping the muscle of the affected arm improves circulation and prevent edema.
- Shoulder shrugs and circles and arm lifts: This exercise was done sitting or standing.
- Shoulder blade squeeze: to improve the movement of patients' shoulders and posture.

For the home-based physiotherapy exercises, patients were provided with written instructions about exercises that were provided after the surgery during the hospitalization, and rehearsal sessions were done to ensure the patient's understanding and compliance with the instructions. Accordingly, patients were encouraged to do home exercises in pain-free ROM at least twice per day for ten minutes over three months. Study coordinators were assigned to ensure the patient received the physiotherapy program and comply with home exercises through strict follow-up and reminders by phone call or text messages and provided with diaries to ensure adherence to the home exercises.

3.4. Data Collection and Measurement

The measurements of the study outcomes took place at three time-intervals (T0=day 1 post-surgery), (T1=day 30), and (T2=day 90). The outcomes were collected using a case report form (CRF) which included patients' demographic and clinical characteristics, such as (age, level of education, affected side, pre-existing shoul-

der complaints, type of surgery, post-surgery complications, and type of adjuvant therapy). The primary study outcome was the restoration of shoulder mobility after the surgery. The secondary outcomes were a decrease in pain level, disabilities of the Arm, Shoulder, and Hand (DASH), handgrip strength, quality of life (QoL), and feasibility assessment of this pilot study. The second part of the CRF measured the restoration of shoulder mobility as a primary outcome (flexion [0-180°], abduction [0-180°]) that was measured by using a digital inclinometer under standardized conditions (with the participant in a sitting position with feet supported, knees fixed at 90°, and a straight back.). Patients were maintained in a seated position for all movements to minimize compensatory movements of the trunk. In addition, pain in the shoulder/arm as a secondary outcome was assessed using the visual analogue scale (VAS) with a scoring system of 0-10 (0 = no pain; 1-3; mild pain, 4-6; moderate pain, 7-10 severe pain). The third part of CRF measured the disabilities in daily life as a secondary outcome, which was measured by using the Quick DASH scale (Disabilities of the Arm, Shoulder, and Hand) questionnaire. The Quick DASH consists of 11 items that allow for cumulative and multiple assessments of a patient over time, and each item has 5 response options. According to the Quick DASH scale scoring system, the scale scores are calculated and range from 0 (no functional disability) to 100 (most severe disability) [29]. The fourth part of CRF assessed the remaining secondary outcomes, the hand grip, and patients' QoL. The handgrip strength was measured using the hand-held dynamometer with response values in kilogram-force [30]. The handgrip strength was measured while the patient stabilized in a seated position with the elbow in 90 degrees of flexion and squeezes three times the dynamometer with each hand. The measurements were recorded to calculate the average handgrip strength score. All measurements were completed by one physiotherapist to avoid inter-rater reliability differences and control bias. Patients' QoL was assessed by using the Functional Assessment of Cancer Therapy-General (FACT-G) scale. FACT-G (version-4) is a validated, self-reported multi-dimensional, 27-items questionnaire measuring QoL for breast cancer patients with a 4-points Likert scale (0-108). The FACT-G comprises of 4-subscales: Physical Well-being (PWB: 7 items; score range 0 to 28), Social Well-being (SWB: 7 items; score range 0 to 28), Emotional Well-being (EWB: 6 items; score range 0 to 24), Functional Well-Being (FWB: 7-items; score range 0 to 28) [31]. Higher scores indicate a better perceived QoL state. Finally, patients were instructed to report any adverse event related to the physiotherapy exercises to the physiotherapist. The secondary outcomes of this pilot study assessed its feasibility in establishing if there is clinical effect size (ES) worth investigation, sample recruitment strategy, adherence to study protocol, and adverse events in preparation to conduct a larger definitive study.

4. Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, ver-

sion 24 (IBM Corp., Armonk, N.Y., USA). Descriptive analysis was used to describe participants' characteristics and study outcomes scores (frequencies, proportions, mean scores and standard deviations). A repeated-measure ANOVA to determine the means of study outcomes across three-time points. Pearson product-moment correlation coefficient was used to measure the strength and direction of association that exists between study outcomes. A p-value of 0.05 was set as a level of significance. Ethics approval and consent to participate: The institutional review board of King Fahad Medical City has approved the study (IRB Log No. 18-115). One day before surgery, patients were approached by the primary investigator and provided with study information and asked to participate in this study. Written informed consent was obtained from each patient who fulfilled the inclusion criteria and was willing to participate in the trial. Informed consent from a legal guardian was obtained for the study participation of illiterate participants. All study methods were carried out in compliance with the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines and institutional regulations.

5. Results

Forty-one women were operated on during the study period, of whom, twenty-three women were eligible for inclusion, completed the study protocol, and entered into final data analysis with a participation compliance rate of 56%. Eighteen women were ineligible to enter the study because they did not consent to participate or it was difficult to comply with the study follow-up visits

because they were living outside Riyadh city. The participants' mean age was 43.70±11.53 years. The majority of the women 15 (65.2%) operated in the non-dominant hand. No post-surgery complications were reported (Table 1). Repeated-measures ANOVA tests determined that mean scores of pain (F=16.88, p = <0.001), DASH (F=29.68, p = <0.001), Anteflexion shoulder (F=46.44, p = <0.001), Abduction shoulder (F=51.01, p = <0.001), Handgrip strength (F=21.41, p = <0.001), FACT-G (F=69.99, p = <0.001) differed significantly across three-time points (Table 2). A post hoc pairwise comparison using the Bonferroni correction showed a statistically significant reduction in pain score between T2 and T0 (ES: -3.39, p<0.001), reduction in DASH (ES: -20.35, p<0.001), improvement in shoulder anteflexion (ES: 69.17, p<0.001), improvement in shoulder abduction (ES: 88.06, p<0.001), improvement in handgrip (ES: 4.19, p<0.001), and QoL as measured by FACT-G (ES: 13.39, p<0.001) (Table 3).

Md: Mean difference; SE: Standard error; CI: Confidence interval; Visual analogue scale (VAS); Disabilities of the Arm, Shoulder, and Hand (DASH); Functional Assessment of Cancer Therapy-General (FACT-G). *: the mean difference is significant at the .05 level; b: Adjustment for multiple comparisons: Bonferroni. There was a strong, positive correlation between shoulder anteflexion at (T2) and shoulder abduction at (T2), which was statistically significant (r=0.792, p <0.001). There was a moderate, negative correlation between pain at (T2) and handgrip (T2), which was statistically significant (r= -0.509, p=0.013) (Table 4).

Table 1. Patient characteristics (n = 23)

Age (mean±SD)	43.70±11.53
Range [Min-Max]	[24-67]
24-29	2 (8.7)
30-39	6 (26.1)
40-49	7 (30.4)
50-59	5 (21.7)
>59	3 (13.1)
Level of Education	
<i>Illiterate</i>	3 (13)
<i>Elementary</i>	4 (17.4)
<i>Secondary</i>	4 (17.4)
<i>University</i>	12 (52.2)
Affected side	
<i>Dominant</i>	8 (34.8)
<i>Non-dominant</i>	15 (65.2)

Pre-existing shoulder Complaints	
<i>Yes</i>	5 (21.7)
<i>No</i>	18 (78.3)
Surgery	
<i>Breast-conserving and ALND</i>	2 (8)
<i>Mastectomy and ALND</i>	21 (92)
Post-surgery complications	
<i>None</i>	23 (100)
Adjuvant therapy	
<i>None</i>	4 (17.4)
<i>Radiation therapy</i>	7 (30.4)
<i>Chemotherapy</i>	8 (34.8)
<i>Hormonal therapy</i>	2 (8.7)

Axillary Lymph Node Dissection (ALND).

Outcomes	T0	T1	T2	F	p-value
VAS for pain (0–10)	5.0±2.31	2.8±2.17	1.6±1.97	16.88	<0.001
DASH (0–100)	36.95±15.53	29.34±11.21	16.60±9.36	29.68	<0.001
Anteflexion shoulder (0–180°)	101.11±29.28	149.44±30.72	170.28±12.42	46.44	<0.001
Abduction shoulder (0–180°)	83.41±21.86	131.47±38.32	171.47±14.55	51.01	<0.001
Handgrip strength (Kg)	15.02±4.21	17.49±5.07	19.20±5.11	21.41	0.005
FACT-G	50.48±6.01	56.17±6.25	63.87±7.91	69.99	<0.001

Visual analogue scale (VAS); Disabilities of the Arm, Shoulder, and Hand (DASH); Functional Assessment of Cancer Therapy-General (FACT-G).

Study Outcomes	Time point	Md*	SE	P-value ^b	95% CI
VAS for pain (0–10)	T1 – T0	-2.13	0.65	0.010	-3.81-0.45
	T2 – T0	-3.39	0.52	<0.001	-4.74-2.04
DASH (0–100)	T1 – T0	-7.60	3.19	0.080	-15.89-0.69
	T2 – T0	-20.35	3.05	<0.001	-28.27-12.42
Anteflexion shoulder (0- 180°)	T1 – T0	48.33	9.02	<0.001	24.38-72.28
	T2 – T0	69.17	7.03	<0.001	50.51-87.83
Abduction shoulder (0-180°)	T1 – T0	48.06	11.03	0.001	18.57-77.55
	T2 – T0	88.06	6.26	<0.001	71.34-04.78
Handgrip strength (Kg)	T1 – T0	2.48	0.67	0.005	0.72-4.23
	T2 – T0	4.19	0.75	<0.001	2.23-6.14
FACT-G	T1 – T0	5.69	1.09	<0.001	2.86-8.53
	T2 – T0	13.39	1.35	<0.001	9.90-16.88

Md: Mean difference; SE: Standard error; CI: Confidence interval; Visual analogue scale (VAS); Disabilities of the Arm, Shoulder, and Hand (DASH); Functional Assessment of Cancer Therapy-General (FACT-G). *: the mean difference is significant at the .05 level; b: Adjustment for multiple comparisons: Bonferroni.

Table 4. Correlations (<i>r</i>) between study outcomes at (T2)							
		Pain (T2)	Shoulder anteflexion (T2)	Shoulder abduction (T2)	DASH (T2)	Handgrip (T2)	FACT-G (T2)
Pain (T2)	<i>r</i>	1					
	p-value						
Shoulder anteflexion (T2)	<i>r</i>	-0.101	1				
	p-value	0.681					
Shoulder abduction (T2)	<i>r</i>	0.113	0.792**	1			
	p-value	0.654	<0.001				
DASH (T2)	<i>r</i>	0.381	-0.096	0.195	1		
	p-value	0.073	0.696	0.438			
Handgrip (T2)	<i>r</i>	-0.509*	0.494*	0.327	-0.344	1	
	p-value	0.013	0.032	0.185	0.108		
FACT-G (T2)	<i>r</i>	0.285	0.583**	-0.301	0.180	0.224	1
	p-value	0.188	0.009	0.225	0.410	0.304	

*. Correlation (*r*) is significant at the 0.05 level (2-tailed).

**. Correlation (*r*) is significant at the 0.01 level (2-tailed).

6. Discussion

Breast cancer surgery and ALND may lead to impaired shoulder mobility, pain, and decreased strength. These postoperative complications may all lead to difficulties in the execution activities of daily life and negatively impact the QoL [32, 33]. Nevertheless, considerable physiotherapy programs can reduce post-surgery complications and associated dysfunctions [5]. Therefore, we aimed in this study to provide an evaluation of the effect of individually tailored, three-month combined program of home-based and institutional physiotherapy interventions in reducing ROM limitations and pain, improving dysfunction and handgrip strength in the upper extremities, and QoL in patients who have undergone BC surgery and ALND. The study findings showed that personalized home-based with minimum physiotherapy exercise in a clinical setting with an educational plan and close follow-up under the supervision and guidance of a trained physiotherapist for three months after mastectomy or ALND improved patients' shoulder function, handgrip strength, and quality of life and reduced shoulder pain with significant ESs. These findings were consistent with and support the findings of Kilgour et al., (2007) which showed that the women who participated in a home-based exercise program reported significant improvements in shoulder ROM and grip strength [34]. A research group had identified four subgroups of patients with distinct trajectories of persistent breast pain following BC surgery (i.e., no (31.7%), mild (43.4%), moderate (13.3%), and severe (11.6%) pain) [35]. Moreover, Miaskowski et al., (2014) suggested that approximately 35% of women experience persistent degrees of moderate arm and shoulder pain in the first six months following breast cancer surgery. Moderate arm/shoulder pain is associated with clinically meaningful decrements

in functional status and QoL [35]. Several studies have proven a positive effect of physiotherapy on reducing shoulders pain which fostered the restoration of shoulders ROM as a result, especially three months after surgery [21,36-39]. These previous studies align with our individual-tailored physiotherapy on reaching a satisfactory reduction of pain intensity from moderate to very mild scores. In addition to improving the sensation of pain, our study findings showed a positive trend in the mean handgrip strength, which was markedly impaired postoperatively and improved to its normal range. A previous study has shown that handgrip strength is associated with pain and shoulder mobility [40]. Based on our results, it was found that women's handgrip strength improved as the pain intensity decreased and the shoulder mobility (anteflexion) increased. The DASH ESs revealed a remarkably significant improvement in disabilities of the arm, shoulder, and hand between T0 and T1 and T1 and T2. These findings (ESs difference) were better than the results reported by Beurskens et al., (2007) (mean ES = -9.0) where we employed the same intervention [21]. We contribute this difference in the ES to the timing of commencing the physiotherapy. Beurskens et al., (2007) started physiotherapy two weeks following surgery among the treatment group in comparison to our physiotherapy program which was started on day 0 after surgery [21]. Moreover, the ES between T1 and T2 was significant as well, which explains the need to provide physiotherapy for at least 3 months to restore the normal function of the arm, shoulder, and hands. To improve the QoL of women post-mastectomy and ALND, several studies have focused on post-surgery complications and concurrent treatment. The limitations in activities of daily life, pain, and disabilities of the arm, shoulder, and hand could collectively and adversely impact the intactness of

well-being and quality of life [41-43]. Beurskens et al., (2007) indicated in their study a significant improvement in women's QoL after physiotherapy, which aligns with our findings [21]. However, Todd et al., (2008) indicated no significant difference between groups in the women's QoL in their study findings, which could be explained by the poor improvement in the hands' strength and prolonged breast wound drainages [44]. Overall, no prolonged impairments of the extremities or post-op complications were reported or detected at short-term assessment after three months in our study that could undermine women's QoL. The significant positive association of QoL with shoulder flexion demonstrates its detrimental effect on women's QoL. The effect of physiotherapy therapy on the overall shoulder function recovery could depend on the time of onset of exercise sessions. De Groef et al., (2015) systematic review showed inconsistency in the studies in terms of the post-operative outcomes between early (24 up to 72 hours) versus delayed exercise therapy [5]. In this systematic review, several clinical trials have been shown to support an early start without demonstrating any loss of function or postoperative complications. On the other side, different clinical trials showed varied incidents of increased pain intensity, accumulation of axillary fluid and seroma formation as adverse effects of the surgery. Nevertheless, these reported studies should be interpreted with caution due to their quality and the varied content of physiotherapy programs. Based on our results, we recommend initiating a tailored low-intensity physical therapy program to avoid seroma formation and have a positive impact on the wound healing process, particularly with post-ALND patients [44,45]. Our study has shown a cultural acceptance of home-based exercise as a model of rehabilitation intervention post-mastectomy. Previous studies that have utilized home-based rehabilitation exercises concluded that home-based physiotherapy support patients' independence in daily activities, and reduce dependence on caregivers, hence improving their QoL [34, 46, 47]. Since this trial was designed as a pilot project, this limits our conclusive recommendations for any changes in the timing, content and intensity of physiotherapy programs in clinical practice. Thus, we cannot generalize our study findings to a larger population and study outcomes need to be interpreted with caution. The small sample size limit the generalizability of the study findings. A possible explanation could be contributed to the pressing concerns of the perceived benefits of study intervention, the timing of the study period, and the overwhelming status of having a life-threatening disease. The convenience sample might result in a selection bias. The majority of the participants were below the age of 50 years. We did not intend to include a control group in this trial due to the pilot nature and purpose of this study and heterogeneity in the physiotherapy interventions applied for comparison, which would limit the implication of the study results. We are uncertain whether or not the study participants followed the exercises described in the written instructions in the provided diaries.

Moreover, the study was conducted over a short follow-up time of three months, and adjuvant treatments like chemotherapy and radiation could confound the generalizability of the made conclusion. This pilot trial showed that our study protocol is feasible, can demonstrate clinical ES, potentially successful sample recruitment strategy, and good adherence to study protocol. Validated instruments for the objective and self-assessed evaluation of shoulder function, pain, DASH, and QoL were used in this trial. Additionally, preventing inter-rater reliability differences and minimizing errors was controlled by employing only one physiotherapist in the evaluation process. Future studies are recommended considering the following: comprehensive pre-operative baseline evaluation of medical history, concomitant medication, and practicing exercise. Moreover, as this study is pragmatic in nature, we recommend as well recruitment of elder BC patients with advanced stages.

7. Conclusion

An individually tailored, three-month combined program of home-based and institutional physiotherapy interventions help to improve in short-term shoulders mobility, reduce pain, improve handgrip strength in the upper extremities, and QoL in patients who have undergone BC surgery. In this study, we reported positive outcomes of early post-operatively physiotherapy exercises. The young age demographic and potentially the early stage of BC at diagnosis given the adjuvant treatment interventions listed may have been factors related to compliance and improvements recorded. Firm conclusions on the effect of individually tailored, three-month combined programs of home-based and institutional physiotherapy interventions warrant larger randomized and controlled studies with at least 12-months follow-up with relevant outcomes. Data availability statement: The data used to support the findings of this study are available from the corresponding author upon request.

8. Funding:

The authors would like to thank the Research Center at King Fahd Medical City, Riyadh [grant number: 018-053] for their financial assistance.

1. Albeshan SM, Mackey MG, Hossain SZ, Alfuraih AA, Brennan PC. Breast cancer epidemiology in gulf cooperation council countries: a regional and international comparison. *Clinical breast cancer*. 2018; 18(3): e381-92.
2. International agency for research on cancer. *Global cancer burden in*. 2020.
3. Althubiti MA, Eldein MM. Trends in the incidence and mortality of cancer in Saudi Arabia. *Saudi medical journal*. 2018; 39(12): 1259.
4. Maajani K, Jalali A, Alipour S, Khodadost M, Tohidinik HR, Yazdani K. The global and regional survival rate of women with breast cancer: a systematic review and meta-analysis. *Clinical breast cancer*. 2019; 19(3): 165-77.
5. De Groef A, Van Kampen M, Dieltjens E, Christiaens MR, Neven

- P, Geraerts I, Devoogdt N. Effect of postoperative physical therapy for upper-limb impairments after breast cancer treatment: a systematic review. *Archives of physical medicine and rehabilitation*. 2015; 96(6): 1140-53.
6. Bruce J, Williamson E, Lait C, Richmond H, Betteley L, Lall R, et al. Randomised controlled trial of exercise to prevent shoulder problems in women undergoing breast cancer treatment: study protocol for the prevention of shoulder problems trial (UK PROSPER). *BMJ open*. 2018; 8(3): e019078.
 7. Stubblefield MD, Custodio CM. Upper-extremity pain disorders in breast cancer. *Arch Phys Med Rehabil*. 2006; 87(3): 96-99.
 8. Ebaugh D, Spinelli B, Schmitz KH. Shoulder impairments and their association with symptomatic rotator cuff disease in breast cancer survivors. *Med Hypotheses*. 2011; 77(4): 481-487.
 9. Land SR, Kopec JA, Julian TB, Brown AM, Anderson SJ, Krag DN, Christian NJ, Costantino JP, Wolmark N, Ganz PA. Patient-reported outcomes in sentinel node–negative adjuvant breast cancer patients receiving sentinel-node biopsy or axillary dissection: National Surgical Adjuvant Breast and Bowel Project Phase III Protocol B-32. *Journal of Clinical Oncology*. 2010; 28(25): 3929.
 10. Gartner R, Jensen MB, Nielsen J, Ewertz M, Kroman N, Kehlet H. Prevalence of and factors associated with persistent pain following breast cancer surgery. *Jama*. 2009; 302(18): 1985-92.
 11. Belfer I, Schreiber KL, Shaffer JR, Shnol H, Blaney K, Morando A, et al. Persistent postmastectomy pain in breast cancer survivors: analysis of clinical, demographic, and psychosocial factors. *The journal of pain*. 2013; 14(10): 1185-95.
 12. Stevens PE, Dibble SL, Miaskowski C. Prevalence, characteristics, and impact of postmastectomy pain syndrome: an investigation of women's experiences. *Pain*. 1995; 61(1): 61-8.
 13. Hidding JT, Beurskens CH, van der Wees PJ, van Laarhoven HW, Nijhuis-van der Sanden MW. Treatment related impairments in arm and shoulder in patients with breast cancer: a systematic review. *PloS one*. 2014; 9(5): e96748.
 14. Levangie PK, Drouin J. Magnitude of late effects of breast cancer treatments on shoulder function: a systematic review. *Breast cancer research and treatment*. 2009; 116(1): 1-5.
 15. Wernicke AG, Goodman RL, Turner BC, Komarnicky LT, Curran WJ, Christos PJ, et al. A 10-year follow-up of treatment outcomes in patients with early stage breast cancer and clinically negative axillary nodes treated with tangential breast irradiation following sentinel lymph node dissection or axillary clearance. *Breast cancer research and treatment*. 2011; 125(3): 893-902.
 16. Ashikaga T, Krag DN, Land SR, Julian TB, Anderson SJ, Brown AM, et al. Morbidity results from the NSABP B-32 trial comparing sentinel lymph node dissection versus axillary dissection. *Journal of surgical oncology*. 2010; 102(2): 111-8.
 17. Levy EW, Pfalzer LA, Danoff J, Springer BA, McGarvey C, Shieh CY, et al. Predictors of functional shoulder recovery at 1 and 12 months after breast cancer surgery. *Breast cancer research and treatment*. 2012; 134(1): 315-24.
 18. Whitworth PW, Shah C, Vicini F, Cooper A. Preventing Breast Cancer-Related Lymphedema in High-Risk Patients: The Impact of a Structured Surveillance Protocol Using Bioimpedance Spectroscopy. *Front Oncol*. 2018; 8: 197.
 19. Brahmabhatt P, Sabiston CM, Lopez C, Chang E, Goodman J, Jones J, et al. Feasibility of prehabilitation prior to breast cancer surgery: a mixed-methods study. *Frontiers in oncology*. 2020; 10: 571091.
 20. de Sire A, Losco L, Cigna E, Lippi L, Gimigliano F, Gennari A, et al. Three-dimensional laser scanning as a reliable and reproducible diagnostic tool in breast cancer related lymphedema rehabilitation: a proof-of-principle study. *Eur Rev Med Pharmacol Sci*. 2020; 24(8): 4476-4485.
 21. Beurskens CH, van Uden CJ, Strobbe LJ, Oostendorp RA, Wobbes T. The efficacy of physiotherapy upon shoulder function following axillary dissection in breast cancer, a randomized controlled study. *BMC cancer*. 2007; 7(1): 1-6.
 22. Didem K, Ufuk YS, Serdar S, Zümre A. The comparison of two different physiotherapy methods in treatment of lymphedema after breast surgery. *Breast cancer research and treatment*. 2005; 93(1): 49-54.
 23. Lauridsen MC, Christiansen P, Hessov IB. The effect of physiotherapy on shoulder function in patients surgically treated for breast cancer: a randomized study. *Acta Oncologica*. 2005; 44(5): 449-57.
 24. Lippi L, de Sire A, Losco L, Mezzan K, Folli A, Ivanova M, et al. Axillary Web Syndrome in Breast Cancer Women: What Is the Optimal Rehabilitation Strategy after Surgery? A Systematic Review. *Journal of Clinical Medicine*. 2022; 11(13): 3839.
 25. Invernizzi M, Lippi L, Folli A, Turco A, Zattoni L, Maconi A, et al. Integrating molecular biomarkers in breast cancer rehabilitation. What is the current evidence? A systematic review of randomized controlled trials. *Frontiers in Molecular Biosciences*. 2022; 9.
 26. Harris SR, Schmitz KH, Campbell KL, McNeely ML. Clinical practice guidelines for breast cancer rehabilitation: syntheses of guideline recommendations and qualitative appraisals. *Cancer*. 2012; 118(S8): 2312-24.
 27. Casley-Smith J, Casley-Smith JR: Modern treatment for lymphoedema. 5th edition. Adelaide, S.A.: Lymphoedema Association of Australia. 1997.
 28. Lacomba MT, Sánchez MJ, Goñi ÁZ, Merino DP, del Moral OM, Téllez EC, et al. Effectiveness of early physiotherapy to prevent lymphoedema after surgery for breast cancer: randomised, single blinded, clinical trial. *Bmj*. 2010; 340.
 29. Gummesson C, Ward MM, Atroshi I. The shortened disabilities of the arm, shoulder and hand questionnaire (Quick DASH): validity and reliability based on responses within the full-length DASH. *BMC musculoskeletal disorders*. 2006; 7(1): 1-7.
 30. Fisher MI, Davies C, Beuthin C, Colon G, Zoll B, Pfalzer L. Breast cancer EDGE task force outcomes: Clinical measures of strength and muscular endurance: A systematic review. *Rehabilitation Oncology*. 2014; 32(4): 6-15.

31. Lee EH, Chun M, Kang S, Lee HJ. Validation of the Functional Assessment of Cancer Therapy-General (FACT-G) scale for measuring the health-related quality of life in Korean women with breast cancer. *Japanese Journal of Clinical Oncology*. 2004; 34(7): 393-9.
32. Devoogdt N, Van Kampen M, Christiaens MR, Troosters T, Piot W, Beets N et al. Short- and long-term recovery of upper limb function after axillary lymph node dissection. *Eur J Cancer Care* 2011; 20(1): 77-86.
33. Hayes SC, Johansson K, Stout NL, Prosnitz R, Armer JM, Gabram S, et al. Upper body morbidity after breast cancer: incidence and evidence for evaluation, prevention, and management within a prospective surveillance model of care. *Cancer* 2012; 118(8 Suppl): 2237-49.
34. Kilgour R D, Jones DH, Keyserlingk JR. Effect of a self-administered, home-based exercise rehabilitation program for women following a modified radical mastectomy and axillary node dissection: a preliminary study. *Breast Cancer Research and Treatment*. 2007; 109(2): 285-295.
35. Miaskowski C, Cooper B, Paul SM, West C, Langford D, Levine JD, et al. Identification of patient subgroups and risk factors for persistent breast pain following breast cancer surgery. *The Journal of Pain*. 2012; 13(12): 1172-87.
36. De Rezende LF, Franco RL, de Rezende MF, Beletti PO, Morais SS, Gurgel MS. Two exercise schemes in postoperative breast cancer: comparison of effects on shoulder movement and lymphatic disturbance. *Tumori* 2006; 92(1): 55-61.
37. Wingate L, Croghan I, Natarajan N, Michalek AM, Jordan C. Rehabilitation of the mastectomy patient: a randomized, blind, prospective study. *Arch Phys Med Rehabil*. 1989; 70(1): 21-4.
38. Box RC, Reul-Hirche HM, Bullock-Saxton JE, Furnival CM. Shoulder movement after breast cancer surgery: results of a randomized controlled study of postoperative physiotherapy. *Breast cancer Res Treat* 2002; 75(1): 35-50.
39. Cantarero-Villanueva I, Fernández-Lao C, Díaz-Rodríguez L, Fernándezde-Las-Peñas C, Ruiz JR, Arroyo-Morales M. The hand-grip strength test as a measure of function in breast cancer survivors: relationship to cancer-related symptoms and physical and physiologic parameters. *Am J Phys Med Rehabil*. 2012; 91(9): 774-82.
40. Mols F, Vingerhoets AJ, Coebergh JW, van de Poll-Franse LV. Quality of life among long-term breast cancer survivors: a systematic review. *Eur J Cancer* 2005; 41(17): 2613-9.
41. Rietman JS, Dijkstra PU, Hoekstra HJ, Eisma WH, Szabo BG, Groothoff JW, et al. Late morbidity after treatment of breast cancer in relation to daily activities and quality of life: a systematic review. *Eur J Surg Oncol* 2003; 29(3): 229-38.
42. Voogd AC, Ververs JMMA, Vingerhoets AJJM, Roumen RMH, Coebergh JWW, Crommelin MA. Lymphoedema and reduced shoulder function as indicators of quality of life after axillary lymph node dissection for invasive breast cancer. *Br J Surg*. 2003; 90: 76-81.
43. Todd J, Scally A, Dodwell D, Horgan K, Topping A. A randomized controlled trial of two programs of shoulder exercise following axillary node dissection for invasive breast cancer. *Physiotherapy* 2008; 94(4): 265-73.
44. Shamley DR, Barker K, Simonite V, Beardshaw A. Delayed versus immediate exercises following surgery for breast cancer: a systematic review. *Breast cancer Res Treat*. 2005; 90(3): 263-71.
45. Buragadda S, Alhusaini AA, Melam GR, Arora N. Effect of complete decongestive therapy and a home program for patients with post mastectomy lymphedema. *Journal of physical therapy science*. 2015; 27(9): 2743-8.
46. Gautam AP, Maiya AG, Vidyasagar MS. Effect of home-based exercise program on lymphedema and quality of life in female post-mastectomy patients: pre-post intervention study. *J Rehabil Res Dev*. 2011; 48(10):1261-8.