



The Impact of Therapeutic Exercises on the Quality of Life and Shoulder Range of Motion in Women After a Mastectomy, an RCT

Mohamad Majed¹ · Charlene A. Neimi² · Sawsan Moustafa Youssef³ · Khaled Ahmed Takey⁴ · Lina Kurdahi Badr⁵

Accepted: 9 October 2020 / Published online: 20 November 2020

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Abstract

Breast cancer ranks highest in incidence and mortality among females and second among both genders. Lebanon has the second highest rate of breast cancer worldwide for those 35–39 years old and the highest for those 40–49. Mastectomy often results in decreased shoulder and arm mobility and decreased quality of life. The objective of this study was to assess the effect of an educational program of therapeutic exercises on the quality of life and functional ability in women after a mastectomy. Sixty women undergoing a mastectomy were randomly assigned to either an intervention or control group. The intervention group received extensive pre-surgery education as well as training on therapeutic exercises. Follow-up phone calls to the intervention group were made to ensure that the exercises were being done. Both groups were visited at home at two and four weeks to obtain the outcome variables. The Breast Cancer Patient Version was used to assess quality of life, and the “Goniometer” was used to assess the range of motion of the affected shoulder. At two and four weeks after surgery, women in the intervention group had significant improvements in their shoulder range of motion: *flexion*, *extension*, and *abduction* were significantly different between the control and intervention group at $p = 0.04–0.00$. For quality of life, physical, psychological, psychological, social, and spiritual well-being were significantly higher for the intervention group at both two and four weeks after surgery, $p < 0.001$. In a middle-income country, one-to-one education provided by a nurse, which included demonstrations, back demonstrations, and weekly phone calls had a positive impact on women’s shoulder range of motion and quality of life. NCT04184102

Keywords Exercise · Education · Mastectomy · Quality of life · Range of motion

Quick points

- Nurses can play an important role in teaching women who are undergoing a mastectomy, exercises that may improve their physical and psychological outcomes.
- This study in a middle-income country found that women who underwent a mastectomy and received education, and exercise training had better range of motion in their affected shoulder and better quality of life.
- This randomized control trial study adds to body of evidence regarding the effect of exercise and education on the outcome of women undergoing mastectomies, which has not been conclusively established.

✉ Lina Kurdahi Badr
lbadr@apu.edu

Sawsan Moustafa Youssef
youssef50@yahoo.com

Khaled Ahmed Takey
khaledtakey@hotmail.com

² California State University Channel Islands, Camarillo, CA, USA

³ Medical-Surgical Nursing Faculty of Health Sciences, Beirut Arab University, Beirut, Lebanon

⁴ Beirut Arab University, Beirut, Lebanon

⁵ School of Nursing, Azusa Pacific University, Azusa, CA 91702, USA

¹ Medical Surgical Unit, American University of Beirut Medical Center (AUBMC), Beirut, Lebanon

Introduction

Cancer is projected to be the leading cause of death worldwide in the twenty-first century. In 2018, the estimated incidence rate of cancer will surpass 18 million with a mortality rate nearing 10 million worldwide [1]. While lung cancer is the most commonly diagnosed cancer and the leading cause of cancer deaths for males and females combined, breast cancer has the second highest rate of incidence in both sexes and the highest rate of incidence and mortality among females [2]. Worldwide, there were over 2 million new breast cancer cases in 2018 [1]. When looking at the age-standardized incidence rate of breast cancer, in 25 countries with the highest rates, Lebanon was rated number six (and third in non-European Mediterranean countries) [3, 4]. Moreover, Lebanon has the second highest rate worldwide for those 35–39 years old and the highest for those 40–49 [5]. Although cancer mortality rates in Lebanon have decreased between 2000 and 2012, new cases of breast cancer were over two times the incidence of any other cancer in 2014. One possible reason for the increase of new cases is the proactive screening campaign by the Ministry of Health (MoH) in Lebanon, which is a small middle-income country with close to 5 million people [5].

The diagnosis of breast cancer has not only physical, but also social and psychological ramifications. Women may feel incomplete due to the loss of their breast, have distorted body image or self-concept, experience a change in relationships with their husbands and families, or suffer fear of recurrence of the disease or death [6]. Although these may decrease with time, they can still be significant factors resulting in changes in daily living and quality of life (QoL) [7].

Treatment options for breast cancer vary depending on the clinical criteria, such as the type, size, stage, and metastasis, and consist of surgery, postoperative radiation therapy, preoperative and/or postoperative systemic therapy [8]. There are five types of mastectomies, namely, total, modified radical, radical, partial, and nipple mastectomies. Modified radical mastectomy (MRM), which is the focus of this study, is the removal of the entire breast along with axillary lymph nodes while leaving the chest muscles in place. This option may result in a deterioration of postoperative function due to decreased shoulder and arm mobility, pain, and muscle weakness [9].

Quality of Life

The World Health Organization (WHO) defines quality of life as “an individual’s perception of their own position in life within the context of the cultural and value system in which they live and in relation to their goals, expectations, standards, and concerns” [10]. Cancer treatments have resulted in better survival rates, albeit accompanied by long-term physical and

psychological problems [11, 12]. Breast cancer survivors have reported experiencing multiple side effects, such as insomnia, pain, axillary web syndrome, lymphedema, fatigue, cognitive dysfunction, depression, sexual dysfunction, spiritual uncertainty, and decreased quality of life [13, 14]. A meta-analysis in 2012 of 40 trials with 3694 participants with cancer randomized to an exercise ($n = 1927$) or comparison ($n = 1764$) group concluded that exercise may have beneficial effects on the QoL of patients, although the positive results should be interpreted cautiously due to the heterogeneity of the exercise programs tested [15].

Exercise

Scientific evidence shows that women with breast cancer can benefit from exercise, which often improves physical and emotional well-being and reduces side effects [6, 16, 17]. A Cochrane review in 2010, which included 24 studies involving 2132 women with breast cancer, examined the effect of early versus delayed implementation of postoperative exercise. This study concluded that early exercise was more effective than delayed exercise in both statistical and clinical significance in shoulder range of motion (ROM). The authors recommended further research that closely monitors the frequency and intensity of exercise program [18]. A more recent systematic review in 2018 of 6 studies, including two randomized controlled trials (RCTs), concluded that training programs for patients undergoing breast cancer surgery can reduce pain and improve functional recovery, especially in enhancing shoulder ROM [19]. The authors likewise concluded that further research, especially RCTs in different settings are required before conclusive evidence is reached.

Therefore, the aim of this study was to determine the effect of a therapeutic exercise program with follow-up calls at home on shoulder ROM and QoL of patients after a mastectomy in a middle-income country [20].

Hypothesis

An educational program of therapeutic exercises preoperatively improves the quality of life and increases functional ability in women after a modified radical mastectomy (MRM) compared with women who did not receive the intervention at two and four weeks post-surgery.

Methods

Design A randomized control trial (RCT) (NCT04184102) pre- and post-design between March 2017 and November 2017 was conducted.

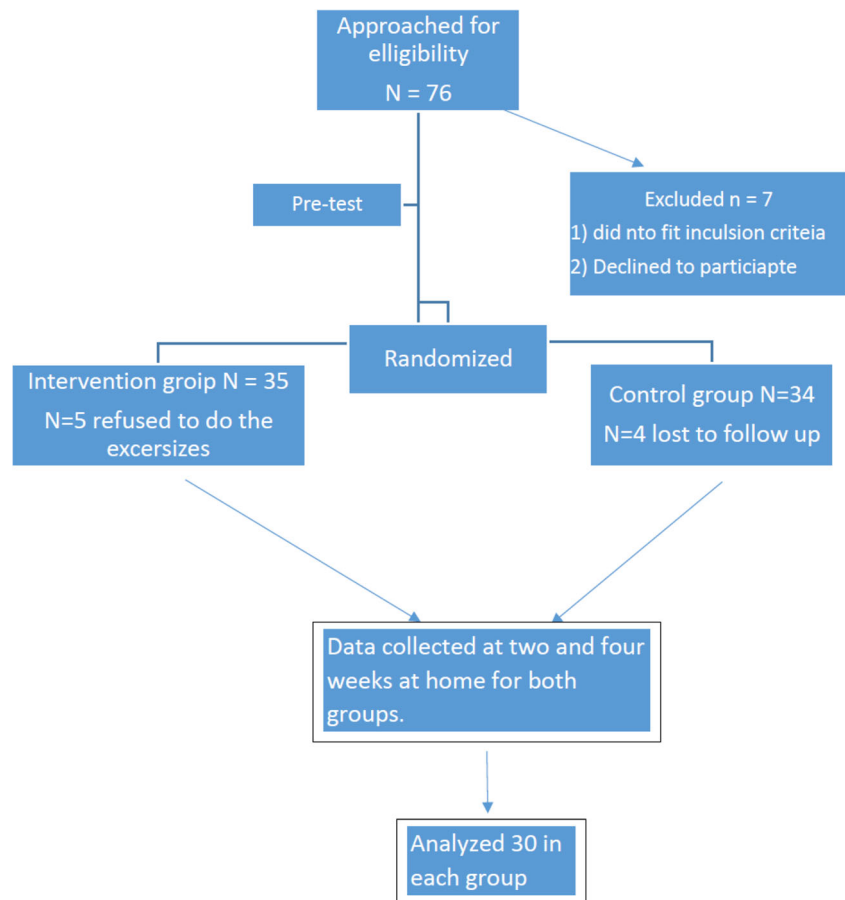
Setting Data was collected at two medical surgical wards at a 365-bed tertiary university medical center in Lebanon. The medical center provides inpatient and outpatient services to the people of Lebanon and the Middle East. The hospital is Joint Commission International (JCI) accredited and Magnet designated. The medical center provides various types of medical, surgical, and specialized services and admits around 35,000 patients a year.

Subjects A convenient sample of 76 women diagnosed with breast cancer and undergoing an MRM were approached while waiting for their surgery after approval from their surgeon. Inclusion criteria included women between 35 and 55 years of age who were diagnosed with breast cancer and scheduled for an MRM. Women who were pregnant, not able to communicate, or who had co-morbidities that affected their QoL were excluded. The sample size was calculated based on a previous study, [21] where the difference in ROM between the two groups was more than or equal to 10%; with an error $\alpha = 5\%$; and a $\beta = 80\%$, the minimum sample size in each group was $n = 22$. The final sample size after exclusions ($n = 7$), refusal to perform the exercises ($n = 5$), and lost to follow ($n = 4$) was 60 women (see Fig. 1).

Instruments Three instruments were used to collect data for this study:

- 1 Quality of life instrument, the Breast Cancer Patient Version (QoL-BC) was used to assess QoL. The QoL-BC is a patient self-reported scale assessing concerns of cancer survivors [22, 23]. It includes 46 items assessing four domain, namely, (1) physical well-being (8 items), (2) psychological well-being, (22 items), (3) social well-being, (9 items), and (4) spiritual well-being (7 items). The items are scored from 0–10, with 0 = worst outcome to 10 = best outcome. Several items have reverse anchors and need to be reversed. The overall and the subscales of the instrument have shown excellent internal and external reliability and moderate to strong validity [24]. The QoL-BC has been translated to Arabic and used with breast cancer patients in several Arab countries with good reliability and validity [25, 26]. For this study, the Cronbach alpha for the total scale was 0.76, and for each domain, the Cronbach alpha ranged between 0.71 and 0.82.
- 2 The “Goniometer” is nonintrusive and the most commonly used method to assess the ROM of a joint due to its simplicity and ease of use [27, 28]. While there are various

Fig. 1 Flow chart of the protocol



means to measure ROM, the goniometer is a reliable tool which has been used in several studies to assess ROM of the affected shoulder in patients after mastectomy [28–30]. The goniometer assesses the range of motion, flexion, unbending, abduction, external rotation, and inward rotation of the shoulder joint.

- 3 Demographic variables included age, education, and marital status.

Procedure Approval for the study was granted by the Institution Review Board (IRB) of the university and the medical center. Seventy-six women were approached while waiting for their appointment, with approval form their surgeon. The principal investigator (PI) explained the study and what was involved in participating. Women who showed interest in participating signed a consent form and were then randomly assigned to one of two groups by flipping a coin. Thirty women ended up in the intervention group and 30 in the control group. Figure 1 details the protocol of the study. The intervention group received pre-surgery education and training on therapeutic exercises by the PI in addition to routine hospital care. Participants were told that they would be called every week and visited at home by the PI to assess their ROM and to fill out a questionnaire. The control group received routine hospital care that did not include any exercise training or education. Routine hospital care included explanation by the surgeon on the surgical procedure with follow-up at two and four weeks after discharge. The educational material was developed by the PI and included a PowerPoint and a booklet with instructions on the exercises as well as information about the surgery and what to expect after the surgery. The educational material was based on previous research [31, 32] and adopted to the population after consultation with a panel of experts, including two nurses and three physicians.

The Intervention The intervention consisted of three phases. Phase 1 took place the day prior to surgery, at which time, both groups completed the QoL-BC survey and shoulder ROM was measured using the goniometer. Phase 2 consisted of one-to-one education with the intervention group prior to surgery. Education consisted of a PowerPoint presentation regarding the therapeutic exercises, information about the surgery, and a booklet with pictures of the exercises to take home. In this phase, demonstration of the exercises by the researcher with a return demonstration by the patient was done to ensure proper techniques. The researcher called the patients at home every week to ensure that the women were continuing the exercises. Phase 3 was conducted for both groups in the patient's homes and entailed reassessment of shoulder ROM and completing the QoL-BC at the second and fourth week after discharge. All patients completed the study. The exercises included deep breathing as well as shoulder exercises such

as extension of the triceps, bicep curl, paddling in sitting position, fluttering with both arms, hands behind neck, forward wall crawls, and side wall crawls. Patients were instructed to perform 10 repetitions of each exercise during hospitalization, with further guidance at the outpatient follow-up appointment. Shoulder flexion was limited to 90° of active assisted ROM for the first few days post-surgery and until the drains were removed, then gradually increased after the third postoperative day. Patients were instructed to keep performing the exercises after discharge.

Data Analysis Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 24. Descriptive statistics were conducted using means, standard deviations for continuous variables, and frequencies or percentages for categorical variables. Significant differences in the ROM and QoL scores between study and control groups were compared using independent two sample *t* test. A *p* value of less than 0.05 was considered significant.

Results

Patient Characteristics

There were no differences between groups at baseline. The majority of patients in both groups were between 35 and 42 years of age, roughly 70% were married, and the majority of patients had a high school or higher education (Table 1).

Shoulder Range of Motion Scores While the shoulder ROM scores were not significantly different between groups prior to surgery, there were significant differences at the second and fourth week after surgery (Table 2). *Flexion* at two weeks for the intervention group was 133.80 ± 6.79 , and for the control group, it was 131.17 ± 2.20 , $p = 0.04$. At four weeks, flexion was 167.97 ± 4.09 for the intervention group and 159.92 ± 1.73 for the control group, $p < 0.001$. *Extension* significantly improved for the study group at two weeks with a mean of 42.77 ± 2.30 versus 38.73 ± 1.46 , $p < 0.001$; and at four weeks 53.07 ± 2.12 versus 49.03 ± 1.25 , $p < 0.001$. Additionally, *abduction* demonstrated a significant difference between the study and control groups, at two weeks 143.50 ± 4.42 versus 138.57 ± 1.78 , $p < 0.001$; and at four weeks 167.03 ± 4.61 versus 159.40 ± 1.69 , $p < 0.001$.

Differences Between Groups on Each of the QoL-BC 4 Subscales

There were no significant differences between groups at baseline on the QoL survey with both groups having low QoL scores. However, there were significant differences between groups at two and four weeks after surgery on the four subscales (Table 3). *Physical well-being* was significantly improved with the intervention group experiencing higher level of physical well-

Table 1 Socio-demographic characteristics of patients in study and control groups

Sociodemographic characteristics	Study group (N = 30)		Control group (N = 30)		p value
	No.	Percent	No.	Percent	
Age					
35–42 years	14	46.7	14	46.7	NS
43–48 years	10	33.3	10	33.3	
49–55 years	6	20.0	6	20.0	
Marital status					
Married	21	70.0	22	73.3	NS
Single	4	13.3	1	3.3	
Widowed	4	13.3	4	13.4	
Divorced	1	3.4	3	10.0	
Level of education					
Illiterate	0	0.0	0	0.0	NS
Read and write	3	10.0	5	16.7	
Intermediate school	12	40.0	7	23.3	
High school or more	15	50.0	18	60.0	
Total	30	100	30	100	

NS, Not significant

being than the control group; at two weeks, 58.37 ± 6.16 versus 50.23 ± 7.78 , $p = 0.001$, and at four weeks 66.67 ± 6.19 versus 54.97 ± 9.55 , $p < 0.001$. For *psychological well-being* there was significant difference between the two groups at two weeks, the study group mean 142.33 ± 15.48 and the control group 122.93 ± 7.34 , $p < 0.001$; and at four weeks, 169.50 ± 26.43 and 145.67 ± 12.44 , $p < 0.001$. *Social well-being* at two weeks was significantly higher for the study group 43.57 ± 7.045 versus 29.30 ± 8.30 for the control group, $p < 0.001$; and at four weeks 54.33 ± 8.73 for the study group versus 42.33 ± 5.08 for the control group, $p < 0.001$. *Spiritual well-being* was significantly improved at two weeks, with a mean for the study group of 51.07 ± 4.37 versus

44.90 ± 6.05 , $p < 0.001$; and at four weeks 56.33 ± 3.96 versus 48.93 ± 2.61 , $p < 0.001$.

Discussion

This is the first RCT assessing the effect of an educational program on the ROM and QoL of Lebanese women after a mastectomy. Breast cancer surgery results in adverse side effects such as upper extremity restricted movements, fatigue, difficulty in performing daily work, and difficulty with functional activities, all of which affect quality of life [33].

Table 2 Shoulder range of motion preoperative and at two and four weeks after discharge

Shoulder (ROM) measurement	Intervention group (mean ± SD)	Control group (mean ± SD)	t test	p value
Flexion				
Preoperative	175.3 ± 2.16	178.60 ± 1.79	- 0.107	0.916
Second week	133.80 ± 6.79	131.17 ± 2.20	1.981	0.04*
Fourth week	167.97 ± 4.09	159.92 ± 1.73	10.002	< 0.001**
Extension				
Preoperative	58.30 ± 1.42	58.93 ± 2.13	- 1.203	0.239
Second week	42.77 ± 2.30	38.73 ± 1.46	8.077	< 0.001**
Fourth week	53.07 ± 2.12	49.03 ± 1.25	8.994	< 0.001**
Abduction				
Preoperative	176.20 ± 2.04	175.27 ± 11.19	0.442	0.662
Second week	143.50 ± 4.42	138.57 ± 1.78	5.500	< 0.001**
Fourth week	167.03 ± 4.61	159.40 ± 1.69	8.339	< 0.001**

Table 3 QoL preoperative and at second and fourth week after discharge

QoL	Mean ± SD for study group	Mean ± SD for control group	<i>t</i> test	<i>p</i> value
Physical well-being				
Preoperative	53.30 ± 5.89	52.50 ± 6.08	0.56	0.578
Second week	58.37 ± 6.16	50.23 ± 7.78	3.84	0.04*
Fourth week	66.67 ± 6.19	54.97 ± 9.55	4.99	< 0.001*
Psychological well-being				
Preoperative	73.63 ± 9.72	74.77 ± 9.30	− 0.41	0.684
Second week	142.33 ± 15.48	122.93 ± 7.34	5.87	< 0.001*
Fourth week	169.50 ± 26.43	145.67 ± 12.44	4.32	< 0.001*
Social well-being				
Preoperative	33.30 ± 4.47	32.50 ± 3.82	0.56	0.570
Second week	43.57 ± 7.04	29.30 ± 8.30	8.25	< 0.001*
Fourth week	54.33 ± 8.73	42.33 ± 5.08	5.80	< 0.001*
Spiritual well-being				
Preoperative	40.20 ± 2.67	40.40 ± 1.79	− 0.33	0.738
Second week	51.07 ± 4.37	44.90 ± 6.05	5.06	< 0.001*
Fourth week	56.33 ± 3.96	48.93 ± 2.61	9.13	< 0.001*

Exercise interventions after breast cancer surgery are linked with improvements in functional capacity, prolonged survival, and improved quality of life [18, 19]. The major findings of this study is that the exercise program had a beneficial effect on both the QoL and shoulder ROM for women undergoing an MRM in Lebanon.

In comparison to earlier studies, patient demographics varied. In the current study, the age range of women was between 35 and 42 years which is younger than most published studies [31, 33]. However, this represents the median age of females presenting with breast cancer in Lebanon, which is 13 years younger than what is reported in Western countries [34]. Most women in both groups were married, which corresponds to previous studies [35]. Both groups had a high school level of education or more, which is in line with most of the studies published in Beirut [36] though this is higher than most studies conducted in high income countries [6, 16, 37].

Shoulder Range of Motion

The ROM of women in the study group significantly improved compared to the control group, which reveals the importance of a detailed one-on-one educational program. Arm immobilization caused by fear and/or pain, as well as the type of surgery, the incision size, and axillary lymphadenectomy are factors that cause women to have a tendency toward little movement of the upper limb. Therefore, to decrease the incidence of these complications, arm exercises immediately after surgery and the educational program given to the study group resulted in functional improvement in the ROM. These results are congruent with several studies in other countries

[31, 32, 37, 38]. A review of 18 RCTs by De Groef et al. [39] concluded that multifactorial physical therapy and active exercises are effective to reduce postoperative pain and to improve ROM after treatment for breast cancer. Our results show 4 to 8° improvements in shoulder flexion, extension, and abduction, which is within the clinical range of at least 6° in ROM of suggested by Mullaney et al. [40] using a standard goniometer. The addition of follow-up phone calls at home may also have had a positive impact, similar to a study by Bluethmann et al. which emphasized that interventions supported by phone calls and e-mails were effective in altering physical activity levels after treatment in patients with breast cancer [41].

Quality of Life Preoperatively, there was no statistical difference between groups on any of the four subscales of the QoL survey. This could be interpreted to mean that neither group received adequate information about the surgery, and they were anxious and stressed about the prognosis and its effect on their health. However, on the second and fourth week after discharge, there was a significant improvement in the *physical well-being* of women in the intervention group, which could be related to the effect of the education and the exercise training that was provided for them. This is supported by Sisman et al. who stated that the risk of development and progression of mastectomy-related lymphedema was reduced with education and exercise provided by trained nurses at an early stage [42]. Likewise, Lee et al. reported that exercises prevented swelling, relieved discomfort, and promoted healing in addition to improving health-related QoL among women after breast surgery [30].

Psychological Well-being The improvement psychological well-being of patients in the study group is in line with several earlier studies which found that appropriate interventions and exercise strategies could improve the QoL of women diagnosed with breast cancer [15–17, 43]. The results could be explained by the possibility that when the fear of the unknown is decreased and expectations are realistic, then psychological status improves. This is supported by Brandstatter et al., who concluded that meaning in life and knowing about a disease are variables that can improve psychological status, including life satisfaction and happiness [44].

Social Well-being At two and four weeks after surgery, there was a significant improvement in the study group in social well-being compared to the control group. It may be that the education and exercise program provided enhanced their social interaction thus leading to the improvement. This finding is supported by several earlier studies that found that exercises have significant effects on females with breast cancer in terms of functional capacity, daily activities, fatigue, flexibility, and QoL [14, 15, 44, 45]. Garlick et al. [46] stated that breast cancer patients do not only need medical therapy but also need psychological, spiritual, and social support [46]. Likewise, Benton et al. found that physical activity was associated with improved body image, emotional well-being, sleep regulation, psychological health, reduced pain and fatigue, sexual health, and social functioning [47].

Spiritual Well-being A cancer diagnosis can influence spiritual well-being by either becoming angry with God or seeking solace through religious activities such as visiting churches or temples, meditation, or praying. The diagnosis creates uncertainty, social isolation, and fear of the future. Garlick et al. found that breast cancer diagnosis and treatment are stressful events and may result in various physical, psychological, behavioral, social, and spiritual concerns [46]. Our results showed an improvement in spiritual well-being on the second and fourth week after surgery, which could mean that women who received education felt supported and were more likely to participate in religious activities. This is supported by Breitbart who found that spiritually based interventions, which include physical exercises, can strengthen the meaning of life, faith, or existential components that compose spirituality [48].

Limitations

While this study clearly demonstrates the importance of a therapeutic exercise program with follow-up phone calls in women following an MRM, there are a few limitations worth noting. First, we did not address the effect of phone calls made to patients on the results; it is possible that the support given to

patients resulted in the better outcomes and not necessarily the exercises themselves. Second, we did not measure the actual duration or frequency of the exercises performed at home; we relied on the participants' self-report, which may not always be accurate. Third, we did not assess the relationship between certain patient characteristics such as their prior physical activity level or their treatment regimen on outcomes, which may have had an effect on the results measured. Finally, assessments were made at two and four weeks after surgery by the same PI that performed the educational sessions, which may have resulted in experimental bias. Considering these limitations, it is advisable to conduct further RCTs with longer follow-up to provide stronger evidence for the efficacy of the intervention.

Conclusion

A one-to-one education by a nurse that incorporated multiple teaching methods, including demonstrations and teach back demonstrations as well as weekly phone calls in a middle-income country, had a positive impact on women's shoulder ROM and QoL. For nurses working in a clinical setting where women undergo mastectomies, implementing an educational program that helps women perform exercises at home may be feasible and effective for the functional recuperation of the upper limb. As patient advocates and educators, nurses need to be aware of the educational needs of patients with breast cancer, which may help in the healing process and improve their QoL.

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