

The Efficacy of Range of Motion Exercise in Reducing Shoulder Pain Related to Mastectomy: Randomized Control Trial

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Abstract

Background: Shoulder pain is a common complication for women after mastectomy. Its affect more than half of the post-mastectomy patients. Shoulder pain is responsible for disability of shoulder and thus, affected patient's quality of life. Range of motion exercise is more effective technique to manage the pain and disability of shoulder following mastectomy.

Objectives: The present study aimed to determine the efficacy of a range of motion exercise in reducing shoulder pain and disability after mastectomy through comparing the shoulder pain intensity before and after the application of that exercise and compared with a comparison group.

Methods: A randomized controlled trial (RCT) was conducted on patients assigned into two groups after the pre-test. A non-probability (homogenous purposive sample) of (80) patients are included in the present study (40 patients for the study group and 40 patients for the comparison group). All patients are medically diagnosed with shoulder pain and disability after mastectomy.

Outcomes: The study results indicated a reduction in the pain intensity and improved shoulder movement in the study group compared with those participants in the comparison group and between pre-test and post-test in the study group.

Conclusion: Implementation of the range of motion exercise program for four weeks is an effective approach to reducing the pain intensity and improving the movement of the shoulder after mastectomy compared with the comparison group.

Recommendations: Researcher suggest the possibility of applying the range of motion exercise in other similar situations, such as lymphedema.

Keywords: Efficacy, Mastectomy, Shoulder pain and disability, Range of motion exercise.

Introduction

Shoulder pain is one of the most common musculoskeletal problems in post-mastectomy patients. It is responsible for activity limitations; approximately 17-60% of post-mastectomy patients suffer from it (Chang et al., 2021). Patients with severe pain have difficulty in dressing, personal hygiene, and overhead activities. In most cases, they depend

on others for the simple activities of daily living (Arsh & Ullah, 2019; Reis et al., 2018).

Shoulder pain in breast cancer survivors is a common condition that should not be ignored. Early detection and treatment is important in preventing long-term complications (Khan et al., 2019). It is considered one of the problems that negatively affect the patient's quality of life, as pain

constitutes 41% of the percentage of patients who undergo mastectomy, arm stiffness constitutes 35%, as well as the rate of arm swelling is 21.6% (Tait et al., 2018 ; Shamley et al., 2012).

A physiotherapeutic approach is currently the first choice for rehabilitation, as it is essential for the prevention and treatment of physical-functional complications after breast cancer surgery (Das et al., 2018). The main physiotherapy modalities include education, exercise, electro-physical agents, and manual therapy (Brennan et al., 2020)..

Progressive upper extremity exercise plays an important role in the rehabilitation of patients after mastectomy (Gultas & Akansel, 2017). Physiotherapy-based rehabilitation after breast cancer surgery has been shown to prevent the progression of upper extremity dysfunction, help return to full function, and promote self-management and maintenance of healthy lifestyle behavior, but very few interventions focus on physiotherapy rehabilitation exercises. Therefore, there is an urgent need to use physical therapy to treat these problems in breast cancer patients (Shao et al., 2021) .

Active exercises have important physiological benefits in maintaining the blood and lymphatic flow to joints and soft tissues, which can prevent the shortening and weakness of the surrounding muscles and connective tissues that may occur following immobilization after surgery (Akbas et al., 2021; Carvalho & Salerno, 2019).

The range of motion exercises (ROM) is measurement of movement around a specific joint or body part. It's reduces pain significantly and reduces shoulder pressure. These exercises are used to treat all shoulder problems and improved the quality of life of patients through improving their ability to perform household and other chores. In addition, to their usefulness in reducing the financial burden required by drug treatments. (Mohammed, 2016; Ribeiro et al., 2019).

In general, there are no studies in Iraq that focus on nursing intervention for patients with shoulder pain and disability after mastectomy. So, the present study focuses on the most important topic in nursing studied to fill the gap in nursing research. So, the research

question was, will patients who train with a range of motion have less pain than those who have not trained?

□ The Study Objective: To evaluate the efficacy of a range of motion exercise in reducing shoulder pain intensity by comparing the pain intensity before and after the application of that exercise and compared with a comparison group.

□ The study Hypothesis: Patients who attend the range of motion exercise exhibit a lower pain intensity compared with those patients who don't attend the program.

Methods and Materials

- Design of the Study: Randomized Controlled Trial (RCTs) was conducted on patients assigned into two groups after the pre-test. In the present study, the researcher uses pre-test and post-test to determine the effectiveness of range of motion exercise on decreasing pain intensity and disability of shoulder after mastectomy.

- Selection of the Study Participants: The participants in the present study (84 participants were selected purposively from the Middle Euphrates Cancer Hospital in Al –Najaf City). Those patients diagnosed with shoulder pain and disability after mastectomy meet the study inclusion criteria. The total number of participants withdrawn and excluded from the study before randomization is four; three of them are refuse to participate in the study, because they are unable to continue in the program, and one patient is died. In the present study the acceptance rate 95%, retention rate 95%, refusal rate 5%, attrition rate 5%, and according to Grove et al.,(2013) the approved percentage of the attrition rate (is <10% to 20%). Therefore, this study has excellent acceptance rate and a very strong sample retention. Thus, the present study represents the target population.

- Study Sample and Sampling Technique: A non-probability (homogenous purposive sampling) technique of 80 patients are included in the present study. Those patients are visit the Middle Euphrates Cancer Hospital in Al –Najaf City for treatment. The researcher uses the double blind technique by

which (80) patients are examined through the pre-test before they divided equally into study and comparison groups.

- **Sample Size and Power Analysis:** Based on statistical power, in randomized controlled trials, statistical power is customarily set to a number greater than or equal to 0.80, with many experts in clinical trials now advocating a power of 0.90 (Nieswiadomy & Bailey, 2017). In the present study, the researcher uses the following factors to determine the adequate sample size through G power program; power (95%), level of significant 0.05, and middle effect size (0.32). Therefore, the sample size is equal to (60). To increase the power to 99%, the researcher increases the sample size to (80).

- **Groups Assignment (Randomization):** The study sample of 80 patients has been randomly divided into two groups after pre-test. The study group consisted of 40 patients who are exposed to a range of motion exercise program by the researcher. The group that didn't expose to the range of motion exercise program by the researcher is considered the comparison group (receiving usual nursing care and treatment) and it consists of 40 patients.

Randomization implementation: After the pre-test, randomly assigned patients were accomplished using a computer-generated random number list via (Excel table) to assign patients randomly. The goal of that the eliminates the source of bias in intervention assignments. The study adhered to establishing a procedure to maintain separation between study and comparison groups. To avoid contact between them. The patients were allocated a specific place used to apply the program. Therefore, outcomes data and post-study analysis; total study sample (80) patients. See participant's flowchart 3.2.

Blinding: In the present study, the researcher uses the double-blinded technique, and it's used between the researcher and the participants for the data collection outcomes. Therefore, the

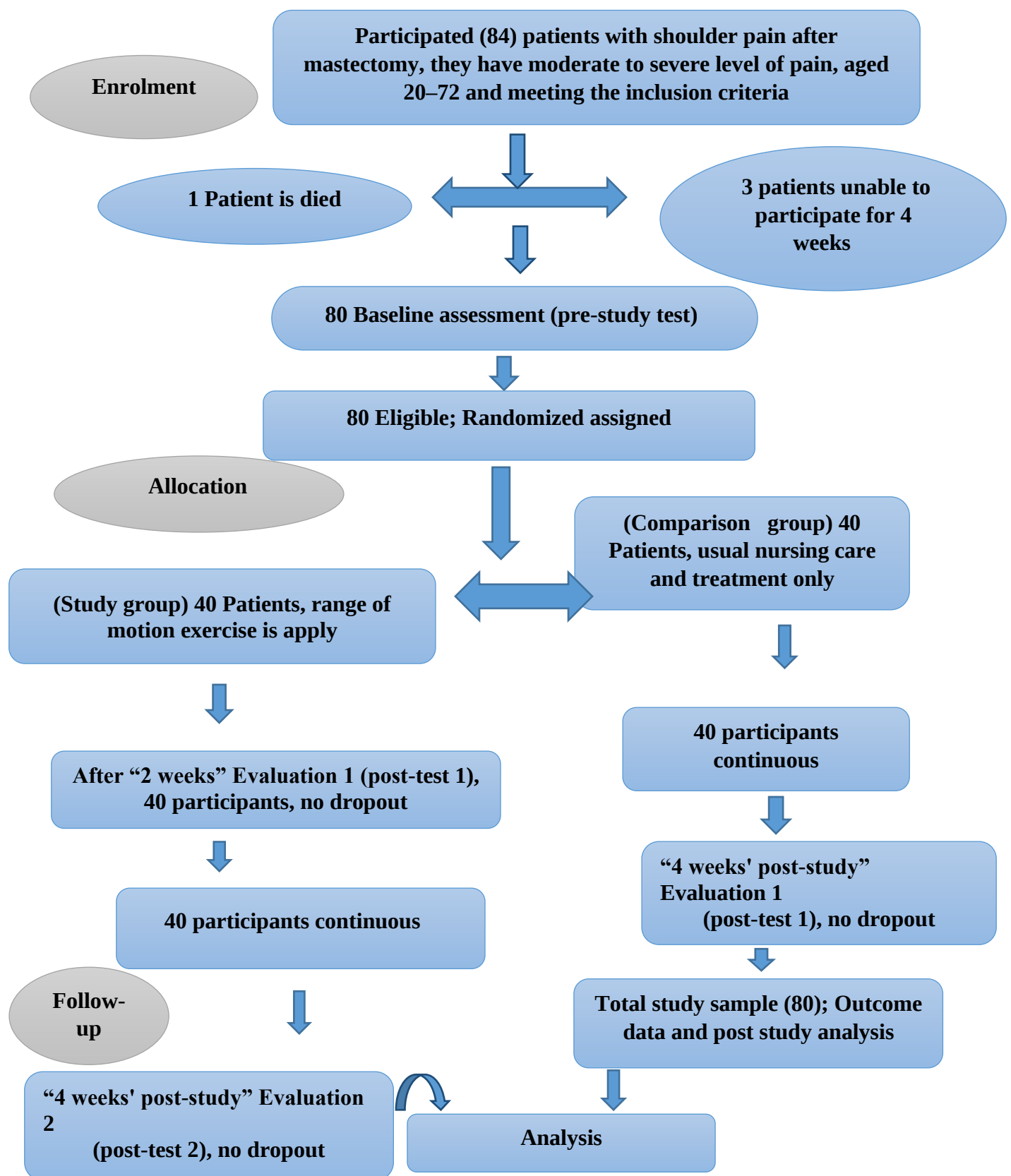
patients and researcher are unaware of the study and comparison groups.

The Study Group: The study group included 40 patients who received nursing interventions (range of motion exercises) with treatment routine and no dropout during the apply program application. The researcher, after the two weeks' evaluation (post-test I) and followed up after 4weeks (post-test II), throughout three periods of measurement the intensity of the pain decreased significantly and the shoulder movement improved in the patients after application of range of motion exercise. This program (ROM) exercises was implemented for 4weeks, three times weekly, where each movement is repeated ten times. Each session took 10 minute.

The Comparison Group: Forty patients were on usual nursing care and treatment. After a "four weeks" follow-up (post-test 1), the intensity of pain and disability increased in the comparison group with the treatment routine. Also no dropout during this period, and the researcher separated the control group from the study group during the program's application period.

- **The Study Instrument:** The researcher adopt the study instrument based on the previous literatures to investigate the study phenomenon. The panel study instrument consists of the following parts related to the patients' shoulder pain and disability Part I: Socio-Demographic Characteristic; Part II: Clinical Characteristics; Part III: Shoulder Pain and Disability Index (SPADI).

- **Ethical consideration:** A legal, governmental agreement obtained the ethical study approval before conducting the study according to the standards for conducting research with human beings from the National Research Ethics Committee (NREC). Although patients were afraid to sign any form, the researcher was able to obtain written informed consent from patients after fully explaining the purpose of the study, explaining the patients' right regarding their voluntary participation, and freedom to withdraw in any time.



Flowchart 3.2: Participants' Flow Diagram

- **Method of Data Collection:** The researcher used face-to-face interviews to collect socio- demographic and clinical data from patients. As for pain and disability after mastectomy, the researcher used the (SPADI) scale to assess the level of pain and disability for all participants before dividing them randomly into two groups. Study group and a comparison group. Also, the researcher compared the level of pain and disability before and after the application of the program. The data collection method started from 13th December 2021 to 15th February 2021.

- **Statistical Analyses:** The data of the present study are analyzed through the application of Statistical Package of social Sciences (SPSS) version 20, and Microsoft

Excel 2016 using both descriptive and inferential data analysis approaches as follow:

Descriptive Data Analysis: Presented as tables, frequencies, and percentage, Graphic presentation by using bar charts (Statistical figures)., Statistical mean and standard deviation. And the researcher used the mean of score 1- 3 mild level 4-6 moderate level, 7-10 severe level.

Inferential Data Analysis: Statistical tests were applied according to the distribution and type of variables, which include one-way analysis of variance (ANOVA), paired t-test, independent sample t-test, and chi-square test.

Study results

Table (4-1) Study Sample Socio- Demographic Characteristics

Socio-Demographics	Rating And Intervals	Statistics	Groups	
			Study	Comparison
Age / Years	20-29	Count	1	2
		% Within Groups	2.5	5.0
	30 – 39	Count	3	5
		% Within Groups	7.5	12.5
	40 – 49	Count	17	15
		% Within Groups	42.5	37.5
	50 – 59	Count	9	6
		% Within Groups	22.5	15.0
	60 and more	Count	10	12
		% Within Groups	25.0	30.0
	Total	Count	40	40
		% Within Groups	100.0	100.0
	Married	Count	39	34

Marital Status	Divorced	% Within Groups	97.5	85.0
		Count	1	4
	Widowed	% Within Groups	2.5	10.0
		Count	0	2
	Total	% Within Groups	0.0	5.0
		Count	40	40
	Total	% Within Groups	100.0	100.0
Occupation	Retired	Count	1	0
		% Within Groups	2.5	0.0
	Housewife	Count	34	34
		% Within Groups	85.0	85.0
	Employee	Count	5	6
		% Within Groups	12.5	15.0
	Total	Count	40	40
		% Within Groups	100.0	100.0
Residence	Rural	Count	4	7
		% Within Groups	10.0	17.5
	Urban	Count	36	33
		% Within Groups	90.0	82.5
	Total	Count	40	40

Table (4.1) shows that (42.5 %) of the study group patients are (40-49) years old; (97.5 %), are married; (85.0 %), are housewives ;(90.0 %) are from urban residential area. Concerning the comparison group patients, the study results indicate that (37.5 %) are (40-49) years old; (85.0 %) married; (85.0%) are housewives ;(82.5 %) are from urban residential area

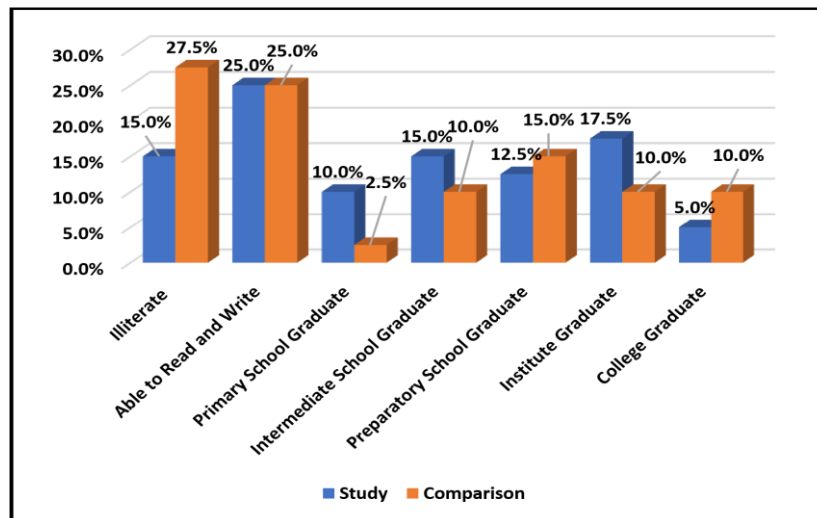


Figure (4.1) Distribution of the Study Sample according to their Levels of Education

Table (4.6) Analysis of Variance (ANOVA) of the Overall Evaluation of Study Group Pain and Disability at Different Periods of Measurements

Main Studied Domains	Periods of Measurements	N	Mean	Std. Deviation	F	p-value
Pain	Pre-Test	40	77.40	14.09	492.723	.0001 S
	Post-Test1	40	25.80	8.92		
	Post-Test2	40	6.83	6.85		
	Total	120	36.68	31.67		
Disability	Pre-Test	40	72.69	16.13	208.747	.0001 S
	Post-Test1	40	39.10	10.30		
	Post-Test2	40	14.85	10.90		
	Total	120	42.21	26.94		
Overall Evaluation	Pre-Test	40	74.50	14.69	298.506	.0001 S
	Post-Test1	40	34.88	10.62		
	Post-Test2	40	10.96	9.24		
	Total	120	40.12	28.77		

Table (4.6) illustrate the analysis of variance of the pain and disability according to different periods of measurement among the study group participants. The study results indicate that there is a significant difference in the studied domains (pain, disability, and the overall

evaluation) throughout three periods of measurement (pre-test, posttest I, post-test II). Based on the statistical mean, the result indicates that there is a decreasing in the pain intensity and disability after application of the ROM program.

Table (4.7) Mean Difference (Paired T-Test) of the Overall Evaluation of Comparison Group Pain and Disability at Different Periods of Measurements

Main Studied Domains	Periods of Measurements	Mean	N	Std. Deviation	t-Value	d.f	p-value
Pain	Pre-Test	80.55	40	14.17	5.430	39	.0001 S
	Post-Test	84.60	40	12.04			
Disability	Pre-Test	72.06	40	12.45	6.532	39	.0001 S
	Post-Test	75.16	40	12.65			
Overall Evaluation	Pre-Test	75.33	40	11.71	7.471	39	.0001 S
	Post-Test	78.79	40	11.21			

Table (4.7) shows that there is a significant difference in the studied domains (pain, disability, and the overall evaluation) throughout two periods of measurement (pre –

test and post-test). Based on the statistical mean, the study results indicate that there is an increasing in the pain intensity and disability after using traditional management.

Table (4.8) Mean Difference (Independent Samples T-Test) of the Overall Evaluation of the Pain and Disability at the Pre-test between Study and Comparison Groups

Main Groups		N	Mean	Std. Deviation	T-Test	d. f	P-Value
Studied Domains							
pain	Study	40	77.40	14.09	0.997	78	.322 NS
	Comparison	40	80.55	14.17			
Disability	Study	40	72.69	16.13	0.194	78	.847 NS
	Comparison	40	72.06	12.45			
Overall Evaluation	Study	40	74.50	14.69	0.278	78	.781 NS
	Comparison	40	75.33	11.71			

Table (4.8) the study results show that there is a non –significant difference in pain and disability between study and comparison

groups. This result indicates that there is a no difference between the study and comparison groups as the baseline level.

Table (4.9) Mean Difference (Independent Samples t-test) of the Overall Evaluation of the Pain and Disability at the Post-test II between Study and Comparison Groups

Main							
Studied	Groups	N	Mean	Std. Deviation	T-Test	d.f	P-Value
Domains							
Pain	Study	40	6.83	6.85	35.501	78	.0001 S
	Comparison	40	84.60	12.04			
Disability	Study	40	14.85	10.90	22.844	78	.0001 S
	Comparison	40	75.16	12.65			
Overall Evaluation	Study	40	10.96	9.24	29.534	78	.0001 S
	Comparison	40	78.79	11.21			

The study results presented in (table 4.9) show that there is a significant difference in pain and disability between the study and comparison groups. According to the statistical mean, the study results indicate that there is a reduction in the pain intensity and disability at the post –test II among the study group comparing with those in comparison group.

Throughout Three Periods of Measurements

Discussion

Range of motion (ROM) exercise is an effective in the treatment of shoulder pain and disability after mastectomy than other modalities (Mehta et al., 2017). It's beneficial in recovery from soft tissue and joint lesions; maintaining existing joint and soft tissue mobility; and minimizing the effects of contracture formation (Shao et al., 2021). ROM exercise have positive effect on patient's daily living activities and quality of life (Kuliński & Kosno, 2021).

The primary outcome of the present study is to examine the effectiveness of range of motion exercises on reducing shoulder pain and disability after mastectomy. The study results indicate that there is a strong improvement in movement and decreased level of pain after 4 weeks of apply the range of motion exercise in

the study group throughout three periods (pre-test, post-test I, post –test II) and compared the study group with those participants in the comparison group. Moreover, this proves the effectiveness of the applied method in reducing pain and improving shoulder range of motion with breast cancer patients after mastectomy. In addition, Akbas et al.,(2021),they mentioned that there is an association between range of motion exercise with reduce pain and disability of shoulder after mastectomy. Also Mohammed (2016) , studied the" Effects of Exercise intervention on pain, shoulder movement, and functional status in women after breast cancer surgery: A randomized controlled trial " the found that the significant differences in the pain intensity after application of exercise therapy between the study and comparison groups.

The study results are also support by other studies done by Lee et al., (2021) , the study "The effects of exercise intervention for post-operative breast cancer patients in Korea: A Systemic Review and Meta-Analysis of Randomized Controlled Trials" they concluded that the important of educational program about range of motion to induce shoulder problems after mastectomy. Furthermore, Cernja & Maka,(2015) they studied "Implementation of an exercise program in breast cancer rehabilitation to improve shoulder outcomes: A pilot study" they found that the

important rehabilitation to reduce complication after mastectomy.

The implementation of the range of motion exercise program was associated with highly significant improvements in the scores of all domains of the shoulder pain and disability index scale. Moreover, the study sample results of the overall assessment, which improved based on the statistical means, study findings indicate that the range of motion exercise program is effective way to decrees shoulder pain and disability after mastectomy.

Conclusion

The study concluded that the range of motion exercise for 4 weeks and follow up three times weekly is an effective way to reduce the pain intensity and disability after mastectomy.

Recommend: Researcher recommends to use the study's findings as a guideline in the management of patients with shoulder pain and disability after mastectomy. Furthermore, the researcher suggest using the range of motion exercises for patients with similar situation such as lymphedema.

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Conflicts of interest: Authors declare no conflict of interest.

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