

RESEARCH ARTICLE

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# Effect of Nurse-led Intervention on Shoulder Dysfunction among Breast Cancer Patients Undergoing Modified Radical Mastectomy (MRM), South India: A Randomized Controlled Trial

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## Abstract

**Background:** Breast cancer can strike women at any age after puberty, though its incidence increases with age. The WHO's Global Breast Cancer Initiative (GBCI), between 2020 and 2040, aims to prevent 2.5 million breast cancer deaths globally. This study aimed to assess the effect of a nurse-led intervention on shoulder dysfunction among breast cancer patients undergoing modified radical mastectomy (MRM) - a randomized controlled trial. **Methods:** A total of 320 breast cancer patients undergoing MRM (Study group-160, Control group-160) who met the inclusion criteria were included in the study. Block randomization was used to allot participants to both groups through a computer-generated random sequence. The experimental group received a nurse-led intervention in addition to routine care, while the control group received routine care only. Shoulder range of motion (ROM) was measured using a goniometer at baseline and at every 3-month interval up to 1 year. Disability of the Arm, Shoulder, and Hand (DASH) was assessed at 6th and 12th month follow-ups using the DASH questionnaire. **Results:** Overtime comparison of shoulder ROM shows the significant effect of time, group, and a significant time × group interaction ( $p < 0.001$ ), indicating that the flexion, extension, abduction, internal rotation, and external rotation angles improved significantly over time, and that the pattern of improvement differed between the intervention and control groups. During the 3rd and 6th month follow-up, Grade II loss of shoulder ROM was observed in one patient (0.68%) in the experimental group, whereas in the control group, it was observed in 25 patients (16.89%) and 18 patients (12.41%), respectively. DASH scores during the 6th and 12th month follow-up were 6 (3.06-10.25) and 5.17 (1.72-8.62) in the experimental group, whereas in the control group, they were 21.5 (14.25-34.25) and 24.14 (15.52-35.34) ( $p < 0.001$ ). **Conclusion:** In this study, early intervention and consistent motivation and reinforcement helped in preventing or reducing shoulder dysfunction, thereby reducing disability and enhancing quality of life (QOL).

**Keywords:** Breast cancer- Shoulder dysfunction- Modified Radical Mastectomy

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## Introduction

Breast cancer is one of the most prevalent cancers affecting women in every country of the globe at any age after puberty, but rates increase in later life. 2.3 million Women were diagnosed with breast cancer in the year 2022, and 670,000 died from the disease globally [1]. In the West, women with breast cancer have an average 5-year survival rate of 90% and an average 10-year survival rate of 83%. As a result, the number of long-term survivors is rising, highlighting the importance of understanding treatment's long-term effects. India likewise has an increasing population of survivors, even

if mortality rates remain high (5-year survival of 66.1%), as compared to their western counterparts [2].

Breast cancer is the most prevalent cancer in India, with an expected 216,108 cases by 2022, making up 28.2% of all female malignancies [3]. In India, breast cancer accounted for 10.6% of all cancer deaths and 13.5% of new cases, making it the primary cause of cancer incidence and mortality [4]. By 2040, the Southeast Asian region's breast cancer mortality rate is predicted to rise to 61.7% [5]. The most prevalent kind of breast cancer, invasive ductal carcinoma (IDC), accounts for about 70–80% of cases. The second most prevalent cancer is invasive lobular carcinoma (ILC); this accounts for 10% to 15%

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of all cases [6].

More than two-thirds of post-mastectomy patients suffer from shoulder pain and disability [7]. Adjuvant radiotherapy given to the mastectomy site and axilla increases the risk of impairment of shoulder function [8]. Women with breast cancer frequently complain of shoulder pain and impaired function following surgery; 10–55% of them have limited glenohumeral range of motion, 22–38% complaint of shoulder pain, and 42–56% have trouble moving their upper limbs [9].

Chronic upper arm disability is one of the most bothersome long-term side effects of breast cancer treatment. 30–50% of breast cancer survivors experience persistent arm and shoulder deficits, which are characterized by limited shoulder mobility, lymphedema, and arm/shoulder discomfort [10]. The most frequent problems following breast cancer surgery were frozen shoulder (30%) and lymphedema (25%)—Axillary Web Syndrome 15%, Post Mastectomy Pain Syndrome 20% [11].

Shoulder dysfunction is a common and significant concern for breast cancer patients after mastectomy. Early intervention, patient education, and tailored rehabilitation programs are crucial in mitigating these effects and enhancing quality of life. The novelty of the study lies in the fact that the nurse-led intervention commenced on the day of admission to the hospital and continued until discharge, followed by every three-month interval thereafter. The participants were followed up through mobile once a week for the first month and reinforced once a month for one year to ensure adherence to the exercise. Additionally, an information booklet was provided for further reference. Most research on shoulder dysfunction in breast cancer patients has focused on post-treatment outcomes, especially a year or more following the completion of therapy. However, there remains a notable gap in the literature regarding patients who begin rehabilitation before surgery and follow them for a year period, which is a critical period marked by significant impairment in shoulder function, which leads to disability of the affected arm and poor QOL. Therefore, the present study aimed to assess the effect of nurse-led intervention on shoulder dysfunction among Breast cancer patients undergoing Modified Radical Mastectomy (MRM).

## Materials and Methods

This study was a randomized controlled trial (RCT) registered under the Clinical Trial Registry of India (CTRI/2021/05/033357) that collected data from 320 Breast cancer patients undergoing MRM (study group-160; control group-160) who met the inclusion criteria and were admitted to surgical wards for MRM at a Tertiary care unit in South India from 2021 to 2023. The sample size was estimated using the statistical formula to estimate two proportions. The minimum expected difference in QOL is 15% between groups with 80% power and a 5% significance level. The estimated sample is 144 in each group. The investigator expected a 10% attrition rate during the study period; the sample size was 160 in each group. After selecting eligible samples based on inclusion and exclusion criteria, block randomization is used to

allot participants to both groups through a computer-generated random sequence. It is a part of an RCT on the effect of a Comprehensive Rehabilitation Program (CRP) on the physical and psychological outcomes of patients with Mastectomy. Figure 1 shows the CONSORT diagram of the study. The participants who satisfied the inclusion criteria were females aged >18 years, all MRM irrespective of the sequence of the chemotherapy (Neo adjuvant/Adjuvant). Patients with bilateral breast cancer surgery, patients with metastasis, any other prior history of malignancy, patients who have lymphoma and sarcomas, prior injury (or) surgery of the affected arm, patients undergoing flap with latissimus dorsi, patients who diagnosed with cardiac failure, renal failure, pulmonary failure (LVEF<40%, NYHA: Class: III & IV, Creatinine >1.2 mg/dl, arthritis, patients with significant visual and hearing impairments, patients diagnosed with psychiatric disorders were excluded from this study. The study group received nurse-led intervention. In Phase I participants were taught exercises, and in Phase II, follow-up every 3 months, with mobile reminders once a week for the first month, and reinforcement once a month for 1 year to ensure adherence to nurse-led intervention. Outcome variables, such as shoulder ROM, were assessed at baseline before surgery and every 3-month interval for one year after surgery. The DASH was assessed at the 6<sup>th</sup> and 12<sup>th</sup> months after surgery.

### Intervention Procedure

The study group received a nurse-led intervention. In Phase I, Participants were taken into a separate room and made to sit comfortably. The investigator demonstrated deep breathing exercises, including pump-it-up exercises, making fist-ball squeezes, arm lifts, and shoulder blade squeezes during the pre-operative period. On the third postoperative day, the participants were taught arm reach, winging, and snow angels, followed by a return demonstration by the participants. The investigator visits the patient every day to make sure the patient is doing the exercise regularly, two times a day, morning and evening for about 30 minutes till the patient gets discharged from the hospital and advises the patient to continue the same at home also, at the time of discharge brisk walking for minimum 30 minutes were taught to prevent or to reduce shoulder dysfunction. Individual counselling and education on adherence to exercise, along with the provision of an information booklet for further reference, were offered. The adherence to the exercise was monitored using a checklist calendar provided for a year. Participants were instructed to mark a tick in the morning and evening after completing their exercises. For those with no formal education, caregivers were advised to ensure that the checklist was completed. The investigator also verified adherence during each follow-up visit. Phase II: Follow up every 3 months, with a mobile reminder once a week for the first month and reinforcement once a month for 1 year, to ensure adherence to the nurse-led intervention. The control group received routine standard care. The outcome variable of shoulder ROM was measured at the 3<sup>rd</sup>, 6<sup>th</sup>, 9<sup>th</sup>, and 12<sup>th</sup> months (after surgery). Disability of Shoulder, Arm and Hand (DASH) was assessed at the 6<sup>th</sup>

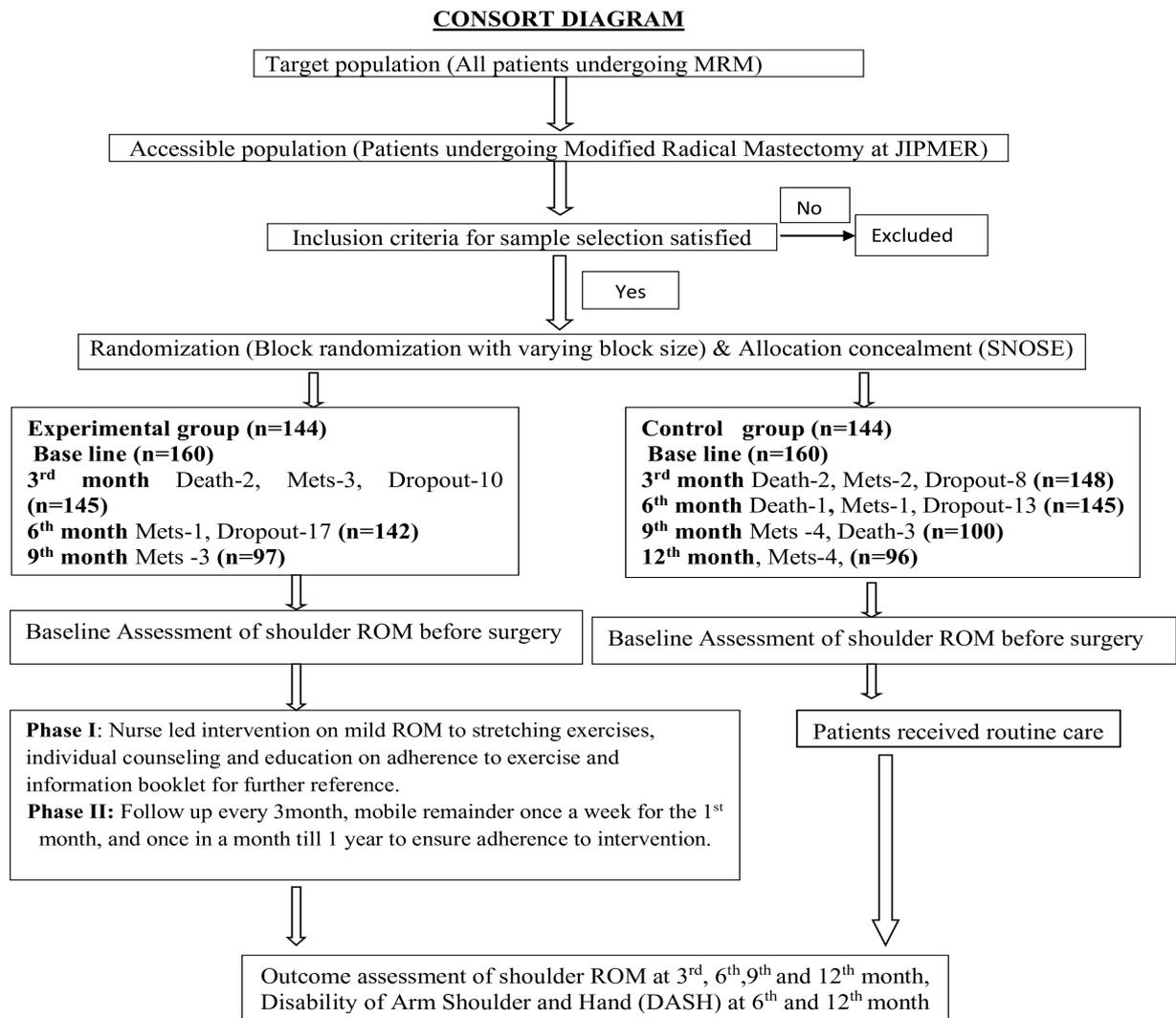


Figure 1. CONSORT Diagram

and 12<sup>th</sup> months.

#### Data collection tool and technique

The study was initiated after approval from the Doctoral Committee and the Institutional Ethics Committee. After obtaining written consent from the study participants, data were collected using a structured questionnaire to gather socio-demographic profiles, including age, educational status, occupation, income, dietary pattern, family history of cancer, and clinical parameters such as BMI, menstrual status, tumour stage, type of tumour, Chemotherapy, and Radiotherapy. Shoulder ROM was measured using the 180° universal Goniometer at baseline (before surgery) and every 3-month interval up to one year after surgery. The investigator ensures the zero point aligns precisely with the reference 0° before each measurement. Normal Range of motion angles are considered from the zero anatomical position. Normal flexion is 180°, extension 60°, abduction 180°, internal rotation 70°, and external rotation 90° [12]. The variation is graded using the Common Toxicity Criteria for Adverse Events (CTCAE) version 4.03. Grade 1:<25% loss of ROM, Grade 2:>25-50% decrease in ROM, and Grade 3:>50% decrease in ROM

[13]. Disability of Arm, Shoulder, and Hand (DASH) was assessed at 6<sup>th</sup> and 12<sup>th</sup> -month follow-ups using the DASH questionnaire. A Score that ranges from (0 - no disability) to (100 - most severe disability). It is a standardized tool with test-retest reliability (interclass correlation coefficient = 0.96) [14]. Permission was obtained to use this tool.

#### Statistical analysis method

The collected data were analysed using descriptive and inferential statistics using Statistical Package for the Social Sciences (SPSS) version 26. The categorical variables are expressed in frequency and percentage. The distribution of continuous variables was expressed in terms of mean with standard deviation or median with interquartile range based on the distribution of data. Over time, comparison of shoulder ROM between experimental and control groups at various timelines was done by the Linear Mixed Model (LMM), and Comparison within the experimental and control groups was done by the Friedman test. Grading of shoulder ROM between experimental and control groups was done by frequency, percentage, and association was done by chi-square test. Comparison of baseline demographic and clinical characteristics is done,

and both groups are homogenous. All statistical analyses were carried out using survival analysis at a 5% level of significance, and a p-value of less than or equal to 0.05 was considered statistically significant.

**Results**

The mean age of the 51.01(9.64) participants in both the study and control groups was 51.01±9.64 and 53.52±9.68, respectively. The Median BMI was 25.25 (22.95-27.8) and 24.8 (22.15-28.3), and the age at menopause was 48 (44-50) and 48 (45-50), respectively. In the experimental group, 44 (27.5%) had no formal education, whereas in the study group, 45 (28.1%) also had no formal education. In both study and control groups, 39 (24.4%) and 49 (30.6%) were widows/ separated. In both the study and control groups, it was observed that 139 (86.9%) participants belonged to the Hindu religion. In both the study group and the control group, 119 (74.4%) and 102 (63.7%) participants were living in a nuclear family (Table 1).

In the study group, 20 (12.5%) had a family history of cancer, and 8 (5.0%) had a family history of breast cancer, whereas in the control group, 28 (17.5%) had

a family history of cancer, and 4 (2.5%) had a family history of breast cancer. In the study group and control groups, 127 (79.4%) and 124 (77.5%) belong to stage III breast cancer. Under the histopathological profile, 67 (41.9%) had invasive ductal carcinoma (IDC), whereas in the control group, 71 (44.4%). Invasive Breast Cancer in the study group was 82(51.2%) and in the control group 74 (46.2%). In the study group, HER2/ Neu status was positive in 41 (25.6%), whereas in the control group, 44 (27.5%) (Table 2).

Table 3 presents an over-time comparison of Shoulder ROM between the study and control groups at various time points. There was a significant effect of time, group, and a significant time × group interaction (p < 0.001), indicating that the flexion, extension, abduction, Internal rotation and external rotation angles improved significantly over time and that the pattern of improvement differed between the intervention and control groups. The box plot illustrates the pair wise comparison of shoulder ROM at various time points among the intervention and control groups (Figure 2).

Table 4, Shows a comparison of shoulder ROM within the experimental and control groups. In experimental group the flexion angle during 3<sup>rd</sup>, 6<sup>th</sup>, 9<sup>th</sup> and 12<sup>th</sup> month

Table 1. Demographic Variables of Breast Cancer Patients Undergoing MRM

Demographic variables		Experimental (n=160)		Control (n=160)		X <sup>2</sup>	P-value
		N	%	N	%		
Educational status	No formal education	44	27.5	45	28.1	3.877	0.423
	Primary Education	49	30.6	51	31.9		
	High school	42	26.2	50	31.2		
	Higher Secondary	15	9.4	8	5		
	Graduate &above	10	6.2	6	3.8		
Occupation	Home Maker	97	60.6	81	50.6	10.281	0.068
	Farmer	20	12.5	31	19.4		
	Labour	29	18.1	39	24.4		
	Government Employee	5	3.1	0	0		
	Private employee	7	4.4	7	4.4		
	Business	2	1.2	2	1.2		
Monthly income in rupees	<5000	145	90.6	152	95	4.748	0.191
	5001-10000	9	5.6	7	4.4		
	10001-15000	2	1.2	1	0.6		
	>15000	4	2.5	0	0		
Marital status	Single	2	1.2	3	1.9	2.11	1.323
	Married	113	70.6	104	65		
	Divorced	6	3.8	4	2.5		
	Widow/Separated	39	24.4	49	30.6		
Religion	Hindu	139	86.9	139	86.9	1.323	0.724
	Christian	6	3.8	8	5		
	Muslim	14	8.8	13	8.1		
	Others	1	0.6	0	0		
Domicile	urban	70	43.8	68	42.5	0.051	0.821
	Rural	90	56.2	92	57.5		
Dietary pattern	Vegetarian	9	5.6	8	5	0.062	0.803
	Non Vegetarian	151	94.4	152	95		

Table 2. Clinical Variables among Breast Cancer Patients Undergoing MRM

Clinical variables		Experimental (n=160)		Control (n=160)		X <sup>2</sup>	P-value
		N	%	N	%		
Diabetes mellitus	Yes	51	31.9	54	33.8	0.128	0.721
	No	109	68.1	106	66.2		
Hypertension	Yes	52	32.5	53	33.1	0.014	0.905
	No	108	67.5	107	66.9		
Hypothyroidism	Yes	11	6.9	6	3.8	1.553	0.213
	No	149	93.1	154	96.2		
Stages of Breast cancer	Stage I	10	6.2	16	10	1.63	0.443
	Stage II	23	14.4	20	12.5		
	Stage III	127	79.4	124	77.5		
	IDC	67	41.9	71	44.4		
IBC	82	51.2	74	46.2			
Histopathological profile	Papillary cancer	4	2.5	4	2.5	2.147	0.342
	Mucinous cancer	5	3.1	5	3.1		
	Apocrine	0	0	1	0.6		
	DCIS high grade	2	1.2	2	1.2		
	Adenocarcinoma	0	0	2	1.2		
	Inflammatory breast cancer	0	0	1	0.6		
	ER Positive	98	61.3	88	55		
Estrogen receptor (ER)	ER Negative	62	38.8	71	44.4	1.081	0.582
	Not available	0	0	1	0.6		
	PR Positive	77	48.1	79	49.4		
Progesterone receptor (PR)	PR Negative	83	51.9	80	50	0.55	0.76
	Not available	0	0	1	0.6		
Human Epidermal Growth Factor 2 status	Positive	41	25.6	44	27.5	0.613	0.434
	Negative	112	70	108	67.5		
	Equivocal	7	4.4	8	5		
Name of surgery	Right MRM	77	48.1	84	52.5	2.013	0.366
	Left MRM	83	51.9	76	47.5		
Auxiliary node dissection	Level II	154	96.2	156	97.5	0	1
	Level III	6	3.8	3	1.9		
	Level III, IV& V cervical LN	0	0	1	0.6		
Radiotherapy status	Yes	110	68.8	109	68.12	4.885	0.299
	No	50	31.2	51	31.87		
Radiotherapy Dosage	42.56 Gy, 16 #	25	15.6	21	13.1	4.885	0.299
	40.05 Gy, 15#	22	13.8	31	19.4		
	50Gy, 25 #	54	33.8	55	34.4		
	>50Gy, 25 #	9	5.6	3	1.9		

LN, Lymph Node; #, Fraction

was 160° (145-172°), 170° (158-180°), 171° (160-180°), 175° (161-180°), whereas in control group 130° (115-145.8°), 138° (120-155°), 140° (120.8-155°), 145° (122-158°). In experimental group the abduction angle during 3<sup>rd</sup>, 6<sup>th</sup>, 9<sup>th</sup> and 12<sup>th</sup> month was 167° (155-180°), 175° (163-180 °), 180 ° (169-180 °), 180(170-180), whereas in control group 140° (126.8-155°), 150° (135-162°), 150° (135-168.5°), 155° (135-165°). There are not much changes in extension, internal and external rotation in the experimental group compared to the control group.

It was observed that, during the 3<sup>rd</sup> and 6<sup>th</sup> months

post-surgery, the Grade II (>25-50%) loss of shoulder ROM in the intervention group was minimal (0.68%), compared to 16.89% and 12.41%, respectively, in the control group. Furthermore, by the 9<sup>th</sup> month, none of the participants in the intervention group exhibited Grade II ROM loss, whereas the control group still reported an incidence of 9% at 9 months and 5.2% at 12 months (Table 5).

Table 6 depicts the comparison of DASH scores between the study and control groups. In the study group, the DASH scores during the 6<sup>th</sup> and 12<sup>th</sup> months following

Table 3. Over Time Comparison of Shoulder ROM (in Degrees) between Intervention and Control Groups (Linear Mixed Model)

Shoulder ROM	Timeline	Intervention group mean	Control group mean	P-value (time x group)
		95% CI	95%CI	
Flexion	Baseline	177.4 (174.7-180.1)	176.5 (173.8-179.24)	< .001
	3 <sup>rd</sup> Month	158.1(155.3-160.9	130.02 (127.2-132.7)	
	6 <sup>th</sup> Month	165.8 (163.06(168.6)	137.05 (134.2-139.8)	
	9 <sup>th</sup> Month	166.2 (163.03-169.4)	139.3 (136.1-142.4)	
	12 <sup>th</sup> Month	167(163.7-170.3)	140.5 (137.3-143.7)	
Extension	Baseline	59.7 (59.07-60.34)	59.9 (59.2-60.5)	0.018
	3 <sup>rd</sup> Month	59.4 (58.7-60.08)	58.2 (57.6-58.9)	
	6 <sup>th</sup> Month	59.6 (58.9-60.3)	58.01(57.6-58.9)	
	9 <sup>th</sup> Month	59.6 (58.8-60.4)	57.87 (57.07-58.6)	
	12 <sup>th</sup> Month	59.9 (59.09-60.7)	58.7 (57.9-59.5)	
Abduction	Baseline	178.5 (175.9-181.1)	178.2 (175.6-180.8)	< .001
	3 <sup>rd</sup> Month	163.5 (160.8-166.2)	137.9 (135.2-140.6)	
	6 <sup>th</sup> Month	169.8(167.05-172.5)	147.5 (144.8-150.2)	
	9 <sup>th</sup> Month	171.9 (168.7-175.1)	149.1(146.04-152.3)	
	12 <sup>th</sup> Month	172.1(168.8-175.4)	151.1(147.9-154.2)	
Internal Rotation	Baseline	69.8 (69.03-70.6)	69.8 (69.05-70.6)	< .001
	3 <sup>rd</sup> Month	68.6 (67.8-69.5)	63.9(63.1-64.82)	
	6 <sup>th</sup> Month	69.05 (68.2-69.9)	65.4 (64.6-66.3)	
	9 <sup>th</sup> Month	69.1 (68.07-70.1)	66.25 (65.2-67.25)	
	12 <sup>th</sup> Month	70.1 (69.1-71.2)	65.9 (64.8-66.9)	
External Rotation	Baseline	89.8 (89-90.6)	89.8 (89.04-90.7)	< .001
	3 <sup>rd</sup> Month	88.1 (87.3-89.04)	84.6 (83.7-85.5)	
	6 <sup>th</sup> Month	89.1 (88.2-89.9)	85.6 (84.7-86.5)	
	9 <sup>th</sup> Month	88.6 (87.6-89.7)	86.2(85.2-87.3)	
	12 <sup>th</sup> Month	89.06 (87.9-90.1)	86.4(85.4-87.5)	

the disability were 6 (3.06-10.25) and 5.17 (1.72- 8.62), whereas in the control group, the scores were 21.5 (14.25-34.25) and 24.14 (15.52-35.34). The results show a statistically significant difference in disability scores between the study and control groups.

### Discussion

Therapeutic advances and improved survival rates of women with breast cancer have implications for long-term effects on disability, psychological function, and quality of life, which may be manageable with rehabilitation. The

Table 4. Comparison of Shoulder ROM (in Degrees) within the Experimental and Control Group among Breast Cancer Patients Undergoing MRM

Shoulder ROM	Baseline	3 <sup>rd</sup> Month	6 <sup>th</sup> Month	9 <sup>th</sup> Month	12 <sup>th</sup> Month	Fried-man Test	P value
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)		
Within the Experimental group							
Flexion	180 (180,180)	160 (145-172)	170 (158-180)	171 (160-180)	175 (161-180)	102.4	<.001**
Extension	60 (60,60)	60 (60,60)	60 (60,60)	60 (60,60)	60 (60,60)	23.68	<.001**
Abduction	180 (180,180)	167(155-180)	175 (163-180)	180 (169-180)	180 (170-180)	82.25	<.001**
Internal Rotation	70 (70,70)	70(70,70)	70 (70,70)	70 (70,70)	70 (70,70)	9.811	0.031*
External Rotation	90 (90,90)	90(90,90)	90 (90,90)	90 (90,90)	90 (90,90)	11.61	0.021*
Within the control group							
Flexion	180 (175-180)	130(115-145.8)	138 (120-155)	140 (120.8-155)	145 (122-158)	193.9	<.001**
Extension	60 (60,60)	60 (55-60)	60 (56-60)	60 (56.75-60)	60 (58-60)	38.39	<.001**
Abduction	180 (180,180)	140(126.8-155)	150 (135-162)	150 (135-168.5)	155 (135-165)	176.3	<.001**
Internal Rotation	70 (70,70)	65 (62-70)	67 (64-70)	68 (65-70)	67 (65-70)	86.18	<.001**
External Rotation	90 (90,90)	86 (84-90)	87 (85-90)	87 (85-90)	88 (85-90)	85.5	<.001**

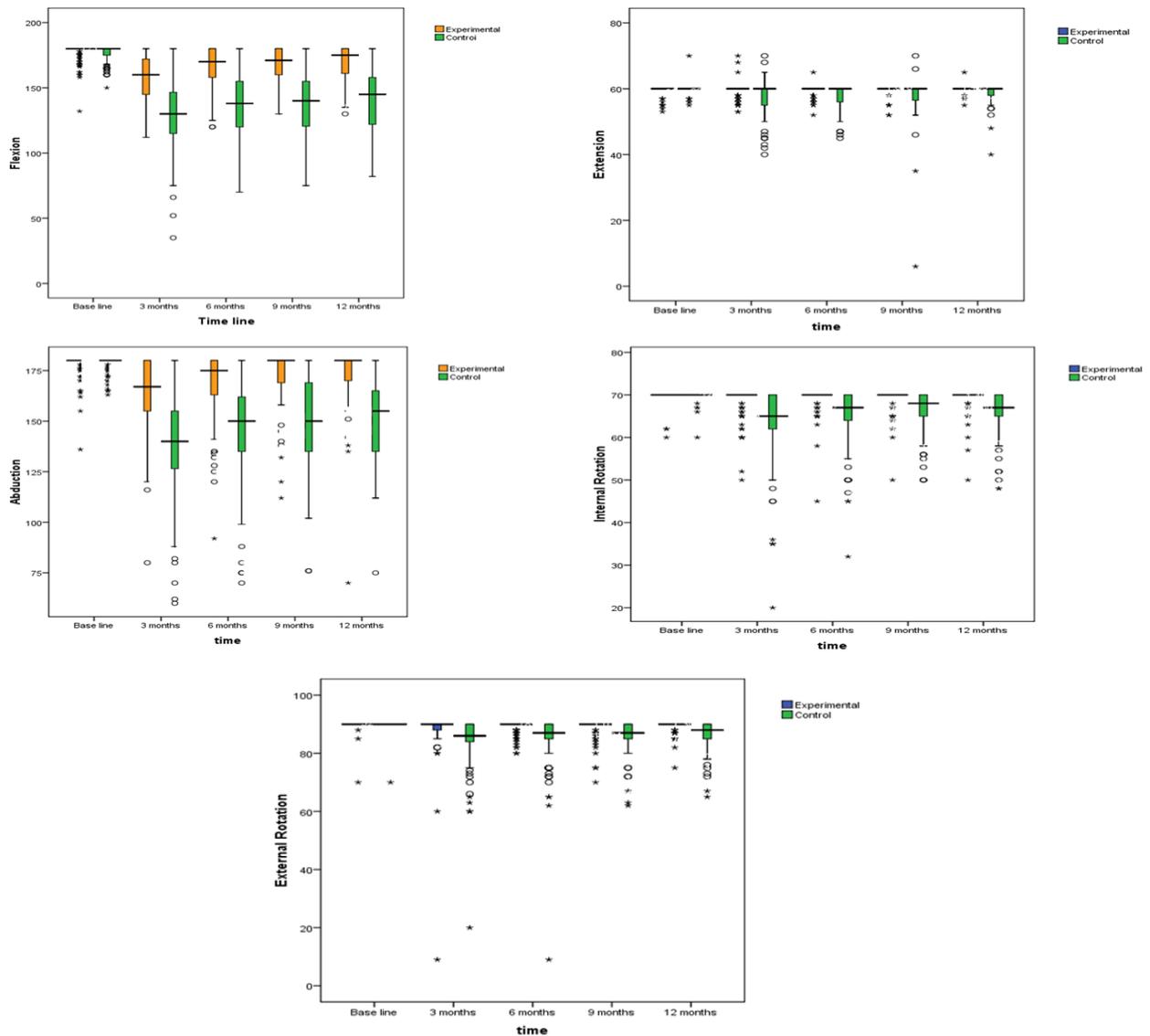


Figure 2. Shoulder ROM at Various Timelines among MRM Patients

Table 5. Comparison of Shoulder ROM Grading between the Experimental and Control Group at Various Timelines among MRM Patients

Time Line	Shoulder ROM	Experimental group		Total	Control group		Total	Chi-square test (d.f)	P value
		N	%		N	%			
Base line	Normal	120	75	160	106	66.25	160	2.952 (1)	0.086
	Grade I	40	25		54	33.75			
3 <sup>rd</sup> Month	Normal	24	16.55		2	1.35	148	41.737 (2)	0.000*
	Grade I	120	82.75	145	120	81.08			
	Grade II	1	0.68		25	16.89			
	Grade III	0	0		1	0.67			
6 <sup>th</sup> Month	Normal	40	28.16	142	10	6.89	145	34.357 (1)	<0.001**
	Grade I	101	71.12		117	80.68			
	Grade II	1	0.7		18	12.41			
9 <sup>th</sup> Month	Normal	29	29.89	97	6	6	100	19.245 (1)	0.000*
	Grade I	68	70.1		85	85			
	Grade II	0	0		9	9			
12 <sup>th</sup> Month	Normal	31	34.06	91	5	5.2	96	25.0262 (1)	0.000*
	Grade I	60	65.93		86	89.58			
	Grade II	0	0		5	5.2			

Table 6. Comparison of DASH Score between Experimental and Control Groups among MRM Patients

DASH Score		Mean	SD	Median (IQR)	Mann-Whitney U test	P-Value
DASH	Experimental	7.771	7.374	6 (3.06-10.25)	2559.5	< 0.001**
6 <sup>th</sup> Month	Control	23.667	12.975	21.5 (14.25-34.25)		
DASH	Experimental	6.438	6.41	5.17 (1.72-8.62)	870	< 0.001**
12 <sup>th</sup> Month	Control	25.087	13.316	24.14(15.52-35.34)		

Disability of Arm, Shoulder, and Hand (DASH), \*\*-P<0.001 highly significant

focus of nurse-led intervention is on managing disability, reducing symptoms, enhancing participation, and societal reintegration to achieve the highest possible independence. The present study aimed to assess the effect of nurse-led intervention on shoulder dysfunction among patients undergoing MRM.

#### Shoulder ROM

The findings of the present study indicate that the nurse-led intervention significantly improved shoulder ROM, including flexion, extension, abduction, and internal rotation, compared to the control group. The difference in shoulder ROM between the experimental and control groups was also statistically highly significant. These results underscore the effectiveness of early, structured rehabilitation in restoring shoulder mobility following breast cancer surgery. The current findings are consistent with previous studies in this area by Mohite et al. on the effectiveness of Scapular Strengthening Exercises on shoulder dysfunction, pain, and Functional Disability after MRM. It showed higher shoulder flexion ( $167.98 \pm 8.230$  vs  $107.05 \pm 8.018$ ), abduction ( $156.91 \pm 8.230$  vs  $107.63 \pm 8.230$ ), and external rotation ( $62.372 \pm 7.007$  vs  $41.907 \pm 6.771$ ) ranges of motion than the conventional group. Scapular strengthening exercises significantly improved pain, functional disability, and external rotation of the shoulder compared to the control group [15]. Similarly, Hawesh et al. demonstrated that a structured nursing rehabilitation program significantly improved knowledge, muscle strength, ROM, and functional ability in post-mastectomy women, with reductions in disability noted among the intervention group. This supports the value of nurse-led, patient-centred interventions in postoperative care [16]. Huo et al. conducted a randomized controlled trial in China. They found that a novel resistance exercise strategy incorporating neuromuscular joint facilitation significantly enhanced shoulder ROM during chemotherapy following radical breast cancer surgery, except for passive external rotation. Their results reinforce the utility of exercise even during ongoing cancer treatment [17]. In a cross-sectional study, Zhang et al. identified pain, body weight, grip strength, and supraspinatus muscle characteristics as significant determinants of shoulder mobility in patients with unilateral breast cancer. This suggests that individualized exercise interventions, considering these factors, may optimize rehabilitation outcomes [18]. Collectively, these studies and our findings affirm that structured exercise interventions including nurse-led programs play a crucial role in improving shoulder ROM, reducing disability, and enhancing overall physical function in breast cancer

patients. Early integration of such interventions into postoperative care can thus significantly enhance quality of life and functional outcomes.

#### Shoulder ROM grading

The present study findings underscore the long-term protective effects of a structured exercise regimen on shoulder function in post-mastectomy patients. The study findings are in concordance with those reported by Jariwala et al., who observed shoulder mobility restrictions of  $>10^\circ$  in 65% of BCSs, with severe restriction ( $>25^\circ$ ) present in 24% of cases [19]. This study's findings emphasize that exercise needs to be continued throughout life to prevent shoulder dysfunction and disability. Moreover, Chrischilles et al. [10] study reveals that 30–50% of breast cancer survivors experience persistent arm and shoulder deficits. Furthermore, these study findings are consistent with those of De Groef et al. [20], supporting the use of active exercises and multifactorial physical therapy, such as stretching exercises, which have been successful in treating postoperative pain and reducing range of motion following breast cancer treatment.

#### Disability of Arm, Shoulder, and Hand (DASH)

The present study further evaluated upper limb functionality using the DASH questionnaire. At the 6<sup>th</sup> and 12<sup>th</sup> month follow-up, the intervention group demonstrated a marked reduction in disability scores. In contrast, the control group reported significantly higher DASH scores at corresponding time points. Notably, the intervention group showed continuous improvement, whereas the control group exhibited a worsening trend in functional disability over time. These findings were statistically highly significant and reinforce the long-term benefits of early, structured nurse-led intervention in preventing upper limb dysfunction in breast cancer survivors. Comparable results were observed in the study conducted by Mbaabu et al., which reported high levels of upper extremity disability among patients post-surgery, with a mean DASH score of 51.7. Participants in the prospective arm scored 47.3, whereas those in the retrospective arm scored 53, indicating persistent and substantial disability in the absence of targeted interventions [21]. Similarly, Mohite et al. demonstrated that the mean reduction in DASH scores was significantly greater in the intervention group compared to the conventional group ( $70.32 \pm 5.28$  vs.  $77.79 \pm 5.10$ ), supporting the importance of tailored physiotherapy in improving postoperative outcomes [14]. Basha et al. also found that structured exercise programs incorporating virtual technologies, such as the Xbox Kinect, significantly improved DASH scores and shoulder

range of motion ( $p < 0.001$ ), indicating their potential role as adjuncts in rehabilitation programs [22]. These results align with our study's findings and collectively emphasize the effectiveness of targeted interventions in mitigating functional impairments among breast cancer patients.

#### *Association of socio-demographic and clinical variables with Shoulder ROM*

The present study demonstrates that several clinical variables, like BMI, Number of childbirths, and menopause, have a positive relationship with Shoulder ROM. Co-morbidities like hypertension and coronary artery disease, HER2/ Neu status, ECOG performance status, Chemotherapy, Radiotherapy dosage, site and complications, and hormone therapy have significant associations with Shoulder ROM. Axillary node dissection, Neoadjuvant Chemotherapy, radiotherapy dosage, and radiotherapy complications of pharyngitis have a significant association with shoulder ROM. These findings are in line with previous evidence suggesting that the multivariable ordinal logistic regression analysis of Kramer et al. found that chemotherapy was a significant predictor of disability. At the same time, race, side, axillary surgery, and age were significant predictors of pain [23]. Furthermore, the findings of Thomas et al. confirm the current study, revealing a strong association between arm function and radiation therapy ( $p = 0.017$ ) [24]. The present study further highlights the effectiveness of a structured, nurse-led intervention initiated on the day of admission and reinforced throughout the year. This approach resulted in a notable decrease in disability in the intervention group compared to the control group.

The study results conclude that early rehabilitation helps the intervention group in preventing shoulder dysfunction and disability among breast cancer survivors. These results will guide the healthcare professionals to do precise and meticulous assessments of each patient from the day of admission and continue till their lifetime, since rehabilitation is essential throughout their lifetime to prevent disability and to improve QOL. According to the present study, many patients engage in exercises only during the early postoperative period, after which they become non-compliant with exercise, and a significant number of patients were found to discontinue exercises in the later stages of recovery. Therefore, this study emphasizes that patient education alone is insufficient; consistent reinforcement, encouragement, and follow-up support are crucial to ensure adherence to rehabilitation protocols. Integrating structured nurse-led intervention into routine oncology care is essential for improving survivorship outcomes, reduces disability and thereby enhances the quality of life.

#### **Author Contribution Statement**

ANS, MJK, BD, TPE, LR: Conceptualization, Design, Definition of intellectual content, Literature search; ANS: Data acquisition; ANS, MJK, BD: Clinical studies, Experimental studies, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing, Manuscript review, Guarantor.

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#### *Scientific Body approved Ph.D. thesis*

The study was approved by the Doctoral Committee (No. JIP/Res/PhD-RMC/DC-1/2020, dated 21.01.2020).

#### *Availability of data*

The datasets are available from the corresponding author on reasonable request.

#### *Was the study registered in any registration dataset (for clinical trials, guidelines, meta-analysis)*

The trial was registered under the Clinical Trial Registry of India (CTRI/2021/05/033357).

#### *Ethical issue handled*

The study was approved by the Institutional Ethics Committee with Approval No. (JIP/IEC/Ph.D./2020/0, dated 13.10.2020) and renewed (JIP/IEC/2022), dated 20.06.2022.

#### *Any conflict of interest*

There is no conflict of interest in this study.

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