Original article

A supervised exercise program and regular care in upper limb disability and lung capacity in patients with breast cancer undergoing radiotherapy: a randomized clinical trial

Um programa de exercícios supervisionados e cuidados regulares na incapacidade dos membros superiores e na capacidade pulmonar em pacientes com câncer de mama submetidos à radioterapia: um ensaio clínico randomizado

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ABSTRACT | BACKGROUND: Breast cancer is a disease in which the cells present in the breast grow abnormally. Musculoskeletal problems and breathing problems are common following breast cancer surgeries. There is evidence suggesting that early postoperative exercise is a safe and effective way to help improve upper limb functions. The study aimed to compare the supervised exercise programme versus regular care in reducing upper limb disability and improving lung capacity in breast cancer patients undergoing radiotherapy. **METHODS:** In this study, 44 female participants were recruited with the age group 18 years and above who had undergone surgery following breast cancer were selected. The demographic information of each subject was recorded, including name, age, gender, weight, and height. Baseline measurements are taken by the DASH questionnaire, goniometer and PFT. Participants were divided into two groups: intervention group (n-22) and control group (n-22). The intervention group gets a supervised exercise programme, whereas the control group gets advised to do usual care at home. **RESULT:** The Shapiro-Wilk test was used to assess the normality of the data, as the sample size was less than 50. Data analysis was done using parametric and non-parametric tests within-group analysis and also in between-group analysis. Wilcoxon sign rank test was used for within-group analysis, and Mann-Whitney U test was used for between-group analysis. There was significant improvement in the outcome measures ($p \leq 0.001$). **CONCLUSION:** A supervised exercise program along with regular care in upper limb might helps in improving lung capacity among patients with breast cancer undergoing radiotherapy.

KEYWORDS: Breast Neoplasms. Upper Extremity. Total Lung Capacity. Exercise Therapy. Rehabilitation.

RESUMO | CONTEXTO: O câncer de mama é uma doença na qual as células presentes na mama crescem anormalmente. Problemas musculoesqueléticos e respiratórios são comuns após cirurgias de câncer de mama. Há evidências sugerindo que exercícios pós-operatórios precoces são seguros e ajudam a melhorar as funções dos membros superiores. O objetivo do estudo foi comparar o programa de exercícios supervisionados com os cuidados regulares na redução da incapacidade dos membros superiores e na melhora da capacidade pulmonar em pacientes com câncer de mama submetidos à radioterapia. **MÉTODOS:** Neste estudo, 44 participantes do sexo feminino foram recrutadas com a faixa etária de 18 anos ou mais que foram submetidas à cirurgia após o câncer de mama. As informações demográficas de cada sujeito foram registradas, incluindo nome, idade, sexo, peso e altura. As medidas basais são feitas pelo questionário DASH, goniômetro e PFT. Os participantes foram divididos em dois grupos: grupo de intervenção (n-22) e grupo de controle (n-22). O grupo de intervenção recebe um programa de exercícios supervisionados, enquanto o grupo de controle é aconselhado a fazer os cuidados habituais em casa. **RESULTADO:** O teste de Shapiro-Wilk foi usado para avaliar a normalidade dos dados, pois o tamanho da amostra foi menor que 50. A análise dos dados foi feita usando testes paramétricos e não paramétricos na análise dentro do grupo e também na análise entre grupos. O teste de classificação de sinais de Wilcoxon foi usado para análise dentro do grupo, e o teste U de Mann-Whitney foi usado para análise entre os grupos. Houve melhora significativa nas medidas de desfecho ($p \leq 0{,}001$). **CONCLUSÃO:** Um programa de exercícios supervisionados juntamente com cuidados regulares no membro superior pode ajudar a melhorar a capacidade pulmonar entre pacientes com câncer de mama submetidos à radioterapia.

PALAVRAS-CHAVE: Neoplasias da Mama. Extremidade Superior. Capacidade Pulmonar Total. Terapia por Exercício. Reabilitação.

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1. Introduction

Breast cancer (BC) constitutes a significant global health concern, characterized by the uncontrolled proliferation of abnormal cells within breast tissue. The healthy tissues around these malignant cells are invaded and destroyed by it.[1] The risk of BC increases with age, with the average diagnosis age being 62 years. Notably, 89.5% of the new cases include women aged 45 years and above. Adherence to a healthy lifestyle and a balanced diet has been demonstrated to positively impact BC outcomes.[2] In 2016, over 3.5 million women in the United States were diagnosed with BC. Recent literature suggests that the BC survival rate has improved significantly to 91%, 86%, and 80% in the last five years, ten years and fifteen years time frame, attributed to advancements in medical treatment modalities.[3]

BC is currently the leading cause of cancer fatalities in India, exceeding cervical cancer.[4] Early pregnancy, proper nursing, and regular exercise lower its incidence risk, while hormone replacement therapy, ionizing radiation, obesity, and alcohol consumption increase it.[5] It significantly impacts various aspects of a woman's life, including reduced shoulder range of motion and lung function following treatment.[6] Cancer treatments can also negatively impact physical fitness, body composition, and mental well-being, increasing the risk of comorbidities.[7] Numerous factors, including the total radiation dose, radiation dose rate, and chemotherapy delivery, have been implicated in the development of pulmonary complications following breast cancer treatment. Respiratory physiotherapy, a cornerstone of physiotherapy practice, plays a crucial role in managing these complications, with interventions such as airway clearance techniques and pulmonary rehabilitation demonstrating positive outcomes.[8]

A 12-week resistance training intervention demonstrated positive outcomes in BC patients undergoing radiation therapy, including enhanced upper and lower limb strength, as well as improved knee flexion and shoulder internal and external rotation. Conversely, another study investigating the effects of 18 weeks of combined aerobic and resistance training in BC patients revealed improvements in muscle strength and cardiorespiratory fitness. However, there was no statistically significant difference in their quality of life (QL) or peak oxygen uptake (VO2peak) when compared to BC patients who did not engage in the exercise.[9]

Despite recommendations for exercise during treatment, patients often lack clarity about the mode of exercise, type of exercise and duration needed, despite the fact that exercise interventions have been highly recommended for BC patients to enhance their physical and mental health and supplement their medical treatment during adjuvant therapy.[9] There is a need to determine the most effective exercise approach for these patients by comparing the efficacy of different exercise programs. So, this study aims to investigate the comparative efficacy of home-based and clinic-based exercise programs in improving outcomes for breast cancer patients undergoing radiotherapy.

2. Material and methods

2.1 Study design

A randomised, controlled, single-blind, prospective study design was utilised to investigate the effects of a supervised exercise program versus standard home care in a cohort of BC patients. The study was conducted from August 2022 to May 2023. On 03/08/2022, approval was granted for project no. IEC-2307 by the Maharishi Markandeshwar University and was registered in the clinical trial registry. (CTRI/2023/04/051883).

2.2 Participants

Female patients were eligible to participate if they were 40 years or older and had unilateral breast cancer. The exclusion criteria were below 40 years of age, women having bilateral breast surgery, history of prior radiotherapy or surgery to the chest or neck, and any contraindication to exercise. Patients with BC who consented to participate in the trial and satisfied the eligibility criteria were randomly assigned to one of two groups (the intervention and control group) using the computer-generated randomisation technique when they visited the radiotherapy department of the

superspeciality hospital for follow-up following a mastectomy. Sequentially numbered, opaque, sealed envelopes (SNOSE) were used to ensure the confidentiality of the allocation. Utilising the statistical programme G* Power 3.1.9.4, the population sample size was determined. With an effect size of 0.5, 0.05 as a significance level, and 80% of the power was selected. At a 25% dropout rate, 22 samples in each group were considered, making the total sample size equal to 44.

2.3 Interventions

The intervention group received a supervised exercise program comprising wall ladder exercises, shoulder wheel exercises, chest wall stretches, side bends (10 repetitions, 1 set, twice daily) and Theraband exercises, including overhead band stretch, front band stretch, and low band row abduction with external rotation; each 10 repetitions, 2 sets, twice daily. It also involved incentive spirometer exercises and deep breathing exercises (10 breaths each, 1 set, twice daily). This supervised program included three face-to-face sessions per week for three weeks, and patients were also advised to carry out the exercise regularly at home, twice a day for 3 months. The control group received usual care, including home-based shoulder range of motion exercises and deep breathing exercises, 10 repetitions each, 1 set, twice daily for three months (Figure 1).[10] Guidance on the home exercise program was provided by a qualified physiotherapist with experience in attending patients with BC. Adherence to the program was monitored with regular phone calls to the patient or their caregiver on every alternative day.

Figure 1. Supervised exercise program (A: Wall ladder exercises, B: Incentive spirometer for pulmonary function, C: Shoulder wheel, D: Lateral stretch)

Source: the authors (2025).

2.4 Outcome measures

The baseline and post-intervention assessments, as well as intervention delivery, were conducted within the Physiotherapy Department of Maharishi Markandeshwar University. The principal investigator was solely responsible for recording all outcome assessments and was moderately experienced with assessment using the stated outcome measures. Due to the nature of the study design, it was not in the scope of the study to blind the assessor. To maintain study integrity, participant blinding concerning both intervention allocation and outcome assessment was implemented. The outcome measures included:

The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, developed by the American Academy of Orthopaedic Surgeons (AAOS) and the Institute for Work and Fitness in 1996, was utilised to assess upper limb musculoskeletal dysfunction. This self-reported instrument comprises 30 items, with higher scores indicating greater severity of disability and lower scores reflecting improved function. The DASH score is calculated using the formula, [(sum of n responses)/n] -1)(25), where 'n' represents the total number of completed items. The DASH score cannot be calculated if more than three items are missing.[11,12]

The shoulder joint range of motion (ROM) was measured using a universal goniometer, a standard instrument for assessing joint angles. The goniometer utilises a fixed arm, a fulcrum, and a movable arm to measure the angle between the two bony segments of a joint.[13] For shoulder flexion, the patient was positioned supine with the knee flexed. The goniometer fulcrum was placed laterally over the centre of the humeral head. The stationary arm was aligned parallel to the trunk, and the movable arm was aligned with the midline of the humerus. The typical active ROM for shoulder flexion is between 0 to 80 degrees. Likewise, for shoulder extension, the patient was positioned prone. The goniometer fulcrum was placed over the greater tubercle of the humerus. The stationary arm was aligned with the lateral midline of the thorax, and the movable arm was aligned with the lateral epicondyle of the humerus. The typical active ROM for shoulder extension is between 0 to 60 degrees. For shoulder abduction, the patient was positioned supine, and the goniometer fulcrum was placed over the humeral head. The stationary arm was aligned parallel to the sternum, and the movable arm was aligned with the midline of the humerus. The typical active ROM for shoulder abduction is between 0 to180 degrees. The study followed the typical value set by AAOS.[13]

Lastly, the spirometry device with a mouthpiece (RMS Helios 401) was used to test the lung functions. Participants were instructed to sit upright and ensure a tight seal of the mouthpiece to maximize the accuracy of the measurement. The test involved a deep inhalation followed by a forceful and rapid exhalation until complete lung emptying.[14]

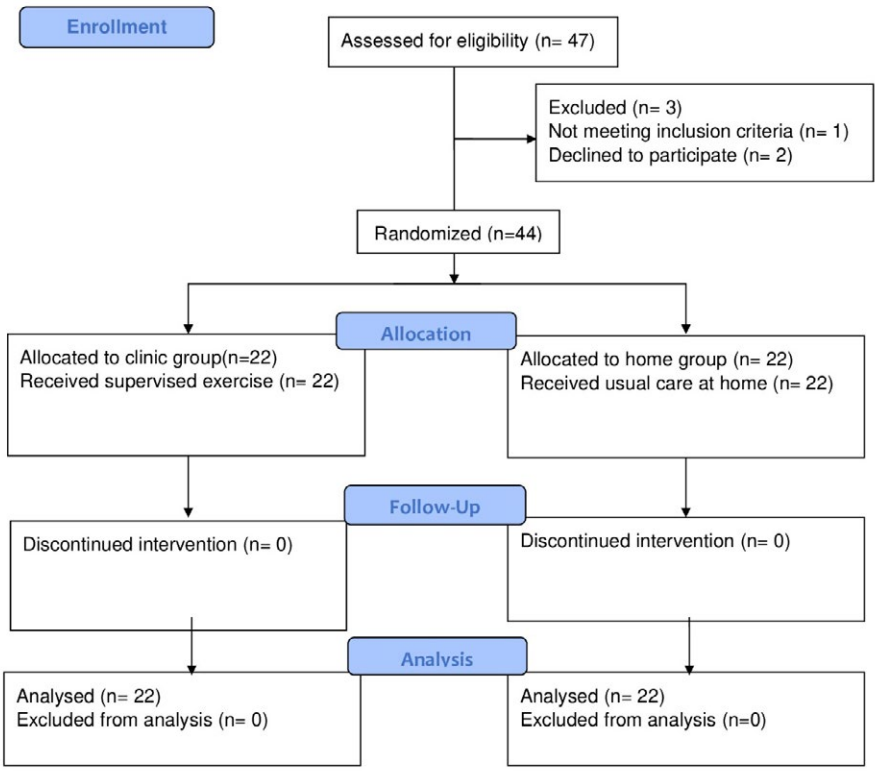
2.5 Statistical analysis

The data collected was analysed using IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). Shapiro-Wilk test was used for estimating normal distribution. Mann-Whitney U test and Wilcoxon Signed Rank test were used to analyse non-normally distributed data for determining between-group, and within-group differences. The level of statistical significance was set for a p-value ≤ 0.05.

3. Results

A total of 47 individuals were assessed for eligibility, of whom 44 were randomised to the intervention or control group. Twenty-two participants were allocated to each group. No participants were lost to follow-up in either group. All 44 randomised participants were included in the final analysis. The sample at the baseline was 22 in each group, and all 44 participants completed the trial, and included in the final analysis. The CONSORT flow diagram of the participants is shown in Figure 2.

Figure 2. CONSORT flowchart of Participant inclusion



Source: the authors (2025).

Demographic dimensions were normally distributed in the intervention group as $p>0.05$ for age (year), weight (Kg), and BMI (Kg/m^2), whereas height (cm) was not normally distributed ($p<0.05$). Demographic dimensions were normally distributed in the Control group as well ($p>0.05$) for age, height, weight, and BMI (Kg/m^2). This is demonstrated in Table 1. Shapiro-Wilk test was used to estimate the normality. As the data follows not normal distribution, non-parametric tests were used for estimating the significance, and data were expressed in median and Inter-quartile range (IQR). For within-group analysis Wilcoxon signed-rank test was used to test the significance ($p<0.05$). For the between-group analysis, Mann-Whitney U test was used to test the significance ($p<0.05$).

Analysis revealed significant improvements in DASH scores, shoulder range of motion (ROM), and FEV1/FVC ratio within both the intervention and control groups ($p < 0.05$) as shown in Table 2. However, the intervention group demonstrated significantly greater improvements compared to the control group ($p < 0.05$) as shown in Table 3. Effect size and power analyses, presented in Table 4, further support the superiority of the intervention group.

Table 1. Demographic characteristics distribution at the baseline for both groups

Demographic	Intervention group (p-value)	Control group (p-value)
Age (year)	0.225	0.085
Height (cm)	0.026	0.723
Weight (kg)	0.215	0.368
BMI (kg/m^2)	0.737	0.231

Source: the authors (2025).

Table 2. Between the group comparison of outcome measures

Outcome measures	Intervention group Median (IQR)	Control group Median (IQR)	P-value (Pre)	P-value (Post)
Sh. Flex.	161.73 (159.62 to 163.83)	158.55 (155.95 to 161.14)	0.063	<0.001*
Sh. Ext.	27.50 (25.92 to 29.08)	26.14 (24.46 to 27.81)	0.226	<0.001*
Sh. Abd.	161.41 (158.80 to 164.01)	158.50 (156.23 to 160.77)	0.087	<0.001*
DASH	35.35 (33.29 to 37.41)	36.40 (34.03 to 38.77)	0.493	<0.001*
FEV1/FVC	91.73(89.48 to 93.98)	87.36(85.06 to 89.67)	0.020	<0.001*

Source: the authors (2025).
Abbreviations: Sh. Flex.: Shoulder flexion; Sh. Ext.: Shoulder Extension; Sh. Abd.: Shoulder Abduction; DASH: Disabilities of the Arm, Shoulder and Hand; FEV1/FVC: Forced expiratory volume/Forced vital capacity ratio.

Table 3. Within the group comparison (Intervention Group)

Outcome Measure	Intervention Group Median(IQR)		p-value	Control Group Median(IQR)		p-value
	Pre-intervention	Post-intervention		Pre-intervention	Post-intervention	
Sh. Flex.	162.50 (157.75-166.00)	176.50 (170.00-179.00)	<0.001*	158.50 (152.75-164.25)	169.00 (167.00-172.25)	<0.001*
Sh. Ext.	28.00 (24.75-30.00)	43.00 (39.00-45.25)	<0.001*	26.50 (23.50-29.00)	37.50 (34.75-40.00)	<0.001*
Sh. Abd.	160.50 (156.75-166.25)	175.50 (171.75-178.25)	<0.001*	158.00 (155.00-161.00)	169.00(165.75-171.25)	<0.001*
DASH	36.00 (31.90-38.72)	25.05 (23.15-27.90)	<0.001*	39.00 (31.32-40.45)	32.90(26.40-35.67)	<0.001*
FEV1/FVC ratio	91.00 (88.00-96.00)	101.00 (99.00-103.50)	<0.001*	88.00 (85.75-9.25)	93.50(91.00-96.25)	<0.001*

Source: the authors (2025).
Abbreviations: Sh. Flex.: Shoulder flexion; Sh. Ext.: Shoulder Extension; Sh. Abd.: Shoulder Abduction; DASH: Disabilities of the Arm, Shoulder and Hand; FEV1/FVC: Forced expiratory volume/Forced vital capacity ratio.

Table 4. Effect size and power estimation of both the groups

Outcome measures	Effect size (Intervention group)	Power (Control group)	Effect size (Control group)	Power (Control group)
Shoulder flexion	3.15	100 %	2.22	100 %
Shoulder extension	4.37	100 %	3.05	100 %
Shoulder abduction	2.67	100 %	2.26	100 %
DASH	2.43	100 %	0.96	99 %
FEV1/FVC ratio	2.09	100 %	1.10	99 %

Source: the authors (2025).

4. Discussion

All of the outcome measures significantly improved as a result of data analysis within groups. Therefore, it was demonstrated that both groups were clinically advantageous with improvements in all outcome measures. The between-group analysis of data of each variable provides a significant difference as $p<0.001$. The results depicted significant improvement in DASH scores within both the intervention and control groups. The effect size is 2.43 in the intervention group as compared to 0.96 in the control group, which shows that the intervention group is clinically higher than the control group.

In a randomized controlled trial in 2022, Bruce et al. found that the post-mastectomy structured exercises programme improved quality of life and there was a significant improvement in DASH scores.[15] In this study, ROM was analysed using parametric and non-parametric tests as it was mixed distributed (normal and not normally distributed. Results of the study depict that both groups improved with supervised exercise and regular care. The result depicted significant improvement in ROM scores within both interventional and control groups ($p<0.001$). The effect size of shoulder flexion is 3.15, shoulder extension is 4.37 and shoulder abduction is 2.67 in the intervention group and 2.22, 3.05 and 2.26, respectively, in the control group, which shows that the intervention group is clinically significantly higher than the control group.

Aboelnour et al. found that post-mastectomy strengthening exercises improved quality of life and there was significant improvement in ROM scores.[16] In this study, FEV1/FVC was analysed using a non-parametric test as data was not normally distributed. The results depicted significant improvement in the FEV1/FVC ratio within both the intervention and control groups. The effect size is 2.09 in the intervention group and 1.10 in the control group, which shows that the intervention group is more clinically significant than the control group. Dieli-Conwright et al. reported in their randomized controlled trial study found that an aerobic and resistance training programme considerably improves physical fitness and quality of life.[17] The study reported that the intervention group has improved, as compared to the control group based on effect size estimation. As both groups had power >90%, hence sample size included in the study was justified.

A small sample size was one of the limitations, the data was collected in two hospitals, and no other specific treatment for the management of lymphedema in breast cancer was applied to the patients. The strength of the study is randomized clinical trials. Effect size and power estimation were evaluated for both groups to measure the effect of the intervention on both groups. Future studies can focus on the comparisons of different interventions and can also conduct large sample randomized clinical trials.

5. Conclusion

A supervised exercise program along with regular care of the upper limb might help in improving lung capacity among patients with breast cancer undergoing radiotherapy. Further large sample randomized controlled trials are needed to establish the feasibility protocol.

Authors contributions

The authors declared that they have made substancial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsability for all aspects of the study.

Competing interests

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

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