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Scapular and shoulder exercises for improving shoulder function and preventing secondary lymphedema following breast cancer surgery – a randomised clinical trial protocol

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Abstract

Introduction. The most prevalent cancer among women worldwide is breast cancer. Those diagnosed with breast cancer usually undergo modified radical mastectomy (MRM) or breast-conserving therapy (BCT). The excision of lymph nodes is likely to result in secondary lymphedema. As there are not many Indian studies on preventing secondary lymphedema through upper limb exercises after breast cancer surgery, the present study investigated the effect of scapular and shoulder muscle strengthening exercises in preventing the development of upper limb lymphedema following breast cancer surgery.

Methods. In this single-blinded, randomised clinical trial, 58 participants will be randomised to receive conventional physiotherapy or conventional physiotherapy along with shoulder and scapular muscle strengthening exercises (four sessions per day) for 24 weeks following MRM or BCT surgery. The primary outcome variables include shoulder and scapular muscle strength, shoulder range of motion, upper limb circumference, volumetry, shoulder pain, and disability. The secondary outcome variable is quality of life assessment.

Results. Outcome variables will be evaluated by a blinded assessor at baseline (second postoperative day) and three, six, 12, 16, and 24 weeks after surgery. A mixed model analysis of variance (ANOVA) will be used to analyse the data for all outcomes. Furthermore, an intention-to-treat analysis will be used, and missing data will be handled with multiple imputations.

Conclusions. Strengthening exercises following breast cancer surgery, if found effective, can be used in breast cancer rehabilitation protocols to improve shoulder function and prevent secondary lymphedema.

Key words: secondary lymphedema, breast cancer surgery, shoulder muscles, strengthening exercises, scapular muscles

Introduction

Breast cancer is the most commonly diagnosed cancer and the primary cause of death among cancer-affected women worldwide, with more than 1.8 million patients diagnosed globally every year. Recent years have seen a considerable increase in breast cancer survival rates due to early screening facilities, improved medical treatment options, and disease identification. Over 80% of those affected can be cured and usually undergo mastectomy [either modified radical mastectomy (MRM) or breast-conserving therapy (BCT)] [1, 2].

With such increased survival rates, one of the associated side effects of surgery is the development of secondary lymphedema (SL). The excision of lymph nodes surgically, or along with radiation therapy, is likely to result in SL. The term "arm swelling and dysfunction" is commonly used to characterise SL, defined as an increase in arm circumference of more than 2 cm or an accumulation of protein-rich fluid in areas with lymphatic vessel damage. Almost 20 to 30% of women with breast cancer develop SL [2].

Based on the available data, the risk of developing SL is highest 12 to 30 months after surgery, though this varies depending on breast cancer treatment. In patients who underwent axillary lymph node dissection without regional lymph node irradiation, the risk of developing SL peaked between 18 and 24 months. However, in individuals who underwent axillary lymph node and regional lymph node dissection, the risk rate peaked in the first six to 12 months. Moreover, the risk rate increased between 36 and 48 months for those who underwent a sentinel lymph node biopsy and regional lymph node irradiation [3].

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Shoulder arm exercises are necessary following surgical treatment to prevent lymphedema and improve shoulder joint movement and strength, which enhance shoulder function and promote quality of life (QoL). Evidence suggests that patients should initially exercise slowly and then introduce light weights, with a few repetitions, increasing gradually and stopping if painful [1]. Resisted muscle training is critical to attenuating and correcting muscular dysfunction during cancer therapy because preventing muscle dysfunction is a priority [4]. Such exercises include scapula-oriented exercises for eight weeks, which involve stretching and strengthening for 40 min, with a five-minute warm-up and cool-down. This approach may reduce pain, improve muscle strength, and enhance QoL in breast cancer survivors [5, 6]. To the best of our knowledge, there is a lack of robust randomised clinical trials in India on the effects of scapular and shoulder exercises in SL prevention among those undergoing breast cancer surgery. Hence, this study was designed to analyse the impact of scapular and shoulder muscle strengthening exercises in improving shoulder function and preventing upper limb SL development.

The primary objective of this study is to determine the effect of scapular and shoulder exercises on muscle strength, range of motion, arm circumference, arm volume, pain, and shoulder disability among women who underwent breast cancer surgery. The secondary objective is to analyse the effect of scapular and strengthening exercises on improving QoL among women who underwent breast cancer surgery and find the relationship between shoulder disability and QoL. Hence, we hypothesised that scapular and shoulder strengthening exercises will improve shoulder function, prevent SL development, and enhance QoL after breast cancer surgery.

Subjects and methods

This study protocol explains the method for a randomised clinical trial as per SPIRIT (the Standard Protocol Items: Recommendations for Interventional Trials) [7].

Trial design and study setting

The protocol adopted a single-blinded randomised clinical trial with two parallel groups design and has a 1:1 allocation ratio for receiving the treatment programme. Screening of participants, allocation, assessments, and interventions will be conducted at the departments of oncology and surgery at the PSG Hospitals, Tamil Nadu, India.

Trial recruitment and allocation

Participants will be recruited from the oncology and general surgery departments of the PSG Hospitals. Participants who undergo MRM will be referred to a physiotherapist (DV) from both departments, and the therapist will teach the conventional exercise protocol. The primary investigator (MV) will teach the strengthening exercises to the interventional group. In order to achieve the expected sample size and adequate participant enrolment, a standardised screening of participants will be carried out based on the inclusion and exclusion criteria.

Study participants

Fifty-eight female participants aged between 25 and 65 years, who will undergo either MRM or BS unilaterally with axillary lymph node dissection for the first time, will be included in this study. Participants who undergo neoadjuvant chemotherapy or adjunct chemotherapy and radiation and those who come under a comprehensive health insurance scheme (sponsored by the state government) will also be included. Participants should agree to be monitored via video call during follow-up assessment and be willing to participate in the study. Criteria for exclusion are cardiovascular symptoms at low-intensity activities [< 3 metabolic equivalents (METs)], impaired cognition, or musculoskeletal, rheumatic or any other conditions precluding their participation.

Sample size

The comparison of the mean formula calculated the sample size using the mean and standard deviation (*SD*) values of shoulder external rotator muscle strength from a previous study [5] (sample size = $2SD^2 \times (Z1\text{-}/2+Z\beta) /d^2$, where $Z1-\alpha/2$ is the standard normal variate [1.96 at 5% error], $Z\beta$ is 0.842 at 80% power, *SD* = the *SD* from previous studies, and *d* = the difference between the mean values of the interventional group. Hence, substituting these values [*SD* (σ) of 13.2; pre-test mean value = 54.5 joules; post-test mean value = 65.1 joules; mean difference = 10.6 joules], sample size = $2\ (13.2)^2 \times (1.96 + 0.84)^2/\ (10.6)^2 = 24$, an approximate sample size of 24 participants in each group was calculated. Considering a 20% dropout (10 participants), the sample size in each group will be 29 per group. Therefore, this study needs a total sample size of 58 participants.

Procedure

Participants referred by a surgical oncologist and a general surgeon will be screened by the primary investigator (MV) for their eligibility to participate in the trial. A patient information pamphlet about the study, postoperative exercises, skin care, and safety during the trial will be provided to the participants, and informed consent will be obtained.

Randomisation

Eligible participants will be allocated randomly to an interventional group or a control group with the help of a web-based tool (www.sealedenvelope.com). The Block randomisation method will be adopted, with ten blocks of six participants each and a 1:1 allocation ratio. The results will be stored in sealed envelopes and maintained confidentially by the investigator (VR) conducting the randomisation procedure. Then, the participants will be allotted to groups according to the sequence generated. The researcher who generates the randomisation sequence will not be involved in the recruitment, assessment, or intervention. The outcome assessor (DR) will be blinded to the allocated groups. Since the therapists and participants will be directly involved in the study, they cannot be blinded to the intervention after the group assignment.

Demographic details and baseline outcome assessments

Demographic details of all participants will be recorded and tabulated, as shown in Table 1. Primary outcome variables include shoulder and scapular muscle strength, shoulder range of motion, upper limb circumference, volumetry, shoulder pain, and disability. The secondary outcome variable is QoL assessment. A baseline shoulder range of motion assessment will be taken on the second postoperative day (A0), while a baseline assessment of all other outcome measures will be taken at the end of the third week after surgery (A1).

Table 1. Details of demographic characteristics

Characteristics	Subcomponents
Age (years)	25–34 35–44 45–54 55–65
BMI (kg/m^2)	underweight, normal, overweight, or obese
Cancer stage	I / II / III / IV
Breast surgery	BCT/MRM
Axillary lymph node dissection	level I, II or III
Side of surgery	right or left
Cancer treatment	chemotherapy, radiation therapy, or hormonal therapy

BMI – body mass index, BCT – breast-conserving therapy, MRM – modified radical mastectomy

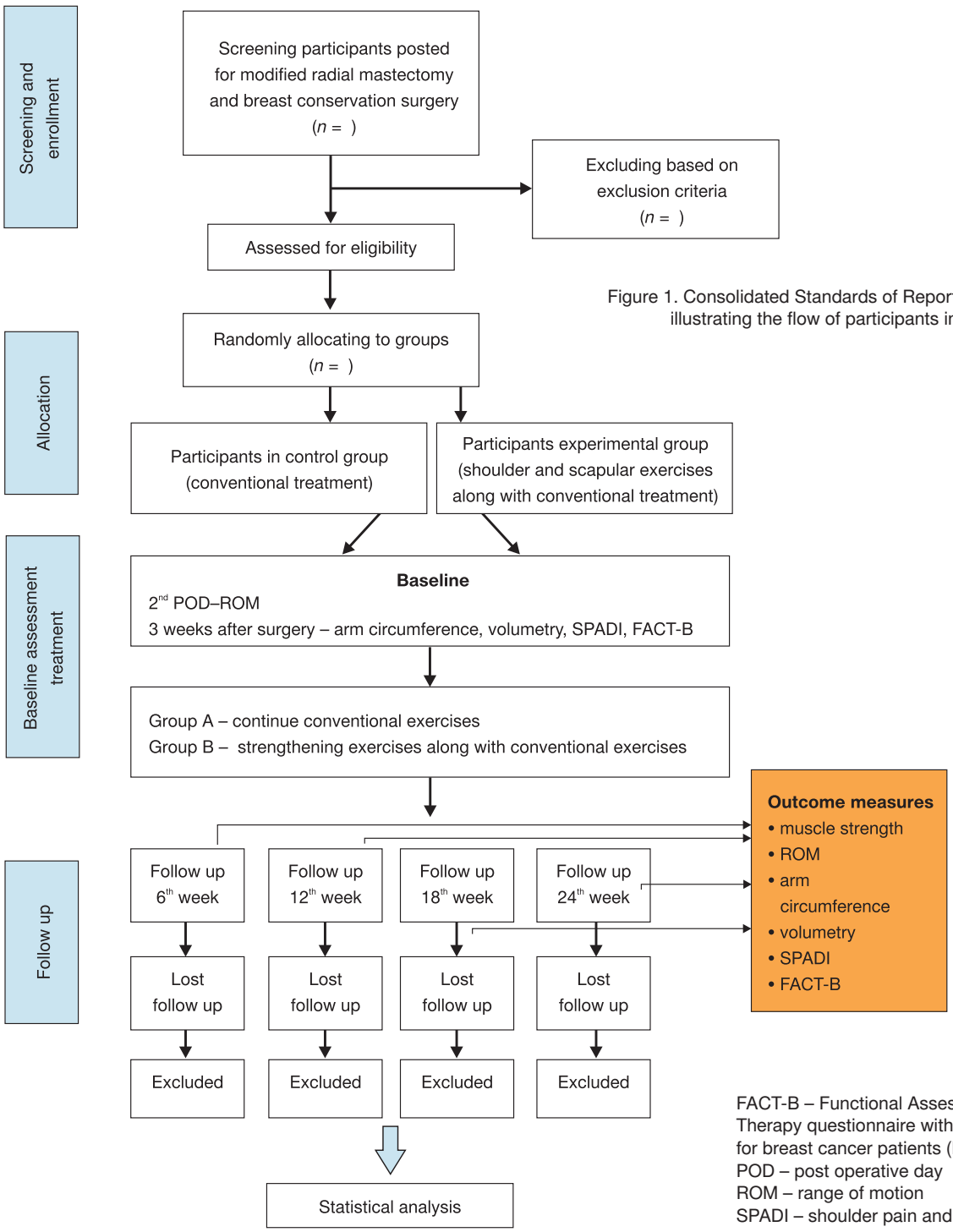

Figure 1. Consolidated Standards of Reporting Trials diagram illustrating the flow of participants in the study

FACT-B – Functional Assessment of Cancer Therapy questionnaire with a specific module for breast cancer patients (FACT-B)
POD – post operative day
ROM – range of motion
SPADI – shoulder pain and disability index

Table 2. Enrolment, allocation, and treatment timeline

Time point	Study period							
			post operative period					
	enrolment	allocation	A0	A1	A2	A3	A4	A5
			2^{nd} POD	3 weeks	6 weeks	12 weeks	18 weeks	24 weeks
Enrolment								
screening for eligibility	✓							
informed consent	✓							
collection of demographic data	✓							
randomisation and group allocation		✓						
Intervention group			⟷	⟷ (dotted)				
Control group			⟷					

POD – postoperative day
The straight arrows mean the conventional exercises followed by both the groups from 2^{nd} POD till 24 weeks.
The dotted arrow mean strengthening exercises followed by interventional group from 4^{th} week till 24 weeks.

Table 3. Outcome assessment timeline

Time point	A0	A1	A2	A3	A4	A5
	2^{nd} POD	3 weeks	6 weeks	12 weeks	18 weeks	24 weeks
Outcome measures						
shoulder muscle strength (N/kg)		✓	⟷			
shoulder ROM (degrees)	✓	⟷				
upper limb circumference (cm)		✓	⟷			
volumetry (ml)		✓				
FACT-B		✓				
SPADI		✓	⟷			

ROM – range of motion, FACT-B – Functional Assessment of Cancer Therapy – Breast, SPADI – Shoulder Pain and Disability Index
POD – post operative day
The arrows indicate follow up assessment.

The participants will be followed up four times after surgery, including weeks six (A2), 12 (A3), 18 (A4) and 24 (A5) (Figure 1). The protocols for patient assessment, group allocation, and treatment programme are outlined in Tables 2 and 3.

Intervention

A Template for Intervention Description and Replication (TIDieR) checklist [8] was implemented to describe the study intervention (Table 4).

Participant withdrawal

The participants will discontinue the study if any adverse events occur and can also leave without consequences if they withdraw their consent. A participant can be removed from the study by the primary investigator due to unavoidable circumstances. The reasons for withdrawal will be documented.

Adverse events during the trial

Adverse events related to exercise might cause fatigue or pain. Participants will be given a washout period of two to four days following chemotherapy for their fatigue and pain to settle down, after which they will resume their exercise programme. If a participant scores over five on the visual analogue scale (VAS) during admission, a transcutaneous electrical nerve stimulator (TENS) will be used for pain relief. Adverse events present during assessment and follow-up sessions will be documented.

Outcome measures

Primary outcome measures

Shoulder and scapular muscle strength

The strength assessment for shoulder flexors, abductors, internal and external rotators, serratus anterior, upper trapezius, and latissimus dorsi will be measured (in kilograms and represented in Newtons) using a baseline push-pull dynamometer (model 12-0300; Fabrication Enterprises, NY, USA). We conducted a pilot study to assess the inter-rater reliability of a baseline push-pull dynamometer on healthy individuals. We found that measuring scapular and shoulder muscle strength had moderate to excellent reliability, with an intraclass correlation coefficient [ICC] of 0.78 (95% confidence interval [CI] = 0.57, 0.89) for shoulder flexor strength and 0.79 (95% CI = 0.59, 0.89) for shoulder abductor strength.

Table 4. A description of the study intervention using the Template for Intervention Description and Replication (TIDieR) checklist

<table>
<tr><th>TiDieR Items</th><th>Description</th></tr>
<tr><td>Intervention allotted to groups</td><td>Shoulder and scapular strengthening and conventional exercise protocols</td></tr>
<tr><td>Rationale</td><td>Muscle strength will be impaired after treatment in cancer patients, causing increased fatigue, altered functional status, loss of autonomy, and frequent falls, compromising the quality of life. Thus, a healthy musculoskeletal condition should be one of the top priorities during and following breast cancer treatment. In addition to impaired muscle strength, restriction of upper limb joints, especially reduced shoulder mobility, represents a stressful physical limitation for patients undergoing breast cancer surgery. Therefore, strength training after breast cancer therapy can alter the consequences of muscle dysfunction in breast cancer rehabilitation [9]. Passive (extrinsic) and active (intrinsic) mechanisms explain lymph formation and transport, which produce propulsion and centripetal lymph movement. During resistance exercises, arterial blood flow increases due to active movements of the extremities acting as an extrinsic mechanism in lymph transport. Increased capillary density, as one of the consequences of exercise adaptation (isometric and dynamic contraction), causes improvements in lymph clearance. During exercise, these extrinsic and intrinsic mechanisms facilitate increased propulsion of lymphatic fluid through the lymphatic vessels. Exercise also increases arterial blood pressure and cardiac output, which may cause capillary filtration [10]</td></tr>
<tr><td>Materials used
in the intervention</td><td>Experimental group: water bottles (500 ml, 750 ml and 1 l, a ball, a chair, a bed, a pillow, and a transcutaneous electrical nerve stimulator (TENS) device. Comparator group: a ball, a bed, a pillow, and a TENS device.</td></tr>
<tr><td>Intervention procedures
Warm-ups and stretches will be performed by all participants before the strengthening exercises [11]

Warm-up:
– Scapular squeezes
– Shoulder circles
Stretches:
– Butterfly stretch
– Overhead clasped hands stretch
– Chest stretch
– Full body stretch
– Cat camel stretch</td><td>
<table>
<tr><th>Exercise description</th><th>Starting position</th><th>Ending position</th></tr>
<tr><td>Internal rotation:
Lie down straight and hold a water bottle in one hand. Move the bottle from outside towards your chest and repeat on the other side.</td><td> </td><td> </td></tr>
<tr><td>External rotation:
Lie down on your side and hold a water bottle in one hand (e.g., the right hand while lying on the left side). Move from inside to outside and repeat on the other side.</td><td> </td><td> </td></tr>
<tr><td>Shoulder rowing:
Kneel on the chair with one knee. Lift a water bottle with the hand on the opposite side and bring it towards the chest. Slowly come back to the starting position. Repeat on the other side.</td><td> </td><td> </td></tr>
<tr><td>Pull-over:
Lie down straight with your knees bent and hold a water bottle in both hands. Slowly lower the bottle over your head and towards the floor until your arms align with your ears. Slowly come back to the starting position.</td><td> </td><td> </td></tr>
<tr><td>Back-fly:
Sit comfortably on a chair without an armrest and hold a water bottle in both hands. Slightly bend forwards towards your knees, keeping your head in line with the spine. Lift the bottles out to the sides to your shoulder height. Slowly return to the starting position.</td><td> </td><td> </td></tr>
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<tr><td></td><td>
<table>
<tr><td>V-raise:
Hold a water bottle in one hand, with your arms held beside your body and thumbs pointing forward. Lift the bottle in a V shape to shoulder height. Slowly come back to the starting position and repeat on the other side.</td><td> </td><td> </td></tr>
<tr><td>Wall push-up:
Stand facing the wall with feet slightly apart. Extend both arms straight without locking your elbows and place your hands (approximately shoulder-width apart) on the wall. Slowly move towards the wall, keeping your elbows close to your chest. Slowly return to the starting position.</td><td> </td><td> </td></tr>
<tr><td>Pelvic bridging:
Lie on your back with your knees bent. Place your arms on the bed at your sides. Squeeze your buttocks and lift your hips up off the bed.</td><td> </td><td> </td></tr>
<tr><td>Bicep curl:
Hold a water bottle in each hand by your side with a firm grip and your thumbs facing forward. Slowly bend your elbows and bring the bottle up with your palm facing your shoulders. Slowly lower the bottle down to the starting position.</td><td> </td><td> </td></tr>
</table>
</td></tr>
<tr><td>Provider</td><td>A physiotherapist (DV) will teach the conventional exercise protocol, and the primary investigator (MV) will teach the strengthening exercises to the interventional group.</td></tr>
<tr><td>Mode of intervention delivery</td><td>Exercises will be taught individually to the patients and be partially supervised.</td></tr>
<tr><td>Setting of intervention</td><td>Screening of patients, intervention, and assessments will be done at the Department of Oncology, PSG Hospitals.</td></tr>
<tr><td>Dosage</td><td>Interventional group

Stretching exercises:
Frequency: four sessions/day (before and after strengthening exercises)
Intensity: Hold time of 15 to 20 s
Duration: 3–5 min
Repetition: 3–5 repetitions

Strengthening exercises: fourth to ninth week
Frequency: four sessions/day
Intensity: filled 500 ml water bottle
Duration: 20 min/session
Repetition: 10 repetitions
Strengthening exercises: tenth to fifteenth week
Frequency: four sessions/day
Intensity: filled 750 ml water bottle</td></tr>
</table>

	Duration: 20 min/session Repetition: 10 repetitions Strengthening exercises: sixteenth to twenty-fourth week Frequency: four sessions/day Intensity: filled 1 l water bottle Duration: 20 min/session Repetition: 10 repetitions Control group Conventional in-hospital exercises: Frequency: one session/day Intensity: no weight Duration: 20 min/session Repetition: 10 repetitions After discharge exercises: Frequency: two sessions/day Intensity: no weight Duration: 20 min/session Repetition: 10 repetitions
Tailoring	Participants in both groups who develop lymphedema during the treatment period will be provided with upper limb stockings to prevent further development and complications. Participants with fatigue and nausea following chemotherapy, hormonal therapy, or radiation therapy will be given a washout period of two days for their symptoms to settle down, following which they will resume their exercise programme. Participants who have a pain score (visual analogue scale [VAS]) of more than five at the incisional area or in the operated side shoulder joint will be treated with high frequency (70 Hz) and low intensity (2 mA) TENS for pain relief. Participants will be asked convenient times for monitoring the exercises through a video call.
Modifications in the trial	None
Fidelity assessment	Exercise programmes will be supervised when the participants are in the hospital and when they get admitted for chemotherapy, hormone therapy, or radiotherapy. A video demonstration of the exercises will be sent to the patient's WhatsApp number. Exercises will be monitored at specified times for participants through a video call. If the participants do not have smartphones, the caretaker's phone number will be documented and used for education and exercise programme supervision.

Shoulder range of motion

The shoulder range of motion will be measured in degrees using a universal goniometer (Mediguard, Uttar Pradesh, India). The test-retest reliability was indicated by an ICC between 0.95 and 0.98 ($p < 0.01$) [12]. The convenience of using the universal goniometer and its availability make it easier to use [12].

Upper limb circumference measurement

The arm volume, measured by upper limb circumference, will be marked in 4 cm segments from the ulnar styloid process towards the axilla (≈ 0 to 40 cm) and 4 and 8 cm down the hand from the ulnar styloid process. The definition of lymphedema is an increase of more than 10% in volume, i.e., > 2 cm in the circumference between the affected and normal upper limbs [13]. Pooled ICC data from studies measuring lymphedema using inch tape measurement of the upper extremities showed an intra-rater reliability value of 0.99 (95% CI = 0.99, 0.99) and an inter-rater reliability value of 0.98 (95% CI = 0.98, 0.98) [14].

Volumetry

The volume of the upper limb will be measured by immersing the affected and unaffected upper limbs in a container of water, with the displacement volume measured at around 5 ml. A customised volumetric assessment water can was devised and modified so that the can is fixed with a tap on top. A mark will be made 40 cm from the ulnar styloid process on both arms, and the participant will immerse the upper limb in the water-filled container until the water level reaches the mark made on the arm. The tap will be kept open when the participant starts immersing their upper limb to collect the displaced water in a beaker and will be closed when the displacement of water stops. The water collected in the beaker will then be measured, and the values for each upper limb compared. Lymphedema is defined as an increase of more than 10% in volume, i.e., more than 200 ml in arm volume between the affected and normal upper limbs [13]. Pooled ICC data of studies measuring lymphedema of the upper extremities using the voltmeter had an intra-rater and inter-rater reliability of 0.99 (95% CI = 0.99, 0.99) [14].

Shoulder pain and disability index

The Shoulder Pain and Disability Index (SPADI) is a questionnaire relating to pain and the difficulty that a participant has with day-to-day activities involving shoulder movements for upper extremity use. The means of the pain and disability subscales are averaged to arrive at a total score ranging between 0 (the best) and 100 (the worst). The Tamil version of SPADI, developed by Jeldi et al. [15], will be used for our study. The scale has good internal consistency for the pain ($\alpha = 0.859$) and disability ($\alpha = 0.895$) subscales. Moreover, the test-retest reliability has been reported to be excellent for pain (ICC= 0.989; minimal detectable change – 6.27) and disability (ICC = 0.990; minimal detectable change – 6.25) [16].

Secondary outcome measure

Functional Assessment of Cancer Therapy – Breast Version 4 questionnaire

Participant QoL will be evaluated using the Functional Assessment of Cancer Therapy – Breast (FACT-B) questionnaire (version 4, in Tamil) [17]. The validated questionnaire has physical, social, emotional, and functional well-being subscales and also includes questions related to several more concerns about breast cancer. FACT-B contains 37 questions and is divided into FACT-general (FACT-G) and a disease-specific domain for breast cancer (BCS).

FACT-B-Total is the total score of all subscales, ranging from 0 to 148, with higher scores indicating greater QoL [16]. The FACT B+4 subscale has shown good internal consistency (Cronbach's alpha = 0.62 to 0.88) and high test-retest reliability (0.97) [17].

Outcome assessments

There will be five evaluation time periods in this study, including baseline at the third week (except for shoulder ROM measured on the second postoperative day) and post-intervention at weeks 6, 12, 18, and 24 after surgery. An assessor blinded to the intervention and trained to perform the assessments will document the outcome measures, though the SPADI and FACT-B questionnaires will be answered by the participants. The timeline for outcome measure assessment is explained in Table 2.

Data analysis

The collected data will be statistically analysed using Statistical Package for the Social Sciences (SPSS) version 16.0 (IBM Corp., NY, USA). Participant demographic and clinical characteristics will be analysed through descriptive statistics, while the outcome variables in the two treatment groups will be described with mean ± *SD*. The Shapiro–Wilk test and histograms will evaluate data normality, and an independent *t*-test will assess if the baseline data are similar between the two groups ($p > 0.05$). Between-group differences for the outcome measures of interest, including all time points, will be assessed using a mixed-model analysis of variance (ANOVA). The incidence of SL will be reported as a percentage, and between-group differences will be assessed using the chi-squared test. Pearson's correlation coefficient will calculate the relationship between QoL and shoulder disability for each group. For missing data, an intention-to-treat analysis will be used and handled through multiple imputations. The level of significance will be set at ≤ 0.05.

Discussion

Impaired muscle function can result from breast cancer surgery and its treatment through atrophy and loss of strength. Muscle weakness reduces a patient's ability to do routine day-to-day activities and stay independent during and following treatment [18]. The present study will analyse the effects of scapular and shoulder muscle exercises in improving shoulder range of motion, preventing SL, and improving QOL after breast cancer surgeries among women in an Indian setting. So far, only shoulder range of motion exercises have been emphasised following surgery. Implementing strengthening exercises will improve shoulder range of motion and prevent muscle atrophy and SL development, thereby contributing to a good functional recovery. Carolyn et al. [11] demonstrated that one to three pounds of weight should be used initially for strength training in mastectomy patients, though it may cause mild fatigue at the end of 10 repetitions. In our study, we will commence strength training with 0.5 kg, which is approximately one pound. Progression should be made by increasing the weight, number of sets, or weekly frequency [11]. In this study, we will progress by starting the exercise with a 500 ml water-filled bottle, slowly increasing to 750 ml and 1 l bottles. To achieve a considerable improvement in the study outcomes, treatment duration will be 24 weeks (four sessions per day; 20 min per session). The results of the several outcome measures of interest will be compared between the two groups to evaluate the effects of scapular and shoulder muscle strengthening exercises in the prevention of SL, among others. The findings of the study will be helpful in setting up a better exercise protocol to prevent SL and improve QoL among Indian women following breast cancer surgery.

Limitations

The partially supervised exercise programme is one of the limitations of the trial, as the participants will only be monitored through video calls. Though a convenient time for monitoring may pose a challenge to the therapist, measures will be taken to motivate the participants by explaining the uses of the study intervention to them and their caretakers. Those who lack adherence to a regular exercise programme will be encouraged by being shown clinical pictures and educational videos related to the development of lymphedema and its consequences. Participants will be given feedback on their muscle strength, shoulder range of motion, arm circumference, arm volumetric assessment, shoulder pain and disability, and QoL scores at each assessment to encourage their performance and adherence to the exercise programme. Future studies with an extended follow-up period are warranted to investigate the long-term effects of the intervention and the occurrence of lymphedema.

Data collection and management

The data of all participants will be maintained by the primary investigator (MV), though all investigators will be able to access the data. Details of the participant's name, address, history, and results of outcome measures will be kept confidential.

Data monitoring

Members of the ethical committee will monitor and ensure the safety of the data.

Dissemination of results

The results of the study will be published in journals, at conferences, and on the Clinical Trial Registry of India. The participants will also be informed of the study outcomes during their follow-up. Researchers who contribute to trial design and conduct, data interpretation, and reporting will be considered for authorship.

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We thank Dr T. Balaji, Dr Sudha Ramalingam, Dr Arun Prasath SV, Dr Dhanpal Singh, Dr K. Lavanya Kumari, Dr G. Ashok Swaminathan, Dr N. Meena, and Mr Raja Regan J for their support with this study.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has

followed the tenets of the Declaration of Helsinki, and has been approved by the Institutional Human Ethical Committee, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India [project No.: 22/133 (Ref.No. PSG/IHEC/2022/Appr/FB/024)]. The study protocol has been registered at the Clinical Trial Registry of India (CTRI/2023/01/049186).

Informed consent

The participants and their attendees will be given detailed information about the possible risks and benefits of the study.

After getting participants signed informed consent, they will be included in the study. Participants will be informed that they can withdraw from the study at any time without any negative implications or consequences.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

Funding

This research received no external funding.

Protocol amendments

If there are any changes in the study protocol through suggestions given by experts or due to any other emerging needs, the amendment will be communicated to the ethical committee. The amendment accepted by the ethical committee will be intimated to the participants and clinical trial registry along with the ethical committee amendment form.

Consent for publication

Consent was obtained from the model, who agreed to include her exercise demonstration photographs with masking of her face.

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