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Effect of early exercise on functional recovery and surgical outcomes after post-mastectomy breast reconstruction: study protocol for a randomized clinical trial

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Abstract

Background Although mastectomy and reconstruction have a positive impact on breast cancer patients' quality of life, postoperative side effects such as shoulder functional limitations and pain are common. To reduce these side effects, the importance of early postoperative exercise has been emphasized, and the need for tailored exercise programs is emerging. Therefore, this randomized controlled trial (RCT) aims to investigate the impact of a tailored early exercise program based on patient symptoms and timing on shoulder and trunk function and health-related outcomes in breast cancer patients who received immediate breast reconstruction.

Methods This pragmatic, two-armed RCT will involve 72 breast cancer patients undergoing immediate breast reconstruction following total mastectomy. Participants will be randomized to either the exercise or control group (36 in the exercise group and 36 in the control group). During the 6-month period, participants in the exercise group will receive a tailored exercise program based on their symptoms over time, treatment stage, and physical function. The exercise intervention will last for a total of 6 months and will be conducted in two ways. Participants will be encouraged to attend one supervised exercise session per week for the first month following surgery (total of four sessions), after which they will be encouraged to switch to home-based exercise and perform 150 minutes of moderate-intensity aerobic exercise and at least 2 resistance exercises per week. The primary outcome is shoulder and trunk function (range of motion [ROM] and strength), with secondary and tertiary outcomes including patient-reported outcomes, body composition, and physical activity levels. Shoulder and trunk function will be measured at postoperative day (POD) 1 (baseline), postoperative day POD5, POD10-14, postoperative 1 month, postoperative 3 months, and postoperative 6 months, while the other outcomes will be measured at the same time points except for POD5.

Conclusion This study is a tailored exercise oncology trial to better understand the short- and long-term effects of exercise on shoulder and trunk function and other health-related outcomes after mastectomy and reconstruction in

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breast cancer patients. The results of this study may prove valuable in providing important insights into the role of exercise in postoperative breast cancer patients and help develop effective exercise programs tailored to their needs.

Trial registration The study protocol for this study is registered with the National Clinical Trials Registry (NCT06552650; first posted on April 30, 2024).

Keywords Breast cancer, Breast reconstruction, Rehabilitation, Exercise

Background

Breast cancer is the most commonly diagnosed cancer among females [1]. The incidence has increased dramatically, accounting for 13% of all new cancer cases each year and about 25% of all female cancers worldwide [2]. In Korea, breast cancer has the highest incidence rate among all cancers in females, accounting for 20% of all cancer cases [3]. However, with advances in diagnosis and treatment, the number of breast cancer survivors has been steadily increasing, bringing greater attention to managing treatment side effects while improving quality of life [4]. In terms of surgical methods, the rate of mastectomy to prevent recurrence has been steadily increasing over the past decade [5–7].

Mastectomy can cause significant psychological and social trauma due to the loss of a breast, leading to disrupted body image, sexual dysfunction, and depression [8, 9]. Breast reconstruction is therefore an important option to consider after mastectomy as it can improve the quality of life for breast cancer patients and alleviate associated psychological distress [10–13]. The need for and number of breast reconstruction surgeries has also been steadily increasing over the past 40 years, especially as the average age of diagnosis has decreased [5, 14], with more than 60% of females who undergo mastectomy opting for breast reconstruction [15].

Despite aesthetically satisfying results and a positive impact on quality of life, it is reported that many patients experience a variety of upper extremity complications after breast reconstruction surgery, including decreased shoulder range of motion (ROM) and strength, pain, paresthesias, and lymphedema [16, 17]. Although minimally invasive techniques have been made in recent breast cancer surgery and breast reconstruction, postoperative exercise restriction still remains inevitable [18–21]. In addition, females who undergo mastectomy compared to breast conservation have been reported to be at greater risk for postoperative shoulder restriction, and breast reconstruction can cause functional inactivity [22]. For example, more than 50% of patients who undergo breast reconstruction experience postoperative pain or functional limitations, which can persist for years [23, 24]. A systematic review of 32 studies found that pain is associated with decreased shoulder function. Furthermore, decreased muscle strength was observed 15 months after reconstruction using autologous tissue and implants [25, 26]. Additionally, shoulder dysfunction negatively impacted patients' physical functioning and ability to perform daily activities [27–29].

Several studies have emphasized the importance of exercise to reduce disability from breast cancer surgery. Postoperative exercise can improve shoulder mobility and physical performance while reducing the risk of postoperative complications such as lymphedema, hematoma, seroma, and wound infection [30–32]. A recent systematic review also found that multifactorial physical therapy (e.g., stretching) and exercise can effectively address postoperative pain and impaired ROM after breast cancer treatment [16], which is further supported by recent high-level evidence, including a meta-analysis of randomized controlled trials and a randomized trial during chemotherapy demonstrating significant improvements in pain, lymphedema, muscle strength, functional capacity, and overall recovery [33, 34]. In terms of timing of exercise, one Cochrane review reported early postoperative exercise significantly improving long-term shoulder ROM in 10 of 24 studies examining exercise after breast cancer surgery [35].

Most previous studies have examined the effectiveness of exercise in patients who have undergone breast conservation or mastectomy only, and intervention studies in patients with breast reconstruction remain limited. In addition, evidence-based exercise programs designed for patients' changing conditions after breast reconstruction are lacking, and the ideal timing and type of exercise have not been well established [18–22]. The purpose of this protocol paper is to provide a study methodology that will evaluate the impact of an early exercise program tailored to postoperative progression on shoulder and trunk function, body composition, and patient-reported outcomes in patients after immediate breast reconstruction.

Study objectives

Objectives

The primary objective of this study is to determine the effect of a tailored early exercise program on shoulder and trunk function (ROM and strength) in patients with breast cancer undergoing mastectomy with immediate reconstruction. Secondary objectives are to evaluate its impact on body composition, patient-reported outcomes (upper-extremity disability, satisfaction), physical activity, and surgical complication parameters, including pain,

wound healing, seroma, hematoma, wound infection, lymphedema, and delayed wound healing.

Methods/design

Study design

This study is a pragmatic, parallel, two-arm randomized controlled trial (RCT). Employing a randomized, controlled, parallel-group design, participants assigned to one of the two groups (Exercise or control group) will undergo a baseline assessment and be evaluated on the effect of the tailored exercise program at each timepoint after surgery (postoperative day [POD]5, POD10-14, and at 1 month, 3 months, and 6 months after surgery). The schedule for the exercise intervention and assessments may be adjusted based on each participant's individual treatment duration and schedule. Participants will be recruited from the Severance Hospital at Yonsei University Health System in Seoul, Korea. Table 1 summarizes the study design and the process of intervention and assessment time points. The trial registration number is NCT06552650. Recruitment and the exercise intervention for this study have been completed. Follow-up assessments and data analysis are currently ongoing.

Eligibility criteria

Female patients aged between 19 and 70 years who have been pathologically diagnosed with breast cancer and are scheduled to undergo either unilateral or bilateral mastectomy with immediate breast reconstruction are eligible to participate in the study. The study will exclude if they are: aged 70 years or older; have previously undergone surgery or radiation therapy on the same side as the affected armpit; scheduled for, or already had delayed breast reconstruction. The study will also exclude patients whose breast cancer has metastasized. Patients who have difficulties reading or understanding Korean or who have problems communicating effectively with the researcher will also be excluded. Lastly, patients with difficulty exercising determined by their healthcare provider will also be excluded from the study. Detailed inclusion and exclusion criteria are presented in Table 2.

Ethics and informed consent

This study protocol has been approved by the Medical Ethics Committee of Severance Hospital, Yonsei University Health System, Seoul, Korea (4-2023-1146). The study will be conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines, including data and patient privacy. All participants will provide written informed consent.

Sample size

The sample size calculation was based on a previous study that evaluated the effect of an evidence-based exercise program on shoulder function (ROM, strength) in breast cancer patients [36]. A power of 95%, two-sided statistical significance level of 5%, effect size of 0.8, number of groups of 2 (exercise group, control group), and 6 measurement time points resulted in a minimum of 30 participants per group. Given the duration of the study and the nature of the intervention, an expected dropout rate of 20% would require the recruitment of 36 participants per group, for a total of 72 participants.

Participants screening, recruitment and consent

The initial screening will be conducted by physicians and specialists. Eligible participants will be screened and identified from the preoperative patient list. Physicians

Table 1 Flow diagram for the schedule of enrollment, interventions, and assessments

TIME POINT	VISIT 1	VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6
	Baseline, (Before surgery)	POD5 (± 1 day)	POD10-14	1 month from the baseline (± 1 week)	3 months from the baseline (± 2 weeks)	6 months from the baseline (± 2 weeks)
ENROLLMENT						
Informed consent	O					
Sociodemographic information	O					
INTERVENTIONS						
Exercise group		O	O	O		
Usual care group						
ASSESSMENTS						
Body composition	O		O	O	O	O
Shoulder ROM & Strength	O	O	O	O	O	O
Trunk ROM & Strength	O	O	O	O	O	O
Physical activity	O		O	O	O	O
Disorders of upper limb	O		O	O	O	O
Postoperative satisfaction	O					O
Surgical outcomes						

Abbreviations: *POD* post-operative day, *ROM* Range of motion

Table 2 Details of exercise protocol for intervention group

Week	Intensity	Exercise Program		Standard Shoulder Function	Patient Status
		Stretching Exercise	Resistance Exercise		
1	Very low	Neck stretching, Shoulder circle, Pendulum exercise	Fist clench, Rowing, Isometric lower limb exercise, Wall pelvic tilt, Calf raise	• Stretching Exercise - FLX < 60°or/& AB < 60° • Resistance Exercise - FLX < 50% of baseline or < 60% of non-surgery arm - AB < 40% of baseline or < 60% of non-surgery arm	• VAS ≥ 4 • Difficult to change the posture of lying or sitting alone
2	Low	Neck stretching, Shoulder circle, Wall shoulder stretching, Wall upper body stretching, Pendulum exercise	Fist clench, Rowing, Isometric chest, Isometric lower limb exercise, Wall pelvic tilt, Calf raise	• Stretching Exercise - FLX ≥ 90°or/& AB ≥ 90° • Resistance Exercise - FLX < 50% of baseline or < 60% of non-surgery arm - AB < 45% of baseline or < 65% of non-surgery arm	
3	Moderate	Neck stretching, Arm circle, Pec stretching, Wall shoulder stretching Wall upper body, Wall pec stretching	Wall pointer, W-rowing, Wall pelvic tilt, Chair squat	• Stretching Exercise - FLX ≥ 100°or/& AB ≥ 90° • Resistance Exercise - FLX ≥ 50% of baseline or ≥ 60% of non-surgery arm - AB ≥ 45% of baseline or ≥ 65% of non-surgery arm	• VAS ≥ 3 • Removal of drainage • Walk more than 20 min a day
4	High	Neck stretching, Breaststroke, Pec stretching, Wall shoulder stretching, Wall upper body stretching, Wall pec stretching, Y-stretching	Palm push, Isometric chest, Seated core exercise, Wall pointer, Wall side push-up, Dynamic squat	• Stretching Exercise - FLX ≥ 120°or/& AB ≥ 120° • Resistance Exercise - FLX ≥ 60% of baseline or ≥ 80% of non-surgery arm - AB ≥ 60% of baseline or ≥ 70% of non-surgery arm	• VAS < 3 • Surgical area and armpit are barely tight or greatly improved pain • Walk more than 30 min a day

The standard shoulder function was average of study 1 results depending on time elapsed after breast cancer surgery.

Abbreviation: *FLX* flexion, abduction, *VAS* visual analog scale

and researchers will then provide a verbal explanation of the study to potentially eligible patients who meet the inclusion criteria. Written consent will be obtained from patients who have indicated their willingness to participate. Participants will then promptly be scheduled for the study by the researchers and receive the necessary information about the study. Further details on the recruitment process are outlined in the study flowchart (Fig. 1).

Randomization

Eligible participants will be randomized into either the exercise or control group with a 1:1 ratio. Randomization will be conducted through the Electronic Case Reporting System with Accuracy, Safety, and Efficacy (e-CASE), an electronic case record system developed at the Severance Hospital Clinical Trials Center. Once recruited participants are enrolled, they will be automatically assigned to an arm (T=treatment, C=control) from a randomized table in the order of enrollment for each arm. An automated confirmation email of allocation will then be generated and sent to the research team. The exercise group will receive a structured, supervised exercise program for 1 month postoperatively starting on postoperative (POD 5), followed by home-based exercise. The control group will receive the same preoperative and postoperative medical care and treatment as the exercise group, except for tailored exercise program. A total of six measurements will be performed on all participants to evaluate the effectiveness of the exercise intervention. Data will be de-identified for analysis, and only the principal investigator at the university hospital will have access to identifiable information on all participants.

Intervention

Control group: usual care

Participants in the control group will be instructed to continue with their normal activities and will receive the same outpatient medical care as the exercise group except for the exercise intervention. Standard postoperative care includes wound management instructions, guidance on activity restrictions, and advice for gradual return to daily activities, but no structured physiotherapy or exercise program is routinely provided. Participants will be measured continuously for 6 months starting the day before surgery and will be given the same exercise program that was given to the exercise group at the end of the 6-month postoperative measurement.

Intervention group: exercise

The exercise group will receive a 4-week intervention from postoperative day 5 to 1 month, consisting of supervised exercise where an exercise specialist will teach

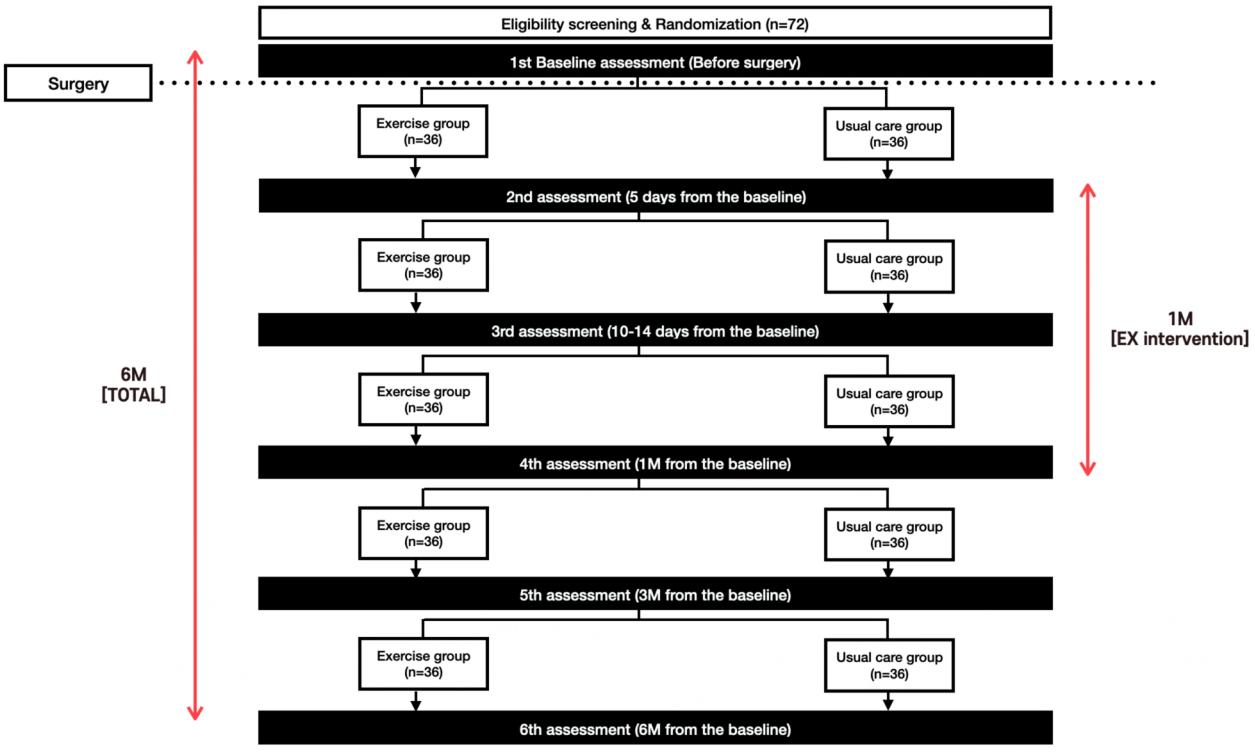

Fig. 1 Overview of the protocol study

participants an exercise program based on their condition, followed by home-based exercise where participants will perform the exercises they learned at home. The intervention will consist of weekly supervised exercise and daily home-based exercise for 1 month after surgery, followed by home-based exercise. The goal of the supervised exercise sessions is to teach subjects to perform the exercises at home on a daily basis through an exercise diary with detailed instructions on how to properly perform each exercise and videos provided via QR code. The exercise program is customized to the participant's condition and intensity at each point in time after surgery.

Exercise program

The exercise program consists of exercises to restore shoulder and trunk ROM and strength, reduce postoperative pain and discomfort, stretch tight muscles, and perform resistance exercises for weakened muscles. This exercise program was developed through a structured, multi-phase process that included a systematic literature review [16, 36, 37], an understanding of patient characteristics [26, 38, 39], surgical observations, and an observational study tracking postoperative recovery. It was further refined through qualitative interviews, expert panel discussions, feasibility study [36] and a pilot study to ensure safety, clinical relevance, and adaptability. The exercise program includes four intensity levels and an exercise journal, with each intensity determined by functional recovery indicators such as shoulder and trunk range of motion (within a pain-free range), muscle strength, and the presence or absence of a drainage tube. When the drainage tube was in place, only gentle active movements and stretching were permitted; after removal, resistance exercises were gradually introduced. Exercise intensity is tailored to each participant's status, considering ROM, muscle strength, surgical site status, and pain tolerance, so that all movements remain within a pain-free range. The number of sets and repetitions is presented as a range (e.g., 1–5 sets) to allow for individualized progression and safety; participants start with the lowest volume (e.g., 1–2 sets) and increase gradually as tolerated, under therapist guidance during the supervised phase. This flexible approach, consistent with recommendations in exercise oncology and our previous feasibility work (Min et al., *JAMA Surg* 2024), supports safe, patient-specific recovery. After completing four weeks of supervised exercise, participants receive a home-based diary for continued training from 1 to 6 months postoperatively. A feasibility study was conducted with postoperative breast cancer patients and physicians to determine the reliability of the exercises and the feasibility of the design.

Supervised: baseline – postoperative 1 month

The goal of the 1-month supervised exercise program progression phase is to facilitate the restoration of

Table 3 Trial inclusion and exclusion data

Inclusion criteria	Exclusion criteria
Age ≥ 16 and < 70	Age ≥ 70
Pathologically diagnosed with breast cancer	Had surgery or radiation therapy to the same side of the armpit
Scheduled to undergo unilateral or bilateral mastectomy and breast reconstruction	Scheduled to undergo or have undergone delayed breast reconstruction
Able to provide written informed consent	Has breast cancer that has spread to other cancers or is metastatic
Medically suitable for evaluation and participation in exercise intervention	Deemed by the healthcare provider to be ineligible to be measured for functional recovery due to postoperative complications (seroma, laceration, lymphedema observed within 1 month of surgery)
	Has problems reading or understanding Korean or has problems communicating with the researcher
	Has difficulty exercising as judged by the healthcare provider

postoperative shoulder and trunk ROM and strength. A tailored exercise program will be provided based on the participant's shoulder ROM and strength status, with a focus on improving shoulder recovery while maintaining whole-body function. The very low-intensity exercise program, which will be performed the day before discharge, or POD5, the first week after surgery, includes eight different exercises: neck stretching, shoulder circle, pendulum exercise, fist clench, rowing, isometric lower limb exercise, wall pelvic tilt, and calf raise. Each exercise will be performed for 5 repetitions or 5 s minimum for 1 to a maximum of 3 sessions per day.

Next, the low-intensity exercise program, which will be provided on the first outpatient day of Week 2, or POD10-14, consists of 11 exercise programs including neck stretching, shoulder circle, wall shoulder stretching, wall upper body stretching, pendulum exercise, fist clench, rowing, isometric chest, isometric lower limb exercise, wall pelvic tilt, and calf raise. Each exercise will be performed for 5 repetitions or 5 s minimum for 1 to a maximum of 3 sessions per day. If the drainage is not completely removed, or if their shoulder joint is in a condition that they are not able to execute the movement, it will be done selectively or at the lowest intensity.

In Week 3, participants will progress to a moderate exercise program including 10 exercises, tailored to their individual conditions. Specific exercises include neck stretching, arm circle, pec stretching, wall shoulder stretching, wall upper body stretching, wall pec stretching, wall pointer, w-rowing, wall pelvic tilt, and chair squat. Each exercise will be performed for 5 repetitions or 5 s minimum for 1 to a maximum of 3 sessions per day.

The final exercise training session in Week 4 will be a moderate-to high-intensity exercise program, including 13 exercises consisting of neck stretching, breaststroke, pec stretching, wall shoulder stretching, wall upper body stretching, y-stretching, palm push, isometric chest, seated core exercise, wall pointer, wall side push-up, and dynamic squat. Each exercise will be performed for 5 repetitions or 5 s minimum for 1 to a maximum of 3 sessions per day.

Recommended intensities are set for each week but are flexible and customizable for each participant based on their shoulder and trunk ROM, strength status, and level of shoulder discomfort and pain. The details of the exercise protocol are summarized in Table 3.

Home-based: postoperative 1 month to postoperative 6 months

The goal of a home-based exercise program from 1 month to 6 months after surgery is to fully restore shoulder and trunk ROM and strength and to maintain cardiorespiratory function and muscle mass. This phase will include tailored resistance and aerobic exercises. Participants will be encouraged to perform daily resistance exercises during this period and to perform at least 150 min of moderate-intensity aerobic exercise per week. The exercise program consists of a total of 13 exercise movements including moderate-to high intensity stretching, resistance, and aerobic exercises. Specific exercises include wall shoulder stretching, wall upper body stretching, palm push, pelvic tilt, sit-up, bridge, squat, back tightening, y-stretching, pec-dec fly, arm circle, dynamic squat, and cross country. For each exercise, participants perform 1–5 sets of 5 repetitions or 5–10 s. To monitor adherence during this unsupervised phase, participants will complete daily exercise diaries, which will be reviewed during clinic visits. In addition, weekly telephone or text check-ins will be conducted by the research team to encourage compliance and address any difficulties, consistent with methods used in other exercise oncology trials.

Study outcome measures

Primary outcome measures

The primary outcome is the recovery rate (%) of shoulder range of motion (ROM) and strength. Recovery rate will be defined as the proportion of the baseline value regained at each follow-up point (POD5, POD10–14, 1, 3, and 6 months postoperatively).

Shoulder ROM [Assessment schedule: Baseline, POD5 (± 1 day), POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

Shoulder ROM will be measured using a digital goniometer (IM-1397) to measure five shoulder motions (flexion, abduction, extension, internal rotation, and external rotation). Shoulder flexion, abduction, internal rotation, and external rotation will be assessed lying down, while shoulder extension will be measured in a standing position (Norkin, 2004). All measurements will be assessed in both arms, and the average value will be used for analysis.

Shoulder strength [Assessment schedule: Baseline, POD5 (± 1 day), POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

Shoulder muscle strength will be measured in Newton(N) using a portable dynamometer (j-tech Medical Industries Inc, Utah, USA). Maximal muscle strength will be assessed using maximum voluntary isometric contraction (MVIC) in flexion, abduction, extension, internal rotation, and external rotation (Bohannon & Andrews, 1987; Ford-Smith, Wyman, Elswick & Fernandez, 2001). All strength measurements will be performed twice in both the affected and unaffected arms, and the average value will be used for analysis.

Trunk ROM [Assessment schedule: Baseline, POD5 (± 1 day), POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

Trunk ROM will be measured using a digital goniometer (IM-1397). The angle will be measured by having participants perform a maximal trunk extension motion from an upright position and then pause for 3 s at the maximal point. A total of two measurements will be taken and the average value will be used for analysis.

Trunk strength [Assessment schedule: Baseline, POD5 (± 1 day), POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

Trunk strength will be measured in two ways. First, in the modified curl-up test, participants will be asked to lie down and with their knees bent at 90 degrees, rest their arms on the bed and lift their trunk to measure the length of their fingertips at full extension. In the isometric abdominal test, participants will be asked to lie down and place their hands on their stomach, place a handheld dynamometer under their sternum, and resist the maximum force applied by the researcher striking their shoulder blades. For both methods, a total of two measurements will be taken and the average value will be used in the analysis.

Secondary and ancillary outcome measures

Demographic parameters and medical information

Socio-demographic information including age, education, marital status, household income, and occupation will be collected at baseline (pre-intervention) using a self-report questionnaire. Medical information such as disease stage, treatment, and medications will be collected from medical records at baseline (pre-intervention) and 6-months post-baseline.

Anthropometric and body composition

For anthropometric measurements, height will first be measured using a standard stadiometer (Jenix, Seoul, Korea). Body composition, including weight, muscle mass, and body fat percentage, will be measured using Inbody (BIO-SPACE®,InBody_720, Korea). Body mass index (BMI) will be obtained dividing weight by the square of height.

Disabilities of the arm, shoulder and hand (DASH)

[Assessment schedule: Baseline, POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

The Disabilities of the Arm, Shoulder and Hand (DASH) is a patient-reported questionnaire that identifies difficulty performing a variety of upper extremity activities, consisting of a total of 30 questions [40]. The scale can be used to assess the impact on the performance of various activities of daily living, such as writing, opening bottles, and lifting heavy bags. The Korean version of the DASH questionnaire, each scale ranging from 1 (not at all difficult) to 5 (very difficult), will be used [41]. Scores will be expressed as percentages, where 0 indicates no disability and 100 indicates complete disability.

Postoperative satisfaction after breast reconstruction

[Assessment schedule Baseline, postoperative 6 months (± 2 weeks)].

The Breast-Q questionnaire will be used to measure patient satisfaction and quality of life after breast reconstruction. Breast-Q is a patient-reported outcome (PRO) measurement tool, primarily used to assess the quality of life of patients who have undergone breast surgery. The main constructs of the questionnaire are breast satisfaction, body image, psychosocial well-being, and sexual well-being. Among the three procedure-specific modules (augmentation, reduction, and reconstruction), the reconstruction module questionnaire will be selected and utilized in this study.

Physical activity

[Assessment schedule: Baseline, POD10-14, postoperative 1 month (± 1 week), postoperative 3 months (± 2 weeks), and postoperative 6 months (± 2 weeks)].

Physical activity of participants will be measured using the Global Physical Activity Questionnaire (GPAQ) [42]. Participants are asked to report all physical activity (including exercise) performed for at least 10 min during a typical week and the amount of time spent in physical activity at work, transportation, leisure, and sedentary activities. A modified GPAQ with the additional items about the number of days and hours of walking and resistance exercise per week will be used in this study. The reliability and validity of the Korean version of the GPAQ used in this study have been validated in a previous study [43].

Surgical outcomes

[Assessment schedule: postoperative 6 months (±2 weeks)]

Surgical outcomes (seroma, hematoma, nipple or skin necrosis and surgical site infection) will be determined by the physicians.

Statistical analyses

All analyses will be performed using SPSS version 29 software (IBM Corp., Armonk, NY, USA). Baseline differences between groups will be assessed using Chi-square tests for categorical variables and independent t-tests for continuous variables. The primary and secondary analyses will be conducted under the intention-to-treat (ITT) principle, whereby all randomized participants will be analyzed in the groups to which they were originally assigned, regardless of postoperative complications. To complement the ITT approach and explore the potential impact of safety-related postoperative complications on exercise adherence and outcomes, per-protocol analyses will be conducted as sensitivity analyses. Missing data will be handled using multiple imputation (five imputations) to account for missing variables. Linear mixed-effects models (LMM) will be used to assess the effects of the intervention on shoulder and trunk range of motion (ROM) and strength, body composition, DASH scores, and physical activity levels over time, including time, group, and their interaction as fixed effects. Within-group changes from baseline to follow-up will be assessed using paired t-tests, while between-group differences at each time point will be compared with independent t-tests. Analysis of covariance (ANCOVA) will be performed to assess the effect of the exercise intervention on postoperative satisfaction at 6 months, adjusting for baseline values. Descriptive analyses will be performed to explore the effects of the exercise intervention across different reconstruction methods on shoulder and trunk ROM and strength. Bonferroni correction will be applied as appropriate to control for multiple comparisons and reduce the risk of Type I error. Statistical significance will be set at $p < 0.05$.

Discussion

Shoulder dysfunction experienced by breast cancer patients following surgery tends to persist not only immediately after surgery but also long after treatment has ended [29]. Patients also experience joint pain, postural problems, and rotator cuff disorders in the short term after surgery [44]. Patients undergoing mastectomy and reconstruction often experience significant limitations in shoulder function. Post-surgery disability and pain reduce physical fitness, impair physical function, and negatively impact mental well-being. These challenges also affect quality of life, delaying patients' timely return to normal activities [45]. Therefore, it is important to develop tailored strategies for these patients to improve their health-related quality of life after surgery.

Several observational and experimental studies have shown that exercise has a significant impact on reducing postoperative complications and side effects in breast cancer patients, and therefore, regular exercise participation is recommended. Exercise has been acknowledged as a feasible and safe intervention improving quality of life, fitness, and body composition, mitigating fatigue and increasing a change of survival for breast cancer patients [46]. However, most existing studies have assessed these outcomes without considering surgical approaches such as reconstruction, potentially overlooking important differences in recovery trajectories and functional outcomes. Tailored exercise programs are therefore essential for patients undergoing mastectomy with immediate reconstruction to address their specific complications, side effects, and the optimal timing for intervention.

The exercise program described in this protocol will combine supervised and home-based exercise programs during the 1-month postoperative period with the goal of rapid recovery of shoulder and trunk function, which are the most prominent features in the early postoperative period. Previous studies reported that shoulder ROM and strength return to baseline levels within 1 month after surgery if an appropriate exercise program is implemented [34]. Therefore, the exercise program during this period should be carefully tailored to the patient's physical condition, with an intensity-specific exercise program that takes into account the timing pattern of postoperative recovery of shoulder and trunk ROM and strength. Then, from 1 month to 6 months after surgery, the participants will be encouraged to perform home-based exercises tailored to their physical condition with the goal of regaining and maintaining full shoulder and trunk function, maintaining muscle mass and strength, and reducing fatigue. In addition, since this is the time when various postoperative treatments are initiated, more active aerobic and resistance exercise is recommended to mitigate the side effects of cancer treatment [47].

This study builds on existing knowledge on key aspects of recovery in breast cancer patients. First, it may ultimately determine whether an early, tailored exercise program can accelerate functional recovery in breast reconstruction patients. Second, by including patients with bilateral breast cancer and various reconstruction methods, the study allows for a broader range of outcomes. Finally, the exercise intervention may have important clinical implications because it could provide criteria for optimal timing, duration, and intensity of exercise in this population.

This study has several limitations that should be acknowledged. First, it is a single-center trial conducted at one tertiary hospital in Seoul, which may limit generalizability to other clinical settings and populations. Second, blinding of participants and exercise specialists is not feasible due to the nature of the exercise intervention, potentially introducing performance and detection bias; however, outcome assessors will be blinded to group allocation where possible. Third, adherence to the home-based exercise phase (months 1–6) is monitored through self-reported exercise diaries and weekly check-ins, which may overestimate actual compliance compared to objective measures. Fourth, the control group receives no structured exercise program, but participants may independently engage in physical activity, potentially diluting between-group differences. Fifth, the study includes participants undergoing various reconstruction methods (e.g., tissue expander, TRAM flap, direct-to-implant, DIEP flap), and heterogeneity in surgical approaches may introduce variability in functional recovery trajectories; however, descriptive subgroup analyses are planned to explore these differences. Finally, the 6-month follow-up period may not capture the long-term effects of the exercise intervention on shoulder function and quality of life.

In conclusion, this protocol describes a tailored exercise oncology trial aimed at evaluating the short- and long-term effects of exercise on shoulder and trunk function, the areas of greatest need for early recovery in breast cancer patients who received post-mastectomy reconstruction. The results of this study may provide insights into the importance of developing time-specific, tailored exercise programs for breast reconstruction patients. With the rise in younger breast cancer patients and advances in surgical techniques, such evidence could inform clinical practice and support functional recovery in this growing population.

Abbreviations

ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
DASH	Disabilities of the Arm, Shoulder, and Hand
GPAQ	Global Physical Activity Questionnaire
POD	postoperative day
RCT	Randomized clinical trial
ROM	Range of motion

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12885-026-15949-9.

Supplementary Material 1.

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The authors of this study have no financial disclosures to declare.

Authors' contributions

RP, JS, KJW, SJY, JYJ and DWL designed the study.RP, DWL, EYL and JYJ drafted the original manuscript.JYJ and DWL provided supervision, and secured funding.All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study has been approved by the medical ethics committee of Severance Hospital, Yonsei University Health System, Seoul, Korea (4-2023-1146). Patients will be asked for permission to participate in the trial, and to collect and use their data by means of a signed informed consent before inclusion in the study. This will be obtained from each participant by the responsible physicians, research nurses, or exercise specialists.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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