OFFICIAL TITLE:
Effects of an Early Physical Therapy Protocol on Pain and Posture in Women Undergoing Reduction Mammoplasty: A Controlled Study

NCT NUMBER:

DOCUMENT DATE:
April 01, 2026

STUDY PROTOCOL

1. Background and Rationale

Reduction mammoplasty is a commonly performed surgical procedure that may lead to postoperative pain, postural alterations, and functional limitations. Early rehabilitation interventions are thought to improve recovery outcomes; however, evidence regarding structured early physical therapy protocols remains limited. This study aims to evaluate the effects of an early-stage physical therapy program on pain and posture in women undergoing reduction mammoplasty.

2. Study Design

This study is designed as a controlled, two-group clinical trial. Participants will be allocated into two groups:

- Intervention group (early physical therapy)
- Control group (standard care)

3. Participants

3.1 Sample Size

A total of 40 female participants will be included.

3.2 Age Range

18–50 years

3.3 Inclusion Criteria

- First-time reduction mammoplasty
- No postoperative complications
- Voluntary participation with signed informed consent

3.4 Exclusion Criteria

- History of breast cancer
- Lymphedema
- Neurological or orthopedic disorders affecting posture

- Systemic diseases (e.g., diabetes, rheumatologic disorders)
- Pregnancy or breastfeeding
- Cognitive impairment affecting compliance

4. Outcome Measures

Assessments will be conducted at:

- Baseline (pre-treatment)
- After 4 weeks of intervention

4.1 Demographic Data

Age, height, weight, BMI, surgery date, medical history

4.2 Pain Assessment

Visual Analog Scale (VAS, 0–10 cm)

4.3 Posture Assessment

- Observational analysis
- New York Posture Rating Test

4.4 Specific Postural Measures

- Scapular protraction
- Anterior cervical tilt

4.5 Range of Motion

Measured using a goniometer (shoulder and cervical region)

4.6 Quality of Life

- SF-12 Health Survey
- BREAST-Q

4.7 Sleep Quality

Pittsburgh Sleep Quality Index (PSQI)

5. Intervention

Treatment will begin in the first postoperative week with physician approval.

- Frequency: 3 sessions/week
- Duration: 4 weeks
- Session length: 40–60 minutes

Week 1:

Postural awareness, isometric activation, breathing exercises

Week 2:

Postural correction, stretching, theraband exercises

Week 3:

Functional posture training, stabilization exercises

Week 4:

Coordination and strengthening, daily activity integration

6. Conventional Therapy

- TENS (20 minutes, cervical region)
- Cold application (5–10 minutes)

7. Manual Therapy

- Myofascial release
- Scar massage

8. Home Exercise Program

Participants will perform exercises 2–3 times daily (10–15 repetitions).

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STATISTICAL ANALYSIS PLAN

1. Overview

This Statistical Analysis Plan defines the methods for analyzing study outcomes.

2. Software

Statistical analyses will be performed using SPSS.

3. Data Handling

- Continuous variables: mean ± standard deviation
- Categorical variables: frequency and percentage

4. Normality Testing

Shapiro-Wilk test will be used.

5. Between-Group Comparisons

- Independent t-test (normal distribution)
- Mann-Whitney U test (non-normal distribution)

6. Within-Group Comparisons

- Paired t-test
- Wilcoxon signed-rank test

7. Significance Level

$p < 0.05$ will be considered statistically significant.

8. Missing Data

Missing data will be handled using appropriate statistical methods (e.g., last observation carried forward if applicable).