

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical Trail of effect of exercise (resistance-core stability) on muscle strength, balance and core stability in women with breast cancer and healthy women

#### Protocol summary

##### Summary

**Objectives:** The purpose of this study was to determine the effect of 6 weeks of selected exercise on muscle strength, balance and core stability in women with breast cancer and healthy women. **Design:** This quasi-experimental study included 120 women in five groups, supervised resistance, supervised combination and home-base resistance and patient control (each n = 25) and healthy controls groups (n = 20) who were randomly selected and was performed at the Cancer Research Center of Isfahan University of Medical Sciences. The study was at the Phase 3 and single Blinded. **Setting and conduct:** After reviewing the 1230 cases and completion of inform consent by patients, qualified samples, initial assessment was carried out and after the 6 week, post - test was done. **Participants:** The main inclusion criteria were aged 29 to 65 years, diagnosed with breast cancer, the completion of treatment period in the 6 previous months. The main exclusion criteria were injury, onset or increased pain during exercise and disease recurrence. **Interventions:** Home based and supervised resistance training groups were done 13 exercises with theraband and supervised combination training group were done 15 exercises with theraband, medicine ball and their body weight, for 6 weeks. Each session lasted 90 minutes. Disease and the healthy control groups had no regular physical activity during the intervention. **Main outcome measures:** Primary outcomes were included muscle strength, balance, core stability and secondary outcomes were included fatigue, quality of life, lymphedema, pain, mood and fall risk.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011426008N1**

Registration date: **2016-07-28, 1395/05/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-28, 1395/05/07

##### Registrant information

###### Name

bahare mahmudieh

###### Name of organization / entity

university of tehran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 4443 2933

###### Email address

baharemahmudieh@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2015-05-18, 1394/02/28

##### Expected recruitment end date

2015-07-21, 1394/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical Trail of effect of exercise (resistance-core stability) on muscle strength, balance and core stability

in women with breast cancer and healthy women

4023085

## Public title

The effect of exercise in women with breast cancer

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: Aged 29 to 60 years; Diagnosed with breast cancer stage I to III; Mastectomy in at least the last 12 months; Course of radiation-therapy and chemotherapy are completed; No new rehabilitation in upper and lower body (6 months before the diagnosis of breast cancer); No any type of breast reconstruction; Without regular exercise or less than 2 sessions training per week in the last 6 months. Exclusion criteria: No participation in the Post-test or no continue exercise program; No participation in two consecutive sessions or 3 non-consecutive sessions; Injury, onset or increased pain during exercise; Disease recurrence.

## Age

From **29 years** old to **65 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

University of Tehran

##### Street address

Kish International Campus, Univesity of Tehran,  
Mirmohanna Boulevard, Kish Island, Iran

##### City

kish Island

##### Postal code

55665-79416

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Breast Cancer

#### ICD-10 code

C50.9

#### ICD-10 code description

Breast, unspecified

## Primary outcomes

### 1

#### Description

Upper extremity muscle strength

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Muscle strength in shoulder abduction, shoulder flexion and shoulder external rotation with hand-held dynamometry (Lafayette Manual Muscle Test System)

### 2

#### Description

Central Stability (Trunk Muscle Endurance)

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Core Stability Tests (Beiring-Sorensen Test, McGill Test, Trunk Flexion Test)

### 3

#### Description

Static balance

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Functional tests in Static balance: Single Leg, Balance Error Scoring System.

### 4

#### Description

Dynamic balance

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Functional tests in dynamic balance: Four Square Step Test, Timed 360° Turn, Timed Up & Go.

### 5

#### Description

Lower extremity muscle strength

#### Timepoint

Before and 6 weeks after intervention

## Method of measurement

Muscle strength in hip abduction, hip flexion and knee extension with hand-held dynamometry (Lafayette Manual Muscle Test System)

## Secondary outcomes

### 1

#### Description

Arm Lymphedema

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Forearm circumference measurements

### 2

#### Description

Shoulder girdle function

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Disability of arm, shoulder and hand (Dash) Questionare

### 3

#### Description

Fear of falling

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Fall Efficacy ScaleInternational (FES-I)

### 4

#### Description

Profile of Mood States

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Profile of Mood State questionnaire (POMS)

### 5

#### Description

Fatigue

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

Piper questionnaire

### 6

#### Description

Quality of Life

#### Timepoint

Before and 6 weeks after intervention

#### Method of measurement

National Medical Center and Beckman Research Institute

## Intervention groups

### 1

#### Description

In the supervised resistance intervention group, exercise protocol was consisted of resistance training (upper body, lower body). Supervised intervention was included bench press, shoulder press, rowing, pull down, biceps curl, triceps extension, Leg curl, Leg extension, Leg press, Lange, calf strengthening, abductions and Adduction hip. Intervention was performed for 6 weeks, 3 sessions a week and each session lasts up to 1.5 hours. Each session included 10 minutes warm up and 5 minutes cool down.

#### Category

Other

### 2

#### Description

In the home-based intervention group resistance, exercise protocol was consisted of resistance training (upper body, lower body). Unsupervised Intervention was included bench press, shoulder press, rowing, pull down, biceps curl, triceps extension, Leg curl, Leg extension, Leg press, Lange, calf strengthening, abductions and Adduction hip. Intervention was performed for 6 weeks, 3 sessions a week and each session lasts up to 1.5 hours. Each session included 10 minutes warm up and 5 minutes cool down.

#### Category

Other

### 3

#### Description

In the combination exercise, intervention group, combination of selected resistance training and balance and core stability training under the supervision of an experienced that was done. Intervention was performed for 6 weeks, 3 sessions a week and each session lasts up to 1.5 hours. Each session included 10 minutes warm up and 5 minutes cool down.

#### Category

Other

### 4

#### Description

The patients and healthy control groups had their daily activities and did not participate in any exercise program during the intervention period.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Şeyedoshohada Hospital in Isfahan  
**Full name of responsible person**  
Doctor Hamid Emami  
**Street address**  
Seyedoshohada Hospital, Pole Shiri Street, Isfahan,  
Iran  
**City**  
Isfahan

+98 76 4443 0055  
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**Email**  
baharemahmudieh@ut.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kish International Campus University of Tehran  
**Full name of responsible person**  
Reza Nuri  
**Street address**  
Kish International Campus, University of Tehran,  
Mirmohanna Boulevard, Kish Island, Iran  
**City**  
Kish Island

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kish International Campus University of Tehran

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
University of Tehran  
**Full name of responsible person**  
Bahare Mahmudieh  
**Position**  
Phd Candidate  
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Kish International Campus, University of Tehran,  
Mirmohanna Boulevard, Kish Island, Iran  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*