

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

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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
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Seyedoshohada Hospital, Pole Shiri Street, Isfahan,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kish International Campus University of Tehran
Full name of responsible person
Reza Nuri
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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

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Person responsible for updating data

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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