

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Evaluation of Effects of Home Based Exercise on the Quality of Life of Breast Cancer Survivors in Clinical Trial

Protocol summary

Study aim

Determine the effect of a home-based exercise on quality of life in breast cancer patients

Design

In this study, 84 breast cancer patients will randomly allocated into control or exercise group. Exercise group will get under a 3-month exercise group. Quality of life will be assessed before and three months after the intervention.

Settings and conduct

This study will be done in the Breast Diseases Clinic in Motamed Cancer institute. Blinding is not a feasible approach in that study.

Participants/Inclusion and exclusion criteria

Breast cancer patients who have less than 55 years of age and in the stage I or II will be included in the study. Patients who have regular exercise or disabling diseases will be excluded

Intervention groups

A home-based exercise for 3 months

Main outcome variables

quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140810018746N1**

Registration date: **2018-01-08, 1396/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**

Update count: **0**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 82880

Email address

nasim.khosravi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of Effects of Home Based Exercise on the Quality of Life of Breast Cancer Survivors in Clinical Trial

Public title

Home-based exercise and quality of life in breast cancer patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

breast cancer stage I and II Age between 18-55 years

Exclusion criteria:

Having regular physical activity Having disease which prevent them to engage in exercise

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization with size of 4 was used. participants in each block were randomly assigned into exercise or control group by flipping the coin. Concealed allocation was not considered .

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Breast Cancer Research Center

Street address

No 146, Gandhi st, Vanak Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2015-10-11, 1394/07/19

Ethics committee reference number

IR.ACECR.IBCRC.REC.1394.11

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50.919

ICD-10 code description

Malignant neoplasm of unspecified site of unspecified female breast

Primary outcomes

1

Description

quality of life

Timepoint

Before and after intervention

Method of measurement

EORTC-QLQ and EORTC-BR23 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Home-based exercise. An intervention combined of walking, stretch and balance exercise which will be done within 3 months.

Category

Lifestyle

2

Description

Control group: usual care

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast cancer research center

Full name of responsible person

Shahpar Haghighat

Street address

Nazari St, Aboreihan St, Enghelab st, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and

research

Full name of responsible person

Alireza Vajhi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Shahpar Haghighat

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Other areas of specialty/work

Epidemiology

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Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Nasim Khosravi

Position

research assistant

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available