Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+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, Gandi 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
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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 updating data

Contact

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Full name of responsible person
Nasim Khosravi

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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