

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The impact of an exercise program on coping self-efficacy and quality of life in breast cancer patients.

Protocol summary

Study aim

Determine the impact of an exercise program on coping self-efficacy and quality of life of breast cancer patients

Design

A clinical trial with a control group, one-sided blind, randomized, is performed on 60 patients. A coin toss is used for randomization.

Settings and conduct

Randomized, one-sided, blinded clinical trial with before and after intervention design in breast cancer survivors referring to Behshahr Oncology Center-Iran, who has a medical record. The number of samples is selected by available sampling method and based on simple randomization, they are placed in two exercise and control groups. In relation to the research, information is provided for the participants. The informed consent form is completed. The intervention group will receive a 12-week supervised exercise program. The control group only performed their normal physical activities.

Participants/Inclusion and exclusion criteria

Eligibility criteria: Patients 15 -75 yr. with grade I-III; Completed intensive breast cancer treatment; Recommendation from the oncologist; Three weeks after chemotherapy or R/T; Exclusion criteria: Having an acute illness or a serious psychiatric illness; Patients with recurrence or metastasis; Suffering from other diseases; Ataxia

Intervention groups

The intervention group will receive a exercises program including 12-week supervised exercises developed by a exercise physiologist, 3 days a week for 50-60 minutes. This program will include aerobic exercises, resistance exercises, flexibility exercises and balance exercises. The control group only performed their normal physical activities and were provided with educational brochures about routine care.

Main outcome variables

quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230919059471N1**

Registration date: **2023-10-28, 1402/08/06**

Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**

Update count: **0**

Registration date

2023-10-28, 1402/08/06

Registrant information

Name

Faridokht Yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of an exercise program on coping self-efficacy and quality of life in breast cancer patients.

Public title

The impact of exercise on breast cancer quality of life

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 15 to 75 who have been diagnosed with grade I to III breast cancer based on pathology; Have completed intensive breast cancer treatment (including surgery, chemotherapy, or radiation therapy); Have the recommendation and permission to participate in the exercises program from the oncologist; Three weeks after chemotherapy or radiation therapy; Less than 6 months have passed since chemotherapy or radiation therapy; Patients should be able to do aerobic and resistance exercises.

Exclusion criteria:

Having an acute illness or a serious psychiatric illness; Patients with recurrence or metastasis; Suffering from other diseases or other continuous treatments such as asthma or osteoporosis and heart disease and blood pressure; Anemia with a decrease in red blood cells; Ataxia (imbalance in walking); Patients have not been approved by the oncologist for exercise.

Age

From **15 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are selected using available sampling method and are placed in two exercise and control groups based on simple randomization. Participants are randomized by random assignment through a coin toss into two exercise and usual care groups. The face of the coin (i.e. lion = control group), and the back of the coin (i.e. line = intervention group) are considered.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the medical personnel (doctors, nurses, physiotherapists, etc.) who are responsible for the care of the patients, and those who analyze the data and evaluate the outcome, and those who prepare the draft of the article; They are blinded to study group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, an exercise program includes a 12-week supervised exercise program set by an exercise physiologist. This program will include aerobic exercises, resistance exercises, balance exercises and flexibility exercises in a combined manner and in a regular sequence, taking into account the guidelines of the American College of Sports Medicine (ACSM). The implementation of the exercise program is carried out by an exercise coach who knows the details of exercise in breast cancer. Timing, duration of exercise, intensity of exercise and type of combined exercises are determined separately.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University-Najafabad branch

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Islamic Azad University, Najaf Abad branch, University Boulevard

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Province

Isfahan

Postal code

8514143131

Approval date

2023-10-05, 1402/07/13

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1402.199

Health conditions studied**1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

The coping self-efficacy score in the questionnaire has 3 dimensions (stopping emotions and unpleasant thoughts), (problem-oriented strategy), and (receiving support from family and friends). The total scores for each item of that dimension are calculated together. Respondents must answer at least 80% of the scale items.

Timepoint

Measuring coping self-efficacy at the beginning of the study (before the start of the intervention) and at the end of the intervention (12 weeks after the start of the study).

Method of measurement

Chesney et al. Coping Self-Efficacy Questionnaire (CSES)

2

Description

The quality of life score of breast cancer patients in the QLQ-Br23 questionnaire includes 23 items that are divided into two dimensions. The first dimension includes four functional scales, (sexual function, sexual pleasure, and future perspective); While the second dimension includes four symptom scales (systemic treatment side effects, breast symptoms, arm symptoms, hair loss discomfort). Each item is scored from 1 to 4 points. Scores are converted to a 0-100 score after linear transformation. The highest scores correspond to better performance (except for sexual performance and sexual pleasure). On the other hand, higher scores on the symptom scale dimension are associated with higher persistence of signs and symptoms.

Timepoint

Measuring quality of life at the beginning of the study (before the start of the intervention) and at the end of the intervention (12 weeks after the start of the study).

Method of measurement

Breast Cancer Quality of Life Questionnaire (EORTC-QLQ-BR23)

Secondary outcomes

1

Description

Reduce anxiety

Timepoint

End of the intervention (after 12 weeks from the start of the intervention)

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Intervention groups

1

Description

Intervention group: intervention group: exercise group; They receive an exercise program including 12-week supervised exercises developed by a sports physiologist, 3 days a week for 50-60 minutes. This program will include aerobic exercises, resistance exercises, flexibility exercises and balance exercises. Aerobic exercise class consists of three parts: warm-up, aerobic exercises, and cool-down.

Category

Rehabilitation

2

Description

Control group: Patients in the control group only do their normal physical activities and are provided with educational brochures about routine care.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Sciences (Khatam Al Anbia hospital, Behshahr)

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

It will be available only to researchers working in

academic and scientific institutions.

Under which criteria data/document could be used

Researchers working in academic and scientific institutions at the rank of assistant professor and higher.

From where data/document is obtainable

Islamic Azad University, Najafabad branch

What processes are involved for a request to access data/document

Apply by email

Comments