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)
Phone
+98 31 4229 8064
Email address
faridokht.yazdani@iau.ac.ir

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

Street address

Islamic Azad University, Najaf Abad branch, University Boulevard

City

Najafabad

Province

Isfehan

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)
Full name of responsible person
Afshin Amirkhanlou
Street address
Abbas Abad Road, Imam Reza Boulevard, Motahar
City
Behshahr
Province
Mazandaran
Postal code
0000000000
Phone
+98 11 3457 9001
Email
shirinkhheadnurse@gmail.com
Web page address
https://h-khatam.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mehdi Rafiei
Street address
Islamic Azad University, Najaf Abad branch, University Blvd.
City
Najafabad
Province
Isfehan
Postal code
8514143131
Phone
+98 31 4229 2305
Email
info @ iaun.ac.ir
Web page address
https://iaun.iau.ir/
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
Islamic Azad University

Full name of responsible person
Faridokht Yazdani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Islamic Azad University, Najaf Abad Branch, University Blvd

City
Najafabad

Province
Isfehan

Postal code
8514143131

Phone
+98 31 4229 2583

Email
faridokht.yazdani@yahoo.com

Web page address
https://research.iaun.ac.ir/pd/yazdani-nurse/indexfa.php

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Faridokht Yazdani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Phone
+98 31 4229 2583

Email
faridokht.yazdani@yahoo.com

Web page address
https://research.iaun.ac.ir/pd/yazdani-nurse/indexfa.php

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Faridokht Yazdani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Postal code
8514143131

Phone
+98 31 4229 2583

Email
faridokht.yazdani@yahoo.com

Web page address
https://research.iaun.ac.ir/pd/yazdani-nurse/indexfa.php

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