

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effectiveness of physical activity at home with group physical activity in anxiety and quality of life of breast cancer patients

Protocol summary

Study aim

Comparing the average score of quality of life and anxiety of breast cancer patients in the exercise group at home with the exercise group in centers (group exercise)

Design

The clinical trial has a control group with parallel groups, randomized with software without blinding and a total sample size of 70 people and 35 people in each group. A simple randomization method was used with the help of computer

Settings and conduct

Patients with breast cancer referred to Imam Reza Kermanshah Hospital who meet the inclusion criteria are randomly divided into two groups (Simple randomization with computer-aided random number table) the sample size is 70 people, (35 person in each). The control groups received the physical activity protocol in written form and received training about it, while the intervention group exercised in a group with the same protocol in the designated place.

Participants/Inclusion and exclusion criteria

Having breast cancer; Completion of chemotherapy; Not taking drugs for anxiety disorders; Not suffering from other psychological and personality disorders; Age range from 15 to 50 years; contraindication for physical activity; Failure to simultaneously participate in other sports courses

Intervention groups

In this research, the exercise protocol includes a combined training course (aerobic-resistance) based on which the patients will participate in three sessions per week for 8 weeks. The control group will do physical activity at home individually and the intervention group will do physical activity in a group at the designated place. The experimental and control group performed concurrent training for eight weeks (three days per week), including resistance training with 60-75 percent of a maximal repeat and aerobic exercise with 60-75 percent of maximum heart rate.

Main outcome variables

Anxiety score with Beck questionnaire and quality of life score with QLQ-C30 questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230112057116N1**

Registration date: **2023-09-24, 1402/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Peigham Heidarpour

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

2023-09-06, 1402/06/15

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of physical activity at home with group physical activity in anxiety and quality of life of breast cancer patients

Public title
physical activity in breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
breast cancer patients Completion of chemotherapy
Exclusion criteria:
Taking psychiatric and psychoactive drugs
Simultaneously participating in other sports courses, performing regular exercise and therapeutic interventions simultaneously with research Physical problems that prevent physical activity (such as musculoskeletal disorders), physical activity contraindication Suffering from other psychological and personality disorders

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with a table of random numbers

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 school of medical education of shahid Beheshti University of medical sciences

Street address

Valiasr street
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2023-05-21, 1402/02/31
Ethics committee reference number
IR.SBMU.SME.REC.1402.027

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C00-C75

ICD-10 code description

C00-C75

Primary outcomes

1

Description

anxiety score based Beck questionnaire

Timepoint

pre and post intervention

Method of measurement

Beck anxiety questionnaire

2

Description

quality of life score

Timepoint

pre and post intervention

Method of measurement

quality of life of cancer patients(QLQ-C30)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group physical activity

Category

Behavior

2

Description

Control group: individual physical activity in home

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza hospital Kermanshah University of medical sciences

Full name of responsible person

Peigham Heidarpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

research and technology affair of Shahid Beheshti University of medical sciences

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7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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

Shahid Beheshti University of Medical Sciences

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Peigham Heidarpour

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

primary outcome of participants, analysis of data , ,
article publication

When the data will become available and for how long

6 months after study publication

To whom data/document is available

researcher in medical universities

Under which criteria data/document could be used

Individuals or academic organizations can use the results
of this study by respecting the moral rights.

From where data/document is obtainable

peigham.heidarpoor@yahoo.com

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

6 months after article publication via email

Comments