Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ofcomputer

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,(35person 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

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Peigham Heidarpoor
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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 commitee of school of medical education of shahid Beheshti University of medical sciences

Street address

Valiasr street

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Province

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
research and technology affair of Shahid Beheshti University of medical sciences

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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 Heidarpoor

Position
assisstant professor

Latest degree
Specialist

Other areas of specialty/work
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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