

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 16 weeks of concurrent home-based exercise on some physiological, psychological, functional, and anthropometric indices in females with breast cancer during the COVID-19 pandemic

Protocol summary

Study aim

The effect of 16 weeks of concurrent home-based exercise on cortisol levels, resting heart rate, quality of life, cancer-related fatigue, body image, cognitive function, cardiovascular endurance, upper and lower body strength, flexibility, and body composition

Design

A randomized clinical trial with a control group, parallel groups on 28 breast cancer patients, block randomization via www.randomization.com

Settings and conduct

This study is conducted at Ilam University with the cooperation of Ilam University of Medical Science. After selecting the participants according to inclusion criteria, the study variables are measured, and then, the experimental group will perform 16 weeks of exercise interventions at home supervised by a specialist via video call. After the termination of the intervention, the variables are measured again. According to the nature and the objectives of the study, blinding will not be applied.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosed with breast cancer by a specialist No less than 3 months and more than 5 years passed from the last cancer-specific treatment Exclusion Criteria: Cardiovascular and pulmonary disease Musculoskeletal disorder

Intervention groups

Intervention group: this group will perform home-based concurrent training 2 times per week for 16 weeks. The training program consists of 3 phases including A (4 weeks), B (6 weeks), and C (6 weeks). Each training session consists of body-weight resistance training followed by step aerobic. During 16 weeks, the intensity, time, and volume of training will increase gradually. Control group: this group will have a normal life during the study

Main outcome variables

Changes in cortisol levels, resting heart rate, quality of life, cancer-related fatigue, body image, cognitive function, cardiovascular endurance, upper and lower body strength, flexibility, and body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N4**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Ehsan Amiri

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 8428

Email address

e.amiri@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-26, 1400/09/05

Expected recruitment end date

2021-12-11, 1400/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of 16 weeks of concurrent home-based exercise on some physiological, psychological, functional, and anthropometric indices in females with breast cancer during the COVID-19 pandemic

Public title
Exercise and Breast Cancer During COVID-19 Pandemic

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with breast cancer by a specialist No signs of relapse or tumor metastasis No less than 3 months and more than 5 years passed from the last cancer-specific treatment (chemotherapy or radiotherapy) Not participating in regular exercise training within last 6 months
Exclusion criteria:
Cardiovascular and pulmonary diseases Alcohol and other kinds of drug addiction Musculoskeletal disorder Pregnancy Refusal to give informed consent

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, permuted block randomization via the www.randomization.com website will be used. To do so, first, a unique number will be allocated to each subject as the identifier code and, a 28-digit sequence (equal to sample size) will be created. Then, treatment labels including 1) Exercise group; 2) Control group will be entered in the relevant section on the website. After defining the treatment groups and to avoid potential problems associated with equal block sizes, permuted block randomization with different block sizes will be applied. In this case, by knowing the sample size, the block sizes will be unequal and a multiple of the number of treatment groups (for example, block sizes of 2, 4, or 6). The website has the ability to randomly specify the sequence of blocks with different sizes. In the final step and upon performing the 'Generate Plan' on the website, all subjects will be randomly assigned to blocks of different sizes that already have a random sequence. Finally, the group (treatment) of each subject will be

specified by the use of the identifier code and checking out the blocks.

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

Research Ethics Committees of Kermanshah Razi University

Street address

Deputy of Research and Technology, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.RAZI.REC.1400.068

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

Change in serum levels of Cortisol

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of blood sample and ELISA method

2

Description

Change in quality of life

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

Cancer quality of life questionnaire (EORTC-QOQ-C30)

3

Description

Changes in cancer-related fatigue

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of Functional Assessment of Chronic Illness Therapy- Fatigue Scale (Version 4)

Secondary outcomes

1

Description

Changes in body image

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of standard cancer-specific 10-item body image scale

2

Description

Changes in cardiovascular endurance

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of sub-maximal 1-mile (1600 m) walking Rockport test

3

Description

Changes in body composition

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of bioelectrical impedance analysis

4

Description

Changes in cognitive function

Timepoint

Before starting the intervention, and 16 weeks after starting the intervention

Method of measurement

By the use of Cognitive Failure Questionnaire (25 items)

Intervention groups

1

Description

Intervention group: This group performs home-based concurrent training including body-weight resistance training and step aerobic 2 times per week for 16 weeks. The training program consists of 3 phases including phase A (4 weeks), phase B (6 weeks), and phase C (6 weeks). The training variables including the intensity, time, and volume of training will gradually increase within 16 weeks. The training type will also change in different phases of the program. The intensity of aerobic and resistance training will be controlled by the use of the Borg Scale and monitoring the heart rate. In each session, participants first perform body-weight resistance training which includes specified cycles with defined rest periods, and then, they do step aerobic according to the instructions. 10 min of warm-up and 10 min of cool-down will be devoted to each session.

Category

Other

2

Description

Control group: this group has the the normal life during the study

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic

Full name of responsible person

Dr. Alireza Esmaeili

Street address

Second Floor, Kimia Building, Motahar Ave, 22 Bahman St

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esmaeili-a@medilam.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Dr. Farzad Veysi

Street address

University St, Taq-e-Bostan

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veysi@razi.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Razi University

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**

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

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Position

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data are shared after the de-identification of the participants

When the data will become available and for how long

3 months after publication

To whom data/document is available

All individuals upon formal request

Under which criteria data/document could be used

Data sharing requests are accepted for any purposes

From where data/document is obtainable

To obtain any data/document, please send an e-mail to Ehsan Amiri, a faculty member at Razi University, through the following e-mail address: e.amiri@razi.ac.ir

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

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail

Comments