Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 differents 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

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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
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Sponsors / Funding sources

1

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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
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
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Full name of responsible person
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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