Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of 12 weeks of continuous training and Interval training on oxidative stress and DNA damage in breast cancer survivors

Protocol summary

Study aim
The effect of 12 weeks continuous moderate training and High intensity interval training on biomarkers of oxidative stress and DNA damage in women rescued from breast cancer

Design
The present study was an applied and quasi-experimental study that was performed in two intervention groups and one control group Randomization Method: Simple Randomization, Randomization Unit: Individual, Randomization Tool: Random Number Table was performed on 45 postmenopausal women

Settings and conduct
This research is a quasi-experimental method that will be performed in two intervention group and a control group.The statistical population of this study includes postmenopausal women after at least six months of terminaion of their treatment for breast cancer. Two groups of continuous exercise with moderate intensity and intermittent exercise with high intensity performed exercise for 12 weeks (36 sessions). Each training session is performed using an ergometer Monark 894E for 20-30 minutes and under the full supervision of the physician.The control group did not perform any exercise intervention.Address: (Nutrition Clinic) No.68, Gulfam Alley, Nelson Mandela Street,Tehran

Participants/Inclusion and exclusion criteria
Admission requirements: 1. Definitive diagnosis of the disease and the history of cancer based on the records. Placement in stage one, two or three diseases and completion of treatment courses (breast resection surgery, chemotherapy, radiation therapy) for at least the last 6 months. Menopause 4. Body mass index more than 25 kg per square meter 5. Body fat more than 30%. Exclusion criteria: 1.Cardiovascular diseases 2. Diabetes 3. Thyroid diseases 4.smoking

Intervention groups
Continuous training group of 15 people and interval training group of 15 people and control group of 15 people

Main outcome variables
oxidative stress biomarkers:GPX,SOD,TAC,8-OHdG

General information

Reason for update
Change the title of the article and Adding interval training to the training protocol

Acronym

IRCT registration information
IRCT registration number: **IRCT20220418054577N1**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **prospective**

Last update: **2022-08-17, 1401/05/26**
Update count: **1**

Registration date
2022-05-14, 1401/02/24

Registrant information

Name
Sahabeh Mahdian

Name of organization / entity
University of tehran(physical education and sport)

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-22, 1401/05/31

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12 weeks of continuous training and Interval training on oxidative stress and DNA damage in breast cancer survivors

Public title

The effect of 12 weeks of continuous training and Interval training on oxidative stress and DNA damage in breast cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

at least 6 months of complete discontinuation of breast cancer treatment permission of the physician to participating in the research women should be on the same levele in terms of health،life ، nutrition ،duration of illness body mass index shoul be above 25kg/m2.weight of body fat more than 30% ability to exercise with the approval of an oncologist and cardiologist menopause

Exclusion criteria:

Cardiovascular disease Diabetes disease Thyroid disease Smoking

Age

From **54 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple Randomization, Randomization Unit: Individual, Randomization Tool: Random Number Table

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 the Institute of Physical Education and Sports Sciences

Street address

No 3, Fifth Alley, Mir Emad St, Ostad Motahhari St, Tehran

City

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Province

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Postal code

1587958711

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.UT.SPORT.REC.1400.036

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

Serum SOD levels

Timepoint

48 hours before and after the desired interventions

Method of measurement

Blood sampling using ELISA method

2

Description

Serum GPX levels

Timepoint

48 hours before and after the desired interventions

Method of measurement

Blood sampling using ELISA method

3

Description

Serum TAC levels

Timepoint

48 hours before and after the desired interventions

Method of measurement

Blood sampling using ELISA method

4

Description
Serum MDA levels
Timepoint
48 hours before and after the desired interventions
Method of measurement
Blood sampling using ELISA method

5

Description
Serum 8-OHdg levels
Timepoint
48 hours before and after the desired interventions
Method of measurement
Blood sampling using ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Medium intensity continuous training: During the research, this group will perform three sessions of moderate intensity continuous training for 12 weeks and a week. All aspects of this study are in line with the basic principles of the Helsinki Declaration. The present study is an applied and quasi-experimental method that is performed in two interventions group and a control group. The statistical population of this study includes 45 postmenopausal women after at least six months of termination of their treatment for breast cancer. After the initial assessments, the subjects are randomly divided into three groups of 15 people with continuous training and interval training and the control group. The subjects of the continuous training are subjected to sports intervention for 12 weeks. Each training session is performed using the Ergometer Monark 894E bicycle for 20-30 minutes and under the full supervision of the instructor and physician. At each training session, subjects' heart rate information is monitored by a Finnish-made Polar heart rate monitor and the exercise pressure perception rate (Borg scale RPE scale 6 to 20) is monitored and recorded regularly throughout the time.
Category
Rehabilitation

2

Description
Control group:The control group consists of 15 postmenopausal women who are followed during this period and do not do any sports intervention and only continue their daily activities and routine medical care.
Category
Lifestyle

3

Description
Intervention group: High intensity interval training:During the research, this group will perform three sessions of high-intensity interval training for 12 weeks.All aspects of this study are in accordance with the basic principles of the Declaration of Helsinki. The current research is applied and semi-experimental in two intervention groups and one control group. The statistical population of this research includes 45 menopausal women after at least six months of breast cancer treatment. After the initial evaluations, the subjects are randomly divided into three groups of 15 people: continuous exercise, intermittent exercise group, and control group.Each exercise session is done using an ergometer Monark 894E bicycle for 20-30 minutes under the full supervision of a trainer and doctor. In each training session, the subject's heart rate information is recorded regularly by means of Polar heart rate monitor made in Finland and the level of perception of training pressure (by Borg RPE scale 6 to 20) during the entire monitoring time. The main training in this group is in At first (the first week), there were four training stages (30 seconds of pedaling and 2 active rests) in a row. The number of steps increases every week until it reaches 7 steps in the fourth week (one step was added every week until the fourth week), from the fourth week to the 12th week, the number of steps is maintained at the same number (7 steps).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
clinic of nutrition
Full name of responsible person
sahabeh mahdian
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Sponsors / Funding sources

1

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Name of organization / entity

Private

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
Private

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Ph.D.

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
No - There is not 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
Patients' personal information is confidential. But access to research methods and information obtained from research is not an obstacle
When the data will become available and for how long
Access period starts 6 months after the results are published "
To whom data/document is available
All students and enthusiasts
Under which criteria data/document could be used
To use the data to conduct research in this area
From where data/document is obtainable
Authors of this article: sahabeh_mahdiann@yahoo.com
What processes are involved for a request to access data/document
By sending an email to the author will cooperate with the applicant at the earliest opportunity
Comments