

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 termination 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)

Phone

+98 21 8860 9716

Email address

sahabeh_mahdiann@yahoo.com

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

tehran

Province

Tehran

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

Street address

Unit 7 No, 68(Doctors Building), Gulfam Alley, Jordan St, Tehran, iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Sahabeh mahdian

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Unit 7, No11, Baharan St, Shiraz South St, Mollasadra St, Vanak Sq, Tehran

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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

Faculty of Physical Education and Sport Sciences - University of Tehran

Full name of responsible person

parisa pournemati

Position

lecture university

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Latest degree

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Name of organization / entity

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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