

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect of 12 weeks continues and interval aerobic training on serum level of irisin, leptin, adiponectin, functional capacity and body composition in women breast cancer patients after completed treatment

Protocol summary

Study aim

Comparison effect of 12 weeks continues (CA) and interval aerobic training (HIT) on serum level of irisin, leptin, adiponectin, functional capacity and body composition in women breast cancer survivors.

Design

Simple randomized, two training groups (continues aerobic group and high interval aerobic training group) and control group.

Settings and conduct

The sample of the study was selected from the population of the patients referred to Imam Hossein and Naft Hospitals in Tehran. After reviewing more than 300 patient records, approximately 90 patients who were eligible for the study were selected. After contacting patients and briefly explaining how the research was performed, 50 patients were invited to the hospital and the stages of the research were fully explained. At the end, 39 subjects, tending to participate in the study. They were divided into 3 groups: 1- periodic aerobic exercise, 2- continuous aerobic exercise and 3- control.

Participants/Inclusion and exclusion criteria

Women treated for breast cancer; age ranging from 30 to 60 years old, subject to rehabilitation after completion of chemotherapy or surgery or radiation therapy (3 to 6 months after treatment); no metastasis; no abnormalities and diseases; chronic diseases such as diabetes, heart and respiratory diseases, and diseases that prevent physical activity and exercise have been the same during the past 6 months.

Intervention groups

2 intervention groups (continues aerobic group and high interval aerobic training group) and 1 control group

Main outcome variables

Serum level of irisin, leptin and adiponectin; Functional capacity and Body composition.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200208046418N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **retrospective**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

somayeh nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3452 0750

Email address

s.f.nazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

2019-04-09, 1398/01/20

Actual recruitment end date

2019-10-07, 1398/07/15

Trial completion date

2019-10-07, 1398/07/15

Scientific title

Comparison the effect of 12 weeks continues and interval aerobic training on serum level of irisin, leptin, adiponectin, functional capacity and body composition in women breast cancer patients after completed treatment

Public title

The effect of exercise on breast cancer survivors

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of 30 to 60 years old Subjects being in rehabilitation after the end of chemotherapy or surgery or radiation therapy (3 to 6 months after treatment) The same phase of treatment Being inactive and the physical inactivity in the past 6 months.

Exclusion criteria:

Having metastases Abnormalities and chronic illnesses such as diabetes, heart and respiratory diseases, and diseases that prevent physical activity and exercise.

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **37**

Actual sample size reached: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by cards or envelopes shuffling.

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

Shahed University

Street address

Shahed University, Kharazmi St.

City

Karaj

Province

Alborz

Postal code

3197937551

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.SHAHED.REC.1389.051

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

D05

ICD-10 code description

Carcinoma in situ of breast

Primary outcomes

1

Description

Measurement of serum levels of Irizine

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

5 cc blood sampling for measurement of serum's Irizine level.

2

Description

Measurement of serum levels of Leptin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

5 cc blood sampling for measurement of serum's Iptin level,

3

Description

Measurement of serum levels of Adiponectin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

5 cc blood sampling for measurement of serum's adiponectin level,

4

Description

Functional capacity

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Functional Muscle Performance test (muscle performance) and modified balk test for aerobic power were used

5

Description

Body composition

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Body composition measurement by In body device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 12 weeks of high interval aerobic training, three times a week of 33 min running on treadmill in 4 interval of 4 min in high intensity (80 to 85% of peak heart rate) and interval with low intensity (60% of peak heart rate)

Category

Rehabilitation

2

Description

Intervention group 2: continues aerobic training group contributed in 12 weeks of continues aerobic training, three times a week of 37 min running intensity of 60% of peak heart rate on treadmill.

Category

Rehabilitation

3

Description

Control group: no intervention on this period of time

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Naft Hospital

Full name of responsible person

Dr Behrooz Gharib

Street address

Sarhang Sokhai Street, Hassan Abad Square

City

Tehran

Province

Tehran

Postal code

11367-74114

Phone

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Email

gharib.dehrooz@yahoo.com

Web page address

http://teh.piho.ir

2

Recruitment center

Name of recruitment center

Emam Hosien Hospital

Full name of responsible person

Ali Ghanbari Motlagh

Street address

Madani Street

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Tehran

Province

Tehran

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1617763141

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+98 21 7755 8004

Email

agmotlagh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Vice chancellor for research, Shahed University

Street address

Khalige Fars highway, Shahed University

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 5080

Email

publicrelation@shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed 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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Somayeh Nazari

Position
University student

Latest degree
Master

Other areas of specialty/work
Physiology

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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

Yes - There is a plan to make this available

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

General information on the patients in descriptive statistics, method of work ranging from the beginning of the illness to the final stage in the dissertation and articles will be publish

When the data will become available and for how long

Every time articles are published.

To whom data/document is available

Everyone

Under which criteria data/document could be used

For future research use

From where data/document is obtainable

To the thesis author

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

If the person needs it for research as soon as possible

Comments