Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 envelops 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 lptin 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
+98 21 6670 0021
Email
gharib.dehrooz@yahoo.com
Web page address
http://teh.piho.ir

2

Recruitment center
Name of recruitment center
Emam Hosen Hospital
Full name of responsible person
Ali Ghanbari Motlagh
Street address
Madani Street
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+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

Academic

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