Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of concurrent resistance and aerobic training on salivary levels of pro-inflammatory and hormonal factors, sleep quality and quality of life in postmenopausal women with breast cancer

Protocol summary

Study aim
Determining the effect of concurrent training on salivary levels of IL-12, TNF-a, IL-12/ TNF-α, testosterone, cortisol, testosterone/ cortisol, sleep quality, quality of life and fitness in postmenopausal women with breast cancer

Design
Clinical trials with community based and pragmatic control group, with parallel groups, one blind, randomized

Settings and conduct
Exercises will be do at the Sports gym of the Physical Education Faculty of Razi University of Kermanshah

Participants/Inclusion and exclusion criteria
Have 30 to 70 years old. Have breast cancer. Survival from surgery and chemotherapy. Be Postmenopausal. Be at I,II stage of the disease. Have no inflammatory the gum and mouth disease.

Intervention groups
Groups include exercises and controls. The exercise group will perform the resistance training 2-3 sets 10-18 repetitions, with 50-70% 1RM and aerobic training with 50-70% maxHR and 12-14 degrees Borg scale, for 20-40 minutes for 8 weeks. The control group will be the same as their previous lifestyle.

Main outcome variables
Changes in Interleukin 12, TNF-a, Cortisol, Testosterone, Sleep Quality and Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181024041445N1**
Registration date: **2019-01-24, 1397/11/04**
Registration timing: **retrospective**
Last update: **2019-01-24, 1397/11/04**
Update count: **0**

Registration date
2019-01-24, 1397/11/04

Registrant information

Name
kheirollah yari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3427 6473

Email address
kyari@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-31, 1397/08/09

Expected recruitment end date
2018-11-14, 1397/08/23

Actual recruitment start date
2018-10-31, 1397/08/09

Actual recruitment end date
2018-12-24, 1397/10/03

Trial completion date
2019-03-11, 1397/12/20

Scientific title
Effect of concurrent resistance and aerobic training on salivary levels of pro-inflammatory and hormonal factors, sleep quality and quality of life in postmenopausal women with breast cancer

Public title
Effect of concurrent training on breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

30 to 70 years old Have breast cancer Survival from surgery and chemotherapy Be postmenopausal Be at I,II stage of the disease Have no inflammatory the gum and mouth disease

Exclusion criteria:

Have metastasized Have other underlying disease Do not have the ability to do sports

Age

From **30 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery

Blinding (investigator's opinion)

Single blinded

Blinding description

Subjects in control and exercise group

Placebo

Not used

Assignment

Parallel

Other design features

Measuring salivary levels of pro-inflammatory and hormonal agents

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Parastar

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.KUMS.1397.708

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

N60.09

ICD-10 code description

Solitary cyst of unspecified breast

Primary outcomes

1

Description

The effect of 8 weeks concurrent resistance and aerobic training on salivary levels of interleukin 12, TNF-a, cortisol, testosterone and quality of sleep and quality of life in postmenopausal women with breast cancer

Timepoint

Before and after 8 weeks of exercise

Method of measurement

Using ELISA kit and questionnaire and body composition analyzer

Secondary outcomes

1

Description

Changes in waist circumference, weight, body mass index, waist-hip ratio

Timepoint

Before and after 8 weeks of exercise

Method of measurement

Body composition analyzer

Intervention groups

1

Description

Intervention is exercise training that will performed, resistance training 3-2 sets of 10-18 repeated, with 70-50% of 1RM and aerobic exercise with 50-70% maxHR and 12-14 degrees Borg scale, 20-40 minutes to 8 weeks.

Category

Lifestyle

2

Description

Control group:The control group will continue to lose its previous lifestyle without exercise training.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital oncology ward of Imam Reza
Full name of responsible person
Mehrdad Payandeh
Street address
Parastar
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royamomenpur@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Amir Abbas Monazzami
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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
Kermanshah University of Medical Sciences

Proportion provided by this source
1

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
Department of Physical Education Razi University
Full name of responsible person
Amirabbas Monazzami
Position
Assistant Professor
Latest degree
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Person responsible for updating data

Contact

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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
Yes - There is 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
Main outcomes and meanings and final charts
When the data will become available and for how long
2019-2
To whom data/document is available
It will be accessible to the public
Under which criteria data/document could be used
Inferential statistics
From where data/document is obtainable
E-mail to royamomenpur@gmail.com
What processes are involved for a request to access data/document
Send mail
Comments