

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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

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6714415333

Phone

+98 83 3426 2252

Email

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

Street address

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monazzami.amirabbas@gmail.com

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

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Biochemistry

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Person responsible for updating data

Contact

Name of organization / entity

Department of Physical Education Razi University

Full name of responsible person

Roya Moumenpour

Position

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

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