

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of 12 weeks of cyclic yoga with vitamin D supplementation on the expression of some genes involved in apoptosis and inflammatory status in women survivors from breast cancer

Protocol summary

Study aim

Evaluation of adding yoga with high and low dose of vitamin D supplementation on physical and mental rehabilitation of breast cancer survivors Evaluation of adding yoga with high and low dose of vitamin D supplementation on inflammatory status of breast cancer survivors

Design

This study is a randomized clinical trial with parallel groups and one-way blind performed on 30 breast cancer survivors and a simple block method was used for randomization (6 blocks). The present study has three experimental groups : high dose group of vitamin D (HVD), yoga group with high dose of vitamin D (Y-HVD), yoga group with low dose of vitamin Di (Y-LVD).

Settings and conduct

This research was conducted at Kharazmi University of Tehran in collaboration with Payam Yoga Center located in Gharb shahrak. Examiners and statistical analysts were blind to the groups. First, the subjects performed pre-tests and then they participated in yoga exercises for 12 weeks and at the same time received different doses of vitamin D based on the treating physician.

Participants/Inclusion and exclusion criteria

Completed chemotherapy and radiotherapy from 2 to 5 years ago, not having any acute medical disorders (cardiovascular diseases, diabetes), and not having any orthopedic conditions

Intervention groups

High dose of VD supplementation (HVD) group Yoga with a high dose of VD (Y-HVD) group Yoga with a low dose of VD (Y-LVD) group

Main outcome variables

The intervention are expected to modifying inflammatory levels of subjects. The intervention are expected to change the subject's mental and physical condition.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210726051993N2**

Registration date: **2022-02-27, 1400/12/08**

Registration timing: **retrospective**

Last update: **2022-02-27, 1400/12/08**

Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

Vahid Khedmati zare

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 6605 2670

Email address

amani_sadegh@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-13, 1399/01/25

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

2020-04-13, 1399/01/25

Actual recruitment end date

2020-04-29, 1399/02/10

Trial completion date

2020-09-05, 1399/06/15

Scientific title

The effect of 12 weeks of cyclic yoga with vitamin D supplementation on the expression of some genes involved in apoptosis and inflammatory status in women survivors from breast cancer

Public title

The effect of exercise training on the inflammation in breast cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer survivors Completed a course of chemotherapy and radiotherapy 35 to 55 years old women Not having any acute medical disorders (cardiovascular diseases, diabetes) Not having yoga training experience Not having any orthopedic conditions

Exclusion criteria:

Not attend to training session more than 4 sessions Lack of interest in continuing to participate in research Recurrence of the disease or worsening of medical situation Not completing the post-test

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **33**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The third person who was not in the research team will divide the subjects into 3 groups using a simple block random method. Allocating subjects to the study groups (interventions) will be done through block randomization using blocks of size 6. This will be by the website. In each block, SIX subjects will be from the intervention groups (HVD.Y-HVD,Y-LVD), which will arrange randomly. Finally, six blocks will use.

Blinding (investigator's opinion)

Single blinded

Blinding description

A specialist who is not part of the research team will take the measurements. The statistical analyst does not know which group the acronyms belong to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute of Iran

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran, Sport Sciences Research Institute of Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.SSRC.REC.1398.111

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

Inflammatory cytokines

Timepoint

Before and after the intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Physical and mental functions

Timepoint

Before and after the intervention

Method of measurement

Fitness measurement tests (handgrip strenght) and quality of life questionnaire

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Mahdieh Molanouri Shamsi

Street address

TMU, Jalal AleAhmad Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14115-111

Phone

+98 21 8288 4683

Email

molanouri@modares.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Jamshid Shanbezadeh

Street address

KhU, No. 43. South Mofatteh Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

15719-14911

Phone

+98 21 8832 9220

Email

jamshid@khu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kharazmi 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

Kharazmi University

Full name of responsible person

Sadegh Amani-Shalamzari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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KhU, No. 43. South Mofatteh Ave., Tehran, Iran

City

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Phone

+98 21 8832 9220

Email

amani_sadegh@khu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi University

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual information of the subjects is confidential and

only average data from all participants would be presented.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Only average data for variables would be shared

When the data will become available and for how long

Access period starts 4 months after the article is published

To whom data/document is available

Researchers, reviewers and scientific institutes

Under which criteria data/document could be used

Perform meta-analysis

From where data/document is obtainable

Email to the corresponding author

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

Emailing to the corresponding author, it may take about 2-3 days to receive the information

Comments