Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 perfomed 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

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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 (handgript 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
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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
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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
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Exercise physiology
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Person responsible for updating data

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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