Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of eight weeks of home aerobic exercise and turmeric supplementation on anthropometric indices, glycemic status, lipid profile and quality of life in middle-aged women with type 2 diabetes during Covid -19 quarantine

Protocol summary

Study aim

Determining the simultaneous and separate effects of 8 weeks of aerobic exercise at home and turmeric supplementation on anthropometric indices, glycemic status, lipid profile and quality of life in middle-aged women with type 2 diabetes in Kermanshah during covid-19 quarantine in 1400

Design

The clinical trial has a control group with parallel groups. Randomly on 40 patients, to analyze the data, first the normal distribution of data will be checked using Shapiro-Wilk test, if the normal distribution of data is confirmed by two-way analysis of variance test and if the natural distribution of data is not, the test Kruskal-Wallis nonparametric will be used to evaluate the intergroup factor and Wilcoxon nonparametric test will be used to evaluate the intragroup factor using SPSS software version 24 at a significance level of P˂0.05.

Settings and conduct

Aerobic exercise for 8 weeks will be done online and at home under the supervision of a specialist doctor and sports specialist. Tests and sampling are performed in the laboratory and under the supervision of a specialist.

Participants/Inclusion and exclusion criteria

Non-insulin type 2 diabetes, HbA1C above 6, TG above 150 mg / dL and LDL above 100 mg / dL, no antioxidants, multivitamin and polyphenol supplements in the last three months, index Overweight body mass (25 to 29.99 kg / m2)

Intervention groups

Subjects will be divided into four groups: aerobic exercise (n = 10), turmeric supplement group (n = 10), aerobic exercise + turmeric supplement (n = 10) and control group (n = 10).

Main outcome variables

anthropometric indices, glycemic status, lipid profile and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049524N1**
Registration date: **2021-05-26, 1400/03/05**
Registration timing: **prospective**

Last update: **2021-05-26, 1400/03/05**
Update count: **0**

Registration date

2021-05-26, 1400/03/05

Registrant information

Name

Mahsa Ahmady darmian

Name of organization / entity

Razi university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-15, 1400/03/25

Expected recruitment end date

2021-07-16, 1400/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of home aerobic exercise and turmeric supplementation on anthropometric indices, glycemic status, lipid profile and quality of life in middle-aged women with type 2 diabetes during Covid -19 quarantine

Public title

The effect of aerobic exercise at home and turmeric supplementation in type 2 diabetes during Covid -19 quarantine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Non-insulin type 2 diabetes HbA1C above 6 TG above 150 mg / dL LDL above 100 mg / dL Do not take antioxidants, multivitamin supplements and polyphenols in the last three months Overweight body mass index (25 to 29.99 kg / m2)

Exclusion criteria:

Change in the amount and type of medication used Physical activity and diet during the study period Fasting blood sugar greater than 200 mg / dL LDL greater than 160 mg / dL Acute heart disease, kidney, liver and thyroid failure Severe gastrointestinal diseases and gastric ulcer Gallstones Pregnancy or breastfeeding

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Razi University of Kermanshah

Street address

Faculty of Physical Education and Sports Sciences, Kermanshah, No. 9, Razi University Blvd.

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Kermanshah

Postal code

6714414971

Approval date

2021-05-12, 1400/02/22

Ethics committee reference number

IR.RAZI.REC.1400.013

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

ICD-10 code description

Type 2 diabetes

Primary outcomes

1

Description

Lipid profile

Timepoint

Before the intervention and after the end of the study

Method of measurement

Using a blood test

2

Description

Glycemic indexes

Timepoint

Before the intervention and after the end of the study

Method of measurement

Using a blood test

3

Description

Anthropometric indicators

Timepoint

Before the intervention and after the end of the study

Method of measurement

With little measuring tools

4

Description

Quality of Life

Timepoint

Before the intervention and after the end of the study

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Aerobic exercise group (10 people), 8 weeks of aerobic exercise with 3 sessions per week online, the first week with an intensity of 60% of maximum heart rate for 20 minutes and in the eighth week to 75% of maximum heart rate for 40 minutes Will take minutes; Thus, during the first 4 weeks with 60% of maximum heart rate for 30 minutes and 3 days per week and during the second 4 weeks with 75% of maximum heart rate for 45 minutes and 3 days per week

Category

Lifestyle

2

Description

Intervention group: Turmeric supplement group (n = 10), in the present study, a dose of 2100 mg of turmeric will be selected.

Category

Lifestyle

3

Description

Intervention group: Aerobic exercise and turmeric supplementation, aerobic exercise group (10 people) and placebo, 8 weeks of aerobic exercise with 3 sessions per week online, the first week with an intensity of 60% maximum heart rate for 20 minutes and in the eighth week to 75% Maximum heart rate will reach 40 minutes; During the first 4 weeks with 60% of maximum heart rate for 30 minutes and 3 days a week and during the second 4 weeks with 75% of maximum heart rate for 45 minutes and 3 days a week and turmeric supplementation (10 people) In the present study, a dose of 2100 mg of turmeric will be selected

Category

Lifestyle

4

Description

Control group:No aerobic exercise and no turmeric supplement

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Diabetes Center

Full name of responsible person

Mahsa Ahmadi Darmian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

No

Title of funding source

Razi University of Kermanshah

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
Razi University of Kermanshah

Full name of responsible person
Rastegar Hosseini

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
All data will be registered in SPSS and can be provided

When the data will become available and for how long
Access starts 9 months after the publication of all articles

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
All data can be used for citation.

From where data/document is obtainable
m.ahmady@stu.razi.ac.ir R.hoseini@razi.ac.ir

What processes are involved for a request to access data/document
If the description of the data needs is convincing, it will be delivered within 3 days

Comments