

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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)

Phone

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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.
City
 kermanshah
Province
 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

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Rastegar Hoseini

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No. 9, Razi University, Daneshgah Blvd., Bostan St., Kermanshah

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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

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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Faculty of Physical Education and Sport Sciences,
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Assistant Professor

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Other areas of specialty/work

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Person responsible for updating data

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Position

Student

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Bachelor

Other areas of specialty/work

Physical Education and Sports Science

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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