

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of 8 weeks of combined home-based exercise and Camelina oil consumption on insulin resistance, lipid profile, quality of life and some psychological indices in women with type 2 diabetes

Protocol summary

Study aim

Effect of eight weeks of combined home-based exercise and Camelina oil consumption on: insulin resistance fasting blood glucose lipid profile quality of life depression severity physical self-concept quality of sleep anxiety self-esteem in women with type 2 diabetes

Design

A clinical trial with a control group, parallel groups on 48 patients, permuted block randomization via www.randomization.com

Settings and conduct

This study is conducted at the Faculty of Sport Sciences of Razi University, Kermanshah, Iran. After the familiarization session, the study variables are measured, and then, 4 experimental groups perform their own relevant prescribed interventions for 8 weeks. Then, the variables are measured again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Not participation in regular exercise over the last 6 months Having type 2 diabetes confirmed by a specialist Fasting blood glucose of equal or more than 126 milligrams in deciliter to 400 milligrams in deciliter No insulin injection Getting the certification of no prohibition of participating in the exercise training from a specialist Exclusion Criteria: Acute or chronic inflammatory diseases Heart diseases Pregnancy Alcohol and other kinds of drug addiction Musculoskeletal disorder Refusal to give informed consent

Intervention groups

1) Exercise + Camelina: home-based aerobic and bodyweight resistance training 3 times a week for 8 weeks and, daily consumption of 27 grams of Camelina oil with meals. 2) Exercise: home-based aerobic and bodyweight resistance training 3 times a week for 8 weeks. 3) Camelina: daily consumption of 27 grams of Camelina oil with meals for 8 weeks. 4) Control: normal life during the project

Main outcome variables

Change in: insulin resistance fasting blood glucose lipid profile quality of life depression severity physical self-concept quality of sleep anxiety self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N2**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Ehsan Amiri

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 8428

Email address

e.amiri@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of combined home-based exercise and Camelina oil consumption on insulin resistance, lipid profile, quality of life and some psychological indices in women with type 2 diabetes

Public title

The effect of exercise training and Camelina oil consumption on type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Not participation in regular exercise training over the last 6 months Having type 2 diabetes confirmed by specialist Fasting blood glucose of equal or more than 126 milligrams in deciliter to 400 milligrams in deciliter No insulin injection Getting the certification of no prohibition of participating in exercise training program from a specialist

Exclusion criteria:

Acute or chronic inflammatory diseases Heart diseases Pregnancy Alcohol and other kinds of drug addiction Musculoskeletal disorder Refusal to give informed consent

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, permuted block randomization via the www.randomization.com website will be used. To do so, first, a unique number will be allocated to each subject as the identifier code and, a 48-digit sequence (equal to sample size) will be created. Then, treatment labels including 1) exercise + Camelina group; 2) Exercise group; 3) Camelina group, and 4) control group will be entered in the relevant section on the website. After defining the treatment groups and to avoid potential problems associated with equal block sizes, permuted block randomization with different block sizes will be applied. In this case, by knowing the sample size, the block sizes will be unequal and a multiple of the number of treatment groups (for example, block sizes of 2, 4, 6, or 8). The website has the ability to randomly specify the sequence of blocks with different sizes. In the final step and upon performing the 'Generate Plan' on the website,

all subjects will be randomly assigned to blocks of different sizes that already have a random sequence. Finally, the group (treatment) of each subject will be specified by the use of the identifier code and checking out the blocks

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Kermanshah Razi University

Street address

Deputy of Research and Technology, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran

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6714414971

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.RAZI.REC.1400.042

Health conditions studied**1****Description of health condition studied**

Type 2 Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Changes in insulin resistance

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By blood sample and Hemostatic Model Assessment for

Insulin Resistance (HOMA-IR). In this case, fasting blood insulin and glucose are measured and then, they will be put in the HOMA-IR formula.

2

Description

Changes in fasting blood glucose

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By blood sample in fasting condition

3

Description

Changes in lipid profile

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By blood sample in fasting condition

4

Description

Change in quality of life

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

World health organization standard quality of life questionnaire (short version)

5

Description

Change in depression severity

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes

1

Description

Change in physical self-concept

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Physical self-concept questionnaire

2

Description

Change in the quality of sleep

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Pittsburgh Sleep Quality Index

3

Description

Change in anxiety

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Beck Anxiety Inventory

4

Description

Change in self-esteem

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Rosenberg's Self-Esteem Scale

Intervention groups

1

Description

Intervention group (Exercise + Camelina): this group performs combined home-based aerobic and bodyweight resistance training 3 times a week for 8 weeks. The intensity of aerobic and resistance training will be controlled by the use of a 6-20 Borg scale. In the first week, the training intensity will be 11 and, in week 8, the intensity will be 13 on the Borg scale. The aerobic training is in category A according to American College of Sports Medicine (ACSM) guidelines that require minimum skill and physical fitness. The resistance training includes Squat, Lunges, and Push-up by the use of body weight. This group also consumes 27 grams of Camelina oil per day with meals for 8 weeks. This oil is transparent yellow in color and has no unusual taste and smell. Camelina oil has a standard document proved by Iran National Standards Organization.

Category

Other

2

Description

Intervention group 2 (Exercise): this group performs combined home-based aerobic and bodyweight resistance training 3 times a week for 8 weeks. The intensity of aerobic and resistance training will be controlled by the use of a 6-20 Borg scale. In the first week, the training intensity will be 11 and, in week 8, the intensity will be 13 on the Borg scale. The aerobic training is in category A according to American College of Sports Medicine (ACSM) guidelines that require minimum skill and physical fitness. The resistance training includes Squat, Lunges, and Push-up by the use of body weight.

Category

Other

3

Description

Intervention group 3 (Camelina): This group consumes 27 grams of Camelina oil per day with meals for 8 weeks. This oil is transparent yellow in color and has no unusual taste and smell. Camelina oil has a standard document proved by Iran National Standards Organization.

Category

Other

4

Description

Control group: this group has the the normal life during the study

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah

Full name of responsible person

Mehr Ali Rahimi

Street address

Next to the Faculty of Medicine, Parastar Blv,
Kermanshah, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Dr. Farzad Veysi

Street address

University St, Taq-e-Bostan

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veysi@razi.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi 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

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Taq-e-Bostan, University St., Kermanshah, Iran

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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 are shared after the de-identification of the participants

When the data will become available and for how long

3 months after publication

To whom data/document is available

All individuals upon formal request

Under which criteria data/document could be used

Data sharing requests are accepted for any purposes

From where data/document is obtainable

To obtain any data/document, please send an e-mail to Ehsan Amiri, a faculty member at Razi University, through the following e-mail address: e.amiri@razi.ac.ir

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

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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