

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The Effects of Multi-Component Exercise Training on Selected Intestinal Microbiomes, and Disease Status and Their Relationship with Cognitive Function in Elderly People with Type 2 Diabetes

Protocol summary

Study aim

Determining the relationship between gut bacteria changes and inflammatory indices with cognitive performance after a multiple exercise training course in the elderly with type 2 diabetes.

Design

The clinical trial has a control group without any intervention of 50 people, an intervention group of 50 people, phase 4 on 100 patients, sealed envelopes are used for randomization.

Settings and conduct

The field of the current study will be sports training and counseling for women with type 2 diabetes. After being diagnosed by telephone, the subjects will appear fasting in the pre- and post-test stages at Tarbiat Modares University. Exercises will be presented to the exercise group in the form of booklets and educational videos, and the coach will contact the patients of the exercise group every week to follow up on the exercises. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : people with type 2 diabetes, age in the range of 50-75 years, Glaciated hemoglobin more than 6.5 Exclusion criteria: having heart and joint problems so that they are not able to perform the sports training protocol. Taking nerve pills and sleeping pills, having orthopedic problems

Intervention groups

50 people in the sports training group and 50 people in the control group without training intervention

Main outcome variables

Measurement of intestinal microbiome factors, cognitive function, physical fitness, blood factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220912055942N1**

Registration date: **2023-07-24, 1402/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-24, 1402/05/02**

Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Alieh Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4403 3484

Email address

alieh.vahed@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-16, 1402/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Multi-Component Exercise Training on

Selected Intestinal Microbiomes, and Disease Status and Their Relationship with Cognitive Function in Elderly People with Type 2 Diabetes

Public title
the effect of exercise on cognitive functions and gut microbiom

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
type 2 diabetes Age range 50-75 years
Exclusion criteria:
Severe orthopedic or respiratory problems Severe cardiovascular patients Dementia Central nervous system disorders A special diet such as vegetarianism Carrying out a regular exercise program during the last 6 months

Age
From **50 years** old to **75 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be determined by the random block method with blocks of 4 and using the random number table of the random allocation software. Blocking and allocation sequence will be done for concealment by a person not involved in the research (allocation concealment). The allocation ratio of the samples will be one to one and they will be placed in two sports intervention and control groups. Then, based on the obtained blocks and according to the allocation sequence, the multiple exercise training program will be given to the exercise intervention group. Blinding will not occur in this study.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee

کارگروه کمیته اخلاق در پژوهش دانشگاه تربیت مدرس

Street address
Jalal ale Ahmad

City
Tehran

Province
Tehran

Postal code
14115-111

Approval date
2022-08-27, 1401/06/05

Ethics committee reference number
IR.MODARES.REC.1401.113

Health conditions studied

1
Description of health condition studied
TYPE 2 DIABETES
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1
Description
Examining intestinal microbiome factors such as Lactobacillus bacteria due to diabetes -
Timepoint
Measurement of stool microbiomes before the intervention and 12 weeks after the intervention
Method of measurement
Through stools of patients and extraction of DNA from stools by Fioragin kit

Secondary outcomes

1
Description
Executive function
Timepoint
Before and after 3 months intervention
Method of measurement
Trail Making Test

2
Description
Respiratory and cardiovascular system, blood circulation and muscle
Timepoint
Trail Making Test
Method of measurement
6-Minute Walk Test

3

Description

Body Mass Index

Timepoint

6-Minute Walk Test

Method of measurement

Weight in kilograms divided by the square of height in meters

Intervention groups

1

Description

Intervention group: implementation of 12 weeks of combined sports training intervention that includes aerobic and strength training, balance, flexibility and cognitive training. The training will start from 3 days a week and will reach 5 days from the 9th week to the end of the 12th week, which includes walking. It is accompanied by cognitive exercises and weight or resistance exercises and yoga movements for balance and stretching the body.

Category

Other

2

Description

Control group: NO EXERCISE

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Research Institute

Full name of responsible person

Dr. Azam Kohkan

Street address

GOLZAR

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2

Recruitment center

Name of recruitment center

Endocrine and Metabolism Research Institute

Full name of responsible person

Dr. Hossein Adib

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ENGHELAB

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dmclinic@tums.ac.ir

Web page address

http://emri.tums.ac.ir/DMC2/Home

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Mahdieh Melanori Shamsi

Street address

JALAL E ALE AHMAD

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pres@modares.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

TARBIAT MODARES UNIVERSITY OF TEHRAN

Proportion provided by this source

10

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

Tarbiat Modares University of Tehran

Full name of responsible person

Dr. Mahdiah Melanori Shamsi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Position

PHD student

Latest degree

Master

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tarbiat Modares University

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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

Tarbiat modares university

Full name of responsible person

ALIEH VAHED

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data related to the main outcome can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

People approved by the supervisor

Under which criteria data/document could be used

For the purpose of additional research in the field of the present study

From where data/document is obtainable

supervisor

What processes are involved for a request to access data/documentE-mail correspondence with the supervisor
molanouri@modares.ac.ir**Comments**