

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effect of Home -based Combined Exercise Training on Serum Level of Interleukin 17 Cytokine and its Relationship with Cognitive Function in Women with Type 2 Diabetes.

Protocol summary

Study aim

Investigating the effect of a combined exercise course at home on the levels of the cytokine interleukin 17 and its relationship with cognitive function in women 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 be present at Tarbiat Modares University of Tehran fasting in the pre- and post-examination stages. Exercises will be presented to the training group in the form of booklets and educational videos, and the trainer will contact the patients of the training 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 HbA1c greater than 6.5 Exclusion criteria: Absence of heart and joint problems so that they are not able to perform the exercise protocol. Not taking nerve pills and sleeping pills Not taking insulin

Intervention groups

Out of 100 subjects, 50 people are in the control group, who do not do any sports activities, and 50 people are in the sports intervention group, who will do sports exercises for 3 months according to the protocol.

Main outcome variables

Cytokine interleukin 17 and cognitive function and physical fitness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220927056048N1**

Registration date: **2023-07-20, 1402/04/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-20, 1402/04/29**

Update count: **0**

Registration date

2023-07-20, 1402/04/29

Registrant information

Name

Samaneh Aghamohammadi

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

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samaneaghamohammadi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The Effect of Home -based Combined Exercise Training on Serum Level of Interleukin 17 Cytokine and its Relationship with Cognitive Function in Women with Type 2 Diabetes.
Public title	The Effect of Exercise on the Cytokine Interleukin-17 and Cognitive Function
Purpose	Education/Guidance
Inclusion/Exclusion criteria	Inclusion criteria: Fasting blood glucose more than 7 mmol/L hba1c more than 6.5 Do not have heart and joint problems People with type 2 diabetes Be in the desired age range Exclusion criteria: Severe orthopedic problem Severe breathing problems Severe cardiovascular disease Dementia Central nervous system disorder A special diet such as vegetarianism Doing regular exercise 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. 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	Working group of ethics committee in research of Tarbiat Modares University
Street address	Jalal Al Ahmad St
City	Tehran
Province	Tehran
Postal code	14115-111
Approval date	2022-05-28, 1401/03/07
Ethics committee reference number	IR.MODARES.REC.1401.046
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	Cytokine factor interleukin 17
Timepoint	Before and after 3 months interventions
Method of measurement	Enzyme-linked immunosorbent assay
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	Before and after 3 months intervention

Method of measurement

6-Minute Walk Test

3

Description

Body Mass Index

Timepoint

Before and after 3 months intervention

Method of measurement

Weight in kilograms divided by the square of height in meters

Intervention groups

1

Description

"Intervention group": A 3-month multi component exercise intervention consisting of stretching, resistance, dual task and balance exercises will be implemented. The intensity of aerobic exercises will be kept 40 to 60 maximum reserve heart rate and the number of sessions will increase from 3 to 5 per week.

Category

Lifestyle

2

Description

"Control group": No intervention will be carried out in this group, and patients will continue their usual routine before the pre-test.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Research Institute

Full name of responsible person

Azam Kohkan

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Fax

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Web page address

<https://royandiabetes.org>

2

Recruitment center

Name of recruitment center

Endocrine and Metabolism Research Institute

Full name of responsible person

Hossein Adib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University of Tehran

Full name of responsible person

Dr. Mahdieh Melanori Shamsi

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Grant name

Grant code / Reference number

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

Yes

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 Molanori Shamsi
Position
Assistant Professor
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Person responsible for updating data

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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

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 study

From where data/document is obtainable

Supervisor

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

E-mail correspondence with the supervisor
molanouri@modares.ac.ir

Comments