

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Effect of a Multi Component Exercise Program on Cognitive Function in Women with Type 2 Diabetes, with a Special Focus on Serum Levels and Geno typing of Selected cytokine TNF alpha and IL-10 Polymorphisms

#### Protocol summary

##### Study aim

Diabetes causes an increase in inflammatory cytokines and disruption in cognitive function and dementia of people, that exercise through different mechanisms reduces risk factors related to diabetes, reduces inflammatory cytokines and improves cognitive function.

##### Design

The clinical trial will have two groups of sports intervention and control, without blinding, randomized on 100 women with type 2 diabetes. 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.

##### 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

Has type 2 diabetes Age in the range of 50-75 years  
Glaciated hemoglobin greater than 6.5  
Absence of heart and joint problems so that they are not able to perform the exercise protocol. Not taking nerve pills and sleeping pills

##### 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

Serum levels and genotyping of cytokines Tumour necrosis factor  $\alpha$  and Interleukin 10, cognitive function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220702055347N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

##### Registration date

2023-06-20, 1402/03/30

##### Registrant information

##### Name

Afsaneh Jamali

##### Name of organization / entity

Tarbiat Modares

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 0000

##### Email address

jamaliafsaneh@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 a Multi Component Exercise Program on Cognitive Function in Women with Type 2 Diabetes, with a Special Focus on Serum Levels and Geno typing of Selected cytokine TNF alpha and IL-10 Polymorphisms

### Public title

The Effect of a Multi Component Exercise Program on Cognitive Function of Women with Type 2 Diabetes

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Fasting blood glucose more than 7 mmol/L Hemoglobin A1c more than 6.5 Do not have cognitive function, heart and joint problems People with type 2 diabetes Be in the desired age range

#### Exclusion criteria:

### 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

Ethics Committee of Tarbiat Modares University

##### Street address

Jalal Al Ahmad St

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

#### Approval date

2022-01-22, 1400/11/02

#### Ethics committee reference number

IR.MODARES.REC.1400.293

## 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

Interleukin 10 genotyping

#### Timepoint

Before and after 3 months interventions

#### Method of measurement

Restriction fragment length polymorphism

### 2

#### Description

Tumour necrosis factor  $\alpha$  genotyping

#### Timepoint

Before and after 3 months interventions

#### Method of measurement

Restriction fragment length polymorphism

## Secondary outcomes

### 1

#### Description

Tumor necrosis factor alpha cytokine

#### Timepoint

Before and after 3 months intervention

#### Method of measurement

Enzyme-linked immunosorbent assay

## 2

### **Description**

Interleukin 10 cytokine

### **Timepoint**

Before and after 3 months intervention

### **Method of measurement**

Enzyme-linked immunosorbent assay

## 3

### **Description**

Executive function

### **Timepoint**

Before and after 3 months intervention

### **Method of measurement**

Trail Making Test

## 4

### **Description**

Respiratory and cardiovascular system, blood circulation and muscle

### **Timepoint**

Before and after 3 months intervention

### **Method of measurement**

6-Minute Walk Test

## 5

### **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 Koohkan

##### **Street address**

QF49+75J, Shahid Sayad Shirazi Highway, Sanyaat Boulevard, South Golzar St., Neda Alley, next to Ghaem Mosquem, Tehran, Iran

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##### **Email**

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### 2

#### **Recruitment center**

##### **Name of recruitment center**

Endocrinology and Metabolism Research Institute

##### **Full name of responsible person**

Hossein Adib

##### **Street address**

P9FM+6W3, Jalal Al Ahmad Highway, next to Dr. Shariati Hospital, Endocrinology and Metabolism Research Institute, Tehran, Iran

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emrc@tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tarbiat Modares University of Tehran

##### **Full name of responsible person**

Dr. Mahdieh Molanouri Shamsi

##### **Street address**

Jalal Al Ahmad St

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molanouri@modares.ac.ir  
**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**  
50  
**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

## 2

**Sponsor**  
**Name of organization / entity**  
Cognitive Sciences and Technology Council  
**Full name of responsible person**  
Majid Nili Ahmadabadi  
**Street address**  
Vali Asr St. (AJ), above Niayesh Crossroad, Ostad Daryabandari St. (West Armaghan), No. 3 (former building of the Supreme Council of Iranians Abroad), 3rd floor, Tehran, Iran  
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research.project@cogc.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Cognitive Sciences and Technology Council  
**Proportion provided by this source**  
50  
**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.Mahdieh Molanouri Shamsi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
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## **Person responsible for scientific inquiries**

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Associate Professor  
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## **Person responsible for updating data**

**Contact**  
**Name of organization / entity**  
Tarbiat Modares University of Tehran

**Full name of responsible person**

Afsaneh Jamali

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

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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 scientific purposes

**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**