

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 α 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 α 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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 2356 2000

Fax

+98 21 2230 6481

Email

info@royaninstitute.org

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

City

Tehran

Province

Tehran

Postal code

1411713139

Phone

+98 21 8863 1298

Email

emrc@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University of Tehran

Full name of responsible person

Dr. Mahdiah Molanouri Shamsi

Street address

Jalal Al Ahmad St

City

Tehran

Province

Tehran
Postal code
1411713116
Phone
+98 21 8288 0000
Email
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
City
Tehran
Province
Tehran
Postal code
1967875319
Phone
+98 21 2266 0770
Email
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
Street address
Nasr Bridge,Jalal Al Ahmad St,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 4683
Email
molanouri@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat Modares University of Tehran
Full name of responsible person
Mahdie Molanori Shamsi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Nasr Bridge,Jalal Al Ahmad St,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 0000
Email
molanouri@modares.ac.ir

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

Street address

Nasr Bridge,Jalal Al Ahmad St,Tehran,Iran

City

tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 0000

Email

jamali.afsaneh@gmail.com

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