

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of a selected exercise course on physical and cognitive function and some factors affecting cognition in elderly women with type 2 diabetes

Protocol summary

Study aim

The effect of a combined exercise training on physical fitness, cognitive function and glycemic control indices in women with type 2 diabetes

Design

The subjects were voluntarily selected and randomly divided into two groups of 12 (experimental and control), of which three in the control group withdrew for personal reasons, and finally 12 in the experimental group and 9 in the control group until the end of the study.

Settings and conduct

From people with diabetes in Sabzevar city who are 55 to 65 years old and . The study was performed for 3 months 3 days a week in Chamran Sports Hall located in Sabzevar city. Exercises were performed in three ways: aerobic, balance and strength

Participants/Inclusion and exclusion criteria

having type 2 diabetes for more than five years, age range 55-65 years, not having a specific disease that conflicts with exercise, not having severe depression due to the effects of mood swings and depression In memory tests, subjects were tested for depression (Beck) and subjects with a score higher than 13 were not included in the study (a score greater than 13 is a sign of depression) (Kokok 2013), literacy , Was sedentary lifestyle and ability to do sports. Exclusion criteria include absenteeism for more than three consecutive or seven non-consecutive sessions, injury, and inability to perform training programs

Intervention groups

The study consisted of two groups of exercise and control. The exercise group received combined exercise (aerobic, strength and balance) for 3 months 3 days a week and the control group did not receive exercise

Main outcome variables

Measurement of physical function (static dynamic balance, muscle strength, vo2max) Measuring cognitive

function Measurement of cognitive blood indices related to cognition (bdnf, irisin, hemoglobin a1c, blood sugar)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220112053699N1**

Registration date: **2022-01-18, 1400/10/28**

Registration timing: **retrospective**

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

nafiseh Ghodrati

Name of organization / entity

Hakim sabzevari university

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 9128

Email address

nafise.ghodrati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

2019-05-20, 1398/02/30

Actual recruitment end date

2019-05-20, 1398/02/30

Trial completion date

2019-10-07, 1398/07/15

Scientific title

The effect of a selected exercise course on physical and cognitive function and some factors affecting cognition in elderly women with type 2 diabetes

Public title

The Effect of Exercise on Physical and Cognitive Function

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria include having type 2 diabetes for more than five years, age range 65-55 years, not having a specific disease that is inconsistent with exercise, not having severe depression due to the effects of mood swings and depression In memory tests, subjects were tested for depression (Beck) and people with a score higher than 13 were not included in the study (a score higher than 13 is a sign of depression), literacy, sedentary lifestyle And was the ability to perform sports movements

Exclusion criteria:

Exclusion criteria include absenteeism for more than three consecutive or seven non-consecutive sessions, injury, and inability to perform training programs.

AgeFrom **55 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30**Actual sample size reached: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization. After determining the sample size using Cochran software, 24 people were included in the study according to the inclusion criteria and then 11 people were selected by lot for the control group and 13 people for the exercise group. Eventually, one person from the training group and two people from the control group gave up.

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**

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tohid shahr sabzevar

City

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Province

Razavi Khorasan

Postal code

5465-7767-8889

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.HSU.REC.1398.007

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

type 2 diabetes

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Physical Function - Cognitive Function - Levels of Blood Factors bdnf Irisine Hemoglobin a1c Blood Glucose

Timepoint

Three months later the intervention currency

Method of measurement

Measuring Cognitive Function Using Moka Questionnaire
- Measuring Physical Function Using Rickley-Jones Tests -
Measuring Blood Indices Using Special Blood Kits

Secondary outcomes**1****Description**

Long-term memory score. Information processing score

Timepoint

tthree month

Method of measurement

Long-term memory using forward digit width test. Data processing using symbol and digit testing

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

HESHMATIYE HOSPITAL

Full name of responsible person

AKRAM FAGHIHI

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HAJ MOLA HADI SCOU

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

hakim sabzevari university

Full name of responsible person

دکتر امیر حسین حقیقی

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3565-7787-798

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nafise.ghodrati@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

hakim sabzevari university

Proportion provided by this source

20

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

hakim sabzevari university

Full name of responsible person

nafiseh ghodrati

Position

student

Latest degree

Master

Other areas of specialty/work

Others

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All the information obtained in this study can be published after statistical analysis and unidentifiable individual

When the data will become available and for how long

1401

To whom data/document is available

free

Under which criteria data/document could be used

Any use of published statistical analyzes is unrestricte

From where data/document is obtainable

Email the responsible author

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

An email to the responsible author will be answered within a week

Comments