Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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 exercis

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.
Age
From **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
دانشگاه حکیم سبزواری
Street address
tohid shahr sabzevar
City
sabzevar
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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2392-3424-4234
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
hakim sabzevari university
Full name of responsible person
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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
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Position
student
Latest degree
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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