

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Effect of Vision and balance training ON vision perception, motor function and quality of life in diabetic patients

Protocol summary

Study aim

Comparison of the effect of combined exercises with vision and balance exercises on visual perception of diabetic patients Comparison of the effect of combined exercises with vision and balance exercises on the static balance of diabetic patients Comparison of the effect of combined exercises with vision and balance exercises on the dynamic balance of diabetic patients Comparison of the effect of combined exercises with vision and balance exercises on the quality of life of diabetic patients Comparison of the effect of combined exercises with vision and balance exercises on motor performance of diabetic patients

Design

A clinical trial with a control group, with three parallel groups of one-sided blind evaluators, randomized on 85 patients. Random allocation software was used for randomization

Settings and conduct

This study will be held at Jenan Sports Club in Najaf Abad, where the evaluator will be blinded and will not know the results of the tests: balance class, eye exercises class and combined class in three different hours.

Participants/Inclusion and exclusion criteria

Conditions for entering the intervention: women between 50 and 65 years old with type 2 diabetes who only use metformin tablets and have been diagnosed with diabetes for more than a year! Conditions for not entering the intervention: women who use insulin, are over 65 years old, have type 1 diabetes or gestational diabetes

Intervention groups

The group of eye, The group of balance, Group of combined exercises that includes combined eye and balance exercises that all groups will attend three sessions a week for eight weeks, each session for one hour The control group, which is without intervention, and only pre-test and post-test will be taken from them

Main outcome variables

Investigating the effect of vision and balance exercises on visual perception, motor function and quality of life of diabetic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220726055557N1**

Registration date: **2022-08-07, 1401/05/16**

Registration timing: **prospective**

Last update: **2022-08-07, 1401/05/16**

Update count: **0**

Registration date

2022-08-07, 1401/05/16

Registrant information

Name

Hanieh Khazaeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4251 5080

Email address

khazaelihanieh200@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-20, 1401/05/29

Expected recruitment end date

2022-10-20, 1401/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vision and balance training ON vision perception, motor function and quality of life in diabetic patients

Public title

Investigating the effect of vision exercises and balance exercises

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Gender and age of (women with type 2 diabetes 50 to 65 years) The only medicine that can be taken is metformin tablets Voluntary participation and informed consent Absence of kidney, cardiovascular, orthopedic and neurological diseases Not using walkers, canes and other aids Balance disorder Literate to read and write to answer the questionnaire and written consent Good visual acuity Having type 2 diabetes that has been diagnosed for more than 12 months Not having regular sports activities other than practical exercises by the researcher during the course

Exclusion criteria:

Drug use other than metformin tablets Simultaneous participation in orthopedic treatment programs (physiotherapy, neuropathy or surgery) and exercise in line with studying during the course. Age less than 50 years and more than 65 years Patients less than one year old who have been diagnosed with type 2 diabetes

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **85**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to four groups vision exercises, balance exercises, combined exercises, and control groups with a 1:1 allocation ratio. Block randomization method will be used for random allocation of patients. The randomized patient allocation sequence will be created by the random allocation software, the name of the software is Random Allocation Software, we put the data in the software, and then the software itself does it.

Blinding (investigator's opinion)

Single blinded

Blinding description

After allocation, it was not possible to keep the trainer

blind to each participant's allocated intervention. But the evaluator remained blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Azad University of Khorasgan branch

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University Blvd, Arghavanieh Ave, Eastern Jey Str, Esfahan Town

City

Esfahan

Province

Isfahan

Postal code

8155139998

Approval date

2022-07-03, 1401/04/12

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.128

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

دیابت نوع 2 و چشم پزشکی

Primary outcomes**1****Description**

Balance level of people with type 2 diabetes

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after eight weeks of intervention

Method of measurement

To measure balance from the Berg Balance Scale and Tinetti Balance Test

Secondary outcomes

1

Description

The level of visual perception of people with type 2 diabetes

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after eight weeks of intervention

Method of measurement

Using the National Eye Institute Visual Functioning Questionnaire 25

2

Description

Motor Function of people with type 2 diabetes

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after eight weeks of intervention

Method of measurement

Using the 6-minute walk test 6Movement Walk Test

3

Description

Quality of life of people with type 2 diabetes

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after eight weeks of intervention

Method of measurement

Using the Quality of Life 36 Question test and the Hospital Anxiety and Depression Scale questionnaire

Intervention groups

1

Description

The first intervention group: the group of balance exercises, which includes three sessions per week and one hour each session for balance exercises, which includes functional strength and resistance exercises and some yoga movements. (subject to the principle of overload)

Category

Rehabilitation

2

Description

Intervention group: eye exercises that are held on the 8th of every week for three sessions and each session is one hour. The exercises include eye saccade exercises and tracking exercises of the week. (subject to the principle of overload)

Category

Rehabilitation

3

Description

Intervention group: The third intervention group, where balance and eye combined exercises will be held in eight weeks, three sessions per week, and each session will be held for one hour. Half of the class will be on balance exercises, which are the exercises of the first intervention group, and half of the class will be on eye exercises, which are in the second intervention class. (subject to the principle of overload)

Category

Rehabilitation

4

Description

Control group: In this group, only people will be helped for the pre-test and post-test, the pre-tests will be taken from the control group in the first session, just like the three intervention groups, and after eight weeks, the post-test will be taken from the group, just like the three intervention groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jenan Diabetes Charitable Association of Najaf Abad city

Full name of responsible person

Ayob Shapoori

Street address

No,55 Anari Alley, Danesh Ave, Sharyati St, Najaf Abad City

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Postal code

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Phone

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghyani

Street address

University Blvd, Arghavanieh Ave, Eastern Jey Str,

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Grant name

Grant code / Reference number

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

No

Title of funding source

Hanieh Khazaeli

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hanieh Khazaeli

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rokhsare Badami

Position

Academic Staff, Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for updating data

Contact

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Full name of responsible person

Rokhsare Badami

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The provided files are in the form of a complete Excel file, in which the history of the patients, fasting blood sugar and hemoglobin A1C levels, underlying diseases and surgery, and the extent of the disease are described. The site consent form will be designed and provided to each participant After completing the intervention steps, a full report of the clinical interventions will be prepared and will be accessible in the file as a document

When the data will become available and for how long

The Excel file of the participants' profile can be accessed after it is completed and before the start of the intervention An informed consent form will be available at the first session after the start of the intervention when all participants have signed it The file of clinical

interventions will be available in the last session of the intervention and after the results and approval of the relevant judges and professors and after printing.

To whom data/document is available

People related to this research will have access permission, such as supervisors, advisors, and referees. Apart from the details of the participants, other researchers working in academic and scientific institutions will have the necessary access

Under which criteria data/document could be used

Access to all parts of this study will be granted solely for treatment and to supplement and improve research

From where data/document is obtainable

To access this information, they can go to the email address: khazaelihanieh200@gmail.com And rokhsareh.badami@gmail.com Visit

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

Applicants can access the information after one working week after entering the email address

Comments