Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 dibetes 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
Street address
University Blvd, Arghavanieh Ave, Eastern Jey Str, Esfahan Town
City
Esfahan
Province
Isfehan
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 Depressin 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
City
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Province
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Postal code
-
Phone
+98 31 4264 8584
Email
info@najafabad-charity.org
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Majid Toghiyani
Street address
University Blvd, Arghavanieh Ave, Eastern Jey Str,

Esfahan Town
City
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Isfehan
Postal code
8155139998
Phone
+98 31 3535 4001
Email
info@khuisf.ac.ir
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
Street address
No.26, Rostam Niya Ave, North Montazeri Blvd, Najaf Abad Town
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Person responsible for scientific inquiries

Contact
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Rokhsare Badami
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Latest degree
Ph.D.
Other areas of specialty/work
Others
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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Rokhsare Badami
Position
Academic Staff، Associate Professor
Latest degree
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Others
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rokhsareh.badami@khuisf.ac.ir

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