Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of physical activity on cognition, vision and motor function in people with Parkinson disease and its animal model

Protocol summary

Study aim

Parkinson's disease (PD) is one of the most common progressive neurodegenerative disorders. Physical exercise takes into account an important protective approach to prevent abnormal function and cell death in the brain. Beneficial effects including molecular changes in the brain to increase memory and learning might reduce apoptosis in Retinal cells. Therefore, it is important to seek more effective therapeutic interventions as well as low-cost ones for PD. In this study, the mechanism of its effect in PD and its animal model will be considered.

Design

A clinical trial with a control group, parallel groups, triple-blind, randomized

Settings and conduct

First, patients are selected according to entry (inclusion) criteria and then therapeutic sessions are arranged. After receiving the consent form from the individuals, their group will be determined completely randomly. Then, initial assessments (cognitive, visual, and motor function) will conduct. After the tests, the presence time of the patients for the exercises will be coordinated.

Participants/Inclusion and exclusion criteria

People diagnosed with Parkinson's Disease Ability to perform the hardest level of laboratory tests

Intervention groups

Intervention group:The exercise program is consisted three categories of cognitive exercises(with emphasis on memory and attentional tasks),motor exercises(with emphasis on balance),and visual training (with emphasis on voluntary and anti-saccadic movements).24 training sessions are based on two principles of the challenge and individual's safety items.The duration of exercises will be provided in 45 to 60-minutes in each session and 3 sessions per week. Control group:The control group will not receive any specific training.

Main outcome variables

Physical exercises can affect cognitive, visual, and motor functions in people with Parkinson's disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140612018077N2**
Registration date: **2018-10-24, 1397/08/02**
Registration timing: **prospective**

Last update: **2018-10-24, 1397/08/02**
Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Maryam Mehdizadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 945 4770

Email address

maryam.mehdizadeh_22@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of physical activity on cognition, vision and motor function in people with Parkinson disease and its animal model

Public title
The effect of physical activity on people with Parkinson disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People diagnosed with Parkinson's Disease Ability to walk independently for a distance of at least 10 meters with and without asistive devices Ability to perform the hardest level of laboratory tests Have a Mini Mental State Examination score equal or more than 21

Exclusion criteria:
Having another disease before entering the study

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
First, people with Parkinson's disease will be selected as available, and then randomly assigned into two groups randomly without any blocks.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study will be triple-blind study. In this study, patients, therapist and data analyst will not be aware of the type of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
ran University of Medical Sciences, Shahid Hemmat Highway, Tehran,1449614535,IRAN.

City
Tehran

Province
Tehran

Postal code
14665-354

Approval date
2018-09-25, 1397/07/03

Ethics committee reference number
IR.IUMS.REC.1397.216

Health conditions studied

1

Description of health condition studied
Parkinson's Disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Postural control (Balance improvement after treatment)

Timepoint
Before and after intervention

Method of measurement
force plate in bio-mechanic lab

Secondary outcomes

1

Description
Cognitive function based on changes in BDNF protein

Timepoint
Before and After intervention

Method of measurement
Study of serum BDNF levels by analyzing blood samples

Intervention groups

1

Description
Parkinson's disease (PD) is one of the most common progressive neurodegenerative disorders. Physical exercise takes into account an important protective approach to prevent abnormal function and cell death in

the brain. Beneficial effects including molecular changes in the brain to increase memory and learning might reduce apoptosis in Retinal cells. Therefore, it is important to seek more effective therapeutic interventions as well as low-cost ones for PD. In this study, the mechanism of its effect in PD and its animal model will be considered.

Category

Rehabilitation

2

Description

Control group: In this study, the control group will not receive any specific training.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-e Rasool General Hospital

Full name of responsible person

Maryam Mehdizadeh

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,1449614535,IRAN.

City

Tehran

Province

Tehran

Postal code

14665-354

Phone

+98 21 8843 3583

Email

Maryam.mehdizadeh_22@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,1449614535,IRAN.

City

Tehran

Province

Tehran

Postal code

14665-354

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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

Iran University of Medical Sciences

Full name of responsible person

Maryam Mehdizadeh

Position

PhD. Candidate

Latest degree

Master

Other areas of specialty/work

Neuroscience

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14665-354

Phone

+98 21 8843 3583

Email

maryam.mehdizadeh_22@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Mehdizadeh

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

NO

From where data/document is obtainable

email addresses

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

NO

Comments