

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Strength-Balance Exercises, Virtual Reality-Based Exercises, and Combined Exercises on Neuroplasticity, Quality of Life, Balance, and Fall Risk in Patients with Parkinson's Disease

Protocol summary

Study aim

The aim of this study is to evaluate the impact of strength-balance exercises, virtual reality-based exercises, and combined exercises on neuroplasticity, quality of life, balance, and fall risk in patients with Parkinson's disease.

Design

This study is a randomized controlled trial with three intervention groups and one control group. Randomization is computer-generated, and outcomes are assessed before and after 8 weeks of intervention using a double-blind design.

Settings and conduct

The study will take place at the Biomechanics Laboratory, Faculty of Physical Education and Sport Sciences, Kharazmi University.

Participants/Inclusion and exclusion criteria

The inclusion criteria consist of patients diagnosed with Parkinson's disease confirmed by a specialist; aged between 50 and 70 years; moderate to severe symptoms based on the UPDRS-III scale; and the ability to engage in physical exercises. The exclusion criteria include individuals with other neurological disorders, severe cardiac, pulmonary, or renal diseases, or musculoskeletal conditions that prevent participation in the exercise regimen.

Intervention groups

Control Group: Receives no intervention and undergoes standard treatment. Intervention Group 1 (Strength-Balance Exercises): Receives strength and balance exercises for 8 weeks, three times a week, including resistance training and balance exercises such as standing on balance boards. Intervention Group 2 (Virtual Reality-Based Exercises): Uses virtual reality systems for balance and movement exercises, three times a week for 8 weeks, with each session lasting 30 minutes. Intervention Group 3 (Combined Exercises):

Receives a combination of strength-balance exercises and virtual reality-based exercises, each for 30 minutes, three times a week for 8 weeks.

Main outcome variables

The primary outcome variables are: neuroplasticity, quality of life, balance, and fall risk.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040251N13**

Registration date: **2025-07-29, 1404/05/07**

Registration timing: **prospective**

Last update: **2025-07-29, 1404/05/07**

Update count: **0**

Registration date

2025-07-29, 1404/05/07

Registrant information

Name

Hassan Sadeghi

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8001

Email address

hassan.sadeghi81@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-01, 1404/05/10

Expected recruitment end date

2025-09-16, 1404/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Strength-Balance Exercises, Virtual Reality-Based Exercises, and Combined Exercises on Neuroplasticity, Quality of Life, Balance, and Fall Risk in Patients with Parkinson's Disease

Public title

"Effect of Strength-Balance Exercises, Virtual Reality, and Combined Exercises on Neuroplasticity, Quality of Life, Balance, and Fall Risk in Parkinson's Disease"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with Parkinson's disease confirmed by a specialist doctor. Individuals aged between 50 and 70 years. Patients with moderate to severe symptoms based on the UPDRS-III scale. Individuals capable of performing physical exercises according to the study protocol. Individuals who have signed a written consent form to participate in the study.

Exclusion criteria:

Individuals with neurological disorders other than Parkinson's disease (such as Alzheimer's or stroke). Individuals with severe psychiatric conditions that impair their ability to participate in exercises. Individuals currently undergoing active or continuous physical therapy.

AgeFrom **50 years** old to **75 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **48****Randomization (investigator's opinion)**

Randomized

Randomization description

After the initial assessment of the participants, randomization was carried out based on four-block randomization. Participants are randomly assigned to one of two groups using four-block randomization. One of the research team members, who is not involved in the sample selection process, determines the random allocation sequence using the online tool (randomizer.org). Sealed opaque envelopes containing the randomization sequence will be used for allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. In this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Kharazmi University

Street address

Shahid Keshvari Sports Complex, Kosha Street, between Shohareh and Hesari, Shahid Haghani Highway, Tehran (Mirdamad neighborhood)

City

Tehran

Province

Tehran

Postal code

15719-14911

Approval date

2025-04-20, 1404/01/31

Ethics committee reference number

IR.KHU.REC.1404.007

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**

Neuroplasticity

Timepoint

The measurement of outcome variables is conducted at two time points: Before the intervention (Pre-test) After the intervention (Post-test)

Method of measurement

Secondary outcomes

1

Description

Quality of Life: To assess the quality of life in Parkinson's patients

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

PDQ-39

2

Description

Balance

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

-Single Leg Stance Test--TUG test

3

Description

fall risk

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

BBS test

Intervention groups

1

Description

Group 1 (Strength-Balance Exercises): Participants in this group receive strength and balance exercises three times a week for 8 weeks. The exercises include resistance training using weights to strengthen lower limb muscles and balance exercises such as standing on balance boards and performing dynamic movements to improve coordination and stability.

Category

Rehabilitation

2

Description

Intervention group: Group 2 (Virtual Reality-Based Exercises): Participants in this group use virtual reality systems to perform balance and movement exercises. These exercises are designed in simulated virtual environments, and patients perform balance and coordination tasks under the supervision of a physiotherapist. Each session lasts 30 minutes, and the exercises are performed three times a week for 8 weeks.

Category

3

Description

Intervention group: Intervention Group 3 (Combined Exercises): This group receives a combination of strength-balance exercises and virtual reality-based exercises. Participants perform 30 minutes of strength and balance exercises followed by 30 minutes of virtual reality-based exercises in each session. The sessions are conducted three times a week for 8 weeks.

Category

Rehabilitation

4

Description

Control group: Intervention group: Control Group: The control group receives no intervention and only undergoes standard treatment protocols.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi University, Faculty of Physical Education and Sport Sciences

Full name of responsible person

Aryan Omid

Street address

Kharazmi University, Tandorosti Boulevard, Pazhuhesh Boulevard, Kaj Boulevard, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

37551-31979

Phone

+98 26 3455 0702

Email

aryan.omidi2911@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Alireza Harifi

Street address

Vice-Chancellor for Research and Technology. No. 43. South Mofatteh Ave., Tehran, Iran

City

Tehran

Province
Tehran

Postal code
15719-14911

Phone
+98 21 2222 8001

Fax

Email
research@khu.ac.ir

Web page address
<https://research.khu.ac.ir/en>

Grant name

Grant code / Reference number

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

Title of funding source
Kharazmi University

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
kharazmi university

Full name of responsible person
Aryan Omid

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Sport Medicine

Street address
No. 12, Allameh Jafari St., Tohid Town, Sabzevar
County, Razavi Khorasan, Iran

City
sabzevar

Province
Razavi Khorasan

Postal code
9617984797

Phone
+98 51 4441 0962

Email
aryan.omidi2911@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person
Hassan Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Faculty of Physical Education and Sports Sciences,
Shahid Keshvari Complex, Shahid Hesari St.,
Mirdamad, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1544733111

Phone
+98 21 2222 8001

Fax

Email
hassan.sadeghi81@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kharazmi University

Full name of responsible person
Hassan Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Faculty of Physical Education and Sports Sciences,
Shahid Keshvari Complex, Shahid Hesari St.,
Mirdamad, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1544733111

Phone
+98 21 2222 8001

Fax

Email
hassan.sadeghi81@yahoo.com

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
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