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

En 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

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Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

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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.
Age
From **50 years** old to **75 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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

Neuroplasticity: Electroencephalogram (EEG)

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
mmediately 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
Rehabilitation

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 Omidi
Position
Master's student
Latest degree
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Other areas of specialty/work
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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
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