Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of a structured vision-therapy program versus usual care on visual performance, fear of falling, and quality of life in individuals with idiopathic Parkinson’s disease: a randomized clinical trial

Protocol summary

Study aim

The aim of this study is to design and conduct a clinical trial to evaluate the effects of vision therapy interventions on visual function, fear of falling, and quality of life in patients with idiopathic Parkinson’s disease.

Design

Randomized controlled trial (RCT) with parallel groups and single-blind design. Participants are allocated to groups using 1:1 block randomization with sealed opaque envelopes. Outcome assessments are conducted by independent blinded assessors.

Settings and conduct

The study is conducted in healthcare and rehabilitation centers for Parkinson’s patients. Participants provide informed consent, are assessed, and receive either vision therapy (intervention) or general health information (control). All procedures are supervised with blinding and randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria (short): Idiopathic Parkinson’s patients aged 30–75, disease stage 1–3 (Hoehn & Yahr), adequate cognition (MoCA > 24, PD-CRS > 82), corrected visual acuity ≥ 20/40, binocular vision problems (CISS > 21, NPC > 8 cm), able to read and write in Persian. Exclusion criteria (short): Severe ocular or neurological diseases, history of brain surgery (except DBS), strabismus or amblyopia, medication changes or disease stage change, drugs affecting binocular vision (except Parkinson’s), incapacitating comorbidities.

Intervention groups

Control group: Receives general health information. Intervention group: Receives vision therapy progressing from simple to complex exercises, monitored with checklists, administered during the ON medication phase.

Main outcome variables

The main outcome variables include: Visual function (visual acuity, stereopsis, contrast sensitivity, near point of convergence, reading speed, fusional vergence reserves, heterophoria, and vergence facility and saccade and pursuit) Fear of falling Vision-related quality of life

General information

Reason for update

Acronym

VTPD

IRCT registration information

IRCT registration number: **IRCT20251122068072N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **prospective**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-09-22, 1405/06/31

Expected recruitment end date
2027-09-22, 1406/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of a structured vision-therapy program versus usual care on visual performance, fear of falling, and quality of life in individuals with idiopathic Parkinson’s disease: a randomized clinical trial

Public title
The effect of vision therapy compared with usual care on vision, fear of falling, and quality of life in people with Parkinson’s disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30 and 75 years. Diagnosis of idiopathic Parkinson’s disease confirmed by a neurologist based on the UK Brain Bank Criteria. Disease severity between stages 1 and 3 on the Hoehn and Yahr scale. Adequate cognitive function defined as a score of 24 or higher on the MoCA test and 82 or higher on the PD-CRS test. Ability to read and write in Persian Absence of young-onset Parkinson’s disease (onset before the age of 21 years). No substance abuse according to the patient and family reports. No other major neurological disorders based on neurologist evaluation. Best corrected visual acuity of 20/40 or better in each eye. Presence of binocular vision dysfunction, including a CISS score greater than 21, near point of convergence exceeding 8 centimeters, and other indicators of binocular vision anomalies if applicable. Stable dosage of antiparkinsonian medications throughout the study period. No severe anxiety or depression based on the HADS questionnaire (scores below 11 on each subscale).
Exclusion criteria:
Presence of severe anterior segment ocular diseases including advanced keratoconus, corneal opacities, advanced glaucoma, and active uveitis. Presence of severe posterior segment diseases such as advanced age-related macular degeneration, proliferative diabetic retinopathy, retinal detachment, optic nerve atrophy, and other major macular disorders. History of brain surgery except for DBS. History of ocular trauma. Presence of manifest strabismus, paralytic deviations, or significant vertical deviations. History of amblyopia. Ocular conditions affecting binocular vision. Use of medications that interfere with binocular vision (other than antiparkinsonian drugs). Any change in antiparkinsonian drug dosage during the study. Use of medications that impair balance as confirmed by the medical team. Occurrence of any new debilitating comorbidity during the study that may affect participation.
Age
From **30 years** old to **75 years** old

Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After screening and confirming eligibility, participants will be assigned to either the intervention or control group using 1:1 block randomization. Sealed, opaque envelopes will be used to ensure allocation concealment for both participants and researchers. Block sizes and sequences will be generated by a randomization software. Optometrists assigned to the intervention and control groups will be different and trained by the research team to ensure standardized administration and minimize bias. To ensure reliability of assessments, the agreement between these evaluators will be tested in a pilot study of ten participants.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a participant-blinded randomized controlled trial. Due to the use of a placebo vision-therapy protocol in the control group, participants will remain blinded to their group allocation. The placebo exercises will be designed to mimic the structure, duration, and therapist–participant interaction of the active vision-therapy sessions, ensuring that participants cannot distinguish between the intervention and control conditions. Outcome assessors will not be blinded to group allocation due to the nature of the visual, functional, and mobility assessments, which require detailed clinical judgment and cannot feasibly be conducted under blinded conditions. Randomization will be performed using a block randomization method with allocation concealment ensured through sequentially numbered, opaque, sealed envelopes (SNOSE). The data analyst will remain blinded to the group assignments, and all datasets will be coded prior to statistical analysis. Accordingly, participants will be blinded to their assigned group, while outcome assessors will not be blinded. The trial will therefore operate as a participant-blinded randomized controlled study.
Placebo
Used
Assignment
Parallel
Other design features
The study is a randomized controlled trial (RCT) with parallel groups. Participants are allocated to intervention or control groups using 1:1 block randomization with sealed opaque envelopes. The study is single-blind: participants are unaware of their group allocation, and outcome assessments are conducted by independent blinded assessors. The intervention group receives vision

therapy (VT), while the control group receives only general health information (inactive control). Assessments include vision-related quality of life, fear of falling, visual and cognitive performance, mobility and functional balance, contrast sensitivity, stereopsis, near point of convergence, fusional vergence, and other relevant visual tests. A pilot study will be conducted to verify assessor agreement and to fine-tune the protocol.

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Shah-Nazari

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ ۱۵۴۵۹

Approval date
2025-11-19, 1404/08/28

Ethics committee reference number
IR.IUMS.REHAB.REC.1404.012

Health conditions studied

1

Description of health condition studied
Idiopathic Parkinson’s disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Visual function, fear of falling, and vision-related quality of life in patients with idiopathic Parkinson’s disease

Timepoint
Baseline, post-intervention, and follow-up

Method of measurement
Visual function tests (acuity, stereopsis, contrast sensitivity, NPC, reading speed, vergence), fear of falling questionnaires, and vision-related quality of life questionnaires

Secondary outcomes

1

Description
Secondary outcomes include functional mobility and balance, contrast sensitivity and color vision, cognitive function, fusional vergence reserves and vergence facility, and the number of falls during the study period. These outcomes are measured using standardized tests and validated questionnaires.

Timepoint
Baseline (before intervention), post-intervention, and follow-up.

Method of measurement
Functional mobility and balance measured using standardized mobility and balance tests; contrast sensitivity and color vision measured with standard visual tests; cognitive function assessed using MoCA and PD-CRS; fusional vergence reserves and vergence facility assessed using optometric tests; number of falls recorded via patient diary or interview.

Intervention groups

1

Description
Intervention Group: Structured Vision-Therapy ProgramParticipants in this group will receive a structured vision-therapy program consisting of evidence-based exercises derived from the Delphi phase of the study. The intervention includes standardized exercises targeting convergence, fusional vergence ranges, accommodative function, saccades, and smooth pursuits.The program will be delivered by trained optometrists. The duration (expected 8–12 weeks), frequency (2–3 sessions per week), and session length (30–45 minutes) will be finalized after the pilot study. Exercises progress from basic to advanced levels and include both in-clinic and home-based components.Monitoring will be conducted using structured checklists during each phase: (1) basic training, (2) advanced/extended exercises with compliance monitoring, and (3) review and consolidation of learned skills.

Category
Treatment - Other

2

Description
Control Group: General Health Education + Placebo Vision TherapyParticipants in the control group will not receive active vision therapy. However, to maintain participant blinding, a placebo vision-therapy protocol will be administered. This placebo protocol consists of a set of exercises designed to resemble the structure, duration, and therapist–participant interaction of the active vision-therapy sessions, but without the therapeutic components expected to produce clinical improvement.In addition to the placebo intervention, the

control group will receive a weekly standardized educational package containing information relevant to general health in individuals with Parkinson’s disease, including recommendations on nutrition, safe and light physical activity, environmental safety, and general symptom management.The number of sessions, their duration, and the content of the placebo exercises and educational materials will be matched to the intervention group and finalized based on the findings of the pilot study to ensure equal attention and contact time across both groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences Iran University of Medical 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

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

Faezeh Fayaz

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Optometry

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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

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

Title: Data and documents from the clinical trial on vision therapy in patients with idiopathic Parkinson’s disease
Details: The dataset includes de-identified participant data, baseline and outcome measures, and study-related documents such as protocol, informed consent forms, and statistical analysis plan. Data may be shared for scientific research purposes upon reasonable request and approval by the ethics committee.

When the data will become available and for how long

The data and study-related documents will become available after publication of the primary results and will remain accessible for up to 5 years.

To whom data/document is available

Data and study-related documents will be available to researchers who submit a reasonable request for scientific purposes and receive approval from the principal investigator and the ethics committee.

Under which criteria data/document could be used

Data and study-related documents may be used only for scientific research purposes, with appropriate ethical approval, and in accordance with the conditions set by the principal investigator and the ethics committee.

From where data/document is obtainable

Data and study-related documents can be obtained by contacting the principal investigator of the study. Contact details will be provided in the study registry.

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

Researchers must submit a reasonable request specifying the purpose of data use. The request will be reviewed and approved by the principal investigator and the ethics committee. Upon approval, the requested de-identified data and documents will be shared under the agreed conditions.

Comments