Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Cognitive Orientation to daily Occupational Performance (CO-OP) interventions with and without motivational feedback on balance confidence, anxiety, occupational function, activities of daily living, and functional balance and mobility in older adults with Parkinson's disease with fear of falling

Protocol summary

Study aim
The effect of Cognitive Orientation to daily Occupational Performance (CO-OP) interventions with and without motivational feedback on balance confidence, anxiety, occupational function, activities of daily living, and functional balance and mobility in older adults with Parkinson's disease with fear of falling

Design
A controlled, parallel-group, double-blind, randomized clinical trial on 75 patients. Randomization will be generated using the website http://www.randomizer.org

Settings and conduct
Study location: Rehabilitation clinics in Tehran; Study population: Elderly aged 65 and over with Parkinson’s disease at Hoehn & Yahr stages 1 to 3; Type of blinding: Single-blind; Blinding method: Participants and outcome assessors are blinded; therapists are not.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 65 years or older; Idiopathic Parkinson’s disease confirmed by a neurologist with a disease severity of 1–3 on the H&Y scale; Adequate cognitive function with a score of ≥24 on the Montreal Cognitive Assessment; Presence of fear of falling confirmed by a single-item question (Yes/No). Exclusion criteria: Presence of other neurological or orthopedic disorders affecting mobility according to physician report; Diabetes mellitus; History of addiction

Intervention groups
Intervention group 1: CO-OP with motivational feedback Participants receive CO-OP training along with motivational feedback. Intervention group 2: CO-OP without motivational feedback Participants receive CO-OP training without motivational feedback. Control group: Conventional occupational therapy Participants receive routine occupational therapy without CO-OP.

Main outcome variables
Satisfaction of performance; performance; balance confidence; functional mobility and balance; motivation; independence in activities of daily living; quality of life; participation; fear of falling.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140304016830N14**
Registration date: **2025-07-11, 1404/04/20**
Registration timing: **prospective**

Last update: **2025-07-11, 1404/04/20**
Update count: **0**

Registration date
2025-07-11, 1404/04/20

Registrant information

Name
Ghorban Taghizadeh

Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical

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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
2026-06-20, 1405/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Cognitive Orientation to daily Occupational Performance (CO-OP) interventions with and without motivational feedback on balance confidence, anxiety, occupational function, activities of daily living, and functional balance and mobility in older adults with Parkinson's disease with fear of falling

Public title
The effect of cognitive-functional intervention with and without motivational feedback on balance confidence and daily functioning in older adults with Parkinson's disease and fear of falling
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 65 years or older Idiopathic Parkinson’s disease confirmed by a neurologist with a disease severity of 1–3 on the Hoehn & Yahr scale Adequate cognitive function, with a score of ≥24 on the Montreal Cognitive Assessment Presence of fear of falling, confirmed by a single-item question (Yes/No)
Exclusion criteria:
Comorbid neurological/orthopedic conditions affecting mobility, per physician report Substance abuse History of diabetes mellitus
Age
From **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
The type of randomization used in this study is block randomization, which will be performed using the website http://www.randomizer.org by a person independent of the therapist and evaluator. Participants in different groups will have no contact with each other and will receive the interventions on different days. All participants in the three groups will be assessed before the intervention, after the intervention, and at follow-up (six weeks after the end of the intervention).
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants in this study will be blinded to their group allocation. Although they are aware that they are participating in a research project involving cognitive-practical interventions, they will not be informed about the number of groups, the specific differences between the groups, or the hypotheses of the study. The outcome assessors, data collectors, and the statistician responsible for data analysis will also be blinded to group allocation. The therapists delivering the interventions cannot be blinded due to the nature of the intervention. The principal investigator will not be involved in the intervention delivery or outcome assessment and will only have access to de-identified data.
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
Iran University of Medical Sciences (IUMS), next to Milad Tower, Hemmat Expressway, Postal Code: 1449614535
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-06-09, 1404/03/19
Ethics committee reference number
IR.IUMS.REC.1404.317

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
Satisfaction of performance
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
The score of satisfaction with performance will be measured using the Canadian Occupational Performance Measure (COPM). This score reflects the participants' level of satisfaction with their performance in daily activities, rated on a 10-point scale, where higher scores indicate greater satisfaction.

2

Description
performance
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
The performance score will be measured using the Canadian Occupational Performance Measure (COPM). This score reflects the participants' level of performance in daily activities and is recorded on a 10-point scale, where higher scores indicate better performance.

Secondary outcomes

1

Description
Functional mobility
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Timed Up and Go (TUG) Test

2

Description
Self-reported confidence in maintaining balance during daily activities
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Activities-specific Balance Confidence (ABC)

3

Description
Assesses the individual's ability to maintain static and dynamic balance through 14 different tasks (e.g., standing unsupported, turning, picking up objects).
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Berg Balance Scale (BBS)

4

Description
Adaptability of gait during complex walking tasks.
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Dynamic Gait Index - DGI

5

Description
Activities of Daily Living (ADL) independence
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Barthel Index - BI

6

Description
Intrinsic motivation
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Intrinsic Motivation Inventory - IMI

7

Description
Quality of life
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Parkinson's Disease Questionnaire (PDQ-39)

8

Description
Frequency and perceived meaningfulness of 28 daily activities
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Meaningful Activity Participation

9

Description
Disability in daily activities specific to PD
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement

UPDRS-ADL

10

Description
Concern about falling during daily activities
Timepoint
Baseline, post-intervention (week 12), and follow-up (week 18)
Method of measurement
Falls Efficacy Scale-International

Intervention groups

1

Description
Intervention group 1: Participants in this group will undergo a 12-session combined intervention program (60 minutes per session, twice weekly for 6 weeks). Each session begins with 20 minutes of conventional occupational therapy focusing on balance, mobility, and functional exercises. The subsequent 40 minutes are dedicated to the structured CO-OP protocol, which employs a client-centered approach to develop: (1) functional skill acquisition, (2) cognitive problem-solving strategies using the "Goal-Plan-Do-Check" framework, and (3) strategy generalization to daily life. Integrated with this process is motivational feedback based on the Human Occupation Model, featuring positive reinforcement, graded challenges tailored to individual capability, and activity meaning enhancement. This dual-focused intervention simultaneously targets functional improvement and intrinsic motivation.
Category
Rehabilitation

2

Description
Intervention group 2: This group follows an identical 12-session structure to Group 1 (20 minutes conventional OT + 40 minutes CO-OP protocol), with the key distinction of excluding motivational components. Therapists focus solely on delivering the cognitive-strategy training component of CO-OP (including goal-setting via COPM, problem-solving strategy development, and real-world application), deliberately omitting motivational feedback, challenge grading, or discussions about activity meaningfulness. This design allows isolation of the pure cognitive-performative effects without motivational confounders. All CO-OP protocol elements (e.g., Goal-Plan-Do-Check framework, dynamic performance analysis) are maintained with fidelity.
Category
Rehabilitation

3

Description
Control group: The control group participants receive 12 sessions (60 minutes each) of evidence-based standard occupational therapy for Parkinson's disease, incorporating neurodevelopmental techniques (NDT), dynamic balance exercises (e.g., directional changes, obstacle negotiation), upper/lower limb strengthening, muscle stretching, motor coordination drills, and activities of daily living (ADL) training. Therapists tailor these components to individual needs while rigorously avoiding structured cognitive strategy training or systematic motivational techniques. This conventional approach serves as an active comparator to isolate the unique effects of the CO-OP protocol beyond standard care benefits.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Movement Disorder centers and rehabilitation clinics
Full name of responsible person
Ghorban Taghizadeh
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Vice Chancellor for research of Iran University of Medical Sciences, Dr. Majid Safa
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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1449614535
Phone
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Email
safa@yahoo.com
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
Ghorban Taghizadeh
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
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Web page address

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
Yes - There is 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
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The shared file will include de-identified data from study participants. Specifically, the dataset will contain general demographic information (age, gender), group allocation, and scores related to the primary outcome measures of

the study. No personal identifiers such as names, contact details, or national ID numbers will be included. Only this specific part of the data will be available to other researchers upon formal request and after obtaining appropriate approvals. The complete dataset or other sensitive information will not be shared.

When the data will become available and for how long

One year after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of the documentation is permitted upon written permission.

From where data/document is obtainable

En Ghorban Taghizadeh Adsress: Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Tel: 00982122227124, E-mail: taghizadeh.gh@iums.ac.ir

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

Just sending a request by email and mentioning the explanation about the cause of the need for documentation is enough.

Comments