

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

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Email address

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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

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

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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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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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Person responsible for scientific inquiries

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Other areas of specialty/work

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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 Address: 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