

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 24$  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)

##### Phone

+98 21 2222 7124

##### Email address

taghizadeh.gh@iums.ac.ir

##### Recruitment status recruiting

## 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  $\geq 24$  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**

Ghorban Taghizadeh

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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****Contact****Name of organization / entity**

Iran University of Medical Sciences

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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**