

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Cognitive Stimulation Interventions Based on Enjoyable Activities with and Without Motivational Feedback on Cognitive, Psychological, and Occupational Functions in the Elderly with Parkinson's Disease and Cognitive Impairment

#### Protocol summary

##### Study aim

To evaluate the effects of cognitive stimulation interventions based on enjoyable occupations with and without motivational feedback on cognitive, psychological, and occupational functions in elderly people with Parkinson's disease and cognitive impairment.

##### Design

A controlled, parallel-group, Single-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: Age  $\geq$  65 years, Idiopathic Parkinson's disease (Hoehn & Yahr stage 1-3), Mild cognitive impairment (MoCA score 18-23) Non-inclusion criteria: Presence of other neurological or orthopedic disorders, Diabetes, or substance abuse

##### Intervention groups

Control group: Routine occupational therapy including stretching, strengthening, balance, postural control, and fine motor training for 12 sessions (6 weeks, two sessions per week). Intervention group 1: Cognitive stimulation based on enjoyable occupations with motivational feedback, involving meaningful activities (e.g., cooking, painting, gardening) integrated with cognitive tasks and motivational feedback, delivered over 12 sessions (6 weeks, two sessions per week). Intervention group 2: Cognitive stimulation based on enjoyable occupations without motivational feedback, involving the same activities and cognitive tasks but

without motivational feedback, delivered over 12 sessions (6 weeks, two sessions per week).

##### Main outcome variables

Satisfaction of performance; performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140612018077N4**

Registration date: **2025-08-30, 1404/06/08**

Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**

Update count: **1**

##### Registration date

2025-08-30, 1404/06/08

##### Registrant information

##### Name

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##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-10-22, 1404/07/30

**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 Stimulation Interventions Based on Enjoyable Activities with and Without Motivational Feedback on Cognitive, Psychological, and Occupational Functions in the Elderly with Parkinson's Disease and Cognitive Impairment

**Public title**

Cognitive Stimulation with Enjoyable Activities for Elderly with Parkinson's Disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being at the age of 65 years or older disease severity of 1-3 on the Hoehn & Yahr scale impairment of cognitive function, with a score of <24 on the Montreal Cognitive Assessment idiopathic Parkinson's disease confirmed by a neurologist

**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**

- Outcome assessor

**Sample size**Target sample size: **60****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 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

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Iran University of Medical Sciences (IUMS), next to Milad Tower, Hemmat Expressway, Postal Code: 1449614535

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**Approval date**

2025-08-18, 1404/05/27

**Ethics committee reference number**

IR.IUMS.REC.1404.522

**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**

Global cognitive function

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Montreal Cognitive Assessment (MoCA), a screening tool assessing short-term memory, executive function, attention and concentration, language, and visuospatial skills. Total score ranges from 0 to 30, with higher scores indicating better cognitive performance.

## 2

### **Description**

Parkinson's disease-specific cognitive function

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Parkinson's Disease Cognitive Rating Scale (PD-CRS), assessing cortical and subcortical cognition. Total score 0-134; lower scores reflect greater impairment.

## 3

### **Description**

Cognitive performance including attention, processing speed, and executive function

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

SCOPA-Cog (Scales for Outcomes in Parkinson's Disease-Cognition), 10 items; total score 0-43, higher scores indicate better performance.

## 4

### **Description**

Cognitive control and selective attention

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up

(week 18)

### **Method of measurement**

Stroop Test, naming ink color in incongruent conditions; outcomes: response time and error count.

## 5

### **Description**

Processing speed and cognitive flexibility

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Trail Making Test (TMT), part A (numbers) and part B (alternating numbers and letters). Main outcome: completion time.

## 6

### **Description**

Executive function and visuospatial memory

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Clock Drawing Test (CDT), drawing a clock with a set time; scored for accuracy and correct placement of hands.

## 7

### **Description**

Anxiety level

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Hospital Anxiety and Depression Scale (HADS), anxiety subscale with 7 items (scored 0-3). Higher scores = greater anxiety.

## 8

### **Description**

Depression level

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Hospital Anxiety and Depression Scale (HADS), Depression subscale with 7 items (scored 0-3). Higher scores = greater Depression.

## 9

### **Description**

Intrinsic motivation in performing activities

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Intrinsic Motivation Inventory (IMI), 45 items across 7 subscales. Total score 45-315.

## **10**

### **Description**

Parkinson's disease-specific quality of life

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Parkinson's Disease Questionnaire (PDQ-39), 39 items across 8 domains. Higher scores = poorer quality of life.

## **11**

### **Description**

General quality of life

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

EQ-5D questionnaire, covering 5 domains and a Visual Analogue Scale (VAS).

## **12**

### **Description**

This variable assesses the behavioral, emotional, and cognitive aspects of apathy, including motivation, interest, and goal-directed behavior. Higher scores indicate greater apathy severity.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Apathy Evaluation Scale (AES): An 18-item instrument where items are rated on a 4-point Likert scale. Total scores typically range from 18 to 72.

## **13**

### **Description**

This variable assesses domains of apathy such as intellectual curiosity, emotional response, action initiation, and self-awareness. Higher scores (in the positive range) indicate more severe apathy.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Lille Apathy Rating Scale (LARS): A structured interview consisting of 33 items. Scores are calculated using weighted responses, producing a total score ranging approximately from -36 to +36.

## **14**

### **Description**

This variable evaluates three apathy subdomains: executive apathy, emotional apathy, and initiation apathy. Higher scores on each subscale reflect greater apathy severity in that specific domain.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

## **Method of measurement**

Dimensional Apathy Scale (DAS): A 24-item scale where items are rated on a 4-point Likert scale. Subscale and total scores are calculated.

## **15**

### **Description**

This performance-based measure assesses functional mobility, balance, and gait speed under a standard condition (single-task) and while simultaneously performing a cognitive task (dual-task). Longer completion times indicate poorer mobility.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Timed Up and Go Test (TUG): A performance-based measure that times the completion of a standardized movement sequence. The dual-task version adds a concurrent cognitive task.

## **16**

### **Description**

This variable assesses fear of movement, injury, and re-injury during physical activity. Higher scores indicate greater fear of movement and avoidance behavior.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Tampa Scale of Kinesiophobia (TSK): A 17-item scale where items are rated on a 4-point Likert scale. Total scores range from 17 to 68.

## **17**

### **Description**

This variable assesses the flow experience, including absorption, fluency of performance, and perceived control during task performance. Higher scores indicate greater flow experience and task engagement.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Flow Short Scale (FSS): A 13-item instrument where items are rated using Likert-type scales.

## **18**

### **Description**

This variable assesses flow during occupational or work-related activities, including concentration, intrinsic motivation, sense of control, and time transformation. Higher scores indicate a stronger flow experience.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Flow State Scale for Occupational Tasks: A 14-item scale where items are rated on Likert scales and summed to

produce a total score.

## **19**

### **Description**

This variable assesses engagement, enjoyment, perceived competence, and immersion during rehabilitation exercises and therapy sessions. Higher scores indicate greater engagement and an optimal experiential state.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Flow State Scale for Rehabilitation Tasks (FSSOT): A 14-item scale adapted to measure flow during rehabilitation activities.

## **20**

### **Description**

This variable assesses fear-related beliefs, avoidance behaviors, and emotional responses related to movement or pain. Higher scores indicate stronger fear-avoidance beliefs and behavioral avoidance patterns.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Fear-Avoidance Components Scale (FACS): An instrument containing 16-20 items that are scored using Likert-type ratings.

## **21**

### **Description**

This variable assesses the level of concern about falling during daily physical and social activities. Higher scores indicate a greater fear of falling and lower balance confidence.

### **Timepoint**

Baseline, post-intervention (week 12), and follow-up (week 18)

### **Method of measurement**

Falls Efficacy Scale-International (FES-I): A 16-item scale where each item is rated on a 4-point scale. Total scores range from 16 to 64.

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1 will receive cognitive stimulation based on enjoyable occupations combined with motivational feedback. The protocol consists of 12 sessions over 6 weeks (2 sessions per week, 60 minutes each). Each session includes: (1) identifying and selecting meaningful activities (e.g., cooking, painting, gardening) using COPM; (2) embedding cognitive tasks (memory, attention, executive functions) within the activities; (3) providing verbal and visual motivational feedback during activities to enhance engagement and

motivation.

#### **Category**

Rehabilitation

### **2**

#### **Description**

The control group will receive routine occupational therapy interventions. These include stretching and strengthening exercises, positioning, postural control training, balance exercises, fine motor skill training, and functional exercises when feasible. The intervention will consist of 12 sessions over 6 weeks (2 sessions per week, 60 minutes each).

#### **Category**

Rehabilitation

### **3**

#### **Description**

Intervention group 2 will receive cognitive stimulation based on enjoyable occupations without motivational feedback. The protocol is identical to group 1, consisting of 12 sessions over 6 weeks (2 sessions per week, 60 minutes each). Activities are selected based on individual preferences and combined with cognitive exercises (memory, attention, executive functions), but no direct motivational feedback (verbal or visual) is provided.

#### **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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**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**

Maryam Mehdizadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**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**

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**

Maryam Mehdizadeh Address: Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, E-mail: Maryam.mehdizadeh\_22@yahoo.com

**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**