Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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 ≥ 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

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Maryam Mehdizadeh

Name of organization / entity
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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
Street address
ran University of Medical Sciences (IUMS), next to Milad Tower, Hemmat Expressway, Postal Code: 1449614535
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Stockholm
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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
Maryam Mehdizadeh
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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
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Position
Assistant Professor

Latest degree
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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