Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of sensory-motor reeducation of the hand on cognitive functions in Parkinson's disease patients with mild cognitive disorders

Protocol summary

Study aim

Determining the effectiveness of hand sensorimotor retraining on cognitive functions compared to the effectiveness of cognitive functions retraining on hand sensorimotor functions in patients with Parkinson's disease

Design

Simple non-random sampling from the patients referred to the occupational therapy department of Ayatollah Kashani Hospital and the Parkinson's Association in Isfahan. Sample size: 30 people with Parkinson's disease(15 people in each group)

Settings and conduct

After approval by Isfahan University of Medical Sciences and acquisition of the IRCT code, 30 patients with Parkinson's disease will be randomly assigned to two groups of 15 each and undergo two types of treatment (intervention: hand sensorimotor retraining; control: cognitive rehabilitation). The person responsible for evaluating study variables will be blinded to groups and interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with Parkinson's disease 2. At least 2 years have passed since the initial diagnosis 3. Disability level of 2.5 and less on the Hoehn & Yahr scale 4. Age 50 to 65 years 5. Mild cognitive disorder (score between 20-26 on Montreal Cognitive Assessment Scale) Exclusion criteria: 1. Coexistence of diseases other than Parkinson's Disease

Intervention groups

Intervention group: Sensorimotor hand retraining for 10, one and a half hour sessions, 3 days per week Control group: Cognitive rehabilitation for 10, one and a half hour sessions, 3 days per week

Main outcome variables

1. Score of Montreal Cognitive Assessment (0-30) 2. score of Cambridge Computerized Cognitive Test 3. Score of Box&Block and Purdue PegBoard tests 4. Muscle strength in Dynamometer and Pinch Gauge testing 5. Tactile Pressure Perception Threshold 6. Score of Michigan Hand Outcome Questionnaire (0-76) 7. Score of KING'S Parkinson's Disease PAIN SCALE (0-12)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250406065222N1**
Registration date: **2026-06-22, 1405/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-22, 1405/04/01**
Update count: **0**

Registration date

2026-06-22, 1405/04/01

Registrant information

Name

Hamid Reza Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 432 8034

Email address

hrr.rostami@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of sensory-motor reeducation of the hand on cognitive functions in Parkinson's disease patients with mild cognitive disorders

Public title

Effects of sensory-motor reeducation of the hand on cognitive functions in patients with Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A patient with Parkinson's disease diagnosed by a neurologist At least 2 years have passed since the initial diagnosis of Parkinson's disease Disability level of maximum 2.5 on the Hoehn & Yahr scale Age 50 to 65 years (age of highest prevalence of Parkinson's disease) Mild cognitive impairment (score between 20 and 26 on the Montreal Cognitive Assessment Scale)

Exclusion criteria:

Presence of diseases other than Parkinson's

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of 30 patients with Parkinson's disease through stratified randomization to two intervention groups (sensorimotor hand rehabilitation) and control (cognitive rehabilitation): - Type of randomization: stratified randomization; - Randomization layers: First layer: score 1 to 1.5 on the Hoehn and Yahr scale, second layer: score 2 to 2.5 on the Hoehn and Yahr scale); - Allocation ratio is 1:1; - Randomization sequence of assigning samples to groups in each stratum: Given that each patient may enter the study at different times, before starting the allocation of samples, a random sequence is generated to randomly assign individuals to each of the study randomization strata based on the time of entry of individuals (first layer: B, B, A, B, A, B, A, B, A, B, A, B, B, A, A; second layer: A, B, B, A, A, A, A, B, B, B, A, B, B, B, A) - A: Intervention group; B: Control group - Concealment of the randomization sequence through a sealed envelope containing the name of the assigned group. The names of the randomization strata (first stratum and second stratum) are written on the envelope and the name of the intervention or control group is placed inside the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person responsible for conducting the assessments is someone other than the people implementing the therapeutic intervention sessions who is not aware of the study groups in terms of the type of therapeutic interventions. The person responsible for conducting the statistical analyses of the study is also someone other than the group implementing and evaluating the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

Postal code

8184667951

Approval date

2026-02-16, 1404/11/27

Ethics committee reference number

IR.MUI.NUREMA.REC.1404.174

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

cognition

Timepoint

Pre-test, Post-test (one month after starting the intervention), follow-up (one month after ending intervention)

Method of measurement

The Cambridge Neuropsychological Test Automated

Battery

2

Description
hand Function
Timepoint
Pre-test, Post-test (one month after starting the intervention), follow-up (one month after ending intervention)
Method of measurement
Box&Block test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group - Cognitive rehabilitation: The intervention group's treatment program will include cognitive rehabilitation for 10 one-and-a-half hour sessions, 3 days a week. In the first part of cognitive exercises, common cognitive problems of Parkinson's patients are targeted for treatment through the following exercises: 1. Elimination 2. Number sequences. 3. Problem clarification. 4. Communication. 5. Text comprehension. 6. Recall. 7. Word search. 8. Maze navigation. 9. Classification. 10. Action sequences. 11. Story memory. In the second part of cognitive exercises, cognitive exercises are performed in the form of daily life activities and based on a task-oriented approach in occupational therapy. To implement this approach, daily life activities that the individual has considered important and meaningful in his or her life in the initial assessment session and that have the ability to be implemented in the occupational therapy clinic environment are practiced.
Category
Rehabilitation

2

Description
Control group: The treatment program includes hand sensorimotor retraining for 10 one-and-a-half hour sessions, 3 days a week, plus cognitive rehabilitation for 10 one-and-a-half hour sessions, 3 days a week.Sensory-motor rehabilitation of the hand: Sensory-motor exercises of the hand for 45 minutes per session and sensory-motor exercises in the form of daily life activities based on a task-oriented approach in occupational therapy for 45 minutes per session. In the sensory-motor retraining exercises of the hand, sensory retraining exercises and motor retraining exercises are performed in combination with the help of various objects and equipment applied to sensory recovery, muscle strength, and range of motion. In the second part of the sensory-motor retraining exercises of the hand, sensory-motor exercises are performed in the form of daily life activities based on a task-oriented approach in occupational therapy. To implement this approach, daily life activities that the individual has considered important and meaningful in his or her life in the initial assessment session and that have the ability to be performed in the occupational therapy clinic environment are practiced.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences, Kashani Hospital
Full name of responsible person
Hamid Reza Rostami
Street address
hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8184667951
Phone
+98 913 432 8034
Email
hrr.rostami@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Research Deputy of Isfahan University of Medical Sciences
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8184667951
Phone
+98 913 432 8034
Email
hrr.rostami@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
hamid Reza Rostami

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
8184667951

Phone
+98 913 432 8034

Email
hrr.rostami@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
hamid reza rostami

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
hezar jarib

City
Isfahan

Province
Isfehan

Postal code
8184667951

Phone
+98 913 432 8034

Email
hrr.rostami@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
hamid reza rostami

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
jezar jarib

City
Isfahan

Province
Isfehan

Postal code
8184667951

Phone
+98 913 432 8034

Email
hrr.rostami@gmail.com

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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
6 months after the publication of the study results, the data of the individuals will be made available anonymously only to scientific and academic researchers, if needed.

When the data will become available and for how long
6 months after the publication of the study results

To whom data/document is available
scientific and academic researchers

Under which criteria data/document could be used
scientific and academic usages

From where data/document is obtainable
Hamid Reza Rostami Isfahan University of medical sciences email: hrr.rostami@gmail.com

What processes are involved for a request to access data/document
Email: hrr.rostami@gmail.com

Comments