Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating Emotional, Cognitive, and Motor Planning Status Following Group Rehabilitation Therapy in Individuals with Parkinson's Disease: A Clinical Trial

Protocol summary

Study aim

assessment of the effects of group therapy on emotional well-being, cognitive function, and motor planning in Parkinson’s disease patients

Design

This clinical trial is a randomized, double-blind, controlled study with parallel groups involving 30 patients. Randomization will be performed using a computer-generated sequence with allocation concealment.

Settings and conduct

The study will be conducted at faculty of rehabilitation of Tabriz University of Medical Sciences. Parkinson’s patients, after assessment and eligibility confirmation, will be assigned to intervention groups. Baseline and follow-up evaluations of emotional, cognitive, and motor status will be performed. The study is double-blind; outcome assessors and data analysts will be blinded to group allocation, and therapists will not be involved in outcome assessments.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of Parkinson’s disease by a specialist physician, Adequate cognitive level, Absence of serious comorbid conditions that would prevent participation in the study, Willingness to participate in the therapeutic interventions of the study, Provision of informed consent to participate in the study Exclusion Criteria: Concurrent participation in other therapeutic interventions that could affect the study outcomes, Presence of severe or chronic comorbid diseases, Inability to complete the required study assessments

Intervention groups

Intervention group will be provided with cognitive, motivational, and motor activities based on the Moho model and with a cognitive-motivational approach, to improve emotion, cognitive function, and motor planning in 12 60-minute group sessions over 4 weeks. Control group will receive a conventional rehabilitation program including stretching, muscle strengthening, and endurance exercises with the same standard equipment, in the same number of sessions and duration.

Main outcome variables

Emotional status, Cognitive function, Motor function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250524065874N1**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-07, 1404/05/16**
Update count: **0**

Registration date

2025-08-07, 1404/05/16

Registrant information

Name

Zeinab Fathipour-Azar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating Emotional, Cognitive, and Motor Planning Status Following Group Rehabilitation Therapy in Individuals with Parkinson's Disease: A Clinical Trial

Public title
Effects of Group Therapy on Patients with Parkinson's Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
•Diagnosis of idiopathic Parkinson's disease confirmed by a neurologist, based on established criteria such as the UK Brain Bank Disease severity at stages 1 to 3 according to the Hoehn and Yahr scale Age range approximately between 30 to 80 years old Adequate cognitive function, typically defined by a score of 24 or higher on the Mini Mental State Examination (MMSE) or Montreal Cognitive Assessment (MoCA) Ability to perform motor tasks relevant to the intervention, including uni-manual and bi-manual activities of daily living Minimum educational level to ensure comprehension and participation in therapy Willingness and ability to provide informed consent and participate actively in group therapy sessions Having a stable medication regimen for Parkinson's disease symptoms for at least two months prior to enrollment in the study
Exclusion criteria:
Significant psychiatric disorders such as major depression, psychosis, or severe anxiety that may interfere with participation Other neurological or musculoskeletal conditions that significantly affect motor function (e.g., stroke, severe arthritis) Participation in other clinical trials or rehabilitation programs that could confound results Severe sensory impairments (e.g., vision or hearing loss) that limit ability to engage in therapy
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: Participants who meet the inclusion criteria and provide informed consent will be randomly assigned in a 1:1 ratio to one of two groups: the intervention group (Group A) or the control group (Group B). Type and Unit of Randomization: In this study, block randomization with variable block sizes will be used to maintain balance in the number of participants in each group throughout the study. The unit of randomization is the individual participant. Block Size: Block sizes will be variable, consisting of blocks of 4 and 6 participants. This method helps to prevent prediction of the allocation sequence. Stratified Randomization: To ensure balance between groups regarding key variables, stratified randomization will be performed. The strata will be defined based on the following two main variables: Disease severity (according to the Hoehn and Yahr scale), Age group (less than 60 years, and 60 years or older) Generation of Random Sequence: The random sequence will be generated using Microsoft Excel and the RAND function. Separate sequences will be created for each stratum and then arranged into variable-sized blocks. Allocation Concealment: The allocation of participants to groups will be performed by an independent researcher who is not involved in recruitment, assessment, or intervention of participants. The randomization sequences will be kept in sealed and numbered envelopes. After each participant is enrolled, the researcher responsible for allocation will open the envelope corresponding to the next sequence to determine the assigned group. This method ensures that group allocation remains concealed from both the researcher and the participant until the appropriate time, thereby preventing selection bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, a double-blind design will be implemented to reduce bias and increase the validity of the results; this means that both the outcome assessors and the data analysts will be blinded to the allocation of participants to the intervention and control groups. Participants will be fully informed of the group to which they are assigned; however, to prevent expectation bias, detailed and specific information about the differences between the interventions will not be provided, and only general explanations regarding the study’s purpose and the type of interventions will be given. This approach is conducted in accordance with ethical principles and respect for participants' right to be informed. Assessors who measure emotional status, cognitive function, and motor planning will operate independently and will have no access to group allocation information. Additionally, therapists delivering the interventions will not be involved in outcome assessment or data analysis. Data analysts will also conduct statistical analyses blinded to group allocation to prevent bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz university of Medical Science

Street address
Third Floor, Deputy of Research and Technology, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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Approval date
2025-05-12, 1404/02/22

Ethics committee reference number
IR.TBZMED.REC.1404.171

Health conditions studied

1

Description of health condition studied
Parkinson's disease

ICD-10 code
G20

ICD-10 code description
Hemiparkinsonism Paralysis agitans Parkinsonism or Parkinson disease: NOSidiopathicprimary

Primary outcomes

1

Description
Emotional status

Timepoint
Before the start of the intervention, 4 weeks after the intervention, 4 weeks after the completion of the intervention

Method of measurement
The emotional status is assessed using the Hospital Anxiety and Depression Scale (HADS) and the Beck Depression Inventory (BDI).

2

Description
Cognitive function

Timepoint
Before the start of the intervention, 4 weeks after the intervention, 4 weeks after the completion of the intervention

Method of measurement
Cognitive function is evaluated with the Montreal Cognitive Assessment (MoCA) and the Mini-Mental State Examination (MMSE).

3

Description
Motor function

Timepoint
Before the start of the intervention, 4 weeks after the intervention, 4 weeks after the completion of the intervention

Method of measurement
Motor planning and performance are measured by Part III of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS Part III) and the Purdue Pegboard Test. Additionally, a motion analysis system may be used for more precise quantitative assessment of motor function.

Secondary outcomes

1

Description
Participation in activity of daily living (ADL)

Timepoint
Before the start of the intervention, 4 weeks after the intervention, 4 weeks after the completion of the intervention

Method of measurement
The Canadian Occupational Performance Measure (COPM) for evaluating patient's participation in Activities of daily living

Intervention groups

1

Description
Intervention Group (1): The treatment is designed based on the group rehabilitation approach and the framework of the Model of Human Occupation (MOHO). MOHO emphasizes the interaction of three core systems of the individual—volition, habituation, and performance capacity—within the environment, aiming to enhance the cognitive, motivational, and motor abilities of the participants. This treatment is delivered as structured and regular group therapy sessions which, in addition to improving individual skills, strengthen social support, increase positive group interactions, and enhance participants' motivation for active engagement in the therapeutic process. The therapeutic methods implemented in the sessions include cognitive exercises such as problem-solving, decision-making, and enhancing attention and focus, using cognitive training tools like memory cards, logical puzzles, and brain games. Motivational exercises incorporate intrinsic motivation enhancement techniques based on the MOHO model, including identifying individual goals and strengthening volition and enthusiasm for activity

engagement. Motor and skill exercises involve hand-eye coordination, balance training, and practicing motor skills with the use of therapy balls, simple balance devices such as balance boards and soft cushions, and mild motor aids like hoops and soft ropes. The group therapy also includes group sports programs executed as coordinated collective activities; these sports involve balance exercises, mild strength activities, coordinated hand-eye movements, and simple team activities designed for levels 1 to 3 of Hoehn and Yahr, representing various ability levels from basic to intermediate. Group sports, tailored to participants' interests and motor capabilities, help promote social participation, increase motivation, and improve physical health. At the end of each session, participants have the opportunity for discussion, performance evaluation, and receiving feedback from the therapist, which promotes ongoing enhancement of individual and group motivation and performance. Between sessions, motivational activities and assignments are specified to help maintain practice in the participants' daily environments and to support continuity of treatment progress. The equipment used includes cognitive tools such as memory cards with various images and words, multistage logical puzzles, and brain games. Motor equipment consists of therapy balls for motor exercises, simple balance tools like balance boards and special cushions, hoops, and soft ropes for group motor coordination practice. The venue is a rehabilitation room equipped with proper lighting, ventilation, and ample open space suitable for conducting group exercises and collective sports. The total course involves 12 sessions held over four weeks with a schedule of three sessions per week, each lasting 60 minutes. The duration and number of sessions are adjustable based on feedback from a pilot study and expert opinions. The treatment is completely non-pharmacological; no chemical substances, drugs, formulations, or dosages are used in the interventions. The treatment cumulatively includes cognitive, motivational, motor, and group sports activities. Group sports are especially suitable for Hoehn and Yahr levels one to three, which correspond to graded motor and cognitive abilities, and are designed and executed according to the participants' interests and motivation. After the pilot study is completed and experts' feedback collected, detailed protocols for each session and the equipment used will be fully documented and finalized.

Category

Rehabilitation

2

Description

Control Group (2):The control group will receive a conventional rehabilitation program based on standardized protocols from previous studies. Treatment Method: Conventional rehabilitation exercises including muscle stretching, strengthening exercises, and endurance activities, which differ from the cognitive-motivational approach of the intervention group. Equipment Used: Standard rehabilitation equipment such as therapy balls, resistance bands, light dumbbells, and basic muscle training tools. Number and Duration of Sessions: Equivalent to the intervention group; 12 sessions over 4 weeks (each session lasting 60 minutes). Session Content: Body warm-up and specific stretching exercises Muscle strengthening exercises tailored to the participants' conditions Endurance training (such as walking on a treadmill or using a stationary bicycle)Basic balance and coordination exercises. Intervention Period:4 weeks (concurrent with the intervention group).Other Details: All exercises will be taught and supervised by trained occupational therapists and physiotherapists, with safety principles ensured throughout. Note: No medications, chemical compounds, or specific supplements are used in this study, and the focus in both groups is on non-pharmacological, functional rehabilitation interventions. Should further details be required (such as a precise session schedule or information on specific equipment), additional information will be provided following the completion of the pilot study and review by the expert panel.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of the Faculty of Rehabilitation, Tabriz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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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
Tabriz 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
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Zeinab Fathipour-Azar
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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