

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of occupation-based interventions with and without responsibility feedback and conventional interventions on participation in people with idiopathic Parkinson's disease

Protocol summary

Study aim

The aim of the present study is to compare the effects of occupation-based interventions with and without responsibility feedback and conventional interventions on participation in people with idiopathic Parkinson's disease.

Design

This study is a parallel and double blinded randomized controlled trial with three groups. Forty-five patients will be randomly assigned to three groups (occupation-based interventions with responsibility feedback, occupation-based interventions without responsibility feedback, and conventional interventions). An independent researcher who is blind to patient assignments will evaluate the primary and secondary outcomes. Patients will also be blinded to group allocation.

Settings and conduct

This study will be conducted in patients' homes. The control group will receive conventional occupational therapy interventions. Interventional groups, in addition to conventional interventions, will receive occupation-based interventions (2 sessions per week, 60 to 90 minutes) with or without responsibility feedback.

Participants/Inclusion and exclusion criteria

People with idiopathic Parkinson's disease will be recruited from Movement Disorders centers. Inclusion criteria include: diagnosis of idiopathic Parkinson's disease based on UK Brain bank criteria, disease progression level based on Hoehn and Yahr stages of I to III, acceptable cognitive function (a score of >24 based on Montreal Cognitive Assessment), ability to read and write in Persian. Patients with impulsive-compulsive disorders, atypical parkinsonian syndromes, juvenile Parkinson's disease and other neurological disorders such as stroke will be excluded.

Intervention groups

Occupation-based interventions with responsibility

feedback; Occupation-based interventions without responsibility feedback; Conventional interventions

Main outcome variables

Participation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N13**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

2022-08-19, 1401/05/28

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

Recruitment complete

Funding source

Expected recruitment start date

2022-08-29, 1401/06/07

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of occupation-based interventions with and without responsibility feedback and conventional interventions on participation in people with idiopathic Parkinson's disease

Public title
The effect of occupational therapy interventions on participation in people with idiopathic Parkinson's disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of idiopathic Parkinson's disease based on UK Brain Bank criteria according to neurologist Disease progression level based on Hoehn and Yahr stages of I to III Acceptable cognitive function (a score of > 24 on Montreal Cognitive Assessment Ability to read and write in Persian to complete self-reported questionnaires
Exclusion criteria:
 Atypical parkinsonian syndromes Other existing neurological disorders, such as stroke Juvenile Parkinson's Disease Impulsive-compulsive disorders

Age
From **35 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who enter the study will be randomly assigned to one of the three groups: A: Occupation-based interventions with responsibility feedback; B: Occupation-based interventions without responsibility feedback; C: Conventional interventions. Participants will be randomly assigned to each group using a sequence generated by <http://www.randomizer.org>. For determining concealment, unique codes will be written on envelopes which contains group specifications.

Blinding (investigator's opinion)
Double blinded

Blinding description
An independent researcher who is blind to patient assignments will evaluate primary and secondary outcomes. To keep the assessor blind, patients and

therapists will be asked not to specify the received intervention or experience regarding the study to assessor. Patients will also be blind to group assignments. To keep patients blind, patients in different groups will not be able to communicate with each other.

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, Shahid Hemmat Highway, Tehran
City
 Tehran
Province
 Tehran
Postal code
 1449614535
Approval date
 2021-11-21, 1400/08/30
Ethics committee reference number
 IR.IUMS.REC.1400.753

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
 Participation satisfaction
Timepoint
 Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)
Method of measurement
 Utrecht Scale for Evaluation of Rehabilitation-Participation Satisfaction

Secondary outcomes

1

Description

Participation frequency and restriction

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Utrecht Scale for Evaluation of Rehabilitation-Frequency and restriction scales

2

Description

Self-perceived performance and performance satisfaction

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Canadian Occupational Performance Measure

3

Description

Motivation

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Social Motivation Questionnaire

4

Description

Volition

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Volitional Questionnaire

5

Description

Sense of agency

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Intentional Binding Task

6

Description

Responsibility

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Allocation of Treatment Responsibility Scale

7

Description

Physical activity

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Phone Frequency, Intensity, Time, and Type (Phone-FITT) Questionnaire

8

Description

Community integration

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Community Integration Questionnaire-Revised

9

Description

Activities of daily living and Instrumental activities of daily living

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Nottingham Extended ADL Scale

10

Description

Upper extremity function

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

9-hole peg Test

11

Description

Fatigue

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Fatigue severity scale

12

Description

Quality of life

Timepoint

Baseline, session 9, session 17, post-intervention (week 13), and follow-up (week 25)

Method of measurement

Parkinson's Disease Questionnaire (PDQ-39)

Intervention groups

1

Description

First Intervention group: This group will receive occupation-based interventions with responsibility feedbacks for 24 sessions (12 weeks, two sessions per week). Participants will receive occupations from simple (stationary condition with no intertrial variability and object manipulation) to hard (in-motion conditions with intertrial variability and object manipulation) levels based on their priorities identified via Canadian Occupational Performance Measure. Moreover, feedback statements that have the potential to create a sense of responsibility (derived from international and national Delphi studies with renowned experts and patients) in patients will be provided to participants as knowledge of performance or knowledge of result. These feedback statements are positive or negative statements in relation to the individual or his/her family. This group will receive conventional interventions for 15 minutes in each session. Participants in this group will receive occupation-based interventions with responsibility feedback for the remaining 45 to 75 minutes.

Category

Rehabilitation

2

Description

Second Intervention group: This group will receive occupation-based interventions with responsibility feedbacks for 24 sessions (12 weeks, two sessions per week). Responsibility feedbacks will not be provided to this group. This group will also receive 15 minutes conventional interventions and 45 to 75 minutes occupation-based interventions.

Category

Rehabilitation

3

Description

Control group: Participants who are assigned to this group will only receive traditional treatment for 24 sessions (12 weeks, 2 sessions per week, 60 to 90 minutes), including passive mobilization, lower extremity strengthening, stretching, motor coordination (upper and lower extremity), balance and walking training, manipulation exercises, breathing, relaxation, and postural exercises.

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. Yunes Panahi

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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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Phone

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Email

yunespanahi@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
 Assistant 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
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Full name of responsible person
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Person responsible for updating data

Contact

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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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the completion of this study, a manuscript regarding the documentation and the results of the study will be prepared and published. If more details are needed, individuals can send their request by email to the person responsible for scientific accountability.

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

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