Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 criterias, 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
Ghorban Taghizadeh
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 2222 7124
Email
taghizadeh.gh@iums.ac.ir

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
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
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

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

Person responsible for scientific 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

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
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Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

Person responsible for updating data

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

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

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 Adsress: 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