Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Cognitive Orientation to daily Occupational Performance (CO-OP) on Satisfaction and Occupational Performance in Individuals with Parkinson’s Disease

Protocol summary

Study aim

The Investigation of the Effectiveness of Cognitive Orientation to daily Occupational Performance (CO-OP) on Satisfaction and Occupational Performance in Individuals with Parkinson’s Disease

Design

Clinical, Randomized, Double-blind trial with two parallel groups

Settings and conduct

For both groups, one-hour individual sessions will be held twice a week for 6 weeks at their home. Participants in the control group benefit from conventional occupational therapy. while in the intervention group, the CO-OP approach is implemented. The evaluations will be performed by a trained assessor who is blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants with Parkinson’s Disease diagnosed by a neurologist, Hoehn and Yahr scale score between stages 1-3, Minimum score of 16 out of 30 in the Montreal test, No other neurological or psychological problems, No verbal problem, Ability to understand the global strategy of the co-op approach. exclusion criteria: Comorbidity with cognitive impairments such as Alzheimer, stroke, brain injury, multiple sclerosis, etc. Lack of cooperation and willingness to continue cooperation.

Intervention groups

Participants in the intervention group will receive the Cognitive Orientation to daily Occupational Performance (CO-OP) approach and Participants in the control group will receive conventional occupational therapy. This study will be presented in 45 to 60 minutes twice a week for 12 sessions at home.

Main outcome variables

Performance, Satisfaction, Goal Attainment, Functional Independence and fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052356N1**
Registration date: **2021-09-20, 1400/06/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-20, 1400/06/29**
Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Atefeh Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 8798

Email address

taheri.atefeh.ot@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-16, 1400/06/25

Expected recruitment end date

2021-11-16, 1400/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of Cognitive Orientation to daily Occupational Performance (CO-OP) on Satisfaction and Occupational Performance in Individuals with Parkinson’s Disease

Public title
Investigating effects of CO-OP approach in Individuals with Parkinson’s Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Parkinson’s Disease by a neurologist Hoehn and Yahr scale score between stages 1-3 A minimum score of 16 out of 30 on the Montreal Test No other neurological or psychological problems Not having a verbal problem And the ability to understand the global strategy of the CO-OP approach

Exclusion criteria:
Comorbidity with cognitive impairments such as: Alzheimer, stroke, brain injury, multiple sclerosis, etc. Lack of cooperation and willingness to continue cooperation

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will select by convenience sampling. we use simple randomization for allocation of samples into the control and CO-OP group. For this purpose, before starting the intervention, through the site randomization.com, according to the sample size, a sequence of placing participants in two groups (both are equal) is created. After the start of the study, each participant who was eligible to enter the study will receive a control or co-op intervention from a pre-prepared sequence list.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not be aware of the group that they are entered. The assessments will be performed by participants and trained assessor who are blind to the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran university of medical sciences

Street address
Tehran university of medical sciences, school of rehabilitation, Enghelab St, Pich-e-Shemiran

City
Tehran

Province
Tehran

Postal code
1148965111

Approval date
2020-02-12, 1398/11/23

Ethics committee reference number
IR.TUMS.FNM.REC.1398.177

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
Performance and satisfaction scores of client-chosen goal

Timepoint
pretest , post test and follow-up (one months after last session)

Method of measurement
Canadian Occupational Performance Measurement (COPM)

Secondary outcomes

1

Description
Goal Attainment

Timepoint
Pretest, post test and follow-up

Method of measurement
Goal Attainment Scale (GAS)

2

Description
Activities of Daily Living
Timepoint
Pretest, post test and follow-up
Method of measurement
Functional Independence Measure (FIM)

3

Description
Fatigue
Timepoint
Pretest, post test and follow-up
Method of measurement
Parkinson Fatigue Scale (PFS)

Intervention groups

1

Description
Intervention group: The intervention group receives the CO-OP approach in 12 sessions of 45-60 minutes and 2 sessions per week. This approach has a specific protocol. The first stage is preparation phase. In this stage, the necessary prerequisites for this approach are checked in the clients and also the purpose of treatment is given to the clients. The first session will be after the preparation phase and is evaluation session. In this session, participants select three performance goals based on the Canadian occupational performance measure Scale (COPM), And they score satisfaction and performance of three goals based on a ten-point scale. The second session will give the necessary explanations about the global cognitive strategy (Goal-Plan-Do-Check) to the clients, the focus of this session is on teaching this global strategy. Sessions three to eleven people acquire skills using these strategies, in these sessions the focus is on learning skills, in these sessions, dynamic performance analysis, guided discovery and the Enabling principles are used continuously, and session twelve Assessments are also performed again.
Category
Rehabilitation

2

Description
Control group: Patients in the control group received conventional occupational therapy. Evidence suggests that these interventions often include stretching and strengthening exercises, improving postural control, improving balance, relaxation techniques, breathing exercises, and gait training.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
DR. Hamid Dalvand
Street address
iaeian Hospital, opposite the municipality of the region 17, Abouzar Street, Tehran,
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Seyedeh Tahmineh Mousavi
Street address
Tehran University of Medical Sciences, school of rehabilitation, Enghelab street, Pich-e-Shemiran
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Email
rehabilitation@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Atefeh Taheri

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Position
Ph.D. of Occupational Therapy, Assistant Professor, Department of Occupational Therapy, School of Re

Latest degree
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Person responsible for updating data

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Position
master student

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Bachelor

Other areas of specialty/work
Occupational Therapy

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Article

When the data will become available and for how long
March 2022

To whom data/document is available
The researcher and occupational therapists

Under which criteria data/document could be used
Other research, critics, check and clinical usage

From where data/document is obtainable
Tehran university of Medical Science, School of Rehabilitation Sciences, Occupational Therapy department

What processes are involved for a request to access data/document
The data and results of the study are available in the final version and are available at the Faculty of Rehabilitation.

Comments