Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of occupation-based habit formation with and without adherence feedback on participation and self-care activity in people with idiopathic Parkinson

Protocol summary

Study aim

The study aims to examine the effectiveness of occupation-based habit formation interventions, with and without adherence feedback, by investigating the mediating roles of adherence mechanisms, motivation, self-regulation, and functional mobility on participation in daily life, social activities, and self-care activities in patients with idiopathic Parkinson's disease.

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 45 patients. Randomization will be generated using the website http://www.randomizer.org

Settings and conduct

Rehabilitation clinics in Tehran, study population: patients with Parkinson's disease at stage 1 to 4 according to the Hoehn & Yahr scale

Participants/Inclusion and exclusion criteria

Aged above 30 years, diagnosis of idiopathic Parkinson's disease by a neurologist (based on UK Brain Bank Criteria), no juvenile Parkinson's disease (onset before age 21), disease stage 1–4 according to the Hoehn & Yahr scale, adequate cognitive function (MoCA score above 24), literacy in Persian, no addiction reported by patient or caregivers, no diabetes, no other neurological diseases, no unresolved orthopedic conditions, ability to perform a simulated eating task at least twice within 30 seconds, no severe anxiety or depression (HADS score below 11), medication unchanged during study, no debilitating comorbid conditions developing during study

Intervention groups

Intervention group: recipients of occupation-based habit formation interventions without adherence feedback, intervention group: recipients of occupation-based habit formation interventions with adherence feedback, control group

Main outcome variables

Participation, self-care activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N16**
Registration date: **2025-10-01, 1404/07/09**
Registration timing: **prospective**

Last update: **2025-10-01, 1404/07/09**
Update count: **0**

Registration date

2025-10-01, 1404/07/09

Registrant information

Name

Ghorban Taghizadeh

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-15, 1404/08/24

Expected recruitment end date

2026-08-15, 1405/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of occupation-based habit formation with and without adherence feedback on participation and self-care activity in people with idiopathic Parkinson

Public title
effect of occupation-based habit formation with and without adherence feedback performance in people with idiopathic Parkinson

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 30 years and above. Having idiopathic Parkinson's disease diagnosed by a neurologist (based on the UK Brain Bank Criteria). Not having juvenile Parkinson's disease, which typically begins before the age of 21. Disease stage 1-4 based on the Hoehn & Yahr scale. Having an adequate cognitive level and scoring above 24 on the Montreal Cognitive Assessment (MoCA) test. Education level sufficient to read and write in Persian. Ability to perform the simulated eating task at least twice within 30 seconds.

Exclusion criteria:
Comorbid neurological/orthopedic conditions affecting mobility, per physician report Substance abuse History of diabetes mellitus The absence of other unresolved orthopedic diseases according to the doctor's report. Individuals whose medication use changes during the study. The occurrence of disabling comorbidities during the study.

Age
From **30 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
The type of randomization used in this study is block randomization, which will be performed using the website http://www.randomizer.org by a person independent of the therapist and evaluator. Participants in different groups will have no contact with each other and will receive the interventions on different days. All participants in the three groups will be assessed before the intervention, after the intervention, and at follow-up (For the same duration as the treatment determined in the pilot study).

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants in this study will be blinded to their group allocation. Although they are aware that they are participating in a research project involving cognitive-practical interventions, they will not be informed about the number of groups, the specific differences between the groups, or the hypotheses of the study. The outcome assessors, data collectors, and the statistician responsible for data analysis will also be blinded to group allocation. The therapists delivering the interventions cannot be blinded due to the nature of the intervention However, the outcome assessor will be blinded. . The principal investigator will not be involved in the intervention delivery or outcome assessment and will only have access to de-identified data.

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 (IUMS), next to Milad Tower, Hemmat Expressway, Postal Code: 1449614535

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2024-11-08, 1403/08/18

Ethics committee reference number
IR.IUMS.REC.1403.666

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
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The score of satisfaction with performance will be measured using the Canadian Occupational Performance Measure (COPM). This score reflects the participants' level of satisfaction with their performance in daily activities, rated on a 10-point scale, where higher scores indicate greater satisfaction

2

Description
participation
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Phone-FITT test is a telephone-based tool designed to measure frequency, intensity, duration, and type of physical activities in older adults across two domains: household and recreational activities. Participants report their level of participation, frequency, and duration of activities. Duration is scored in intervals, and intensity is assessed based on breathing and conversational ability. The participation score for each activity is calculated by summing these components, with zero indicating no participation. The maximum score for each activity is 12. This tool has demonstrated good validity and reliability.

3

Description
Self-Care Activity
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Self-Care Activity of Chronic Illness Inventory (SCA-CII) is a disease-independent tool designed to assess self-care activities. It consists of three subscales: self-care maintenance, self-care monitoring, and self-care management. The 20-item questionnaire uses a 5-point Likert scale. Participants rate maintenance and monitoring activities by answering "How often do you usually perform these items?" from never to always. For management activities, they respond to "How likely are you to perform these items?" on a scale from not likely at all to very likely.

Secondary outcomes

1

Description
adherence
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Self-Report Habit Index (SRHI) is designed to assess habit formation based on habit strength, repetition history, behavior control, awareness, and efficacy. This is a 12-item, single-factor questionnaire. It uses 5-, 7-, or 11-point Likert scales to measure agreement or disagreement with each item.

2

Description
adherence
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Self-Report Behavioral Automaticity Index (SRBAI) consists of 4 items designed to assess behavioral automaticity as a measure of habit strength. Participants rate the extent to which they perform a behavior automatically on a 7-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree).

3

Description
adherence
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Generic Multifaceted Automaticity Scale is designed to assess various dimensions of habit formation. In addition to measuring habit strength through overall behavioral automaticity, it evaluates metacognitive aspects such as lack of control, lack of intention, and efficiency. The scale consists of 9 items rated on a 5-point Likert scale.

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Description
adherence
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Daily Habit Index assesses daily habits across 7 domains, including hygiene, leisure activities, housekeeping, exercise, and sleep. It consists of 38 items measuring frequency and automaticity of behaviors on a 0 to 5 Likert scale. Two final questions identify other habits not listed

5

Description
adherence
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Creature of Habits Scale is a 30-item questionnaire with two subscales: habits related to routine behaviors (e.g., low mental effort and emotional responses) and habits related to food consumption (e.g., food preferences, automatic responses, and lack of planning).

6

Description
motivation
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Intrinsic Leisure Motivation Scale assesses individual differences in intrinsic motivation for leisure activities across four domains: autonomy, competence, commitment, and challenge. Each domain includes 6 items rated on a 7-point Likert scale from "strongly disagree" to "strongly agree." Scores for each domain are summed and averaged, resulting in a score between 1 and 7, with 7 indicating high motivation

7

Description
motivation
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Social Motivation Questionnaire is designed to measure motivation in information seeking and emotion regulation during social interactions. It includes two domains: information seeking and emotion regulation, each with 4 items. Responses are rated on a 7-point Likert scale. The maximum score is 56, with higher scores indicating greater motivation.

8

Description
Self-regulation
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Self-regulation Assessment Questionnaire is designed to evaluate self-regulation performance in patients attending rehabilitation centers. It covers four domains: insight into health status, insight into abilities, self-regulatory actions, and organizing support. The questionnaire contains 22 items rated on a 5-point Likert scale from "strongly disagree" to "strongly agree."

9

Description
functional mobility
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The Timed Up and Go (TUG) test is a simple screening tool to assess lower limb mobility and fall risk in older adults. The patient, wearing their usual shoes, starts seated, then upon the therapist’s command stands up, walks 3 meters, turns around, and sits back down. The test is performed under both single-task and dual-task cognitive conditions. Scoring is based on the total time taken to complete the test. According to recent studies, a time under 10 seconds is considered normal, 10 to 20 seconds borderline, and over 20 seconds abnormal.

10

Description
functional mobility
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
This test is designed to assess walking, balance, and fall risk. It consists of 8 items including walking on flat surfaces, changing speed, head turns in horizontal and vertical directions, walking and turning 180 degrees to stop, stepping over obstacles, and ascending and descending stairs. Each item is scored on a scale from 0 to 3, where 3 indicates normal performance and 0 indicates severe impairment. In older adults, scores below 19 indicate a high risk of falling

11

Description
functional mobility
Timepoint
Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)
Method of measurement
The functional mobility score will be measured using the 6 Minutes Walking Test. This simple test assesses the distance an individual can walk in 6 minutes at their usual walking speed. Scoring is based on the distance covered in 6 minutes, adjusted for age, gender, and height; greater distances indicate better functional capacity and health.

12

Description

Fatigue

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

Fatigue severity score will be measured using the Fatigue Severity Scale. This scale consists of 9 items, where individuals rate their agreement with each statement on a scale from 1 to 7. The total score ranges from 9 to 63, with higher scores indicating pathological fatigue.

13

Description

Frailty

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

Frailty score will be measured using the Tilberg Frailty Indicator. This indicator consists of two parts; the first part includes 10 questions assessing frailty determinants and diseases, and the second part consists of 15 questions covering physical, psychological, and social domains. The maximum score is 15, indicating the highest level of frailty.

14

Description

Freezing Of Gait

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

Freezing of gait will be measured using the New-Freezing Of Gait Questionnaire. This self-reported questionnaire consists of 9 items specifically designed for Parkinson's patients. It includes three sections: distinguishing between individuals with and without freezing (scored 0 or 1), freezing severity (scored 0 to 19), and the impact of freezing on daily life (scored 0 to 9

15

Description

Anxiety and Depression

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The depression and anxiety score will be measured using a 14-item questionnaire. This score reflects participants' levels of depression and anxiety and is recorded on a scale of 0 to 3 for each item, where higher scores indicate greater levels of depression or anxiety.

16

Description

sleep quality

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The sleep quality score will be measured using the Pittsburgh Sleep Quality Index (PSQI). This score reflects various aspects of sleep quality during the past month and is recorded based on seven factors: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction due to excessive sleepiness. Higher scores indicate better sleep quality.

17

Description

Home Safety

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The risk of falls score will be measured using the Home Safety Assessment Tool (HSAT). This score reflects the presence of 64 risk factors in various areas of the elderly's living environment, including front and back entrances, hallways, living room, bedroom, kitchen, stairs, basement, and laundry room

18

Description

Fall Efficacy

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The fear of falling score will be measured using the Falls Efficacy Scale (FES). This score reflects the individual's fear or concern about falling during daily activities and is recorded based on 16 items using a 0–4 Likert scale, with a total score of 64. Higher scores indicate greater fear of falling.

19

Description

Mental Health

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The mental health score will be measured using the General Health Questionnaire (GHQ). This score reflects the individual's mental health status and is recorded based on 18 items across six domains: personal

satisfaction, personal records, self-control, autonomy, problem-solving, and interpersonal communication skills. Higher scores indicate better mental health status.

20

Description

Social and Emotional Lonelines

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The emotional and social loneliness score will be measured using the Adult Emotional and Social Loneliness Scale (AESLS). This score reflects the level of emotional and social loneliness experienced by the individual and is recorded based on 15 items across three subscales: romantic loneliness (5 items), family loneliness (5 items), and social loneliness (5 items). Emotional loneliness is derived from the sum of the romantic and family subscale scores. Each item is rated on a 5-point scale from “strongly disagree” (1) to “strongly agree” (5), and all items except items 14 and 15 are reverse-scored. Higher scores in each dimension indicate greater loneliness in that dimension.

21

Description

Loneliness

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The loneliness score will be measured using the De Jong Gierveld Loneliness Scale (DJGLS). This score reflects the individual’s level of loneliness and is recorded based on 11 items across two subfactors: social loneliness (5 items) and emotional loneliness (6 items). Higher scores indicate greater loneliness.

22

Description

Apathy

Timepoint

Baseline, post-intervention (The duration will be determined after the pilot study), and follow-up (For the same duration as the study)

Method of measurement

The apathy score will be measured using the Lille Apathy Rating Scale (LARS). This score reflects the level of apathy in adults and is recorded based on 33 items across nine subscales. Higher scores indicate greater apathy.

Intervention groups

1

Description

Intervention Group: Recipients of Occupation-Based Habit Formation Interventions Without Adherence FeedbackIn occupation-based habit interventions, the therapist engages the participant in selecting occupation-based habits and aligning them with the intended occupational activities, using these habits as a therapeutic tool to create behavioral change. In this group, the interventions progress from simpler to more complex occupation-based habits.The rehabilitation process, as defined in the preliminary study, is divided into three phases. During the first third of the intervention, the importance of forming occupation-based habits is emphasized, and simpler habits—such as medication management and clinic visits—are introduced. In the second third, checklists are used to monitor the performance of habits taught in the previous phase, while more complex habits, such as longer physical activities, are introduced. It should be noted that the occupation-based habits were identified in the Delphi study conducted in the earlier phases.In the final third of the intervention, the focus is on repeating all previously taught occupation-based habits, using checklists to ensure that each habit is performed consistently.

Category

Rehabilitation

2

Description

Intervention group: Recipients of Occupation-Based Habit Formation Interventions With Adherence Feedback This intervention group receives the same program as the previous group, with the key difference that the performance of occupation-based habits is accompanied by therapist-provided feedback in every session. The feedback is structured according to adherence feedback categories identified in the Delphi study. Participants receive the interventions at the time of maximum drug effect. The total number of sessions and the duration of each session will be determined based on the preliminary study. After completing the interventions, a secondary assessment is conducted, followed by a follow-up period of the same length, during which a re-evaluation is performed.

Category

Rehabilitation

3

Description

Control group: Based on studies on habit formation, the control group in the present study will receive a set of health information. This information, provided in the form of a catalog on general health for Parkinson’s patients, is designed not to interfere with the interventions of the other groups and will be sent to participants on a weekly basis. The total number of distributions depends on the number of intervention weeks for the other groups, which will be determined in the preliminary study.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
مراکز اختلالات حرکتی و کلینیک‌های توانبخشی
Full name of responsible person
قربان تقی زاده
Street address
تهران، بزرگراه شهید همت، دانشگاه علوم پزشکی ایران
City
تهران
Province
Tehran
Postal code
1449614535
Phone
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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
Ghorban Taghizadeh
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 910 146 2167
Email
taghizadeh.gh@iums.ac.ir
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
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
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Iran University of Medical Science
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ghorban Taghizadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Tehran
Postal code
1449614535
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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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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Email

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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

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

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The shared file will include de-identified data from study participants. Specifically, the dataset will contain general demographic information (age, gender), group allocation, and scores related to the primary outcome measures of the study. No personal identifiers such as names, contact details, or national ID numbers will be included. Only this specific part of the data will be available to other researchers upon formal request and after obtaining appropriate approvals. The complete dataset or other sensitive information will not be shared.

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

En 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