Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Minimal Clinically Important Difference (MCID) for four balance measures in people with Parkinson's disease

Protocol summary

Study aim

Determining the minimum clinically important difference (MCID) for four balance assessment tools in individuals with Parkinson’s disease.

Design

Interventions will be carried out in the form of balance exercises over eight weeks. Balanced physical activity on different surfaces (hard and foam) in different vision states (eyes open and closed) will be performed as a single and dual cognitive or physical task. These tasks will be based on Gentile’s taxonomy, progressing from simple to complex according to each patient’s condition and level of progress. The amount of repetition and the duration of each physical activity will be based on the theory of learning. The balance activity will be designed based on four main parameters: repetition, time, type, and intensity. In terms of the repetition parameter (number of sessions per week), which suggests two to three sessions per week as suitable for balance activity, three sessions per week will be considered. In terms of the time parameter (the duration of physical activity in each session), between 45-60 minutes is deemed the most suitable time for balance activity.

Settings and conduct

Shafa Yahyaian Hospital in Tehran

Participants/Inclusion and exclusion criteria

1-Having idiopathic Parkinson’s disease, as diagnosed by a neurologist and according to the criteria of the Parkinson’s Disease Society Brain Bank in the UK. Having a disease level of 1 to 3 according to the Hoehn and Yahr scale. Having a score of 21 or above on the Mini-Mental State Examination.

Intervention groups

Individuals will be placed in an intervention group as available cases.

Main outcome variables

1-Berg Balance Scale 2-Dynamic Gait Index 3-Timed Up and Go

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140612018077N3**
Registration date: **2023-12-25, 1402/10/04**
Registration timing: **retrospective**

Last update: **2023-12-25, 1402/10/04**
Update count: **0**

Registration date

2023-12-25, 1402/10/04

Registrant information

Name

Maryam Mehdizadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 945 4770

Email address

maryam.mehdizadeh_22@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-23, 1402/10/02

Expected recruitment end date

2024-05-10, 1403/02/21

Actual recruitment start date

2023-02-02, 1401/11/13

Actual recruitment end date

2023-11-22, 1402/09/01

Trial completion date

empty

Scientific title
Minimal Clinically Important Difference (MCID) for four balance measures in people with Parkinson's disease

Public title
Investigating the clinical application of four balance measurement tools in people with Parkinson's disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having idiopathic Parkinson's disease as diagnosed by a neurologist and based on the Brain Society Parkinson's Disease UK Bank criteria having disease level 1 to 3 according to the Yahr & Hoehn scale Having a score of 21 and above in the Mental Mini Examination Stat

Exclusion criteria:
Having other diseases, including diabetes and stroke

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences

Street address
Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran 14496-14535, IRAN

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2023-11-21, 1402/08/30

Ethics committee reference number
IR.IUMS.REC.1402.751

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
Functional Balance

Timepoint
Before and after intervention

Method of measurement
Timed Up and Go test, Berg balance scale, Dynamic Gait Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Balanced physical activity on different surfaces (hard and foam) in different vision states (eyes open and closed) will be performed as a single and dual cognitive or physical task. These tasks will be based on Gentile’s taxonomy, progressing from simple to complex according to each patient’s condition and level of progress. The amount of repetition and the duration of each physical activity will be based on the theory of learning. Specifically, when a patient can easily repeat a pose three times, the task will become more difficult. This progression will change from standing on two legs with eyes open in a short period of time without a cognitive or physical dual task, to standing on one leg on foam with eyes closed along with a cognitive or physical task.The balance activity will be designed based on four main parameters: repetition, time, type, and intensity. In terms of the repetition parameter (number of sessions per week), which suggests two to three sessions per week as suitable for balance activity, three sessions per week will be considered. In terms of the time parameter (the duration of physical activity in each session), between 45-60 minutes is deemed the most suitable time for balance activity. The type of physical activity (control of the body’s center of gravity from static to dynamic) will be selected based on Gentile’s

theory, progressing from simple to complex as described above

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital in Tehran

Full name of responsible person

Maryam Mehdizadeh

Street address

Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran 14496-14535, IRAN

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran University of Medical Sciences

Proportion provided by this source

20

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

Maryam Mehdizadeh

Position

Graduated

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The participants of this study did not give written consent for their data to be shared publicly, so due to the sensitive nature of the research supporting data is not 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

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

No - There is not a plan to make this available

Title and more details about the data/document

Data available on request due to privacy/ethical restrictions

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

The data that support the findings of this study are available on request from the corresponding author

Under which criteria data/document could be used

Performing advanced analyzes and comparing different diseases

From where data/document is obtainable

The data that support the findings of this study are available on request from the corresponding author.

What processes are involved for a request to access data/document

Data available on request from the authors

Comments