

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

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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**

**Name of organization / entity**

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## Person responsible for updating data

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

Maryam Mehdizadeh

**Position**

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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**