

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effects of routine physical therapy with and without action observation therapy on freezing of gait and functional mobility in patients with parkinson's disease

#### Protocol summary

Freezing of Gait and functional mobility.

#### Study aim

The objective was study the effects of routine physical therapy with and without Action observation on freezing of the gait and functional mobility in patients with Parkinson's disease.

#### Design

Randomized, parallel group design of 21 patients, single blinded randomized control trial.

#### Settings and conduct

Study was conducted at THQ Civil Hospital Daska. The study population was consisted of Parkinson's Disease, The study was single blinded. The outcome assessors did not know while they were receiving experimental or conventional treatment

#### Participants/Inclusion and exclusion criteria

Inclusion 1. The participants with set diagnostic criteria of UK society for Parkinson's Disease Bank Criteria based on clinical findings. 2. Age between 50 to 80 3. The patients were selected on the condition of severely affected gait and enrolled if there was freeing of their gait minimum once in a week (having a score of 1 on FOG outcome tool in item No.2) and having a larger episode of greater than 2 seconds (and if have 2 scores on the FOG item No. 4) 4. Hoehn & Yahr criteria with labeled as stage  $\leq 3$  Exclusion Criteria: 1. Any of the substance abuse ,illness systematic disease and neurological issues that can affect the outcomes including cognition level 2. Implantation for deep brain stimulation 3. Cognitive impairment, in particular patients with a Mini mental State Examination (MMSE) score  $< 24$  4. Visual or acoustic limitations.

#### Intervention groups

Group A-(Routine Physical Therapy) Group (B) (RPT+ AOT) In this group patient were treated with action observation therapy (AOT) as well as with routine physicaltherapy (RPT).

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230723058901N1**

Registration date: **2023-10-06, 1402/07/14**

Registration timing: **retrospective**

Last update: **2023-10-06, 1402/07/14**

Update count: **0**

##### Registration date

2023-10-06, 1402/07/14

##### Registrant information

##### Name

Kiran Maqsood

##### Name of organization / entity

University of Lahore

##### Country

Pakistan

##### Phone

+92 323 9578501

##### Email address

kiranfaryal555@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2023-06-22, 1402/04/01

##### Actual recruitment start date

2023-05-22, 1402/03/01

##### Actual recruitment end date

2023-06-22, 1402/04/01  
**Trial completion date**  
2023-07-22, 1402/04/31

**Scientific title**  
Effects of routine physical therapy with and without action observation therapy on freezing of gait and functional mobility in patients with parkinson's disease

**Public title**  
Effects of action observation therapy on freezing of gait and functional mobility in patients with Parkinson's disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
participants with clinical diagnosis of PD according to UK Parkinson's Disease Society Brain Bank criteria Age between 50 to 80 In order to select PD subjects for those FoG severely impacted gait, patients were enrolled if the occurrence of freezing was at least once a week (minimum score of 1 on item 2 in the new FoG Questionnaire (FoG-Q)) and the longest episodes was > 2 seconds (minimum score of 2 on item 4 of the FoG-Q Hoehn & Yahr (H&Y) stage ≤ 3  
**Exclusion criteria:**  
medical illnesses or substance abuse that could interfere with cognition; any (other) major systemic or neurological illness. implantation for deep brain stimulation cognitive impairment, in particular patients with a Minimental State Examination (MMSE)score < 24 visual or acoustic limitations

**Age**  
From **50 years** old to **80 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **21**  
Actual sample size reached: **16**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization in this study was conducted using a computer-generated randomization method. The unit of randomization was at the individual level, where each participant was assigned to one of two groups. The random sequence was constructed using specialized software designed for randomization purposes. Allocation concealment was rigorously carried out through the use of opaque sealed envelopes. These envelopes were prepared in advance and remained sealed until each participant's allocation decision was made.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The study was single blinded the outcome assessor

didn't know while they were receiving experimental or conventional treatment

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Time up and go test for functional mobility and freezing of gait(FOG) questionnaire to assess freezing of gait.

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Research Ethical Committee, Faculty of Allied Health Sciences, The University of Lahore  
**Street address**  
-Km Defence Road,, near Bhuptian Chowk,, Lahore  
**City**  
Lahore  
**Postal code**  
54590

**Approval date**  
2023-05-22, 1402/03/01

**Ethics committee reference number**  
REC-UOL-421-06-2023

**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**  
Freezing of gait

**Timepoint**  
at baseline week 6 and week 12

**Method of measurement**  
FOG (freezing of gait questionnaire)

**2**

**Description**  
Functional Mobility

**Timepoint**  
at baseline week 6 and week 12

**Method of measurement**

TUG (Time Up and Go test)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In this group patient were treated with routine physical therapy. The exercise program consists of stretching, strengthening and isometric exercise based on the severity of functional mobility and freezing of Gait. According to the patient's physical condition, the therapist conducted each treatment for 45 minutes, once a day, 5 times a week, for a total of 12 weeks.

### Category

Rehabilitation

2

### Description

Intervention group: In this group patient were treated with action observation therapy (AOT) as well as with routine physical therapy (RPT). To reduce the aspects of freezing of gait, the tasks were assigned to the persons who took participate in the daily sessions of thirty minutes twice a day. These aspects include ankle tapping, taking back and forth steps and counting the steps during walk. In these sessions, the patient was asked to follow every step and movement of therapist

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

THQ Civil Hospital Daska

#### Full name of responsible person

Dr Jansher Mansoori

#### Street address

1 Stadium Rd, Habibpura

#### City

Daska

#### Postal code

51010

#### Phone

+92 321 5909269

#### Email

jansher.mansoor31@gmail.com

#### Web page address

<https://thqdaska.punjab.gov.pk/>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

THQ Civil Hospital

#### Full name of responsible person

Dr Jansher Mansoori

#### Street address

Stadium Rd, Habibpura

#### City

Daska

#### Postal code

51010

#### Phone

+92 321 5909269

#### Email

jansher.mansoor31@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### Title of funding source

University Of Lahore

### Proportion provided by this source

100

### Public or private sector

Private

### 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

University of Lahore

#### Full name of responsible person

Dr Ayesha jamil

#### Position

Assistant Professor

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Physiotherapy

#### Street address

1-Km Defence Road,, near Bhuptian Chowk

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Punjab

#### Postal code

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#### Phone

+9233244481031

#### Email

Ayesha.jamil@uipt.uol.edu.pk

#### Web page address

<https://uol.edu.pk/admissions/?gclid=Cj0KCQjw84anB>

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xe3Xd0eWkUzA2zBtj53GobjD9rVIYlWp1ZGyUFid3GFu\_  
Xp7UjTjMaAh3pEALw\_wcB

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University Of Lahore

**Full name of responsible person**

Dr Ayesha jamil

**Position**

Assistant professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physiotherapy

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1-Km Defence Road,, near Bhuptian Chowk

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[https://uol.edu.pk/admissions/?gclid=Cj0KCQjw84anBhCtARIsAISl-xfOb4dc3Cl\\_bkmgP9tq2Dg9GSnrVT-gKnzLvuGhV\\_ZZfeaWI1aav1AaAn--EALw\\_wcB](https://uol.edu.pk/admissions/?gclid=Cj0KCQjw84anBhCtARIsAISl-xfOb4dc3Cl_bkmgP9tq2Dg9GSnrVT-gKnzLvuGhV_ZZfeaWI1aav1AaAn--EALw_wcB)

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Kiran Maqsood

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

College Road, mohallah younas abad Daska Distt Sialkot

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**Province**

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**Web page address**

[https://uol.edu.pk/admissions/?gclid=Cj0KCQjw84anBhCtARIsAISl-xfOb4dc3Cl\\_bkmgP9tq2Dg9GSnrVT-gKnzLvuGhV\\_ZZfeaWI1aav1AaAn--EALw\\_wcB](https://uol.edu.pk/admissions/?gclid=Cj0KCQjw84anBhCtARIsAISl-xfOb4dc3Cl_bkmgP9tq2Dg9GSnrVT-gKnzLvuGhV_ZZfeaWI1aav1AaAn--EALw_wcB)

## 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**

Demographic data and data related to final outcome will be shared by maintaining the confidentiality.

**When the data will become available and for how long**

Data will be available from April 2024 to June 2024 after the six months of Publication. The data sharing plan for the clinical trial(i.e., what data will be shared when and under what conditions) will be publicly available at a third-party site that shares data with and meets the data requirements of WHO's international clinical trial registry platform , this occur before the first participant is enrolled.

**To whom data/document is available**

Dr Kiran Maqsood( Corresponding Author )

**Under which criteria data/document could be used**

For Research Purpose

**From where data/document is obtainable**

To the Corresponding Author of the study; dr Kiran Maqsood and can contact on +923239578501, Kiranfaryal555@gmail.com can visit the search engines, you can find my study data will be available from April 2024 to June 2024 after six months of publication. The data sharing plan for the clinical trial(i.e., what data will be shared when and under what conditions) will be publicly available at a third-party site that shares data with and meets the data requirements of WHO's international clinical trial registry platform , this occur before the first participant is enrolled.

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

Open Access and there is the traditional public data release where anyone can get access to the data with no registration or conditions. The request will be reviewed by director in charge and in case of eligibility, it would be shared in two weeks.

**Comments**

I want randomized clinical trial registration.