

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 ≤ 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

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Phone

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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

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<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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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

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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

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.