Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Study aim

The objective was study the effects of routine physical therapy with and without Action observation on freezing of the gait andfunctional 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

Freezing of Gait and functional mobility.

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

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Email address

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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 ifthe occurance 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 of12 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

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1 Stadium Rd, Habibpura

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr Jansher Mansoori

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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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hCtARIsAISI-xe3Xd0eWkUzA2zBtj53GobjD9rVIYlwP1ZGyUFid3GFu_Xp7UjTxjMaAh3pEALw_wcB

Person responsible for scientific inquiries

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Person responsible for updating data

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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.