

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effectiveness of treadmill training alone versus treadmill training with external clues in improving gait and functional ability in parkinson's patient

Protocol summary

Study aim

the aim of the study is to check the effectiveness of the treadmill training alone versus treadmill training with external clues in improving gait and functional ability in parkinson patient

Design

Randomized control trial

Settings and conduct

this trial will be conducted at Physicaltherapy and rehabilitation ward of Chauhary akram teaching hospital (Teaching hospital associated with Azra Naheed Medical College ,The superior University ,Lahore)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: (1) Age 50 to 65 years (2) Male and female both (3) idiopathic Parkinson's disease (4) disease severity of II to V on the Hoehn and Yahr Scale and with minimum assistance and support required (5) ability to stand independently and to walk on a treadmill (with body weight support, if required) (6) sufficient visual capacity to see the cues Exclusion Criteria: (1) Patient with Parkinson disease wheel-chair bond and bed-ridden (2) any other neurologic or orthopedic disorder affecting gait and postural stability; (3) change in medication for the treatment of Parkinson's disease during the study period (4) cognitive impairment (5) severe cardiovascular disorders (6) vestibular dysfunctions

Intervention groups

Interventions: Group 1 (Control group) Group 1 in training session will receive the treadmill training session over 30 minutes. Patients in 1 receive the same treatment protocol in 5 days per week and the this treatment protocol must be continue for 6 weeks. Group 2 (Experimental Group): Group 2 in training session received the treadmill training session over 30 minutes along with the external clues like visual, auditory,etc.In 5 days per week and this treatment protocol must be

continuing for 6 weeks

Main outcome variables

Gait it will be assessed by usiing wisconsin gait scale and Functional ability will be assessed by Motor Aspects of Experiences of Daily Living (M-EDL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220414054537N1**

Registration date: **2022-06-14, 1401/03/24**

Registration timing: **retrospective**

Last update: **2022-06-14, 1401/03/24**

Update count: **0**

Registration date

2022-06-14, 1401/03/24

Registrant information

Name

Faisal Ghafoor

Name of organization / entity

The Superior University

Country

Pakistan

Phone

+92 42 38104221

Email address

faisal.ghafoor@superior.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-05-25, 1401/03/04
Actual recruitment start date
2022-05-22, 1401/03/01
Actual recruitment end date
2022-06-05, 1401/03/15
Trial completion date
2022-07-24, 1401/05/02

Scientific title
comparison of the effectiveness of treadmill training alone versus treadmill training with external clues in improving gait and functional ability in parkinson's patient

Public title
effect of treadmill training alone versus treadmill training with external clues in treatment of parkinson's

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 50 to 65 years Male and female both idiopathic Parkinson's disease disease severity of II to V on the Hoehn and Yahr Scale and with minimum assistance and support required ability to stand independently and to walk on a treadmill (with body weight support, if required) sufficient visual capacity to see the cues

Exclusion criteria:

Patient with Parkinson disease wheel-chair bond and bed-ridden any other neurologic or orthopedic disorder affecting gait and postural stability; change in medication for the treatment of Parkinson's disease during the study period cognitive impairment severe cardiovascular disorders vestibular dysfunctions

Age
From **50 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **72**
Actual sample size reached: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
participants fullfilling the inclusion and exclusion criteria will be allocated randomology into control group and experimental group.the process of allocation will be concealed from participants and the researcher.

Blinding (investigator's opinion)
Single blinded

Blinding description
in our study we used a blinding protocol in which the outcome assessor is fully blind he didnot have the idea about the intervention being provided to the participants, the this process which mostly used in clinical trials in which the participants, investigators and/or assessors remain ignorant concerning the treatments which

participants are receiving.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

committe Azra Naheed Centre for Research & Development the Superior University ,Lahore

Street address

main riwind road 17 km ,Lahore

City

Lahore

Postal code

54000

Approval date

2022-05-05, 1401/02/15

Ethics committee reference number

SU/ANCRD/IERC/56

Health conditions studied

1

Description of health condition studied

Parkinson's disease is a brain disorder that causes unintended or uncontrollable movements, such as shaking, stiffness, and difficulty with balance and coordination. Symptoms usually begin gradually and worsen over time. As the disease progresses, people may have difficulty walking and talking

ICD-10 code

G00-G99

ICD-10 code description

<https://icd10monitor.com/icd-10-coding-of-parkinson-s-disease-code-carefully/#:~:text=ICD%2D10%2DCM%20Coding%3A,%2C%E2%80%9D%20code%20G20%20is%20listed.>

Primary outcomes

1

Description

Gait: Gait is the rhythmical movement of the limb and trunks which help in the forward movement of the central of gravity and it help in the shifting of the weight forward. Gait Cycle: Step Length,,Stride length: Stance phase.Swing phase: mid swing Acceleration,deacceleration.Stance phase divided into 5 major sub-division like:Initial contact: rFoot flat: Mid stance: tHeel off: Toe off:

Timepoint

after 6 weeks

Method of measurement

wisconsin gait scale for gait measurement and Functional ability will be assessed by Motor Aspects of Experiences of Daily Living (M-EDL)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in both treatments will complete training sessions over 6 weeks (5 sessions per week) and the patient will assess at base line and then it will assess after 6 weeks respectively. During the first session, all patients will be trained for 20 minutes at their own pace. All patients will complete at least 30 training sessions over 45 minutes at the last session. Group 1 (Control group) Group 1 in training session will receive the treadmill training session over 30 minutes. Patients in 1 receive the same treatment protocol in 5 days per week and the this treatment protocol must be continued for 8 weeks. Group 2 (Experimental Group): Group 2 in training session received the treadmill training session over 30 minutes along with the external clues like visual, auditory, etc. In 5 days per week and this treatment protocol must be continuing for 8 weeks.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

committee Azra Naheed Centre for Research & Development the Superior University ,Lahore

Full name of responsible person

Dr zohaib Shahid

Street address

main riwind road 17 km ,Lahore

City

Lahore

Postal code

54000

Phone

+92 333 6979114

Email

zohaib.rana@superior.edu.pk

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

committee Azra Naheed Centre for Research & Development the Superior University

Full name of responsible person

DR Zohaib Shahid

Street address

main riwind road 17 km ,Lahore

City

Lahore

Postal code

54000

Phone

+92 333 6979114

Email

zohaib.rana@superior.edu.pk

Grant name

no

Grant code / Reference number

no

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

No

Title of funding source

no funding

Proportion provided by this source

1

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

committee Azra Naheed Centre for Research & Development the Superior University ,Lahore

Full name of responsible person

Dr Zohaib Shahid

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

main riwind road 17 km ,Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 333 6979114

Email

zohaib.rana@superior.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

committe Azra Naheed Centre for Research & Development the Superior University ,Lahore

Full name of responsible person

Dr zohaib Shahid

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

main riwind road 17 km ,Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 333 6979114

Email

zohaib.rana@Superior.edu.pk

Person responsible for updating data

Contact

Name of organization / entity

committe Azra Naheed Centre for Research & Development the Superior University ,Lahore

Full name of responsible person

Dr Faisal Ghafoor

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Rehabilitation management

Street address

main riwind road 17 km ,Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 333 4816348

Email

faisal.ghafoor@superior.edu.pk

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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

comparison of the effectiveness of the treadmill training alone versus treadmill training with external clues in improving the gait and functional ability in parkinson's patient

When the data will become available and for how long

data will be availabe on 7 weeks (2022-07-26)

To whom data/document is available

not sure but vailable on request

Under which criteria data/document could be used

on request

From where data/document is obtainable

o request

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

on request

Comments