Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparsion of the effectiveness of treadmil training alone versus treadmil 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 treadmil trainng alone versus treadmil training with external clues in improving gait and functional ability in parkinsion patient

Design
Randomized control trial

Settings and conduct
this trial will be conducted at Physicaltherapy and rehablitation 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 assesed by usiing wisconsin gait scale and Functional ability wil be assesd 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

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Faisal Ghafoor

Name of organization / entity
The Superior University

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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

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

Public title

effect of treadmil training alone versus treadmil training with external clues in treatment of parkinsion'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 assesor 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

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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 measeuremnt and Functional ability will be assessd 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 asses after 6 week 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 continue 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
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committe Azra Naheed Centre for Research & Development the Superior University ,Lahore
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Sponsors / Funding sources

1

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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
committe Azra Naheed Centre for Research & Development the Superior University ,Lahore
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Position
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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
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
comparsion of the effectiveness of the treadmil training alone versus treadmil training with external clues in improving the gait and functional ability in parkinsion'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 sured 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