

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative effects of modified otago exercise program(MOEP) and perturbation-based balance training(PBT)on reactive postural control and balance in patients with sub-acute stroke

Protocol summary

Study aim

To compare the effects of modified otago exercise program (MOEP) and perturbation based balance training (PBT) on reactive postural control and balance in patients with sub-acute stroke.

Design

Parallel group design of 64 patients and single blinded randomized control trial

Settings and conduct

Data will be collected from District Headquarter hospital ,Toba Tek Singh, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Sub-acute stroke patients. Subjects should have stable condition after the stroke incidence. Tolerance of balance and gait tasks without fatigue. Both genders can participate in the study. Age from 50 to 70years. Exclusion Criteria: Patients with any other neurological conditions Patient with visual and vestibular impairment

Intervention groups

Modified otago exercise program: (MOEP) it consists of 17 strength and balance exercises and a walking program, 15 minutes walking before and after strength and balance exercises. Perturbation based balance training: (PBT) is a form of reactive balance training aimed at improving reactive balance control after unexpected external perturbations. Time for perturbation- based balance training will be 60 minutes.

Main outcome variables

Reactive postural control and balance are main outcomes variables. Assessment of reactive postural control: Mini-bestest scale will be used. Each item is scored based on ordinal scale scoring from 0- 3 where 3 representing best performances and 0 representing worst performances. □ Assessment of balance: Berg balance scale will be used. Scores range from 0 to 4, with 0 indicating inability and 4 representing independent

completion. The total score, out of 56, categorizes balance as impaired (0-20), acceptable (21-40), or good (41-56).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240503061639N1**

Registration date: **2024-05-13, 1403/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2024-05-13, 1403/02/24**

Update count: **0**

Registration date

2024-05-13, 1403/02/24

Registrant information

Name

Rida Zahid

Name of organization / entity

Riphah international university Lahore

Country

Pakistan

Phone

+92 325 0405631

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-08, 1403/02/19

Expected recruitment end date

2024-06-10, 1403/03/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effects of modified otago exercise program(MOEP) and perturbation-based balance training(PBT)on reactive postural control and balance in patients with sub-acute stroke

Public title
Comparative effects of modified otago exercise program(MOEP) and perturbation-based balance training (PBT)on reactive postural control and balance in patients with sub-acute stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Sub-acute stroke patients Survivors of ischemic stroke
Subjects should have stable condition after the stoke incidence Tolerance of balance and gait tasks without fatigue Both genders can participate in the study Age from 50 to 70yearsPatient who can follow written, verbal directions and demonstration
Exclusion criteria:
Patients with any other neurological conditions (Brain Injury, Multiple Sclerosis, Parkinson's disease and Vestibular Disorders). Subjects with diagnosed peripheral neuropathy Patient with visual and vestibular impairment

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done through simple random sampling using lottery method. this will be cluster randomization because we had large sample size for two intervention groups with 32 patients in each group. In lottery method , we will assigned a number to patient as 1,23.....64, after which we select a random numbers for each interventions groups, so first 32 selected patients will receive modified otago exercise program and next 32 will receive perturbation based balance training.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants are blind in my study, because they are divided into two intervention groups without knowing it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah International University

Street address

Raza street 25, Bhabra' block M, Gulberg 3, Lahore, Pakistan

City

Lahore

Postal code

54660

Approval date

2024-04-29, 1403/02/10

Ethics committee reference number

REC/RCR&AHS/23/02106

Health conditions studied

1

Description of health condition studied

Sub-acute Stroke

ICD-10 code

Z82.3 G46.

ICD-10 code description

Family history of stroke, Cerebellar stroke syndrome , Brain stem stroke syndrome, Cerebrovascular disease, unspecified, Sequelae of cerebrovascular disease, Sequelae of stroke, not specified as haemorrhage or infarction,

Primary outcomes

1

Description

Reactive postural control

Timepoint

Before intervention, after 4 weeks of intervention program and 8 weeks after completion of intervention program

Method of measurement

Mini- bestest scale will be used for assessment of reactive postural control.

Secondary outcomes

1

Description

Balance
Timepoint
on start of treatment, after 4 weeks of treatment and 8 weeks after completion of intervention program
Method of measurement
Berg balance scale will be used for the assessment of balance

Intervention groups

1

Description

Intervention no 1 will be modified otago exercise program and routine physical therapy treatment. Participants will engage in 20 minute of routine physical therapy which includes range of motion and isometric exercises and 60 minutes of moderate-intensity otago exercises. The modified otago exercises consists of 17 strength(with 10 repetitions, with and without support) and balance exercises and a walking program, 15 minutes walking before and after strength and balance exercises. Balance exercises will be knee bends, backwards walking with or without assistive device, walking and turning around with or without assistive device, sideways walking with or without assistive device, tandem stance (heel toe stand) with or without assistive device , tandem walk (heel toe walk) with or without assistive device , one leg stand with or without assistive device , heel walking with or without assistive device , toe walk with or without assistive device , heel toe walking backwards with or without assistive device, sit to stand with or without assistive device , stair walking with or without assistive device. Intervention program will be continued for 8 weeks, and 3 times a week. Assistive devices will be used like canes etc.

Category

Rehabilitation

2

Description

Intervention group 2 will be Perturbation based balance training and routine physical therapy treatment. Participants will engage in 20 minute of routine physical therapy which includes range of motion and isometric exercises and 60 minutes of perturbation based balance training which includes double-leg foam balance activity, tilt board training and roller board and platform perturbations. Devices used are knee cushion, foam, tilt board and platform. Intervention program will be continued for 8 weeks, and 3 times a week. Assistive devices will be used like canes etc.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

District headquarter hospital
Full name of responsible person
Kashif bajwa
Street address
Rajana road, near Sabzi mandi Toba Tek Singh, Pakistan
City
Toba Tek Singh
Postal code
36050
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Riphah international university
Full name of responsible person
Sana riaz
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Raza Street 25, Bhabra' Block M Gulberg III, Lahore
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Sana.rcrs@riphah.edu.pk

Grant name

Grant code / Reference number

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

No

Title of funding source

Rida zahid

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
Riphah international university Lahore
Full name of responsible person
Rida Zahid
Position
Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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