

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 items 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

ridazahid173@gmail.com

##### 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 70years  
Patient 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

#### Phone

+92 46 2200083

#### Email

Dhqts@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Riphah international university

##### Full name of responsible person

Sana riaz

##### Street address

Raza Street 25, Bhabra' Block M Gulberg III, Lahore

##### City

Lahore

##### Postal code

54660

##### Phone

+92 300 0720825

##### Email

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

**Street address**

Street no 5 New Islam Pura ,Toba Tek Singh,Pakistan

**City**

Toba Tek Singh

**Province**

Punjab

**Postal code**

36050

**Phone**

+92 325 0405631

**Fax****Email**

ridazahid173@gmail.com

**Person responsible for scientific 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

**Street address**

Street no 5 New Islam Pura ,Toba Tek Singh,Pakistan

**City**

Toba Tek Singh

**Province**

Punjab

**Postal code**

36050

**Phone**

+92 325 0405631

**Fax****Email**

ridazahid173@gmail.com

**Person responsible for updating data****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

**Street address**

Street no 5 New Islam Pura ,Toba Tek Singh,Pakistan

**City**

Toba Tek Singh

**Province**

Punjab

**Postal code**

36050

**Phone**

+92 325 0405631

**Fax****Email**

ridazahid173@gmail.com

**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