# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

# EFFECTS OF MODIFIED OTAGO EXERCISES VERSUS ACTION OBSERVATION THERAPY ON BALANCE AND POSTURAL STABILITY IN SUB-ACUTE STROKE

## Protocol summary

**Study aim**
The objective of this study is to compare the effects of modified otago exercises and Action observation therapy on balance and postural stability in sub-acute stroke

**Design**
Randomized Clinical Trial, Single blinded study

**Settings and conduct**
This study will be conducted in Society hospital Lahore single blinded study , Participant will be blinded

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: patients should be diagnosed with stroke; both male and female. Participant's Age will be between 45 to 60 years patients should be able to walk at least 10 meters. Patients should be able to understand and follow instruction, mini mental status examination (MMSE)>24. Exclusion criteria: If patient has any other neurologic disease other than stroke Any auditory or visual deficit that can affect data collection of this study Patient having any abnormality in the vestibular System. Patients having any other orthopedic conditions

**Intervention groups**
Group A: Experimental group (n=19) Group A will be treated by modified otago exercise program and Conventional physical therapy. A session of 40 minutes for 6 weeks including 3 sessions per week will be given to each patient. 10 minutes of conventional treatment will be given to every participant and then 30 minutes of modified otago exercise program. Experimental group (n=19) Group B will be treated by Action Observation Therapy and Conventional physical therapy 40 minutes session will be given 3 times per week for 6 weeks. Prior to Action observation therapy patient will receive session of conventional physical therapy of 10 minutes.

**Main outcome variables**
Balance Postural stability

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240505061662N1**
Registration date: **2024-05-17, 1403/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-17, 1403/02/28**
Update count: **0**

**Registration date**
2024-05-17, 1403/02/28

**Registrant information**

**Name**
Nazima Tariq

**Name of organization / entity**
Riphah International University

**Country**
Pakistan

**Phone**
+92 340 4900463

**Email address**
nazimatariq96@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-03-20, 1403/01/01

**Expected recruitment end date**
2024-06-15, 1403/03/26

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
EFFECTS OF MODIFIED OTAGO EXERCISES VERSUS ACTION OBSERVATION THERAPY ON BALANCE AND

POSTURAL STABILITY IN SUB-ACUTE STROKE

**Public title**
EFFECTS OF MODIFIED OTAGO EXERCISES VERSUS ACTION OBSERVATION THERAPY ON BALANCE AND POSTURAL STABILITY IN SUB-ACUTE STROKE
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients should be diagnosed with stroke Both male and female. Participant's Age will be between 45 to 60 years Patients should be able to walk at least 10 meters Patients should be able to understand and follow instruction, mini mental status examination (MMSE)>24
**Exclusion criteria:**
If patient has any other neurologic disease other than stroke Any auditory or visual deficit that can affect data collection of this study Patient having any abnormality in the vestibular System. Patients having any other orthopedic conditions
**Age**
From **45 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **38**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A total of 38 patients will be recruited according to convenience sampling into two intervention groups based on inclusion and exclusion criteria. Patients will be randomized through Lottery method into Group A (n = 19) and Group B (n = 19).
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Participant will be blinded in this study
**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**
Gulberg Lahore
**City**
Lahore
**Postal code**
54660
**Approval date**
2024-05-05, 1403/02/16
**Ethics committee reference number**
F22C14G37036

## Health conditions studied

### 1

**Description of health condition studied**
Sub-acute stroke
**ICD-10 code**
I64
**ICD-10 code description**
Stroke, not specified as haemorrhage or infarction

## Primary outcomes

### 1

**Description**
Balance
**Timepoint**
Outcome will be measured after 6 weeks of intervention
**Method of measurement**
Berg balance scale will be using for pre and post assessment of variable

### 2

**Description**
Postural stability
**Timepoint**
postural stability will be measured after 6 weeks of treatment
**Method of measurement**
The postural Assessment Scale for Stroke patients (PASS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Group A will be treated by modified ottago exercise program and Conventional physical therapy. A session of 40 minutes for 6 weeks including 3 sessions per week will be given to each patient. 10 minutes of coneventional treatment will be given to every participant and then 30 minutes of modified otago exercise program.
**Category**
Rehabilitation

**2**

**Description**
Intervention group: Group B will be treated by Action Observation Therapy and Conventional physical therapy 40 minutes session will be given 3 times per week for 6 weeks. Prior to Action observation therapy patient will receive session of conventional physical therapy of 10 minutes.

**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Society Hospital

**Full name of responsible person**
Nazima Traiq

**Street address**
Nabipura, Lahore

**City**
Lahore

**Postal code**
05480

**Email**
tariqnazima@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Riphah international university

**Full name of responsible person**
Dr Sana Riaz

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Gulberg , 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?**
Yes

**Title of funding source**
Riphah international university

**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

**Full name of responsible person**
Nazima Tariq

**Position**
Researcher

**Latest degree**
Master

**Other areas of specialty/work**
Physiotherapy

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

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Not applicable

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable