

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 ottago 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

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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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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

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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