

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A comparison of the effectiveness of modified otago exercises and vestibular rehabilitation therapy on balance, postural stability, and risk of fall in sub-acute stroke.

Protocol summary

Study aim

To compare the effects of modified Otago exercises and Vestibular rehabilitation therapy on balance, postural stability, and risk of fall in sub-acute stroke.

Design

Randomized Clinical Trial, a single blinded study, sample size 42, computer generated randomization

Settings and conduct

Data is being collected from General Hospital, Lahore.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed cases of ischemic stroke. Age between 40-70 years Both males and females. Stroke with unilateral hemiplegia in less than 6 months. Participants are able to walk 10 meters with or without assistive device. Participants should be able to understand and follow simple verbal instructions, Mini-Mental Status Examination (MMSE ≥ 24). Exclusion criteria: Participants with spasticity (modified Ashworth scale grade ≥ 3) or flaccidity in lower limbs and upper limbs. Individuals suffering from unstable angina, symptomatic heart failure or uncontrolled hypertension. Balance or gait impairments prior to the stroke. Visual field defects Severe unilateral spatial neglect. Neurological and orthopedic comorbidities like significant osteoarthritis, particularly in the lower limbs.

Intervention groups

Group A will be treated by Vestibular Rehabilitation Therapy (25 minutes) and Conventional physical therapy (30 minutes). Group B will be treated by Modified Otago Exercises (25 minutes) and Conventional physical therapy (30 minutes).

Main outcome variables

Balance, postural stability and risk of fall.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240503061638N1**

Registration date: **2024-05-09, 1403/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-05-09, 1403/02/20**

Update count: **0**

Registration date

2024-05-09, 1403/02/20

Registrant information

Name

Aaminah Nawaz

Name of organization / entity

Riphah International University Lahore

Country

Pakistan

Phone

+92 332 4080727

Email address

aaminahnawaz7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-08-15, 1403/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness of modified otago exercises and vestibular rehabilitation therapy on balance, postural stability, and risk of fall in sub-acute stroke.	
Public title	Comparative effects of modified otago exercises and vestibular rehabilitation therapy on balance, postural stability, and risk of fall in sub-acute stroke.
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosed cases of ischemic stroke. Age between 40-70 years Both males and females. Stroke with unilateral hemiplegia in less than 6 months. Participants are able to walk 10m with or without assistive device. Participants should be able to understand and follow simple verbal instructions, Mini-Mental Status Examination (MMSE ≥ 24). Exclusion criteria: Participants with spasticity (modified Ashworth scale grade ≥ 3) or flaccidity in lower limbs and upper limbs. Individuals suffering from unstable angina, symptomatic heart failure or uncontrolled hypertension. Balance or gait impairments prior to the stroke. Visual field defects Severe unilateral spatial neglect. Neurological and orthopedic comorbidities like significant osteoarthritis, particularly in the lower limbs.
Age	From 40 years old to 70 years old
Gender	Both
Phase	N/A
Groups that have been masked	Outcome assessor
Sample size	Target sample size: 42
Randomization (investigator's opinion)	Randomized
Randomization description	After baseline assessment, eligible subjects will be randomly allocated into two groups, Group A and Group B through computerized table generator method of randomization.
Blinding (investigator's opinion)	Single blinded
Blinding description	The assessors involved in outcome assessment will be blinded to the treatment, ensuring an unbiased evaluation of the measured outcomes.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Riphah International University
Street address	25 Raza Saeed Rd, Bhabra Block M gulberg 3, Lahore, Pakistan
City	Lahore
Postal code	54660
Approval date	2024-01-01, 1402/10/11
Ethics committee reference number	F22C14G37037
Health conditions studied	
<u>1</u>	
Description of health condition studied	Sub-acute Stroke
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	First outcome variable is balance.
Timepoint	Variable will be assessed after 6 weeks of time, including 5 sessions per week.
Method of measurement	Balance will be assessed by using the Berg Balance Scale (BBS).
<u>2</u>	
Description	The second outcome variable is postural stability.
Timepoint	Variable will be assessed after 6 weeks of time, including 5 sessions per week.
Method of measurement	Postural stability will be assessed using the Functional Reach Test.
<u>3</u>	
Description	Third outcome variable is risk of fall.
Timepoint	Variable will be assessed after 6 weeks of time, including 5 sessions per week.
Method of measurement	The risk of fall will be assessed using the Falls Efficacy Scale-International (FES-I).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: This group will receive a modified otago exercise intervention along with conventional physical therapy.

Category

Rehabilitation

2

Description

Intervention group 2: This group will receive a vestibular rehabilitation therapy intervention along with conventional physical therapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

General Hospital, Lahore

Full name of responsible person

Dr Umul Baneen

Street address

Street no 3 house no 9 Jahangir tomb, Shahdara,
Lahore, Pakistan

City

Lahore

Postal code

54940

Phone

+92 332 4080727

Email

aaminahnawaz7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University Lahore

Full name of responsible person

Dr Sana Riaz

Street address

Shalimar Lahore

City

Lahore

Postal code

32579

Phone

+92 347 4716107

Email

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 Lahore

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

Dr Sana Riaz

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Shalimar Lahore

City

Lahore

Province

Punjab

Postal code

32579

Phone

+92 347 4716107

Email

sana.rcrs@riphah.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International University Lahore

Full name of responsible person

Dr Sana Riaz

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Shalimar Lahore
City
Lahore
Province
Punjab
Postal code
32579
Phone
+92 347 4716107
Email
sana.rcrs@riphah.edu.pk

Person responsible for updating data

Contact

Name of organization / entity
Riphah International University Lahore
Full name of responsible person
Dr Sana Riaz
Position
Associate professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Shalimar Lahore
City
Lahore
Province

Punjab
Postal code
32579
Phone
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sana.rcrs@riphah.edu.pk

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