Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

1

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

1

Description of health condition studied

Sub-acute Stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

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).

2

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.

3

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
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Lahore
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54940
Phone
+92 332 4080727
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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
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32579
Phone
+92 347 4716107
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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 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
Assosiate professor
Latest degree
Master
Other areas of specialty/work
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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

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