

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Multimodal Balance Training with and without Auditory Cues on Balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Stroke

Protocol summary

Study aim

To evaluate the efficacy of multimodal balance training with auditory cues on gait, balance performance, functional mobility, quality of life, and fear of falling in chronic stroke survivors.

Design

A two-arm, parallel-group, randomized controlled clinical trial conducted at multiple centers.

Settings and conduct

Conducted across the rehabilitation units of Islam Teaching Hospital and Imran Idrees Teaching Hospital. Outcome assessors are blinded to the participant group allocation.

Participants/Inclusion and exclusion criteria

Inclusion: Confirmed chronic stroke (>6 months), age 40-70, independent ambulation with/without assistive device, BBS score <45. Exclusion: Severe cognitive impairment, active lower limb orthopedic conditions, severe visual/auditory deficits.

Intervention groups

Intervention group: Multimodal balance training with rhythmic auditory stimulation (metronome cues), 45 minutes, 2 times/week for 12 weeks. Control group: Identical multimodal balance training program without auditory cues.

Main outcome variables

Primary outcomes: Berg Balance Scale (BBS) and Timed Up and Go (TUG) test. Secondary outcomes: Fall Efficacy Scale-International (FES-I) and Stroke Specific Quality of Life Scale (SSQOL).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260715070212N1**

Registration date: **2026-07-20, 1405/04/29**

Registration timing: **retrospective**

Last update: **2026-07-20, 1405/04/29**

Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

Name

Muhammad Hassan Bari

Name of organization / entity

Islam College of Physical Therapy, Sialkot, Pakistan

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-01, 1404/06/10

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

2025-09-01, 1404/06/10

Actual recruitment end date

2026-03-01, 1404/12/10

Trial completion date

2026-06-01, 1405/03/11

Scientific title

Effects of Multimodal Balance Training with and without Auditory Cues on Balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Stroke

Public title

Effects of Multimodal Balance Training with and without Auditory Cues on Balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with a unilateral chronic stroke (>1 year post-stroke), aged between 45 to 70 years

Exclusion criteria:

Aphasia Moderate to severe cognitive impairment (MMSE < 24) Severe cardiac diseases Uncontrolled hypertension Non-healing ulcers Osteoporosis Severe visuospatial deficits

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were gathered using non-probability convenient sampling and randomly assigned into two equal groups of 21 using a simple randomization method (lottery system). The unit of randomization was the individual patient, and allocation concealment was maintained using sealed envelopes until group assignments were determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study utilized a single-blind approach. The outcome assessors who recorded the data at baseline, 6 weeks, and 12 weeks were kept completely blinded to the treatment group assignments of the participants. The physical therapists delivering the interventions and the participants themselves were not blinded due to the nature of physical exercise protocols.

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee, Islam Teaching Hospital

Street address

Pasrur Road, Islam teaching hospital, Sialkot

City

Sialkot

Postal code

51310

Approval date

2025-08-15, 1404/05/24

Ethics committee reference number

ICPT-REC-2025-084

Health conditions studied

1

Description of health condition studied

Chronic Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Gait, balance performance, and functional mobility

Timepoint

Measured at baseline (0 weeks), at mid-intervention (6 weeks), and post-intervention (12 weeks)

Method of measurement

Berg Balance Scale (BBS)

2

Description

Dynamic balance and functional mobility status

Timepoint

Measured at baseline (0 weeks), at mid-intervention (6 weeks), and post-intervention (12 weeks)

Method of measurement

Timed Up and Go (TUG) test

Secondary outcomes

1

Description

Fear of falling and balance confidence during daily activities

Timepoint

Measured at baseline (0 weeks), at mid-intervention (6 weeks), and post-intervention (12 weeks)

Method of measurement

Fall Efficacy Scale-International (FES-I)

2

Description

Health-related quality of life across specific stroke domains

Timepoint

Measured at baseline (0 weeks), at mid-intervention (6 weeks), and post-intervention (12 weeks)

Method of measurement

Stroke Specific Quality of Life Scale (SSQOL)

Intervention groups

1

Description

Intervention group: Multimodal balance training with auditory cues. Includes trunk stability, weight shifts, visual cue walking, ball-based diagonal reaching, and rhythmic auditory stimulation (RAS) delivered via a digital metronome. Sessions lasted 45 minutes, administered 2 times a week for 12 weeks (24 sessions total).

Category

Rehabilitation

2

Description

Control group: Multimodal balance training without auditory cues. Includes identical trunk stability, weight shifts, visual cue walking, and ball-based diagonal reaching exercises without rhythmic audio feedback. Sessions lasted 45 minutes, administered 2 times a week for 12 weeks (24 sessions total).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Islam Teaching Hospital

Full name of responsible person

Hammad Sattar

Street address

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Recruitment center

Name of recruitment center

Imran Idrees Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islam College of Physical Therapy

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islam College of Physical Therapy

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islam College of Physical Therapy

Full name of responsible person

Hammad Sattar

Position

Principal Investigator

Latest degree

Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data (IPD) including demographic variables, baseline characteristics, and pre/post intervention clinical scale scores (BBS, TUG, FES-I, SSQOL) along with the study protocol and data dictionary.

When the data will become available and for how long

Data will become available immediately following publication of the study results and will remain accessible indefinitely.

To whom data/document is available

Available to researchers, clinicians, and academic students working in the fields of physical therapy, neurological rehabilitation, and clinical biomechanics.

Under which criteria data/document could be used

For the purpose of systematic reviews, meta-analyses, secondary independent data analysis, or replication studies.

From where data/document is obtainable

The dataset will be publicly accessible via the open-access science repository medRxiv.

What processes are involved for a request to access data/document

No formal request process is required as the data will be directly downloadable as open-access files from the repository repository URL.

Comments