Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Muhammad Hassan Bari
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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
Pasrur Road, Sialkot
City
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51310
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2

Recruitment center
Name of recruitment center
Imran Idrees Hospital
Full name of responsible person
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Cantt, Sialkot
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islam College of Physical Therapy
Full name of responsible person
Hammad Sattar
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info@icpt.edu.pk
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
Physical Therapy
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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