# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**
**Name**
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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
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**2**

**Recruitment center**
**Name of recruitment center**
Imran Idrees Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Email**
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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
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**Position**
Principal Investigator
**Latest degree**

Master
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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**