Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Multi-modal Balance Training with and without Auditory cues on balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Sroke

Protocol summary

Study aim
To determine the effects of multi-modal balance training with and without auditory cues on balance, mobility, risk of fall and quality of life in chronic stroke.

Design
A randomized, single blinded clinical trial with a parallel group design of 42 patients (divided into two groups), were selected from Physical Therapy Department of Islam teaching hospital and Imran idrees hospital cantt. and followed for 12 weeks

Settings and conduct
The data will be collected from the Islam teaching Hospital and Imran idrees hospital cantt.. The study population will be patients witrh chronic stroke which will randomly allocated into two groups. Group A (Multimodal Balance Training with Auditory cues) and Group B (Multimodal Balance Training without Auditory cues).

Participants/Inclusion and exclusion criteria
Inclusion criteria will be both genders with the age between 45-70 years , having one sided stroke with no or less than grade 2 spasticity in modified ashworth scale and less than 52 score in berg balance scale. Exclusion criteria will be the patients with any respiratory disorders (i.e. asthma), orthopedic disorder (i.e. arthritis), non-healing ulcers, visuospatial problems (i.e. hemineglect) and cardiac disorder (i.e. myocardial infarction)

Intervention groups
Both experimental groups received balance training; one intervention group (Group A) received exercises combined with auditory cues provided by using a google metronome (RAS-supported multimodal balance intervention), whereas the other intervention group (Group B) received balance training without auditory cues (only multimodal balance training). All the participants perform exercises for 45 minutes session with 10 minutes of rest break, on two alternative days in a week for a period of 12 weeks. Effects of intervention will be measured after 6th and 12th weeks

Main outcome variables
Balance, Gait mobility, Risk of fall, Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240714062437N1**
Registration date: **2024-11-15, 1403/08/25**
Registration timing: **retrospective**

Last update: **2024-11-15, 1403/08/25**
Update count: **0**

Registration date
2024-11-15, 1403/08/25

Registrant information

Name
Hammad Sattar

Name of organization / entity
University of Lahore

Country
Pakistan

Phone
+92 344 7089190

Email address
hammadsattarpt@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-29, 1403/03/09

Expected recruitment end date
2024-10-30, 1403/08/09

Actual recruitment start date

2024-05-29, 1403/03/09

Actual recruitment end date

2024-10-31, 1403/08/10

Trial completion date

2024-12-02, 1403/09/12

Scientific title

Effects of Multi-modal Balance Training with and without Auditory cues on balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Sroke

Public title

Effects of Multi-modal Balance Training with and without Auditory cues on balance, Gait Mobility, Risk of Fall and Quality of Life in Patients with Chronic Sroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

both genders are included individuals with the age of between 45-70 years individuals with absent or less than grade 2 spasticity in modified ashworth scale in affected extremity indviduals having only one sided stroke individuals having score of less than 52 out of 56 in berg balnce scale

Exclusion criteria:

individuals who have any kind of cardiac disorder i.e. myocardial infarction etc individuals who have any orthopedic disorder i.e. arthritis etc indivduals who have any respiratory condition such as asthma etc. individuals who have non-healing ulcers individuals who have some visuospastial problems i.e. hemi-neglect etc

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

all the screened and willing participants will be randomly allocated into tw groups (Group A and Group B) by computerized generated method

Blinding (investigator's opinion)

Single blinded

Blinding description

study will be single and assessor blinded. Participants will be masked about other groups but they will know what treatment they will be receiving or what exercises they will be doing. Principal investigator would also not be masked or blinded because investigator would be applying the techniques or participants of both groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore, Punjab, Pakistan

City

Lahore

Postal code

55150

Approval date

2024-05-22, 1403/03/02

Ethics committee reference number

REC-UOL-205-08-24

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46

ICD-10 code description

Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description

Balance

Timepoint

12 weeks

Method of measurement

The Berg Balance Scale (BBS) is one of the most widely used tools for balance assessment. The BBS is a 14-item scale that quantitatively assesses balance and risk for falls in older community-dwelling adults through direct observation of their performance. The scale requires 10 to 20 minutes to complete and measures the patient’s ability to maintain balance—either statically or while performing various functional movements for a specified duration of time. The items are scored from 0 to 4, with a score of 0 representing an inability to complete the task and a score of 4 representing independent item completion. A global score is calculated out of 56 possible points. Scores of 0 to 20 represent balance impairment, 21 to 40 represent acceptable balance, and 41 to 56 represent good balance. The BBS measures both static and dynamic aspects of balance.

2

Description
Gait mobility
Timepoint
12 weeks
Method of measurement
The TUG test is a composite measure of functional mobility. The TUG was originallycreated to predict fall risk in geriatric patients. It includes executive function (listening andinitiating movements), transfer tasks (standing up and sitting down), walking, and balance.The TUG is performed by having the patient seated in a chair and with the command “go”,rise from the chair, walk 3 meters, turn around, return to chair and sit. The trial is timedfrom when the patient’s back leaves the backrest to when the patient returns to the seatedposition, and the patient is allowed one practice trial. TUG score of 13.5 seconds or morecould rule in the risk of a fall.

3

Description
Risk of fall
Timepoint
12 weeks
Method of measurement
The Falls Efficacy Scale International (FES-I) is a measure of “fear of falling” or “concerns about falling”. The FES-I is intended to be used in adult population to measure the level of concern about falling during social and physical activities inside and outside the home whether or not the person actually does the activity. It is a 16 item questionnaire, useful to the researchers and clinicians interested in fear of falling, with a score ranging from minimum 16 (no concern about falling) to maximum 64 (severe concern about falling). In this scale individuals are instructed to score their concern of falling during an activity on a 4 point Likert scale with 1 as not concerned at all and 4 as very concerned. The item scores are summed up to obtain a total, with higher the score, higher being the concern for falling.

4

Description
Quality of life
Timepoint
12 weeks
Method of measurement
The Stroke Specific Quality of Life scale (SS-QOL) is a patient-centered outcome measureintended to provide an assessment of health-related quality of life (HRQOL) specific topatients with stroke. Patients must respond to each question of the SS-QOL with referenceto the past week. It is a self-report scale containing 49 items in 12 domains. The score is between 49-245, having high score with better quality of life.

Secondary outcomes

empty

Intervention groups

1

Description
in this study, patients are allocated into two groups. Both experimental groups received balance training; one intervention group received multi modal balance training exercises combined with auditory cues provided by a metronome (RAS-supported multimodal balance intervention), whereas the other intervention group received balance training exercises without auditory cues (only multimodal balance training). Multimodal balance training exercises in the intervention are: Ball lifted over head in sitting position, Trunk stability in seatedposition, Stability upright posture when holding a stick, Trunk twist with ball in sittingposition, Weight shifts, Balance on both feet with visual cues, Latero-lateral stepsingle-leg balance, walking with visual cues and foam, make side-steps, walking withvisual cues and cones, Diagonal reaching with ball, sit to Stand, Twisting. Participants of each group will perform 24 sessions (over 12 weeks) on alternative days in a week. The duration ofeach session will be 45 minutes lasting 10 minutes each with rest breaks. Effects of interventions will be measured after 6th week and after 12th week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Islam teaching hospital sialkot and Imran idress hospital cantt. sialkot
Full name of responsible person
Dr. Husna and Dr. Ayesha zulfiqar
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Sponsors / Funding sources

1

Sponsor
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The University of Lahore
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
None
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
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Full name of responsible person
Hammad Sattar
Position
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidenfidentially

When the data will become available and for how long

Data will be available after the publication of findings till twelve months

To whom data/document is available

Hammad Sattar

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding of the study, Hammad Sattar, and can contact on 00923447089190, hammadsattarpt@gmail.com

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

Open access and there is traditional public data release where anyone can get access to the data

Comments