

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of intensive multidimensional trunk training exercises combined with dual-task compared to routine physiotherapy on balance, mobility, and fall in stroke patients; a randomized controlled clinical trial

Protocol summary

Study aim

To determine the effects of intensive multidimensional trunk training exercises combined with dual-task compared to routine physiotherapy on balance, mobility and fall risk in stroke patients

Design

Randomised, superiority, parallel-group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site. The sample size was 84 out of which 74 patients completed the study.

Settings and conduct

Patients were recruited from the University clinic of the University of Lahore, a 400-bed hospital with separate physiotherapy and stroke rehabilitation facility. It was single-blinded (assessor blinded) study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with an ability to stand 30 seconds or more without any assistance, score 24 or over on mini-mental status examination, and ability to sit independently at least for 30 seconds on a stable surface. Exclusion criteria: Patients with comorbid conditions such as cerebellar disorders, Parkinson's disease, a vestibular lesion, arthritis or degenerative diseases of the lower limbs affecting motor performance, self-reported problems with device use (orthopaedic, medical, and/or painful conditions), a body mass index greater than 31 kg/m² who are not able to perform exercises for 30 minutes or longer, any medical contraindication against trunk exercise and patient with pusher syndrome.

Intervention groups

Intervention group: multidimensional trunk exercises combined with dual-task, flexibility and task-oriented exercises Comparison group: trunk exercises, flexibility and task-oriented exercises

Main outcome variables

Balance & mobility measured with time up and go test, timed walking test, go up and down standard 10 stairs, trunk performance measured with trunk impairment scale, and fall risk measured with fall risk assessment tool.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046275N1**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **retrospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Umair Ahmed

Name of organization / entity

The University of Lahore

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-15, 1395/11/27

Expected recruitment end date

2017-11-15, 1396/08/24
Actual recruitment start date
 2017-02-17, 1395/11/29
Actual recruitment end date
 2017-11-28, 1396/09/07
Trial completion date
 2018-11-30, 1397/09/09

Scientific title
 Effects of intensive multidimensional trunk training exercises combined with dual-task compared to routine physiotherapy on balance, mobility, and fall in stroke patients; a randomized controlled clinical trial

Public title
 Effects of intensive multidimensional trunk training exercises combined with dual-task compared to routine physiotherapy on balance, mobility, and fall in stroke patients; a randomized controlled clinical trial

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient with score 24 or over on Mini-Mental Status Examination Patient with ability to stand 30 second or more without any assistance Patient with an ability to sit independently at least for 30 seconds on a stable surface
Exclusion criteria:
 Patients with comorbid conditions such as cerebellar disorders, Parkinson's disease, a vestibular lesion, arthritis or degenerative diseases of the lower limbs affecting motor performance Patient with self-reported problems with device use (orthopedic, medical, and/or painful conditions) A body mass index greater than 31 kg/m² who are not able to perform exercises for 30 minutes or longer. Patient with medical contraindication against trunk exercise Patient with pusher syndrome.

Age
 From **18 years** old to **85 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **84**
 Actual sample size reached: **74**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomisation was centralised and computerised with concealed randomisation sequence in an enclosed envelope carried out at an external site by independent personnel.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Independent assessors, who were not familiar with the aims and objectives of the study, assessed & evaluated

the patients' outcomes. Furthermore, all trial participants were informed about blind outcome assessments and its importance and requested not to reveal their group allocation on the following occasions: 1. Baseline assessment; both immediately prior to, and after, randomization. 2. On each time when participants were requested to arrange follow-up visits. 3. At the commencement of each follow-up visit The outcome assessor had no access to any study data and therapist/personnel involved in the study, no access to the password-protected study database controlled by the Data Safety and Monitoring Board and no access to completed assessments, treatment notes or questionnaires. The follow-up questionnaire item was used to measure outcome assessor's awareness of group allocation during follow-up visits. Therapists who provided the care to the patients were unaware of the identity of the assessors. If any support were needed to therapist and assessors, the lead research was responsible to provide all the guidance to them in strict accordance with the Data Safety and Monitoring Board. The Board does not allow the lead researcher to have direct contact and meet with the assessors anywhere except permitted site. In case of provision of any support, he had to provide video-recorded evidence of the support given to the assessors to prevent the breach in blinding. Data analyser was kept blinded by coding groups, participants and their assessments, and he did not have any direct or indirect access to the patients or personnel involved in the study. He was also completely unaware of the aims & objectives of the study.

Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids
 empty

Ethics committees

1
Ethics committee
Name of ethics committee
 Institutional review board
Street address
 1 - KM defence road,
City
 Lahore
Postal code
 54770
Approval date
 2017-02-06, 1395/11/18
Ethics committee reference number
 IRB-UOL-FAHS/293/2018

Health conditions studied

1

Description of health condition studied

Vascular syndromes of brain in cerebrovascular diseases

ICD-10 code

G46

ICD-10 code description

Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description

Mobility & Balance

Timepoint

Before intervention , post intervention (12 weeks), two follow up measurements with 6 months interval after post-intervention

Method of measurement

Time up and go test, timed walking test, go up and down standard 10 stairs

2

Description

Trunk motor performance

Timepoint

Before intervention , post intervention (12 weeks), two follow up measurements with 6 months interval after post-intervention

Method of measurement

Trunk impairment scale, postural assessment scale for stroke patients

Secondary outcomes

1

Description

Fall risk

Timepoint

Before intervention , post intervention (12 weeks), two follow up measurements with 6 months interval after post-intervention

Method of measurement

Fall risk is assessed by fall risk assessment tool

Intervention groups

1

Description

Intervention group: Multidimensional trunk exercises combine with cognitive dual-task for 40 minutes in each session, 5 times per week for 3 months. Instruments used are plinth, physio balls, balance/wobble board, thera-bands timed watch. Flexibility exercises (A & PROM, stretches) 15 minute in each session, 5 sessions in a week for three months. Task-oriented exercises including gait training for 60 minutes per session, 5 sessions per week for 3 months. Instruments used are

body weight support treadmill and also depend upon the goals and task of the patients.

Category

Rehabilitation

2

Description

Control group: Trunk exercises without dual-task for 40 minutes per session, 5 times per week for 3 months. Instruments used are plinth, physio balls, balance/wobble board, thera-bands timed watch. Flexibility exercises (A & PROM, stretches) 15 minute per session, 5 sessions in a week for three months. Task-oriented exercises including gait training for 60 minutes per session, 5 sessions per week for 3 months. Instruments used are body weight support treadmill and also depend upon the goals and task of the patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University clinic of University of Lahore

Full name of responsible person

DR Ashfaq Ahmad

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1-Km Defence Road, Near Bhupatian Chowk

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

IDTT

Grant code / Reference number

293

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

Yes

Title of funding source

The University of 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**

The University of Lahore

Full name of responsible person

Umair Ahmed

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physiotherapy

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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