Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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/m 2 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

Phone

+92 42 86705503

Email address

umairahmednpt@gmail.com

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/m 2 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
Street address
1-Km Defence Road، Near Bhuptian Chowk
City
Lahore
Postal code
54770
Phone
+92 42 35322501
Email
ashfaq.ahmad@uipt.uol.edu.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
Umair Ahmed
Street address
1 - KM Defence Road, Lahore
City
Lahore
Postal code
54770
Phone
+92 42 86705503
Email
umair.ahmed@uipt.uol.edu.pk
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
Street address
1 - KM Defence Road, Lahore
City
Lahore
Province
Punjab
Postal code
54770
Phone
+92 42 35321761
Email
umair.ahmed@uipt.uol.edu.pk

Person responsible for scientific inquiries

Contact
Name of organization / entity
The University of Lahore
Full name of responsible person
DR Umair Ahmed
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Physiotherapy
Street address
1 - KM Defence Road, Lahore
City
Lahore
Province
punjab
Postal code
54770
Phone
+92 42 86705503
Email
umair.ahmed@uipt.uol.edu.pk

Person responsible for updating data

Contact
Name of organization / entity
The University of Lahore
Full name of responsible person
Dr Bilal Umar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Physiotherapy
Street address
1- KM defence Road
City
Lahore
Province
Punjab
Postal code
54770
Phone
+92 42 86705513
Email
dptbilal@gmail.com

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