Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Comprehensive Trunk Control Exercises in comparison to Balance Exercises on Balance and Activities of Daily Living in Individuals with Stroke: A Randomized Controlled Trial

Protocol summary

Study aim
The Effect of Comprehensive Trunk Control Exercises on Balance and Activities of Daily Living in Individuals with Stroke

Design
This study is 2-armed, A-blind RCT compared Comprehensive Trunk Control exercise, to Balance exercises in individuals with stroke. this randomized clinical trial with one to one allocation in two groups (group 1: Comprehensive Trunk Control exercise, group 2: balance exercise). Where the person evaluating the outcome measures is completely blind to the type of exercise each group received.

Settings and conduct
The intervention is performed in the physiotherapy clinic. In this study, the assessor and data analyst are blind.

Participants/Inclusion and exclusion criteria
Individuals aged 60 to 80 years, having had a stroke between 3 months and 10 years, being able to sit without support for at least 30 seconds, and being able to stand on one leg on the affected side with or without assistance for at least 3 seconds will be included in the study. Individuals with pusher syndrome will not be included in the study.

Intervention groups
Participants in the intervention group will receive comprehensive trunk control exercises, and in the control group will receive balance exercises, 3 sessions per week for 6 weeks.

Main outcome variables
The main outcomes are Balance and Activities of Daily Living scores

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140222016680N11**
Registration date: **2026-11-12, 1405/08/21**
Registration timing: **prospective**

Last update: **2026-11-12, 1405/08/21**
Update count: **0**

Registration date
2026-11-12, 1405/08/21

Registrant information

Name
Shohreh Noorizadeh Dehkordi

Name of organization / entity
Iran University of Medical Sciences, School of Rehabilitation Sciences

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2028-11-21, 1407/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Comprehensive Trunk Control Exercises in comparison to Balance Exercises on Balance and Activities of Daily Living in Individuals with Stroke: A Randomized Controlled Trial

Public title

The Effect of Trunk Exercises on Balance and Activities of Daily Living in Individuals with Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having age range between 60 and 80 years Diagnosis of hemorrhagic or ischemic stroke based on CT scan or MRI imaging with physician confirmation Stroke occurrence within 3 months to 10 years Having a Montreal Cognitive Assessment score >18 Having a trunk control test score >48 Be able to stand for at least one minute or be able to walk independently for at least 10 meters with or without assistance. Ability to sit without support for at least 30 seconds Disability severity ≥3 according to the modified Rankin Scale Being in phase three or higher of recovery according to the Brunnstrom stages Ability to single leg stance on the affected side with or without assistance for at least 3 seconds

Exclusion criteria:

Having other neurological diseases (such as Parkinson, muscular dystrophy and neuropathy) and severe orthopedic diseases (such as amputations and surgeries related to lumbar discs and lumbar fixation) that affect motor function and balance Patients whose stroke occurs solely and exclusively in the cerebellum and brainstem Having unstable cardiovascular and respiratory vital functions Having pusher syndrome Having a visual field defect when performing a confrontation test Having Star Cancellation Test score <44, indicating unilateral spatial neglect Occurrence of recurrent stroke during the study period Having contractures of the elbow, wrist, and fingers in the less affected upper limb

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

All stroke patients who are eligible for inclusion in the study will be assigned to two groups: control and comprehensive trunk control exercises using a block randomization method with variable block sizes of 4 or 6 people and an allocation ratio of 1:1.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants and intervention providers will not be possible. However, to reduce bias, the assessment of study outcomes will be conducted by assessors who are unaware of the group allocation of participants. Also, the statistical analyst will be unaware of the actual group allocation until the statistical analyses are finalized, and the groups will be identified by anonymous codes (such as A and B).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Rehabilitation Sciences-Iran University of Medical Sciences

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School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran

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Approval date

2026-10-12, 1405/07/20

Ethics committee reference number

IR.IUMS.REHAB.REC.1405.040

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G81.1

ICD-10 code description

Spastic hemiplegia

Primary outcomes

1

Description

The Balance score in Berg Balance Scale

Timepoint

before first treatment session, after 15th session (last session) and 6 months after the last session.

Method of measurement
Berg Balance Scale

Secondary outcomes

1

Description
Timed Up and Go Test
Timepoint
before first treatment session, after 18th session (last session) and 6 months after the last session.
Method of measurement
Timed Up and Go

2

Description
postural stability
Timepoint
before first treatment session, after 18th session (last session) and 6 months after the last session
Method of measurement
balance Biodex system

3

Description
Activities Daily Living
Timepoint
before first treatment session, after 18th session (last session) and 6 months after the last session
Method of measurement
Functional Independence Measure

4

Description
Trunk Control Test
Timepoint
before first treatment session, after 18th session (last session) and 6 months after the last session
Method of measurement
Trunk Control Test

Intervention groups

1

Description
Intervention group: In this group, Comprehensive Trunk Control exercises, will be given in a period of 6 weeks, three sessions per week. During eighteen sessions, 12 exercises are given with focus on improving balance in supine, sitting and standing positions. Each treatment session, depending on the patient needs to rest, lasts between 75 to 90 minutes. Required equipment are mats, swiss ball, chair, wall bar, inclined wedge and tilt board.
Category
Rehabilitation

2

Description
Control group: In this group, Comprehensive Trunk Control exercises, will be given in a period of 6 weeks, three sessions per week. During eighteen sessions, 12 exercises are given with focus on improving balance in supine, sitting and standing positions. Each treatment session, depending on the patient needs to rest, lasts between 75 to 90 minutes. Required equipment are mats, wall bar.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
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Grant name
Vice Cancellor for Research of Iran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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

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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