

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Core Muscles Strengthening Exercises With Routine Physical Therapy on Trunk Balance and Functional Mobility in Stroke Patients: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the effects of core muscles strengthening exercises with routine physical therapy on trunk balance and functional mobility in stroke patients.

Design

Single blinded, Randomized controlled trial

Settings and conduct

Mubarak Medical Complex

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Patients who has the first on set of ischemic stroke. 2) Age between 40-60 years. 3) Medically stable, understand and follow simple verbal instructions. 4) Both male and female with chronic stroke (6 months post stroke). 5) MMSE > 24 Exclusion Criteria: 1) Patients who could not communicate (severe aphasia). 2) Participants having neglect of paretic limb 3) Participants with severe spasticity (modified ash worth scale score >3). 4) Patient having visual and sensory deficit. 5) If patient had a neurological disease affecting balance other than stroke, such as cerebellar disease, Parkinson's disease or vestibule disease.

Intervention groups

All the participant who came to physiotherapy department was considered and screened for chronic phase of stroke. 74 patients were allotted in two groups i.e.; group A(RPT) and group B(RPT+ Core strengthening exercises) via lottery method, 37 in each group. Consider the inclusion and exclusion criteria before concerning them in study. Both groups will receive the routine physical therapy. Patient in A group will be treated by routine physical therapy and in B group with routine physical therapy plus core strengthening exercises. Dosage:- 30 minutes RPT in both groups and core strengthening exercises with 7-10 repetitions for 15-20 minutes with adequate rest interval in experimental group. □ Duration: - Four sessions/week (alternative days) and treatment last for 8 weeks.

Main outcome variables

1: Trunk Balance 2: Functional Mobility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053070N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Iqra Nadeem

Name of organization / entity

University of Sargodha

Country

Pakistan

Phone

+92 48 3219551

Email address

iqra.nadeem@uos.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-28, 1400/08/06

Expected recruitment end date

2022-04-28, 1401/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Core Muscles Strengthening Exercises With Routine Physical Therapy on Trunk Balance and Functional Mobility in Stroke Patients: A Randomized Controlled Trial

Public title

Effects of Core Muscles Strengthening Exercises With Routine Physical Therapy on Trunk Balance and Functional Mobility in Stroke Patients: A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who has the first on set of ischemic stroke Age between 40-60 years. Medically stable, understand and follow simple verbal instructions Both male and female with chronic stroke (6 months post stroke). MMSE > 24

Exclusion criteria:

Patients who could not communicate (severe aphasia). Participants having neglect of paretic limb Participants with severe spasticity (modified ash worth scale score >3) Patient having visual and sensory deficit If patient had a neurological disease affecting balance other than stroke, such as cerebellar disease, Parkinson's disease or vestibular disease

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

A total no. of 74 participants suffering from stroke fulfilling the inclusion criteria will be recruited to volunteer in this randomized controlled study. Subjects will be randomized into two groups using lottery method.

Blinding (investigator's opinion)

Single blinded

Blinding description

it will be a single blinded study in which participant/ patients are kept blind for treatment techniques and patients are blind about which group they belong either intervention or control group.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Lahore

Street address

House no.85, Umer block Sargodha homes main Fsd road near 49 tail Sargodha

City

Sargodha

Postal code

40100

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IRB-UOL-FAHS/1007/2021

Health conditions studied**1****Description of health condition studied**

Stroke population

ICD-10 code**ICD-10 code description**

ischemic stroke, core strengthening exercise, trunk balance, functional mobility

Primary outcomes**1****Description**

Trunk balance

Timepoint

8 weeks

Method of measurement

Trunk Impairment Scale

Secondary outcomes**1****Description**

Functional Mobility

Timepoint

8 weeks

Method of measurement

Timed up and Go Test

Intervention groups

1

Description

Intervention group: Routine physical therapy + core muscle strengthening exercises for 15-20 minutes (4 sessions per week) for 8 weeks

Category

Rehabilitation

2

Description

Control group: group A : Routine physical therapy for 30 minutes (4 sessions per week) for 8 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mubarak medical complex, Sargodha

Full name of responsible person

Iqra Nadeem

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore, Lahore

Full name of responsible person

Dr sara khawar Butt

Street address

Defense Road Campus University College of Medicine & Dentistry: 1-Km, Defence Road, Bhupatian Chowk, Off Raiwind Road, Lahore

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Grant name

iqra nadeem

Grant code / Reference number

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

No

Title of funding source

academic support only

Proportion provided by this source

20

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

Mubarak medical complex, Sargodha

Full name of responsible person

Iqra Nadeem

Position

Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Lahore, Lahore

Full name of responsible person

Dr. Sarah khawar Butt

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

EFFECTS OF CORE MUSCLES STRENGTHENING
EXERCISES WITH ROUTINE PHYSICAL THERAPY ON
TRUNK BALANCE AND FUNCTIONAL MOBILITY IN STROKE
PATIENTS: A RANDOMIZED CONTROLLED TRIAL

When the data will become available and for how long

Study is completed after 6 months and become available after its publication

To whom data/document is available

person in academic institute. Patient data will not be shown

Under which criteria data/document could be used

under the usage with terms in which journal is accessed /processed for publication it could be used in request

From where data/document is obtainable

+923246461428 from the University office and Responsible supervisor and from journal we will process in future

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

can be on call or mail It will be only used in confidential way for improving research and benefit of humanity

Comments

data can be provided on request