

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of core strengthening exercises with and without proprioceptive neuromuscular facilitation on mobility, balance, and coordination in post stroke hemiplegic patients

#### Protocol summary

##### Study aim

To determine the effects of core strengthening exercises with and without proprioceptive neuromuscular facilitation on balance, coordination and mobility in post stroke hemiplegic patients

##### Design

Two arm parallel group randomised trail with single blinded outcome assessment.

##### Settings and conduct

This study was e a single blinded study in which assessor was kept blinded. Department of Physical Therapy, The university of lahore teaching hospital

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Aged between 40-65 years • Both Male and females • Stroke Onset  $\geq 3$  months • Ambulatory with and without aid • Patients with berge balance scale score less than 45 Exclusion Criteria: • Patients with Cardiopulmonary disease • Patients with any type of orthopedic injury • Patients with visual and vestibular dysfunction • Patients who struggle to follow exercise instructions

##### Intervention groups

Two groups of thirty-one stroke patients, ages forty to sixty-five, were chosen at random. Proprioceptive neuromuscular facilitation was applied with core strengthening exercises among Group A and only proprioceptive neuromuscular facilitation were applied among Group B.

##### Main outcome variables

1. Balance (Berg Balance Scale) 2. Mobility (Barthel Index) 3. Coordination (Trunk Impairment Scale)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241125063846N1**

Registration date: **2025-02-18, 1403/11/30**

Registration timing: **retrospective**

Last update: **2025-02-18, 1403/11/30**

Update count: **0**

##### Registration date

2025-02-18, 1403/11/30

##### Registrant information

###### Name

Amara Rubab

###### Name of organization / entity

University of Lahore

###### Country

Pakistan

###### Phone

+92 303 2555480

###### Email address

amararubab@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-06-07, 1403/03/18

##### Expected recruitment end date

2024-12-12, 1403/09/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of core strengthening exercises with and without proprioceptive neuromuscular facilitation on mobility,

balance, and coordination in post stroke hemiplegic patients

**Public title**

Effects of core strengthening exercise with and without proprioceptive neuromuscular facilitation on mobility, balance, and coordination

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged between 40-65 years Both Male and females Stroke Onset  $\geq$ 3 months Ambulatory with and without aid Patients with Berge balance scale score less than 45

**Exclusion criteria:**

Patients with Cardiopulmonary disease Patients with any type of orthopedic injury Patients with visual and vestibular dysfunction Patients who struggle to follow exercise instructions

**Age**

From **45 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **62**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Lottery method will be used for randomization by an independent statistician. Randomization will be done by one of the research team members who will not involve in patient recruitment or assessment or data analysis. In this method Group names are mentioned on separate slips of paper of same size, shape and color. They will be folded and mixed up in a container. A blind fold selection will be made and each member of the population will be assigned a number. Randomization assignments will be kept in opaque, sealed envelopes and unsealed by a researcher after baseline testing. Outcome assessors will not be unaware of group assignment.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Single blinded study in which assessor will be kept unaware of which treatment is given to two groups being studied while participants know about their treatment protocol

**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**

2024-05-24, 1403/03/04

**Ethics committee reference number**

REC-UOL-/240/08/24

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

Stroke is defined as 'rapidly developing clinical signs of focal or global disturbance of cerebral function, with symptoms lasting 24 h or longer, or leading to death, with no apparent cause other than of vascular origin 'Stroke definition includes both cerebral infarction and intracerebral subarachnoid hemorrhage.

**ICD-10 code**

I63.30

**ICD-10 code description**

Cerebral infarction due to thrombosis of unspecified cerebral artery

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

The Berg Balance Scale (BBS) is used to objectively determine a patient's ability (or inability) to safely balance during a series of predetermined tasks.

**Timepoint**

6 weeks

**Method of measurement**

It is a 14 item list with each item consisting of a five-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 the highest level of function and takes approximately 20 minutes to complete. It does not include the assessment of gait. Cut-off scores for the elderly were reported  $<45$  indicates individuals may be at greater risk of falling

**2****Description**

Trunk impairment scale aims to evaluate the trunk in patients who have suffered a stroke. TIS assesses static and dynamic sitting balance and trunk coordination in a sitting position.

### Timepoint

6 weeks

### Method of measurement

For each item, a 2-, 3- or 4-point ordinal scale is used. On the static and dynamic sitting balance and coordination subscales the maximal scores that can be attained are 7, 10 and 6 points. The total score for TIS ranges between 0 for a minimal performance to 23 for a perfect performance

### 3

#### Description

The Barthel Index for Activities of Daily Living is an ordinal scale which measures a person's ability to complete activities of daily living (ADL). Each item is scored based on whether or not the individual can perform a task or activity independently, with assistance or if they are fully dependent

#### Timepoint

6 weeks

#### Method of measurement

. The scoring is as follows: 0 = unable, 1 = needs assistance/help, 2 = independent. The for the ten items are summed and x 5 to get a total score out of 100. Proposed guidelines for interpreting Barthel scores are as :1) 0-20 indicate "total" dependency, 2) 21-60 indicate "severe" dependency, 3) 61-90 indicate "moderate" dependency, 4) 91-99 indicate "slight" dependency and most studies use a score of 60/61 (moderate dependency) as a cutting point

### Secondary outcomes

empty

### Intervention groups

### 1

#### Description

Intervention group A: The participants in Group A were received one-on-one PNF-based therapy lasting for 30 minutes, three times a week, for six weeks (18 treatment sessions). Sessions were divided into resisted mat exercises and resisted walking training. Exercises were repeated 10-15 times up to tolerance. Different PNF techniques were used in response to the participant's needs. Rhythmic initiation (movement of limb or body through the desired range starting with passive motion and progressing to active resisted movement) was used to teach the movements. Stabilizing reversals (alternating isotonic contractions with enough resistance to prevent motion) Dynamic reversals (active motions changing from one direction to the opposite), and combination of isotonic (combined concentric, eccentric and stabilizing contractions of one muscle group) was used to improve the strength and coordination of the movement. Core strengthening exercise: These exercises consisted of 9 basic exercises. In each class, each exercise was held for 10-60 seconds followed by 10-20 seconds of rest as shown in table 2. Repetition was 3-5 times

### Category

Treatment - Other

### 2

#### Description

Intervention group B: The participants in Group B was received a treatment session 10 minutes of heat therapy and exercises for 10 minutes, then core strengthening exercises were performed as in group B with duration of 30 minutes. Repetition was 3-5 times and other exercises without PNF including pelvic rolling, bridging, sitting and standing exercises and walking practice in parallel bars.

#### Category

Treatment - Other

### Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The University of Lahore Teaching hospital

##### Full name of responsible person

Dr. Asim Arif

##### Street address

1 -km Defence road , near Bhuptian chowk , Lahore , Punjab

##### City

Lahore

##### Postal code

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##### Phone

+92 303 2555480

##### Email

amararubab@gmail.com

### Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The university of Lahore

##### Full name of responsible person

Amara Rubab

##### Street address

1 km Defence Road , near Bhuptian Chowk , Lahore , Punjab

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#### Grant name

#### Grant code / Reference number

#### 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**  
Amara Rubab  
**Position**  
Consultant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
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1 km Defence Road , near Bhuptian Chowk , Lahore ,  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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

Yes - There is 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 confidentiality

### When the data will become available and for how long

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

### To whom data/document is available

This is available for people working in academic

institutions or also for those who are working in clinics.

**Under which criteria data/document could be used**

Research purpose

**From where data/document is obtainable**

To the corresponding author of the study , Amara Rubab and contact on +923032555480 and

amararubab@gmail.com

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

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

**Comments**