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 ≥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

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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 ≥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 isotonics (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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The university of Lahore
Full name of responsible person
Amara Rubab
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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
Concultant

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Position
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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 confidentially

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 correspomding 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