

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of gait training with and without Proprioceptive Neuromuscular Facilitation on balance and gait in chronic stroke patients.

#### Protocol summary

##### Study aim

To compare the effects of gait training with and without proprioceptive neuromuscular facilitation on balance and gait in chronic stroke patients.

##### Design

randomized, parallel group trial with double blinded outcome assessment.

##### Settings and conduct

Data was collected from University Physical Therapy and Rehabilitation Clinic, Lahore Pakistan. Patients and outcome assessors/data collectors were unaware of group allocation

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were hemiplegic patients having single episode of ischemic or hemorrhagic stroke diagnosed by neurologist, male and female patients of age between 35 to 85 years, duration of stroke more than 6 months, participants able to walk with or without support for 10 m and participants having Mini-Mental Status Examination [MMSE]  $\geq 24$ . Exclusion criteria were participants with severe spasticity (modified ashworth scale grade  $\geq 3$ ) or severe flaccidity in lower limbs and upper limbs, patients having orthopedic injury that could interfere with walk, patients having visual and auditory impairments.

##### Intervention groups

In experimental group, Proprioceptive Neuromuscular Facilitation based gait training along with routine physical therapy was performed. Control group received gait training and routine physical therapy. Treatment was provided for six weeks, 3 days per week (on alternative basis) up to six weeks.

##### Main outcome variables

balance and gait

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201101049221N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **retrospective**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

##### Registration date

2020-11-24, 1399/09/04

##### Registrant information

###### Name

Momna Asghar

###### Name of organization / entity

The University of Lahore

###### Country

Pakistan

###### Phone

+92 56 3785097

###### Email address

momna2april@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-07, 1398/12/17

##### Expected recruitment end date

2020-04-25, 1399/02/06

##### Actual recruitment start date

2020-03-10, 1398/12/20

##### Actual recruitment end date

2020-07-15, 1399/04/25

##### Trial completion date

2020-08-26, 1399/06/05

##### Scientific title

Effects of gait training with and without Proprioceptive Neuromuscular Facilitation on balance and gait in chronic stroke patients.

## Public title

Effects of Proprioceptive Neuromuscular Facilitation on balance and gait in chronic stroke patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Hemiplegic patients having single episode of hemorrhagic or ischemic stroke Participants who are more than 6 months post stroke Having Mini Mental Status Exam greater than 24 Patients who are able to walk with or without support for 10 m Patients having no orthopedic injuries

### Exclusion criteria:

participants with severe spasticity (modified ashworth scale grade $\geq$ 3) or severe flaccidity in lower limbs and upper limbs participants having visual and auditory dysfunctions

## Age

From **35 years** old to **85 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **60**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

randomization was done by lottery method

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants and Outcome evaluators were unaware of group allocation. After randomization, study participants were only informed about their allocated exercise program, they remained unaware of the interventions in the other group. Information about the details of both programs was not provided except for similar exercises among both groups. Researchers who assessed outcomes or involved in data analyses will be masked to group allocation. Moreover, if two or more study participants were in the clinic at the same time, they were assigned to different treatment areas without any opportunity to observe each other or their treatment times were rearranged to prevent unintended crossover.

## Placebo

Not used

## Assignment

Parallel

## Other design features

The study is double blinded randomized control trial. two groups are taken, control group and experimental group for comparison

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Review Board of The University of Lahore

##### Street address

207 B block, AWT phase 2, Lahore , Pakistan

##### City

Lahore

##### Postal code

75500

#### Approval date

2020-03-05, 1398/12/15

#### Ethics committee reference number

IRB-UOL-FAHS/718- IV/2020

## Health conditions studied

### 1

#### Description of health condition studied

stroke

#### ICD-10 code

I67

#### ICD-10 code description

Other cerebrovascular diseases

## Primary outcomes

### 1

#### Description

balancing capability

#### Timepoint

before intervention and six weeks after intervention

#### Method of measurement

Berg Balance Scale

### 2

#### Description

Gait parameters

#### Timepoint

before interventions and six weeks after interventions

#### Method of measurement

GAITrite platinum

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Experimental group in which routine physical therapy was performed for 20 minutes and PNF with gait training for 30 minutes (total 50 minutes session). Routine physical therapy involved muscle strengthening exercises, range of motion exercises and stretching exercises up to patient's tolerance based gait training involved PNF pelvic patterns, PNF lower extremity D1 Flexion and PNF lower extremity D1 extension, each exercise was repeated 10 to 20 times or up to patient's tolerance, progressed from rhythmic initiation to stabilizing reversals and then followed by dynamic reversals up to 4th week of treatment session. Other exercises involved pelvic bridging, rolling, sitting and standing exercises and walking practice in parallel bars and treadmill training up to patients tolerance. The treatment was provided at rehabilitation clinic 3 days per week on alternate basis, for 6 weeks (18 sessions). parallel bars, couch, standard chair and treadmill were used during treatment.

### Category

Rehabilitation

## 2

### Description

Control group had a treatment session of 40 minutes, 20 minutes of routine physical therapy as that in experimental group that included muscle strengthening exercises, range of motion exercises and stretching exercises up to patient's tolerance and 20 minutes of gait training alone, that included pelvic rolling, bridging, sitting and standing exercises and walking practice in parallel bars and treadmill training up to patients tolerance. The treatment was provided at rehabilitation clinic 3 days per week on alternate basis, for 6 weeks (18 sessions). parallel bars, couch, standard chair and treadmill were used during treatment.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

University Physical Therapy and Rehabilitation center,  
University of Lahore

##### Full name of responsible person

Dr. Ashfaq Ahmed

##### Street address

1 km, Defence road Bhubatian Chowk, Lahore,  
Pakistan

##### City

Lahore

##### Postal code

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##### Phone

+92 56 3785097

##### Email

momna2april@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Lahore

##### Full name of responsible person

Dr Ashfaq Ahmed

##### Street address

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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

Foreign

#### Category of foreign source of funding

Sponsor: country of origin

#### Country of origin

PK

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

University of Lahore

#### Full name of responsible person

Dr Ashfaq Ahmed

#### Position

Head of Department

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

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1 Km, Defence Road Campus, Bhubatian Chowk,  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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momna2april@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

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

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Effects of gait training with and without proprioceptive neuromuscular facilitation on balance and gait in chronic stroke patients.

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

six months after publication

### To whom data/document is available

It will be available to persons involved in patient rehabilitation in academic institutes and clinical settings

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

persons involved in patient care

### From where data/document is obtainable

communication can be done through emails

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

data and documents can be shred through email after publication

### Comments