

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparative study to assess the effect of balance training with and without taping on mobility and balance in stroke patients

#### Protocol summary

##### Study aim

1.To assess the effect of taping with balance training on mobility and balance in participants with stroke. 2.To assess the effect of balance training on mobility and balance in participants with stroke. 3.To compare effect of taping with and without using balance training on mobility and balance in participants with stroke.

##### Design

Randomized Control Trial (RCT) Single blind study.

##### Settings and conduct

Pakistan Institute of Medical Sciences Islamabad.  
Physiotherapy department.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants of both genders with age more than 35 year will be enrolled. Participants those with hemiparesis with onset more than three months of stroke onset and less than one and a half year. A score of 24 or higher on the MMSE, those who can walk more than 10 m independently with or without a walking aid. Those who are having spastic paralysis of lower limb, those who understand the purpose of the study and provided written consent form. Exclusion Criteria: Participant those with a history of surgery on the lower extremities. High skin sensitivity or skin diseases. Those who complained of pain during dorsiflexion of the ankle joint, and those with a modified Ashworth Scale >2.

##### Intervention groups

There are two interventional group 1. Experimental group (A) Balance training with taping group and 2) Control group (B) Balance training without taping group.

##### Main outcome variables

Ten meter walk test, Berg Balance Scale, Timed up and go test, Six Minute Walk Test, Self structured Questionnaire

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20211022052835N7**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

#### Registration date

2023-05-03, 1402/02/13

#### Registrant information

##### Name

Fouzia Batool

##### Name of organization / entity

Shifa Tameer-e-Millat University

##### Country

Pakistan

##### Phone

+92 51 8441752

##### Email address

fouzia\_dpt.ahs@stmu.edu.pk

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-05-08, 1402/02/18

#### Expected recruitment end date

2023-06-20, 1402/03/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study to assess the effect of balance training with and without taping on mobility and balance in stroke patients

**Public title**

A comparative study to assess the effect of balance training with and without taping on mobility and balance in stroke patients

**Purpose**

Treatment

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

Participants of both genders with age more than 35 year will be enrolled. Participants those with hemiparesis with onset more than three months of stroke onset and less than one and a half year. A score of 24 or higher on the MMSE, those who can walk more than 10 m independently with or without a walking aid. Those who are having spastic paralysis of lower limb, those who understand the purpose of the study and provided written consent form.

**Exclusion criteria:**

Participant those with a history of surgery on the lower extremities. High skin sensitivity or skin diseases. Those who complained of pain during dorsiflexion of the ankle joint, and those with a modified Ashworth Scale >2.

**Age**

From **35 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Random numbers is written on index cards and placed in thick and opaque sealed envelopes before the study. After taking consent from the participants for their participation in the study, the therapist opens the envelop and give the respective protocol to the individual. The study is single blinded as participants is not aware of the intervention group they are placed in. Participants will be placed either in to the experimental group 1 (Balance training with taping) or control group 2 (Balance training without taping) keeping the process completely randomized ,sealed envelope method will be used.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Prior to collecting data, participants would be informed about both the treatment techniques used in both groups; experimental group A (Balance training with taping) and control group B (Balance training without taping). Further they are informed that you will get one of these treatment depending upon the group written on

the card inside the envelop you choose. The group A or B belongs to which way of treatment is known to therapist but the patient doesn't know about it.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

N/A

**Secondary Ids**

empty

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

Institutional review board and ethical committee and ethical committee of shifa tameer-e-millat univ

**Street address**

Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

**City**

Islamabad

**Postal code**

44000

**Approval date**

2023-04-04, 1402/01/15

**Ethics committee reference number**

IRB#018-23

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

Hemiparesis

**ICD-10 code**

G46

**ICD-10 code description**

G46

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

Balance

**Timepoint**

Pre intervention at 0-week, and Post Intervention data after 4 weeks will be taken.

**Method of measurement**

Ten meter walk test, Berg Balance Scale, Timed up and go test, Six Minute Walk Test

**2****Description**

- Mobility

## Timepoint

Pre intervention at 0-week, and Post Intervention data after 4 weeks will be taken.

## Method of measurement

Ten meter walk test, Berg Balance Scale, Timed up and go test, Six Minute Walk Test

## Secondary outcomes

### 1

#### Description

To compare the effect of balance training with and without taping on mobility and balance in stroke patients.

#### Timepoint

Pre Intervention at 0 week, and Post Intervention data after 4 weeks will be taken.

#### Method of measurement

Ten meter walk test, Berg Balance Scale, Timed up and go test, Six Minute Walk Test

## Intervention groups

### 1

#### Description

Intervention Group A: Group A would receive Balance training with taping. There would be 3 sessions per week for 4 weeks. Session would be comprised of 20 minutes with 5 minutes of warm and 5 minutes of cool down before and after the session. Experimental group (taping group), for taping with balance training, kinesio tape will be used for ankle taping. Kinesio tape is used to stabilize the ankle joint during static standing or walking in stroke patients. In this study, the tape will be attached to the peroneus tertius, peroneus longus, tibialis anterior, and extensor hallucis longus, which are used widely for ankle joint stability in stroke patients. With kinesio tape attached to the four muscles, each participant will be given balance training for 20 minutes. Balance training plan: (1) 5 minutes warm-up, (2) 10 minutes static balance exercises, such as Squats (two leg stance), One leg stance, (3) 10 minutes dynamic balance exercises, such as Jogging end to end, Sideways walking or running with crossovers, Forward walking or running in a zigzag line, Backward walking or running in a zigzag line, and (4) 5 minutes of cool-down.

#### Category

Rehabilitation

### 2

#### Description

Intervention Group B: Group B would receive Balance training without taping. There would be 3 sessions per week for 4 weeks. Session would be comprised of 20 minutes with 5 minutes of warm and 5 minutes of cool down before and after the session. Balance training plan: (1) 5 minutes warm-up, (2) 10 minutes static balance exercises, such as Squats (two leg stance), One leg stance, (3) 10 minutes dynamic balance exercises, such

as Jogging end to end, Sideways walking or running with crossovers, Forward walking or running in a zigzag line, Backward walking or running in a zigzag line, and (4) 5 minutes of cool-down. These are traditional balance exercise. The treatment duration for the control group will be 20 minutes/3 times a week for 4 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Pakistan Institute of Medical Sciences

##### Full name of responsible person

Dr. Amina Farid Khan

##### Street address

Ibn-e-Sina Rd, G 8/3, G-8, Islamabad

##### City

Islamabad

##### Postal code

44000

##### Phone

+92 306 5007123

##### Email

khan.amina0166@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shifa Tameer-e-Millat University

##### Full name of responsible person

Fouzia Batool

##### Street address

Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

##### City

Islamabad

##### Postal code

44000

##### Phone

+92 51 8441752

##### Email

fouzia\_dpt.ahs@stmu.edu.pk

##### Web page address

<https://stmu.edu.pk/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shifa Tameer-e-Millat University

#### 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**

Shifa Tameer-e-Millat University

**Full name of responsible person**

Fouzia Batool

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**Pitras Bukhari Road, Shifa Tameer-e-Millat University,  
H-8/4, Islamabad**City**

Islamabad

**Province**

Islamabad

**Postal code**

44000

**Phone**

+92 332 7120385

**Email**

fouzia\_dpt.ahs@stmu.edu.pk

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shifa Tameer-e-Millat University

**Full name of responsible person**

Fouzia Batool

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Phone**

+92 332 7120385

**Email**

fouzia\_dpt.ahs@stmu.edu.pk

**Person responsible for updating data****Contact****Name of organization / entity**

Shifa Tameer-e-Millat University

**Full name of responsible person**

Fouzia Batool

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

There is no such plan

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

There is no such plan

**To whom data/document is available**

There is no such plan

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

There is no such plan

**From where data/document is obtainable**

There is no such plan

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

There is no such plan

**Comments**