

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Visual Scanning Exercises on Balance, Gait and Activities of Daily Livings in Patients with Post Stroke Eye Movement Disorders; A Randomized Controlled Trial

#### Protocol summary

##### Study aim

To compare the effects of visual scanning exercises on balance, gait and activities of daily livings in patients with post stroke eye movement disorders.

##### Design

Double blinded Randomized controlled clinical trial

##### Settings and conduct

Out patient department of Physical Therapy Department, University of Lahore Teaching Hospital, Lahore

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients who suffered with eye-movement disorder either an ischemic or hemorrhagic stroke • Clinically diagnosed by a neurologist • Information on the type of stroke will be obtained from the patients' medical records • Both male and female patients between the age group of 19-60 years • Minimum score of 7 on Mini-Mental State Examination • Patients in the sub-acute stage after the stroke and able to follow instructions and have the capacity to provide informed consent Exclusion Criteria: • Repeated stroke • Severe dementia, identified by applying the MMSE • History of an organic disorder or major psychiatric impairment • Disability or other comorbid disease such as cancer or amputation that will limit or prevent assessment of the patients • Participation in other interventional or pharmacological studies which can affect the results of this study • Patients with vestibular problems who have positive dix-hallpike test • Patients with facial palsy • Patients with ophthalmological problems before stroke onset • Patients suffering from balance problems as a result of muscular problem

##### Intervention groups

The patients will be randomly divided into experimental and control group. 32 patients in each group. Experimental group will receive visual scanning exercises along with task-specific approach while control group will receive task-specific approach alone.

#### Main outcome variables

1. Berg Balance Scale 2. The Dynamic Gait Index 3. Barthel index scale

#### General information

##### Reason for update

I want to mention actual recruitment start and end date of my data collection. Also I want to mention trial completion date.

##### Acronym

RCT

##### IRCT registration information

IRCT registration number: **IRCT20190717044237N1**

Registration date: **2019-11-10, 1398/08/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-14, 1401/02/24**

Update count: **1**

##### Registration date

2019-11-10, 1398/08/19

##### Registrant information

###### Name

Sana Batool

###### Name of organization / entity

University of Lahore, Main campus

###### Country

Pakistan

###### Phone

+92 42 99200600

###### Email address

sana.batool1@uipt.uol.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-20, 1397/07/28  
**Expected recruitment end date**  
2020-03-20, 1399/01/01  
**Actual recruitment start date**  
2019-05-01, 1398/02/11  
**Actual recruitment end date**  
2020-10-01, 1399/07/10  
**Trial completion date**  
2020-11-01, 1399/08/11

**Scientific title**  
Effects of Visual Scanning Exercises on Balance, Gait and Activities of Daily Livings in Patients with Post Stroke Eye Movement Disorders; A Randomized Controlled Trial

**Public title**  
Effects of Visual Scanning Exercises on Balance, Gait and Activities of Daily Livings in Patients with Post Stroke Eye Movement Disorders; A Randomized Controlled Trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients who suffered with eye-movement disorder either an ischemic or hemorrhagic stroke Clinically diagnosed by a neurologist Information on the type of stroke will be obtained from the patients' medical records Both male and female patients between the age group of 19-60 years Minimum score of 7 on Mini-Mental State Examination (MMSE) Patients in the sub-acute stage after the stroke and able to follow instructions and have the capacity to provide informed consent

**Exclusion criteria:**

Repeated stroke Severe dementia, identified by applying the MMSE History of an organic disorder or major psychiatric impairment Disability or other comorbid disease such as cancer or amputation that will limit or prevent assessment of the patients Participation in other interventional or pharmacological studies which can affect the results of this study Patients with vestibular problems who have positive dix-hallpike test Patients with facial palsy • Patients with ophthalmological problems before stroke onset Patients suffering from balance problems as a result of muscular problem

**Age**  
From **19 years** old to **60 years** old

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **64**  
Actual sample size reached: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A double-blind, randomized controlled design will be used. Assessors and patients will be blinded in the

present study. They will not know about the group allocation and treatment allocation given to patients. All patients will be allocated randomly into experimental and control groups by using computer-generated random number table. All random numbers will be kept in a sealed envelope. All envelopes will be kept by a third person who will not be involved in this study. For each patient a sealed envelope will be opened and mentioned group will be allocated.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and outcome assessors will be blinded in this study. Patients will not know about the treatment and group allocation and it will be achieved by random numbers. Random numbers will be kept in a sealed envelope. For each patient a sealed envelope will be opened and mentioned group will be allocated. Outcome assessors will just assess the outcomes of treatment at baseline and after four weeks in outcome measure questionnaires. They will not know that they are recording the outcome of which group so in this way they can not be biased.

**Placebo**

Not used

**Assignment**

Other

**Other design features**

No

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Institutional Review Board

**Street address**

University of Lahore, Main Campus, Lahore

**City**

Lahore

**Postal code**

54000

**Approval date**

2018-09-20, 1397/06/29

**Ethics committee reference number**

IRB-UOL-FAHS/373-V/2018

**Health conditions studied**

**1**

**Description of health condition studied**

Stroke

**ICD-10 code**

164

**ICD-10 code description**

164 Stroke, not specified as haemorrhage or infarction

## Primary outcomes

### 1

#### Description

Berg balance scale

#### Timepoint

Before intervention and at 4 weeks of intervention

#### Method of measurement

Scoring

## Secondary outcomes

### 1

#### Description

Dynamic gait index scale to assess the gait impairments and risk of fall

#### Timepoint

Before and after 4 weeks of intervention

#### Method of measurement

A four -point ordinal scale ranging from 0-3 will be used

### 2

#### Description

Barthel index scale to measure the activities of daily living functions

#### Timepoint

Before and after 4 weeks of intervention

#### Method of measurement

A three -point ordinal scale ranging from 0-2 will be used

## Intervention groups

### 1

#### Description

Intervention group: Intervention group will receive visual scanning exercises along with task-specific approach

#### Category

Treatment - Other

### 2

#### Description

Control group: Control group will receive task-specific approach which is used as routine physiotherapy. Task specific activities will be given in following steps. Step 1: In step 1 the physiotherapist will identify the missing components of movement by asking the patient to perform task. Step II: In step II the physiotherapist advice the patient to practice those missing components which were identified in step I. Step III: In step III the physiotherapist will advise the patient to practice the task as a whole. Step IV: In step IV the task is practiced in different environments i.e engage patients in practicing the functional tasks according to the level of balance and gait functions.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

OPD of Physical Therapy Department, University of Lahore Teaching Hospital (ULTH), Lahore

##### Full name of responsible person

Dr. Sana Batool

##### Street address

University of Lahore, Main Campus, Lahore

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 99200600

##### Email

sana.fizza@gmail.com

##### Web page address

<https://www.uol.edu.pk>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Lahore, main campus

##### Full name of responsible person

Dr. Sana Batool, PT

##### Street address

University of Lahore, Main Campus, Lahore

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 99200600

##### Email

sana.batool1@uipt.edu.pk

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<https://www.uol.edu.pk>

#### Grant name

N/A

#### Grant code / Reference number

N/A

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

Yes

#### Title of funding source

University of Lahore, main campus

#### 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**

University of Lahore

**Full name of responsible person**

Dr. Sana Batool, PT

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Neurological Physical therapy

**Street address**

University of Lahore, Main Campus, Lahore

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Dr. Sana Batool, PT

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Neurological Physical therapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Lahore, main campus

**Full name of responsible person**

Dr. Sana Batool, PT

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Assistant Professor

**Latest degree**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

All collected deidentified IPD

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

Data will be available to other people after the completion of study and remained available till 6 months

**To whom data/document is available**

Data will be available to people working in academic institutions

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

Data can be accessed by communicating with principle investigator "Sana Batool" through institutional email address: sana.batool1@uipt.uol.edu.pk

**From where data/document is obtainable**

Data/document is available from principle investigator "Sana Batool" through institutional email address: sana.batool1@uipt.uol.edu.pk

**What processes are involved for a request to access**

**data/document**

Data/document can be accessed through communicating with principle investigator "Sana Batool" on institutional

email address: sana.batool1@uipt.uol.edu.pk

**Comments**

N/A