

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

I64 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

Web page address

<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

City

Lahore

Province

Pakistan

Postal code

54000

Phone

+92 42 99200600

Email

sana.batool1@uipt.edu.pk

Web page address

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

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

Street address

University of Lahore, Main Campus, Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 42 99200600

Email

sana.batool1@uipt.edu.pk

Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

University of Lahore, main campus

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

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 42 99200600

Email

sana.batool1@uipt.edu.pk

Web page address

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

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