

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effectiveness of core stability exercises on energy expenditure during gait in stroke patients

#### Protocol summary

##### Study aim

To determine the effect of core stability exercises on energy expenditure in stroke patients.

##### Design

A Randomized controlled trial

##### Settings and conduct

A study will be conducted at Rehman Medical Institute, Peshawar. Outcome assessor will be blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Stroke patients between 30 to 55 years of age • Both ischemic and hemorrhagic stroke. • Patients who experienced a single stroke. • Patients who can walk for 10 minutes on ground at a comfortable speed(with or without assistive device) • Patients having MMSE score of 24 or more. Exclusion Criteria: • Patients who has cerebellar and pontine stroke. • Patients who has orthopedic problems. • Patients who have vertigo, dizziness, angina or resting heart rate is not between 40-100bpm range. • Patients who cannot follow instructions given by the therapist.

##### Intervention groups

Control Group: Control group will receive the conventional physical therapy program for the stroke 20 minutes a day for 5 days a week. Conventional group will receive motor relearning program protocol. Experimental group: Experimental group each participant will have to attend a 6-weeks program of core stability exercises with 5 minutes each exercise, 5 days a week along with conventional physical therapy. Core stability exercises includes: 1. Bridging exercises 2. Unilateral pelvic bridging 3. Abdominal drawing in maneuver with leg lifts 4. Curl up.

##### Main outcome variables

10 m walk test and energy expenditure will be calculated by physiologic cost index formula.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230907059376N2**  
Registration date: **2023-10-22, 1402/07/30**  
Registration timing: **retrospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

##### Registration date

2023-10-22, 1402/07/30

##### Registrant information

###### Name

Sarmad Khattak

###### Name of organization / entity

Rehman Medical Institute, Peshawar

###### Country

Pakistan

###### Phone

+92 91 5838666

###### Email address

sarmadkhattak007@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-27, 1402/07/05

##### Expected recruitment end date

2023-09-30, 1402/07/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of core stability exercises on energy expenditure during gait in stroke patients

**Public title**

Effectiveness of core stability exercises on energy expenditure during gait in stroke patients; A randomized controlled trial

**Purpose**

Treatment

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

Stroke patients between 30 to 55 years of age Both ischemic and hemorrhagic stroke Patients who experienced a single stroke. Patients who can walk for 10 minutes on ground at a comfortable speed(with or without assistive device) Patients having MMSE score of 24 or more.

**Exclusion criteria:**

Patients who has cerebellar and pontine stroke. Patients who has orthopedic problems. Patients who have vertigo, dizziness, angina or resting heart rate is not between 40-100bpm range. Patients who cannot follow instructions given by the therapist

**Age**

From **30 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In our trial, randomization will be conducted using a lottery method. The unit of randomization is the individual participant. For each participant, a unique identifier will be assigned, and these identifiers will be placed in separate, opaque, and sealed envelopes. The envelopes will be thoroughly mixed before a neutral third party, who is not involved in the trial, draws an envelope for each participant. The treatment assignment corresponding to the label inside the drawn envelope will determine whether the participant receives core stability exercises or conventional physical therapy program. This method ensures the transparency and fairness of the allocation process, eliminating any potential for selection bias. Allocation concealment will be maintained throughout the trial, as the envelopes will be securely stored and opened only at the time of participant allocation

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The Randomized Controlled Trial (RCT) registry is designed to ensure complete blinding of the outcome assessor, guaranteeing the integrity and impartiality of the study's results. By maintaining strict confidentiality protocols and employing a comprehensive masking system, the registry safeguards against any potential biases that may arise from the assessor's knowledge of

the intervention groups, thereby enhancing the reliability and credibility of the trial's findings.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

KMU AS&RB

**Street address**

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa

**City**

Peshawar

**Postal code**

25000

**Approval date**

2023-10-20, 1402/07/28

**Ethics committee reference number**

KMU/MSPT/21

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

Brain stem stroke syndrome

**ICD-10 code**

G46.3

**ICD-10 code description**

Brain stem stroke syndrome

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

Physiological cost index

**Timepoint**

Pre assessment will be done on baseline assessment and Post assessment will be done after 6 weeks

**Method of measurement**

Physiologic cost index(PCI) is an indicator of energy expenditure that includes heart rate during gait along with speed and the formula used will be energy expenditure: walking heart rate-resting heart rate/walking velocity

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Control group: The control group will receive the Modified Rehabilitation Program (MRP) for stroke patients three times a week, administered by trained physical therapists. The intensity of the MRP for the control group will be adjusted based on the patients' specific functional abilities, focusing on moderate-intensity exercises and activities to facilitate gradual recovery. Each session of the MRP for the control group will last for 30 minutes, ensuring an adequate duration to engage in a variety of tailored therapeutic exercises, functional tasks, and mobility training. The MRP for the control group will encompass a comprehensive range of evidence-based physical therapy techniques, including strength-building exercises, balance and coordination drills, as well as activities targeting range of motion and flexibility, tailored to the individualized needs of stroke patients.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Each participant in experimental group will have to attend a 6-weeks program of core stability exercises with 5 minutes each exercise, 5 days a week along with conventional physical therapy. Core stability exercises includes: 1. Bridging exercises 2. Unilateral pelvic bridging 3. Abdominal drawing in maneuver with leg lifts 4. Curl up.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehman Medical Institute, Peshawar

##### Full name of responsible person

Raheela Naz

##### Street address

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad,  
Peshawar, Khyber Pakhtunkhwa

##### City

Peshawar

##### Postal code

25000

##### Phone

+92 91 5838666

##### Email

raheela.naz@rmi.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khyber Medical University, Peshawar

##### Full name of responsible person

Raheela Naz

##### Street address

F1 Phase-6 Rd, Phase 5 Hayatabad, Peshawar, Khyber  
Pakhtunkhwa

##### City

Peshawar

##### Postal code

25100

##### Phone

+92 91 5862514

##### Email

IPHSS@kmu.edu.pk

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Khyber Medical University, Peshawar

#### Proportion provided by this source

50

#### Public or private sector

Public

#### 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

Rehman Medical Institute, Peshawar

##### Full name of responsible person

Raheela Naz

##### Position

Physical Therapist 1

##### Latest degree

Master

##### Other areas of specialty/work

Rehabilitation management

##### Street address

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad,  
Peshawar, Khyber Pakhtunkhwa

##### City

Peshawar

##### Province

Khyber Pakhtunkhwa

##### Postal code

25000

##### Phone

+92 91 5838666

##### Email

raheela.naz@rmi.edu.pk

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rehman Medical Institute, Peshawar

**Full name of responsible person**

Raheela Naz

**Position**

Physical Therapist 1

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad,  
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**City**

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**Province**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rehman Medical Institute, Peshawar

**Full name of responsible person**

Raheela Naz

**Position**

Physical Therapist 1

**Latest degree**

Master

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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**

Effectiveness of core stability exercises on energy expenditure during gait in stroke patients; A randomized controlled trial

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

Data will be available after completion of RCT and will be available for 1 year

**To whom data/document is available**

To all the researchers, students and teachers.

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

All the authors registered with Iranian clinical trial registry

**From where data/document is obtainable**

Data will be available by emailing the principal author on raheela.naz@rmi.edu.pk

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

Just email the author

**Comments**