

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of motor imagery on hemiplegic gait and walking energy cost in sub-acute stroke patients

#### Protocol summary

##### Study aim

This study aims to find the effectiveness of motor imagery techniques in reducing the walking energy cost of stroke patients.

##### Design

Two-arm parallel-group randomized trial with blinded postoperative care and outcome assessment

##### Settings and conduct

data will be collected from Rehman Medical institute Peshawar Pakistan. from 31st March 2022. the total duration of the trial will be 6 weeks. patients will be randomly allocated to the experimental and control groups. The experimental group will receive motor imagery techniques along with conventional Physical therapy however the control group will receive only conventional physical therapy. Both groups will receive 3 sessions per week for a total of six weeks. at the end of the study, a blinded assessor will assess the outcomes of walking energy costs from all the recruited patients.

##### Participants/Inclusion and exclusion criteria

Mini-mental state examination score equals or greater than 24. Modified Ashworth scale score less than or equal to +1. Manual muscle testing equals or greater than 3. Other neurological disorders excluded Unilateral neglect Unstable cardiovascular patient Acute stroke patient with evidence of flaccidity

##### Intervention groups

the intervention group will be provided with a motor imagery session for 15 minutes followed by 30 minutes of conventional therapy a total of 45 minutes sessions 3 times per week will be given. in the control group, only conventional physical therapy and gait training exercises will be given to the patients the total duration of the session will be 45 minutes 3 times per week for a total of 6 weeks.

##### Main outcome variables

the main outcomes will be gait improvement which will be checked using the Gait Assessment and intervention tool. and energy expenditure will be checked using

Physiological cost index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211011052727N3**

Registration date: **2023-04-10, 1402/01/21**

Registration timing: **prospective**

Last update: **2023-04-10, 1402/01/21**

Update count: **0**

##### Registration date

2023-04-10, 1402/01/21

##### Registrant information

##### Name

Salman farooqi

##### Name of organization / entity

Khyber Medical University Peshawar Pakistan

##### Country

Pakistan

##### Phone

+92 91 5823496

##### Email address

salman.farooqi@kmu.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-15, 1402/01/26

##### Expected recruitment end date

2023-05-30, 1402/03/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Effectiveness of motor imagery on hemiplegic gait and walking energy cost in sub-acute stroke patients

## Public title

Effectiveness of motor imagery on hemiplegic gait and walking energy cost in sub-acute stroke patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Mini mental state examination score > 24 Modified ashworth scale score > 3 Manual muscle testing > 3 Age between 40 - 75

### Exclusion criteria:

Other neurological disorder excluded unstable acute stroke patient Unilateral neglect Cardiovascular patient Cardiovascular patient With evidence of flaccidity

## Age

From **40 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After meeting the inclusion criteria and giving a written informed consent, a total of 44 patients will be enrol in this study. These participants will be randomly allocated into two groups namely; the Experimental group (motor imagery along with conventional therapy) and the Control group (conventional therapy only). The random allocation will be performed by using sealed envelope (opaque). Total 44 envelopes will be made, 22 will be having a paper with group A (control group) written on it and 22 will have group B (experimental group). This will be for equal distribution of subjects in the two groups. Each participant will be asked to pick an envelope and will handed over to the researcher. Participants will not be blinded about their allocation. All the participants will be inform about the goals and intervention of the study by providing details.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The outcome assessor who will be recording the outcome scores will be blinded he will not be aware weather the participant was in control group or experimental one.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutionl ethical review committee. Institute of Physical Medicien and rehabilitation Khyber Medi

##### Street address

Hayatabad phase 5

##### City

Peshawar

##### Postal code

25001

#### Approval date

2022-06-20, 1401/03/30

#### Ethics committee reference number

KMU/IPMR/IERC/22-06-09

## Health conditions studied

### 1

#### Description of health condition studied

Stroke rehabilitation

#### ICD-10 code

G81

#### ICD-10 code description

Hemiplegia and hemiparesis

## Primary outcomes

### 1

#### Description

Physiological cost index

#### Timepoint

the outcome will be checked pre intervention then on 2nd and 4th week after intervention and finally on 6th week post intervention

#### Method of measurement

the formula to calculate the physiological cost index is exercising heart rate minus resting heart rate divided by walking velocity. ( heart rate will be recorded using a pulse oximeter and walking velocity will be measured using 6-meter walk test)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

"Intervention group:" All the recruited patients in the interventional group will start each session with a mental

rehearsal of the motor imagery technique for 15 minutes followed by 30 minutes of conventional physical therapy techniques including gait training exercises and Neuro-developmental techniques each session will last for 45 minutes. The patients will attend 3 sessions per week for a total of 6 weeks. The patient's baseline assessment includes walking speed, resting heart rate, oxygen saturation, and walking energy cost will be calculated using the physiological cost index.

**Category**

Rehabilitation

**2****Description**

Control group: Patients in the control group will attend 45 minutes of conventional physical therapy techniques including gait training exercises and Neuro-developmental techniques each session will last for 45 minutes. The patients will attend 3 sessions per week for a total of 6 weeks. At the end of 6 weeks patient walking energy cost will be calculated by a blinded assessor.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rehman Medical Institute

**Full name of responsible person**

Dr Shakir Ullah

**Street address**

Hayatabad peshawar

**City**

Peshawar

**Postal code**

25001

**Phone**

+92 332 9344799

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shakir.ullah@kmu.edu.pk

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Khyber Medical University

**Full name of responsible person**

Dr Masood Ifrah

**Street address**

Hayatabad Phase 5 Peshawar Pakistan

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**Postal code**

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**Phone**

+92 321 6710675

**Email**

ifrah.masood@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Khyber Medical University

**Proportion provided by this source**

100

**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**

Khyber Medical University

**Full name of responsible person**

Salman Farooqi

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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264 F6, phase 6 hayatabad

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

Khyber Medical University

**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

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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**

as this is the first trail on this case the initial plan is not to disclose it in the beginning.

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Khyber Medical University

**Full name of responsible person**

fahad Ali

**Position**

teaching Assistant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Hayatabad

**City**