

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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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Salman Farooqi

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

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Latest degree
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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 trial 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