Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+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
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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

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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, 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

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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

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Person responsible for updating data

Contact

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Position
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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