

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Stepping Forward: Evaluating the Impact of Gait Training on Post-Stroke Patients' Energy Cost of Walking

Protocol summary

Study aim

The aim of this quasi-experimental Pre/Post study design was to examine the efficacy of gait training exercises in reducing the energy cost (EC) of walking in post-stroke patients. The secondary objective was to assess the impact of gait training on overall gait pattern. .

Design

A single group quasi experimental pre-test post study design.

Settings and conduct

The data collection will be performed in the institute of physical medicine and rehabilitation Khyber Medical University Pakistan after approval of the clinical trial registry. as this will be a single group trial we will not follow any blinding process.

Participants/Inclusion and exclusion criteria

Patients having history of stroke at least 3 months before the start of the study, Stroke patients walking Independently (with or without assisted devices). With a score of 3 or above on Fictional Ambulatory Category (FAC). Patients having mini mental status score greater than 24..were included in the study. The patients with major psychological disorders or inability to follow commands were excluded from study. Patient who experienced pain during walking. Stroke patients with the history of unilateral neglect was also excluded.

Intervention groups

The total duration of the intervention will be for six weeks with three sessions per week the total sessions of gait training exercises administered to stroke patient will be 18. The overall duration of each session will last for 60 minutes. the gait training exercise intervention includes, Range of Motion Exercises, Lower Extremity Strengthening, Stepping Over Obstacles, Side-Stepping Gait Exercises, Target Stepping, Retro Walking, Balance and Proprioception Exercises.

Main outcome variables

The energy cost of the participants will be calculated using Physiological cost index PCI which is a valid and

reliable tool. for gait assessment the Gait intervention and assessment tool will be used.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211011052727N2**

Registration date: **2023-03-10, 1401/12/19**

Registration timing: **prospective**

Last update: **2023-03-10, 1401/12/19**

Update count: **0**

Registration date

2023-03-10, 1401/12/19

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

2023-03-15, 1401/12/24

Expected recruitment end date

2023-04-15, 1402/01/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Stepping Forward: Evaluating the Impact of Gait Training on Post-Stroke Patients' Energy Cost of Walking

Public title
Effectiveness of Gait Training Exercises for Post-Stroke Gait Pattern Improvement

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients having history of stroke at least 3 months before the start of the study. Stroke patients having the capability to walk Independently (with or without assisted devices). With a score of 3 or above on Fictional Ambulatory Category (FAC) Patients having mini mental status score greater than 24 Medically stable patients with no known case of uncontrolled Hypertension, arrhythmia, or unstable cardiovascular diseases No significant Musculoskeletal problems relating to conditions other than stroke Patients having the age of 18 or above were included in the study
Exclusion criteria:
The patients with major psychological disorders or inability to follow commands were excluded from study. Patients with history of Myocardial Infarction before stroke or known case of angina were excluded Patients having previous history of Chronic obstructive pulmonary disease (COPD), or other chronic respiratory disorders were excluded from the study Patient who experienced pain during walking. • Stroke patients with the history of unilateral neglect was also excluded.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Quasi experimental pre-test post-test study design

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of the institute of physical medicine and rehabilitation khyber medical university

Street address

Phase 5 street 1 Hayatabad

City

Peshawar

Postal code

25100

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

KMU/IPMR/IERC/03-22/11

Health conditions studied

1

Description of health condition studied

sub acute stroke patients with level 3 on functional ambulatory category

ICD-10 code

G81.9

ICD-10 code description

Hemiplegia, unspecified

Primary outcomes

1

Description

The walking energy cost of stroke patients

Timepoint

the walking energy cost will be calculated before intervention then at 3 weeks post intervention and finally at the end of 6th week of intervention

Method of measurement

The walking energy cost of stroke patients will be calculated using the Physiological cost index

Secondary outcomes

1

Description

level of spasticity

Timepoint

pre intervention and post intervention

Method of measurement

Modified Ashworth Scale

Intervention groups

1

Description

Intervention group: As this study will involve only one group, all eligible patients will receive an intervention consisting of gait training exercises. These exercises will include range of motion exercises, lower limb strengthening exercises, stepping over obstacles, side stepping gait exercises, target stepping, and retro walking. Each exercise session will last 60 minutes, and patients will receive gait training exercise intervention three times per week. The study will last for a total of six weeks, during which patients will participate in a total of 18 gait training exercise sessions

Category

Rehabilitation

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

Khyber Medical University Pakistan

Full name of responsible person

Farooqi Salman

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

Capital Medical University/ China Rehabilitation and Research Center

Full name of responsible person

Professor Zhang Tong

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Fengtai District Beijing

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100068

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+86 135 2099 4786

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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

Capital Medical University/ China Rehabilitation and Research Center

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

CN

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

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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