

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

COMPARING THE EFFECTIVENESS OF FACILITATED ELECTRIC STIMULATION OF TWO ALTERNATING PATTERNS ON LOWER EXTREMITY FUNCTION IN HEMIPLEGIC STROKE PATIENTS

Protocol summary

Study aim

To find the effectiveness of facilitated electric stimulation of two alternating patterns (abdominals cross hamstrings and lower back muscles cross quadriceps) on lower extremity in stroke patients.

Design

Randomized Clinical Trial

Settings and conduct

Allied hospital Faisalabad, Sahil hospital Faisalabad, Aziz Fatima hospital Faisalabad, Maqsooda Zia hospital Faisalabad

Participants/Inclusion and exclusion criteria

24 hemiplegic stroke patients 6 months post stroke aging between forty five to sixty years old Inclusion criteria • All men and women • Hemiplegic stroke patients • Age between forty five to sixty years old • Patient with static and dynamic sitting balance • Patients with static standing balance Exclusion criteria • All patients had imaging tests to rule out their diagnosis for stroke during the acute stage. • People who frequently have strokes. • Patients with peripheral or orthopedic neuropathy, substantial vision field defects, or hemi neglect issues were not included. • Poorly controlled epilepsy • Pregnancy • Heart pacemaker. • Patients with malignant tumors • Exposed metal • Suspected, recognized, or uncontrolled cardiovascular conditions • Neurological problems other than ischemic brain injury or hemorrhage that can result in hemiplegic stroke. Fracture

Intervention groups

Group A Abdominals cross Hamstrings and additional exercises 3 days per week with 30 minutes. Additional exercises will include lower limb joint mobilizations, stretching of lower extremity, and ROMS. Group B Lower back cross Quads and additional exercises 3 days per week with 30 minutes stimulation each session. Additional exercises will include ,lower limb joint

mobilizations (including hips, knees, ankles and feet) stretching of lower extremity, and ROMS.

Main outcome variables

Pelvic tilt, Functional gait analysis, modified Ashworth scale, ranges of motion and cadence

General information

Reason for update

Acronym

Functional Gait Assessment (FGA) Modified Ashworth scale (MAS) Facilitated/functional electric stimulation (FES) Range of Motion (ROM) Anterior pelvic tilt (APT) Posterior pelvic tilt (PPT) Total pelvic tilt (TPT)

IRCT registration information

IRCT registration number: **IRCT20230716058795N2**

Registration date: **2023-09-23, 1402/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-23, 1402/07/01**

Update count: **0**

Registration date

2023-09-23, 1402/07/01

Registrant information

Name

Moater Iftikhar

Name of organization / entity

The university of Faisalabad

Country

Pakistan

Phone

+92 301 6085203

Email address

moaterhassankazmi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-09, 1402/06/18

Expected recruitment end date

2023-11-09, 1402/08/18

Actual recruitment start date

2023-09-15, 1402/06/24

Actual recruitment end date

2023-11-15, 1402/08/24

Trial completion date

2023-11-30, 1402/09/09

Scientific title

COMPARING THE EFFECTIVENESS OF FACILITATED ELECTRIC STIMULATION OF TWO ALTERNATING PATTERNS ON LOWER EXTREMITY FUNCTION IN HEMIPLEGIC STROKE PATIENTS

Public title

Comparing the effectiveness of facilitated electric stimulation of two alternating patterns on lower extremity function in hemiplegic Stroke patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

- All men and women will be included in study.
- Hemiplegic stroke patients will be included in study
- Age between forty five to sixty years old will be included in study.
- Patient with static and dynamic sitting balance will be included.
- Patients with static standing balance will be included in this study.

Exclusion criteria:

All patients had imaging tests to rule out their diagnosis for stroke during the acute stage.

- People who frequently have strokes. Patients with peripheral or orthopedic neuropathy, substantial vision field defects, or hemi neglect issues were not included. Hemiplegic stroke not due to a stroke but due to another neurological condition.
- Poorly controlled epilepsy: When medicine is being used to treat epilepsy and there haven't been any seizures in a while People who frequently have strokes FES may be used.
- Pregnancy: The effects of FES on the growing child during pregnancy are unknown.
- Heart pacemakers: Any electrical activity could interfere with the electrical impulses that the pacemakers send out, rendering them inoperative.
- Patients with malignant tumors should not be considered since the electrical stimulation's potential to increase local blood flow could promote the growth of the tumor.
- Exposed metal: In patients with exposed orthopedic metalwork, electrical stimulation in the afflicted area should be avoided
- Suspected, recognized, or uncontrolled cardiovascular conditions: The circulatory demand brought on by the FES-induced muscular contractions may necessitate taking extra precautions both before and during stimulation delivery.
- Neurological problems other than ischemic brain injury or hemorrhage that can result in hemiplegic stroke. If the muscles around a fracture that hasn't healed up contract, the fracture may get displaced.
- People who have cerebellar, brain stem, or bilateral hemisphere lesions.

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized through sealed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and data analyzer

Placebo

Not used

Assignment

Parallel

Other design features

purposive sampling technique

Secondary Ids

empty

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

The University of Faisalabad

Street address

University of Faisalabad, canal road campus, Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2023-02-03, 1401/11/14

Ethics committee reference number

TUF/Addl Reg/SB/387

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

HEMIPLEGIC STROKE

ICD-10 code

I69.359

ICD-10 code description

Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side

Primary outcomes

1

Description

Pelvic tilt

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Inclinometer

Secondary outcomes

1

Description

Cadence

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Carbon Foot Prints

2

Description

Range of motion of lower extremity

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Universal Goniometer

3

Description

Spasticity

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Modified Ashworth Scale

4

Description

Gait analysis

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Functional Gait Analysis

Intervention groups

1

Description

Intervention group: Abdominals cross Hamstrings and additional conventional exercises 3 days per week with 30 minutes. Additional conventional exercises will include lower limb joint mobilizations(including hips, knees, ankles and feet), stretching of lower extremity, and ROMs. .

Category

Rehabilitation

2

Description

Intervention group: : Lower back cross Quads and additional conventional exercises 3 days per week with 30 minutes stimulation each session. Additional conventional exercises will include lower limb joint mobilizations (including hips, knees, ankles and feet), stretching of lower extremity, and ROMs

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied hospital Faisalabad

Full name of responsible person

Maria Hussain

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Recruitment center

Name of recruitment center

Sahil hospital Faisalabad

Full name of responsible person

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Recruitment center

Name of recruitment center

Aziz Fatima hospital Faisalabad

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Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

The University Of Faisalabad | TUF University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The University Of Faisalabad | TUF University
Full name of responsible person
Marium Zafar
Position
Assistant Professor
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Person responsible for updating data

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Position

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Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Punjab

Postal code

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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

patient confidentiality

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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

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When the data will become available and for how long

starting from September 2023

To whom data/document is available

People working in Academics

Under which criteria data/document could be used

To the researchers with valid affiliation to any institute

From where data/document is obtainable

moaterhassankazmi@gmail.com

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

Signed consent form from valid institute and \$5

Comments