

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 tecjnique

**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

##### Street address

Dr. Tusi Rd, Faisalabad, Punjab

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 9210082

##### Email

mariahussain@gmail.com

##### Web page address

### 2

#### Recruitment center

##### Name of recruitment center

Sahil hospital Faisalabad

##### Full name of responsible person

Moater Iftikhar

##### Street address

house # 43, university villas, Ismail road, faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 2409608

##### Email

moaterhassankazmi@gmail.com

##### Web page address

### 3

#### Recruitment center

##### Name of recruitment center

Aziz Fatima hospital Faisalabad

##### Full name of responsible person

Moater Iftikhar

##### Street address

house # 43, university villas, Ismail road, faisalabad

##### City

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**Postal code**

38000

**Phone**

+92 41 2409608

**Email**

moaterhassankazmi@gmail.com

**Web page address****4****Recruitment center****Name of recruitment center**

Maqsooda Zia hospital Faisalabad

**Full name of responsible person**

Moater Iftikhar

**Street address**

house # 43, university villas, Ismail road, faisalabad

**City**

FAISALABAD

**Postal code**

38000

**Phone**

+92 41 2409608

**Email**

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

The University Of Faisalabad | TUF University

**Full name of responsible person**

Moater Iftikhar

**Street address**

house # 43, university villas, Ismail road, faisalabad

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**Postal code**

38000

**Phone**

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**Email**

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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

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

TUF University canal campus,Faisalabad

**City**

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**Province**

Punjab

**Postal code**

38000

**Phone**

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**Email**

mariam.zafar@tuf.edu.pk

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

The University Of Faisalabad | TUF University

**Full name of responsible person**

Marium Zafar

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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Punjab

**Postal code**

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**Phone**

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**Email**

mariam.zafar@tuf.edu.pk

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

The University Of Faisalabad | TUF University

**Full name of responsible person**

Moater Iftikhar

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

house # 43, university villas, Ismail road, faisalabad

**City**

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**Province**

Punjab

**Postal code**

38000

**Phone**

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**Email**

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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**