

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

##### 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

FAISALABAD

**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**  
moaterhassankazmi@gmail.com

## **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  
**City**  
FAISALABAD  
**Postal code**  
38000  
**Phone**  
+92 301 6085203  
**Email**  
moaterhassankazmi@gmail.com

##### **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**  
Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 41 2409608  
**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  
**Street address**  
The University Of Faisalabad | TUF University canal campus Faisalabad  
**City**  
Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 41 2409608  
**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**

FAISALABAD

**Province**

Punjab

**Postal code**

38000

**Phone**

+92 301 6085203

**Email**

moaterhassankazmi@gmail.com

**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**

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

**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**