Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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+92 301 6085203
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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
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2

Recruitment center
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Web page address

3

Recruitment center
Name of recruitment center
Aziz Fatima hospital Faisalabad
Full name of responsible person
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Recruitment center
Name of recruitment center
Maqsooda Zia hospital Faisalabad
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University Of Faisalabad | TUF University
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
Latest degree
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Person responsible for updating data

Contact
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Full name of responsible person

Moater Iftikhar

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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house # 43, university villas, Ismail road, faisalabad

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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