

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing the effects of Carr & Shepherd approach and mirror therapy on hand motor function among sub-acute stroke patients; a randomized clinical trial

#### Protocol summary

##### Study aim

To compare the effects of Carr & Shepherd approach and mirror therapy on hand grasp, precision grip, pinching grip, gross motor function and grip strength among sub-acute stroke patients

##### Design

Three arm parallel group randomised with blinded outcome assessment.

##### Settings and conduct

The current study was multi-centered study that included centers of Faisalabad, Punjab, Pakistan. Allied Hospital District Headquarters Hospital Nusrat Abdul Rauf Centre for Enablement

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both genders within range of 40 years-65 years with first stroke attack at subacute stage, with MMSE scoring > 21 and MAS scoring < 3 Exclusion Criteria: Patients with cognitive impairment, orthopedic deformity, fracture, subluxation, any other co morbidity related to upper limb, history of aphasia, visual impairment, tumor and neurological deficit.

##### Intervention groups

Group A: participants will receive FES 10 minutes with parameters of; frequency 20-50 Hz, width of pulse 0µs-300µs, peak current at <70 mA, 1s ramp up and down which remained turned on and off for next 5s alternatively. Group B: participants will receive FES same as group A. in combination with 20 reps of each maneuver of Carr & Shepherd Holding a cup, pen, plate, pouring water from one glass to another, pinching of ball bearing etc. Group C: participants will receive FES with same as group A in combination with mirror therapy with 10 reps of each movement. Flexing and extending the elbow and wrist, ulnar and radial deviation of wrist, making a Thumb-up gesture, empty hand grip, spherical grip, and Opposition with all fingers

##### Main outcome variables

The outcomes of current study were; Hand Grasp  
Pinching grip Precision grip Gross Motor Function Grip strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230731058992N1**

Registration date: **2023-09-11, 1402/06/20**

Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**

Update count: **0**

##### Registration date

2023-09-11, 1402/06/20

##### Registrant information

##### Name

Tayyaba Falak

##### Name of organization / entity

The University of Faisalabad

##### Country

Pakistan

##### Phone

+92 332 0772705

##### Email address

tayyabafalak14@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-15, 1402/06/24

##### Expected recruitment end date

2023-10-15, 1402/07/23

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparing the effects of Carr & Shepherd approach and mirror therapy on hand motor function among sub-acute stroke patients; a randomized clinical trial

**Public title**  
Comparing the effects of Carr & Shepherd approach and mirror therapy on hand motor function among sub-acute stroke patients; a randomized clinical trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Both male and female genders will be included Patients having age within range of 40 years-65 years The stage of stroke attack was sub-acute Patients had first attack of stroke in their life Patients with Mini Mental State Examination (MMSE) scoring > 21 Patients with Modified Ashworth Scale scoring < 3  
**Exclusion criteria:**  
Patients with cognitive impairment Patients with inability of cooperation and follow simple instruction given by instructor Patients with history of orthopaedic deformity, fracture, subluxation, and any other co morbidity related to upper limb Patients with history of aphasia, visual impairment, tumor, and neurological deficit

**Age**  
From **40 years** old to **65 years** old

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
According to inclusion exclusion criteria, all the enrolled participants would be allocated into three groups randomly by chit and draw method. The randomization process in this study will follow a simple randomization method at the individual level. Unit of randomization would be individual participant, that means each individual participant would be randomly assigned to three groups that are Carr & Shepherd approach group, mirror therapy group and Function electrical stimulation group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The current study will be single blinded, as the outcome assessor should be kept blinded to reduce risk of biasness. Outcome assessors should have no information

about the recruitment of participants. As they would not know which participant belongs to Group A, B and C, the risk of biasness will be reduced.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethical Review Committee

**Street address**

University Avenue, Faisal Town Canal Road, Faisalabad.

**City**

Faisalabad

**Postal code**

38000

**Approval date**

2023-08-09, 1402/05/18

**Ethics committee reference number**

TUF/DR/SA/MSPP/2023/246

## Health conditions studied

### 1

**Description of health condition studied**

Sub-acute stage of stroke (3 weeks- 6 months)

**ICD-10 code**

G46.4

**ICD-10 code description**

Cerebellar stroke syndrome

## Primary outcomes

### 1

**Description**

Hand Grip Strength

**Timepoint**

1,3,6 week

**Method of measurement**

Dynamometers are the cheap, portable and best used device for the measurement of grip strength by using static effort of muscles, having excellent inter rater and intra rater reliability for all the performed movements with ICC  $\geq$  0.855.

### 2

**Description**

Hand Grasp

**Timepoint**

1,3,6 week

**Method of measurement**

Action research arm test is reliable tool with the inter-rater reliability of 0.99. The range of ARAT score vary from 0 (no movement) to 57 (maximum movement).

**Secondary outcomes****1****Description**

Gross Motor Functions

**Timepoint**

1,3,6 week

**Method of measurement**

Action research arm test is reliable tool with the inter-rater reliability of 0.99. The range of ARAT score vary from 0 (no movement) to 57 (maximum movement).

**2****Description**

Grip

**Timepoint**

1,3,6 week

**Method of measurement**

Action research arm test is reliable tool with the inter-rater reliability of 0.99. The range of ARAT score vary from 0 (no movement) to 57 (maximum movement).

**Intervention groups****1****Description**

Intervention group:

**Category**

Treatment - Devices

**2****Description**

Intervention group:

**Category**

Rehabilitation

**3****Description**

Intervention group:

**Category**

Rehabilitation

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

Allied Hospital

**Full name of responsible person**

Dr. Sobia Nawaz

**Street address**

Jail Road adjacent Faisalabad Medical University, Near Sargodha Road, Faisalabad

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+92 41 9210082

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info@pmc.edu.pk

**Web page address**

http://www.pmc.edu.pk

**2****Recruitment center****Name of recruitment center**

Civil Hospital

**Full name of responsible person**

Dr. Shaista Bano

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Mall Road, Faisalabad

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dhqfaisalabad@gmail.com

**3****Recruitment center****Name of recruitment center**

Nusrat Abdul Rauf Centre for Enablement; NACE

**Full name of responsible person**

Mr. Imran Saqi

**Street address**

433-D, Main Boulevard, D-Ground, Peoples Colony

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**Phone**

+92 333 7204761

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imran.saqi@hotmail.com

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

The University of Faisalabad

**Full name of responsible person**

Tayyaba Falak

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**Email**

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**Grant name**

No

**Grant code / Reference number**

No

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Self Funded

**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**

Other

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

The University of Faisalabad

**Full name of responsible person**

Tayyaba Falak

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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

Nusrat Abdul Rauf Centre of Enablement

**Full name of responsible person**

Areasha Jameel

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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

The University of Faisalabad

**Full name of responsible person**

Asma

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Comparing the effects of Carr & Shepherd approach and mirror therapy on hand motor function among sub-acute stroke patients; a randomized clinical trial

**When the data will become available and for how long**

Data will be available for other people almost 6 months after the completion of study.

**To whom data/document is available**

Data will be available for other people almost 6 months after the completion of study

**Under which criteria data/document could be used**

The data/document could be used by communicating with the principle investigator Tayyaba Falak gmail : tayyabafalak14@gmail.com

**From where data/document is obtainable**

Tayyaba Falak Gmail: tayyabafalak14@gmail.com

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

The data/document could be used by communicating with the principle investigator Tayyaba Falak gmail : tayyabafalak14@gmail.com

**Comments**