Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 combintion 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 Commitee

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 ≥ 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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Phone
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2

Recruitment center
Name of recruitment center
Civil Hospital
Full name of responsible person
Dr. Shaista Bano
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3

Recruitment center
Name of recruitment center
Nusrat Abdul Rauf Centre for Enablement; NACE
Full name of responsible person
Mr. Imran Saqi
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433-D, Main Boulevard, D-Ground, Peoples Colony
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Faisalabad
Full name of responsible person
Tayyaba Falak

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
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Other areas of specialty/work
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Punjab
Postal code
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Phone
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Email
baigasma96@gmail.com

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 patents; 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