

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

COMPARATIVE EFFECTS OF HAND ARM BIMANUAL INTENSIVE TRAINING (HABIT) AND PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION (PNF) PATTERNS ON UPPER EXTREMITY DYSFUNCTION IN PATIENTS WITH SUBACUTE STROKE

Protocol summary

Study aim

To compare the effects of Hand Arm Bimanual Intensive Training and Proprioception Neuromuscular Facilitation patterns on upper extremity dysfunction in patients with subacute strokes.

Design

Randomized Clinical Trial, single blind

Settings and conduct

Allied Hospital Faisalabad, Aziz Fatima Hospital Faisalabad and District Head Quarter Hospital Faisalabad.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes Stroke patient clinically diagnosed or with scan of CT computed tomography or MRI magnetic resonance imaging, Sub-acute stroke patients, Age 35-60 years, Patient with GCS score >8 and vitally stable, On Mini-Mental State Exam score must be >24 and having no severe cognitive problems and Patients suffered from first time stroke and able to give informed consent. Exclusion criteria includes Patients with severe cardiopulmonary complications, Any intracranial implant, Patient with pacemaker, Any kind of cranial defect, Patients with worsening condition that causes difficulties for physiotherapy treatment, All the medical conditions except stroke that limited the use of upper limb, Patients with epilepsy and Patients having previous history of stroke on same side that diminish upper extremity function.

Intervention groups

Group A will receive Hand Arm Bimanual Intensive Training (HABIT) and Group B will receive Proprioceptive Neuromuscular Facilitation (PNF) patterns

Main outcome variables

Spasticity, Motor function of upper extremity, Activities of Daily Living.

General information

Reason for update

Acronym

HABIT & PNF

IRCT registration information

IRCT registration number: **IRCT20230526058301N1**

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

Registration timing: **registered_while_recruiting**

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

Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Ayesha Affi

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 8868326

Email address

2021-ms-pt-066@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-24, 1402/05/02

Expected recruitment end date

2023-09-30, 1402/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
COMPARATIVE EFFECTS OF HAND ARM BIMANUAL INTENSIVE TRAINING (HABIT) AND PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION (PNF) PATTERNS ON UPPER EXTREMITY DYSFUNCTION IN PATIENTS WITH SUBACUTE STROKE

Public title
COMPARATIVE EFFECTS OF HAND ARM BIMANUAL INTENSIVE TRAINING (HABIT) AND PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION (PNF) PATTERNS ON UPPER EXTREMITY DYSFUNCTION IN PATIENTS WITH SUBACUTE STROKE

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Stroke patient clinically diagnosed or with scan of CT computed tomography or MRI magnetic resonance imaging Sub-acute stroke patients Age 35–60 years Patient with GCS score >8 and vitally stable On Mini-Mental State Exam score must be >24 and having no severe cognitive problems Patients suffered from first time stroke and able to give informed consent

Exclusion criteria:
Patients with severe cardiopulmonary complications Any intracranial implant Patient with pacemaker Any kind of cranial defect Patients with worsening condition that causes difficulties for physiotherapy treatment All the medical conditions except stroke that limited the use of upper limb Patients with epilepsy Patients having previous history of stroke on same side that diminish upper extremity function

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by using Lottery method, in this method computerized generator will be used and patients will allocated into two groups according to numbers given to them.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will be single blind in the study. He/ She kept blind about his/her own treatment group.

Placebo
Not used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of The University of Faisalabad
Street address
West Canal Road, Faisalabad
City
Faisalabad
Postal code
37610
Approval date
2023-03-24, 1402/01/04
Ethics committee reference number
TUF/DR/SA/MSPP/2023/242

Health conditions studied

1
Description of health condition studied
Stroke
ICD-10 code
169.4
ICD-10 code description
Subacute stroke

Primary outcomes

1
Description
Spasticity
Timepoint
At baseline, after second week of intervention, after fourth week of intervention, after sixth week of intervention and after eight week of intervention
Method of measurement
Modified Ashworth Scale

Secondary outcomes

1
Description
Motor Function of upper limb
Timepoint
At baseline, after second week of intervention, after fourth week of intervention, after sixth week of intervention and after eight week of intervention
Method of measurement

Fugl-Meyer assessment scale for Upper Extremity

2

Description

Activities of daily living and motor function of upper limb

Timepoint

At baseline, after second week of intervention, after fourth week of intervention, after sixth week of intervention and after eight week of intervention

Method of measurement

Motor activity log-28 scores

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital

Full name of responsible person

Ayesha Affi

Street address

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

City

Faisalabad

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38800

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Email

vcfmuf@gmail.com

Web page address

<https://pmc.edu.pk/S-Result.aspx>

2

Recruitment center

Name of recruitment center

District Headquarter Hospital

Full name of responsible person

Ayesha Affi

Street address

Mall Road, Faisalabad

City

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Email

vcfmuf@gmail.com

Web page address

<https://www.businesslist.pk/company/189531/dhq-hospital-civil-hospital>

3

Recruitment center

Name of recruitment center

Aziz Fatima Hospital

Full name of responsible person

Ayesha Affi

Street address

Gulistan Colony No. 1, Faisalabad.

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marketing@afh.com.pk

Web page address

<https://afmdc.edu.pk/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Ayesha Affi

Street address

Gulberg Road, St#1, H#p-14, opposite national
Hospital, Faisalabad

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Email

ayesha.affi000@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

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**

Academic

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

The University of Faisalabad

Full name of responsible person

Ayesha Affi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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

The University of Faisalabad

Full name of responsible person

Ayesha Affi

Position

Student

Latest degree

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Other areas of specialty/work

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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

No further information

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Study Protocol Statistical Analysis Plan Informed Consent
Form Clinical Study Report

When the data will become available and for how long

After six months

To whom data/document is available

To all the researchers and institutes

Under which criteria data/document could be used

Data will be shared for further clinical research

From where data/document is obtainable

Data will be shared through email addresses.

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

After the publication of research

Comments