Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.
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Recruitment center
Name of recruitment center
District Headquarter Hospital
Full name of responsible person
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Faisalabad
Full name of responsible person
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Street address
Gulberg Road, St#1, H#p-14, opposite national Hospital, Faisalabad
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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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Person responsible for updating data

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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