Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of segmental muscle vibration and bimanual task-oriented training on upper extremities functional ability in poststroke patients

Protocol summary

Study aim

To evaluate the effectiveness of segmental muscle vibration (SMV) and bimanual task-oriented training (TOT) on hemiparetic upper extremity functional performance in a patient with subacute ischemic stroke.

Design

A concealed, single-blinded, randomized control trial with parallel group design of 50 patients, enrolled between July to August 2022, and followed for 2 months.

Settings and conduct

Data was collected from Dr. Ajaz Ali Physical Therapy clinic Gujrat and District Head Quarter hospital Jhelum, Punjab Pakistan and conduct between month of August and November. Data analyst was blinded in this research because he was kept unaware of which interventions apply to which group.

Participants/Inclusion and exclusion criteria

inclusion criteris 1. Patients 30-70 year of age. 2. Patients with hemiplegic ischemic stroke. 3. patients in the subacute phase after having a stroke (within 1 to 6 months after stroke) 4. Able to understand and follow instructions. 5.stable medical conditions The participants were excluded if they had: 1. Other neurological disease (e.g. Parkinson`s disease or Alzheimer`s disease) 2. Musculoskeletal problems (e.g. carpal tunnel syndrome, tendinitis of the forearm and wrist and recent fracture) 3. Myopathy (like muscular dystrophy, myasthenia gravis or myotonia) 4. All type of aphasia. 5. visual problems that could not be corrected

Intervention groups

Group A (Experimental group): Segmental muscle vibration along with bimanual task-oriented training was prescribed to the participants of this group. Group B (Control group): Conventional exercise program was prescribed to participants of this group.

Main outcome variables

Wolf motor function test Modified Ashworth Scale ABILHAND questionnaire Visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221210056761N1**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **retrospective**

Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

Afifa Tariq

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 346 5762379

Email address

afifatariq186@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-15, 1401/03/25

Expected recruitment end date

2022-09-15, 1401/06/24

Actual recruitment start date

2022-07-01, 1401/04/10

Actual recruitment end date

2022-09-25, 1401/07/03

Trial completion date

2022-12-09, 1401/09/18

Scientific title
Effectiveness of segmental muscle vibration and bimanual task-oriented training on upper extremities functional ability in poststroke patients

Public title
effectiveness of segmental muscle vibration and bimanual task-oriented training in post-stroke patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 30-70 year of age. Patients with hemiplegic ischemic stroke. Patients is in the subacute phase after having a stroke (within 1 to 6 months after stroke) Able to understand and follow instructions Stable medical conditions

Exclusion criteria:
Other neurological disease (e.g. Parkinson`s disease or Alzheimer`s disease)• Musculoskeletal problems (e.g. carpal tunnel syndrome, tendinitis of the forearm and wrist and recent fracture) Myopathy (like muscular dystrophy, myasthenia gravis or myotonia) All type of aphasia. visual problems that could not be corrected

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **56**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling is used. Randomization by lottery method. Allocation concealment through sealed envelope. In a bowl, we put closed slips of group A and group B. Participants fulfilling inclusion criteria will randomly pick up groups and then allocated them through sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the data analyst is kept unaware of the treatment assigned to the experimental group and control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethical committee of University of Lahore, Gujrat campus.

Street address
The University of Lahore, G.T. Road, adjacent Chenab Bridge, Gujrat,

City
Gujrat

Postal code
50700

Approval date
2022-08-21, 1401/05/30

Ethics committee reference number
REG/GRT/22/AHS-87

Health conditions studied

1

Description of health condition studied
Stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
spasticity

Timepoint
baseline, after 3 weeks and after 6 weeks of intervention

Method of measurement
modified ashworth scale

Secondary outcomes

1

Description
functional ability

Timepoint
baseline, after 3 weeks and after 6 weeks

Method of measurement
Wolf motor functional test and ABILHAND questionnaire

Intervention groups

1

Description
Intervention group A: Segmental muscle vibration along with bimanual task-oriented training was prescribed to the participants of this group. Each participant practiced

four of the six functional tasks they chose, depending on their preference. All participants performed a 10-minute warmup. Then they practice the selected functional task for 30 minutes. During that 30-minute TOT, there was a 3-minute break after continuous practice every 10 minutes. Group A received the segmental muscle vibrator (SMV) at the end of each TOT session for 5 min.

Category

Rehabilitation

2

Description

Control group: Group B received conventional exercise program along with EMS. The conventional exercise program (CEP) included a practice of active movements, active-assisted movements, and passive movements, stretching, strengthening, and coordination exercises to improve the range of motion, muscle strength, and coordination of the affected upper limb.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ajaz Ali physiotherapy services

Full name of responsible person

dr. Ajaz Ali

Street address

Illahi Plaza opposite Gujrat Gymkhana, Bhimber Road,. Gujrat

City

Gujrat

Postal code

50700

Phone

+92 53 3515229

Email

ejazalisheikh@gmail.com

2

Recruitment center

Name of recruitment center

District Head Quarter Hospital Jhelum

Full name of responsible person

Dr. Amir Minhas

Street address

DHQ Hospital, Old G.T Rd, Mujahidabad, Jada, Jhelum, Punjab.

City

Jhelum

Postal code

49600

Phone

+92 300 9519439

Email

youraamer@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

self

Full name of responsible person

Afifa Tariq

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Street no 1, House no 116, village baherwal, Teh kharian

City

Kharian

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50090

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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

self

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 Lahore

Full name of responsible person

Afifa Tariq

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Position

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Other areas of specialty/work

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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

there is 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

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

data collected from the primary outcomes only

When the data will become available and for how long

starting 6 months after publication. when it will be published

To whom data/document is available

people working in academic and clinical practice

Under which criteria data/document could be used

for clinical trial data can be shared

From where data/document is obtainable

through email afifatariq186@gmail.com

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

when anyone want to review it and request through email then data will be provided

Comments

empty