

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of modified constraint induced movement therapy with trunk restraint versus bobath approach on motor function and activities of daily livings in hemiplegic upper extremity after stroke

Protocol summary

Study aim

To compare the effectiveness of modified constraint-induced movement therapy with trunk restraint with bobath concept to improve upper extremity motor function and activities of daily livings in subacute stroke patients

Design

Randomized Controlled Trial

Settings and conduct

University of Lahore Teaching Hospital, Lahore

Participants/Inclusion and exclusion criteria

- Patient with an episode of the first stroke between 2 to 12th week of the subacute stage.
- Both genders, age lies 40-70 years.
- Patient is able to perform a functional test of 20° wrist extension and 10° finger extension.
- Patient had active range of motion of 45° or more of shoulder flexion, abduction, or scaption and had the capacity to sustain standing balance for 2 min
- Patient had Mini-Mental State Exam score of greater than or equal to 7. Individuals will be excluded if they • s.

Intervention groups

Group-A: Modified Constraint-Induced Movement Therapy with trunk restraint. The training was provided at the rehabilitation clinic during a 1-hour therapy session, 5 days per week, for 4 weeks (a total of 20 sessions). The training was based on repetitive and task-specific practice. Group-B: Bobath approach. This approach usually takes one hour per day during 20 sessions. The interventions will group into 5 major items: facilitated movement; mobilization; practicing an activity component; and/or whole task and teaching patients.

Main outcome variables

Motor Assessment Scale and Barthel Index

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20210615051586N1**

Registration date: **2021-09-09, 1400/06/18**

Registration timing: **retrospective**

Last update: **2021-09-09, 1400/06/18**

Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Tanveer Hussain

Name of organization / entity

The university of Lahore

Country

Pakistan

Phone

+92 42 35963424

Email address

tanveerhussainpt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2021-01-01, 1399/10/12

Actual recruitment start date

2020-01-01, 1398/10/11

Actual recruitment end date

2021-01-01, 1399/10/12

Trial completion date

2021-01-01, 1399/10/12

Scientific title

Effectiveness of modified constraint induced movement therapy with trunk restraint versus bobath approach on motor function and activities of daily livings in hemiplegic upper extremity after stroke

Public title

Effectiveness of modified constraint induced movement therapy with trunk restraint versus bobath approach on motor function and activities of daily livings in hemiplegic upper extremity after stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with episode of first stroke between 2 to 12th week of subacute stage. Both genders, age lies 40-70 years The first stroke confirmed by C.T, MRI, or clinically by a neuro-physician. Patient able to perform a functional test of 20° wrist extension and 10° finger extension The patient had an active range of motion of 45° or more of shoulder flexion, abduction, or scaption and had the capacity to sustain standing balance for 2 min Patient had Mini Mental State Exam score of greater than or equal to 7

Exclusion criteria:

Patients with shoulder pain (frozen shoulder etc.) or other neurological and orthopedic conditions affecting the reaching movement ability or trunk, hemispatial neglect, or apraxia. Patient with any comorbidity or disability other than stroke that precludes upper-extremity training Patient with any uncontrolled health condition for which exercise is contraindicated. Patient have any psychosocial problems

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers will be generated from 1-30 using an online random numbers generator in two sets. Set 1 will be assigned modified Constraint-Induced Movement Therapy and set 2 will be physical therapy based on both Concepts. The sealed envelope method will be used to assign patients to both groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Random numbers will be generated from 1-30 using an online random numbers generator in two sets. Set 1 will be assigned modified Constraint-Induced Movement Therapy and set 2 will be physical therapy based on both

Concepts. The sealed envelope method will be used to assign patients to both groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board, Faculty of Allied Health Sciences, The University of Lahore

Street address

Defense Road Lahore The University Of Lahore

City

Lahore

Postal code

54000

Approval date

2019-12-26, 1398/10/05

Ethics committee reference number

IRB-UOL-FAHS/684/2020

Health conditions studied

1

Description of health condition studied

Sub Acute Hemiplegic Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar Stroke Syndrome

Primary outcomes

1

Description

Motor Function

Timepoint

At Baseline, At The End Of 4th Week, And At The End Of 8th Week

Method of measurement

Motor Assessment Scale

2

Description

Activity Of Daily Livings

Timepoint

At Baseline, At The End Of 4th Week, And At The End Of 8th Week

Method of measurement

Barthel Index Scale

Secondary outcomes

empty

Intervention groups

1

Description

Group-B: Bobath approach. This approach usually takes one hour per day during 20 sessions. The interventions will group in 5 major items: facilitated movement; mobilization; practicing an activity component; and/or whole task and teaching patients. All interventions, individually program, aims to improving postural control of trunk and shoulder girdle enabling more selective arm movement and increasing strength and function, to recover full motor range patterns, in order to enhance efficiency and maximize function and reducing the severity of impairments where they influence function.

Category

Rehabilitation

2

Description

Group-A: Modified Constraint Induced Movement Therapy with trunk restraint. The training was provided at the rehabilitation clinic during a 1-hour therapy session, 5 days per week, for 4 weeks (a total of 20 sessions). The training was based on repetitive and task-specific practice. Participants mCIMT +TR group will be asked to perform tasks with the paretic arm only, with the less-paretic arm restraint in a mitt. During the 4-week period, the participants' less-paretic hands and wrists will be placed in mitts with self-adhesive straps. Patients in the mCIMT + TR group will be restrained at the trunk by a non-elastic strap during the intervention to limit compensatory movements of the trunk. Arm movement, and pelvic motion were not restricted. The therapist provided consistent verbal feedback to increase the effectiveness of the training. More-affected arm restraint was accomplished by use of a padded mitt that prevented use of the fingers of the less-affected arm.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore Teaching Hospital

Full name of responsible person

Dr. Waqar Afzal

Street address

Defense Road Lahore The University Of Lahore

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+92 42 35963424

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waqar.afzal@uipt.uol.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University Of Lahore

Full name of responsible person

Prof. Dr. Ashfaq Ahmad

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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

The University Of Lahore

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 Lahore

Full name of responsible person

Tanveer Hussain

Position

Post Graduation Student

Latest degree

Master

Other areas of specialty/work

Neurology

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Position

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Latest degree

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

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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

all collected deidentified IPD

When the data will become available and for how long

starting in January 2020

To whom data/document is available

people working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

types of analyses, and by what mechanism. Information about who will review requests and criteria for reviewing requests may also be provided.

From where data/document is obtainable

addresses for websites, telephone and fax numbers, and contact persons to whom the applicant should talk.

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

Your description should give sufficient insight to the applicant into the amount of time needed to follow through these processes.

Comments