Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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Defense Road Lahore The University Of Lahore
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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
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Other areas of specialty/work
Neurology
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Person responsible for updating data

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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