Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of modified Constraint Induced Movement Therapy (mCIMT) and mirror therapy (MT) in addition to neuromuscular electrical stimulation (NMES) on upper extremity function of chronic stroke patients.

Protocol summary

Study aim
To compare the effect of modified constraint induced movement therapy with mirror therapy in addition to neuromuscular electrical stimulation on upper extremity of chronic stroke patients

Design
Randomized Control Trial (RCT) Single blind study Study groups: mCIMT group and MT+NMES group Phase: N.A Sample size : 20 Randomization: In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in. Study center: Single center study

Settings and conduct
Smart Medical & Diagnostic Center Islamabad. Physiotherapy department In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 40 to 65 years; both gender; Hemiplegic stroke patients past 6 months; minimal function of hand includes 10° wrist extension, 10° thumb extension, 10° finger extension; absence of severe attentive deficit; will able to understand and follow simple verbal instructions; have no severe cognitive disorder that interferes with the study. Exclusion criteria: upper limb fracture; peripheral nerve injury; Apraxia; visual field defect; serious cardiac disease (arrhythmias and pacemakers); skin or peripheral circulation disorder; those who participate in other studies or rehabilitation program; chronic synergies.

Intervention groups
There are 2 groups A and B. Group A : modified CIMT group; Group B: Mirror therapy MT group

Main outcome variables
1. Modified Barthel Index 2. Wolf Motor Function test 3. Upper Limb Motor assessment Scale

General information

Reason for update

Acronym
Nill

IRCT registration information
IRCT registration number: **IRCT20211022052835N2**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **retrospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date
2022-01-10, 1400/10/20

Registrant information

Name
Fouzia Batool
Name of organization / entity
Shifa Tameer-e-Millat University
Country
Pakistan
Phone
+92 51 8441752
Email address
fouzia_dpt.ahs@stmu.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-07-19, 1400/04/28

Expected recruitment end date

2021-08-16, 1400/05/25

Actual recruitment start date

2021-07-26, 1400/05/04

Actual recruitment end date

2021-08-23, 1400/06/01

Trial completion date

2021-08-23, 1400/06/01

Scientific title

Comparison of modified Constraint Induced Movement Therapy (mCIMT) and mirror therapy (MT) in addition to neuromuscular electrical stimulation (NMES) on upper extremity function of chronic stroke patients.

Public title

Comparison of modified Constraint Induced Movement Therapy (mCIMT) and mirror therapy (MT) in addition to neuromuscular electrical stimulation (NMES) on upper extremity function of chronic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40 to 65 years Both gender Hemiplegic stroke patients past 6 months Minimal function of hand includes 10° wrist extension, 10° thumb extension, 10° finger extension Absence of severe attentive deficit Will able to understand and follow simple verbal instructions Have no severe cognitive disorder that interferes with the study.

Exclusion criteria:

Upper limb fracture Peripheral nerve injury Apraxia Visual field defect A serious cardiac disease (arrhythmias and pacemakers) Skin or peripheral circulation disorder Those who participate in other studies or rehabilitation program. Chronic synergies

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **34**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Random numbers is written on index cards and placed in thick and opaque sealed envelops before the study. After taking consent from the patient for their participation in the study, the therapist opens the envelop and give the respective treatments to the patients . The study is single blinded as participants is not aware of the intervention group they are placed in.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are single blinded as they don't know which treatment plan or intervention is given to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional review board and ethical committee shifa tameer-e-millat and shifa international hospi

Street address

Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

City

Islamabad

Postal code

44000

Approval date

2021-07-16, 1400/04/25

Ethics committee reference number

IRB#182-21

Health conditions studied

1

Description of health condition studied

Only diagnosed hemiplegic stroke patients past 6 months who do have minimal function of hand thumb and fingers.

ICD-10 code

G81.90

ICD-10 code description

Hemiplegia, unspecified affecting unspecified side

Primary outcomes

1

Description

To compare the effect of modified constraint induced movement therapy with mirror therapy in addition to neuromuscular electrical stimulation on upper extremity of chronic stroke patients.

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Modified barthel index , Wolf motor scale and Upper limb

Motor assessment scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A is given mCIMT treatment. This group received modified constraint-Induced therapy for 4 sessions per week for 4 weeks, applied for 30 minutes. Patient wore a mitt on his/her unaffected arm.Patient performed repetitive task training with his/her affected arm such as picking up the ball from the basket and placing it back, picking up the coins, counting numbers on finger, slowly opening and closing of fist, turning of palm. Patient was also advised to keep performing activities with his/her paretic arm while wearing the mitt on less affected arm at home as well.

Category

Rehabilitation

2

Description

Intervention group B. This group received mirror therapy (MT) in addition to NMES.Mirror therapy 4 sessions per week for 4 weeks applied for 30 minutes. Activity based therapy was done like opening and closing of fist, touching thumb with the tip of each finger, wipe the table with washcloth in circular motion, back and forth, up and down, picking up the coins. Along with this, NMES was applied on extensor muscles of wrist and hand for 20 minutes for which frequency was set between 20-50 Hz, with 30-70 mA intensity lasted for 8 seconds and then stopped for 8 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Smart Medical & Diagnostics Centre
Full name of responsible person
Aqsa Siddique
Street address
Crescent Arcade opp Motorway Express, G-8 Markaz
City
Islamabad
Postal code
44000
Phone
+92 51 8433604
Email
saqsa567@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shifa Tameer-e-Millat University
Full name of responsible person
Fouzia Batool
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Postal code
44000
Phone
+92 51 8441752
Email
fouzia_dpt.ahs@stmu.edu.pk
Web page address
https://stmu.edu.pk/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shifa Tameer-e-Millat University
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
Shifa Tameer-e-Millat University
Full name of responsible person
Fouzia Batool
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Province
Islamabad Capital Territory
Postal code

44000

Phone
+92 332 7120385

Email
fouzia_dpt.ahs@stmu.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shifa tameer-e- millat university islamabad

Full name of responsible person
Aqsa Siddique

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
House no. 274, Street no. 11 Block-I Gulberg Residencia

City
Islamabad

Province
Islamabad Capital Territory

Postal code
44000

Phone
+92 340 3789675

Email
saqsa567@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shifa tameer-e- millat university islamabad

Full name of responsible person
Aqsa Siddique

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
House no. 274, street no. 11, Block-I Gulberg Residencia Islamabad

City
Islamabad

Province
Islamabad Capital Territory

Postal code
44000

Phone
+92 340 3789675

Email
saqsa567@gmail.com

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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable