

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Nil

##### 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 envelopes 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

## 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

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##### 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

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+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

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Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

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**Person responsible for scientific inquiries**

**Contact**

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Shifa tameer-e- millat university islamabad

**Full name of responsible person**

Aqsa Siddique

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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Aqsa Siddique

**Position**

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**Latest degree**

Master

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Physiotherapy

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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**

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