

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Robotic Hand Therapy and Mirror Therapy in Motor Hand Recovery in Chronic Stroke Patients

#### Protocol summary

Motor Assessment Scale, Upper extremity fugl-meyer Scale, Box and Block Test, Self structured Questionnaire

#### Study aim

1.To determine the effect of hand functional recovery through robotic hand training. 2.To compare the effects of robotic hand training and mirror therapy in regaining hand mobility.

#### Design

Randomized Control Trial (RCT) Single blind study. Study groups: (Mirror Therapy) and (Robotic Hand Therapy) group Phase: N.A Sample size : 34 Randomization: In this study simple random sampling technique is used by sealed envelop method through 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

National Institute of Rehabilitation Medicine 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: All participants age 40-85 years suffered from a single right hemisphere ischemic or hemorrhagic stroke and were at least 6 months post stroke at time of their enrollment into study. All participants demonstrated mild to moderate upper extremity impairment as defined by Upper extremity fugl-meyer score (range 34-62) and mild to severe hand impairments as defined by the box and block test (range of 1-55).Exclusion criteria will include previous cerebrovascular disease, cognitive dysfunction to an extent that would interfere with therapy participation and any contracture formation in affected extremity.

#### Intervention groups

There are 2 experimental group 1. Experimental group (A) Robotic Hand Therapy group and 2) Experimental group (B) Mirror Therapy group.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211022052835N6**

Registration date: **2022-03-29, 1401/01/09**

Registration timing: **prospective**

Last update: **2022-03-29, 1401/01/09**

Update count: **0**

##### Registration date

2022-03-29, 1401/01/09

##### 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

2022-04-01, 1401/01/12

##### Expected recruitment end date

2022-05-31, 1401/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of Robotic Hand Therapy and Mirror Therapy in Motor Hand Recovery in Chronic Stroke Patients

**Public title**  
Comparison of Robotic Hand Therapy and Mirror Therapy in Motor Hand Recovery in Chronic Stroke Patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age 40-85 years Single right hemispheric ischemic or hemorrhagic stroke At least 6 months post stroke at time of their enrollment into study Mild to moderate upper extremity impairment as defined by Upper Extremity Fugl-Meyer score (range 34-62) Mild to severe hand impairments as defined by the Box and Block test (range of 1-55)

**Exclusion criteria:**  
Previous cerebrovascular disease Cognitive dysfunction to an extent that would interfere with therapy participation Contracture formation in affected extremity

**Age**  
From **40 years** old to **85 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **34**

**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 participants for their participation in the study, the therapist opens the envelop and give the respective protocol to the individual. The study is single blinded as participants is not aware of the intervention group they are placed in. Participants will be placed either in to the experimental group 1 (Robotic Hand Therapy) or experimental group 2 (Mirror Therapy) keeping the process completely randomized ,sealed envelope method will be used.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Prior to collecting data, participants would be informed about both the treatment techniques used in both

groups; experimental group A (Robotic Hand Therapy) and experimental group B (Mirror Therapy). Further they are informed that you will get one of these treatment depending upon the group written on the card inside the envelop you choose. The group A or B belongs to which way of treatment is known to therapist but the patient doesn't know about it.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

N/A

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Institutional review board and ethical committee and ethical committee of shifa tameer-e-millat univ

**Street address**

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

**City**

Islamabad

**Postal code**

44000

**Approval date**

2022-02-02, 1400/11/13

**Ethics committee reference number**

IRB#278-21

**Health conditions studied**

**1**

**Description of health condition studied**

Right hemispheric stroke, at least 6 months post stroke , mild to moderate upper extremity impairment and mild to severe hand impairment.

**ICD-10 code**

G81.92

**ICD-10 code description**

Hemiplegia, unspecified affecting left dominant side

**Primary outcomes**

**1**

**Description**

To determine the effect of hand functional recovery through robotic hand training.

**Timepoint**

Pre intervention at 0-week, and Post Intervention data after 6 weeks will be taken.

**Method of measurement**

Motor Assessment Scale, Box and Block Test

## Secondary outcomes

### 1

#### Description

To compare the effects of robotic hand training and mirror therapy in regaining hand mobility.

#### Timepoint

Pre Intervention at 0 week, and Post Intervention data after 6 weeks will be taken.

#### Method of measurement

Upper Extremity Fugl Meyer Scale

## Intervention groups

### 1

#### Description

Intervention Group A: Group A would receive Robotic Hand Therapy along with conventional therapy. There would be 3 sessions per week for minimum 6 weeks. Session would be comprised of 60 minutes. Conventional therapy for left side upper extremity of total 30 minutes included sustained stretching exercises of Elbow Flexors, Pronators, Wrist Flexors and Finger Flexors, PNF techniques (D1 Flexion, D2 Flexion, D1 Extension, D2 Extension Patterns), Active Assisted and Active Range of motion exercises, Weight bearing on affected upper extremity, Manual mobilizations, and Compression on joints (Shoulder, elbow, wrist and hand). Robotic Hand Therapy: 30 minutes, 3 sets, 12-15 repetitions, Robotic therapy would be delivered by syrebo robotic hand rehabilitation device. There are 2 modes used in training which includes innovative mirror therapy and task oriented training. In mirror training mode synchronized flexion and extension movement of hand. In task oriented, with help of robot patient practice grasping and releasing (cylindrical grasp, spherical grasp, hook grasp), stacking cups, positioning the cup upright, carrying blocks, putting a ball and drinking water.

#### Category

Rehabilitation

### 2

#### Description

Intervention Group B would receive mirror therapy along with conventional therapy. There would be 3 sessions per week for minimum 6 weeks. Session would be comprised of 60 minutes. Conventional therapy for left side upper extremity of total 30 minutes included sustained stretching exercises of Elbow Flexors, Pronators, Wrist Flexors and Finger Flexors, PNF techniques (D1 Flexion, D2 Flexion, D1 Extension, D2 Extension Patterns), Active Assisted and Active Range of motion exercises, Weight bearing on affected upper extremity, Manual mobilizations, and Compression on joints (Shoulder, elbow, wrist and hand). In Mirror therapy, a mirror will be positioned between the two arms. The reflecting side of the mirror was adjusted to the non-affected arm. Patients

would move both arms while looking in the mirror. The affected arm should be moved as well as possible, it would take 30 minutes, 3 sets, 12-15 repetitions included Hand flexion and extension, grasping and releasing (cylindrical grasp, spherical grasp, hook grasp), stacking cups, positioning the cup upright, carrying blocks, putting a ball and drinking water.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

National Institute of Rehabilitation Medicine

##### Full name of responsible person

Salma Abbas

##### Street address

Street 9, G-8/2, Islamabad Capital Territory

##### City

Islamabad

##### Postal code

44000

##### Phone

+92 306 0327821

##### Email

drsalmaabbaspt@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?

No

#### 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,  
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**Person responsible for scientific 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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**Person responsible for updating data**

**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**

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**Email**

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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**

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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

There is no such plan

**When the data will become available and for how long**

There is no such plan

**To whom data/document is available**

There is no such plan

**Under which criteria data/document could be used**

There is no such plan

**From where data/document is obtainable**

There is no such plan

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

There is no such plan

**Comments**

