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

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

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

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 envelops 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),staking 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 be 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),staking 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

Street address

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

City

Islamabad

Province

Islamabad

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

Full name of responsible person

Fouzia Batool

Position

Assistant Professor

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Other areas of specialty/work

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City

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Phone

+92 332 7120385

Email

fouzia_dpt.ahs@stmu.edu.pk

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

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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 51 8441752

Email

fouzia_dpt.ahs@stmu.edu.pk

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