

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of robotic hand training on upper limb motor function, hand dexterity and grip strength in post stroke patients

Protocol summary

Study aim

Effects of Robotic hand training device on upper limb motor functions, dexterity, and grip strength in chronic stroke patients in Pakistan

Design

A concealed, randomized, single blinded, sham controlled clinical trial with a parallel group design of 38 patients, enrolled between August 2022 and November 2022.

Settings and conduct

Physiotherapy outpatient department of DHQ Hospital, Sheikhpura.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age: 45-70 years. • Including both genders. • Chronic Stroke Patients. • Medically stable patients. • History of stroke 6 to 24 months. • A score 24-30 in mini-mental test. Exclusion criteria: • Severe apraxia • Recurrent Stroke • Acute Stroke • Unwilling Patients • Any Systemic Disease • Severe decompensated comorbidities (cardiopulmonary, neurological, orthopedic and psychiatric, etc.). • Cardiac pacemakers or other implanted electronic system.

Intervention groups

This group will receive conventional treatment that will include ROM exercises, Strengthening and stretching exercises (30 Minutes) along with electrotherapy (20-25 Minutes), 5 days a week, and for 8 weeks.

Main outcome variables

Upper limb motor function variable is find through Fugl Meyer assessment scale. Spasticity is measured by using Modified ashworth scale. Dexterity and Grip strength will be assessed by Nine hole peg test. Where as Sf-36 questionnaire is use to assess Quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230508058127N1**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **retrospective**

Last update: **2023-08-01, 1402/05/10**

Update count: **0**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Syeda Pakeeza Bukhari

Name of organization / entity

Riphah International university Lahore

Country

Pakistan

Phone

+92 334 4373747

Email address

pakeeza100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-11-30, 1401/09/09

Actual recruitment start date

2022-08-05, 1401/05/14

Actual recruitment end date

2022-11-21, 1401/08/30

Trial completion date

2023-07-30, 1402/05/08

Scientific title

Effects of robotic hand training on upper limb motor function, hand dexterity and grip strength in post stroke patients

Public title

Effects of robotic hand training on upper limb motor function, hand dexterity and grip strength in post stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 45-70 years. Including both genders. Chronic Stroke Patients Medically stable patients. History of stroke 6 to 24 months A score 24-30 in mini-mental test

Exclusion criteria:

Severe apraxia Recurrent Stroke Acute Stroke Unwilling Patients Any Systemic Disease Severe decompensated comorbidities (cardiopulmonary, neurological, orthopedic and psychiatric, etc.). Cardiac pacemakers or other implanted electronic system.

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant

Sample size

Target sample size: **38**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Concealed, single blinded Randomized Clinical Trail is done on 38 post stroke patients divided into two groups

Blinding (investigator's opinion)

Single blinded

Blinding description

A type of clinical trial in which only the researcher doing the study knows which treatment or intervention the participant is receiving until the trial is over.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Research & Ethical review Committee Riphah College of Rehab. & Allied Health Sciences Lahore

Street address

28-M, Quaid-e-azam Industrial Estate Kot Lakhat, Lahore

City

Lahore

Postal code

39101

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

REC/RCR & AHS/23/0217

Health conditions studied

1

Description of health condition studied

Chronic Stroke Patients

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

To provide a reliable guidance for clinicians to select suitable device for the patients and for scientists to reveal the research gaps and future directions.

Timepoint

4 Weeks after intervention

Method of measurement

Modified Ashworth Scale , Fugl-Meyer Assessment, Quality of Life Scale (SS-QOL) & Nine-Hole Peg Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive robotic hand treatment that will be pneumatically controlled by closing and opening of hand facilitated by the pressurization and depressurization respectively. Robotic hand will perform continuous passive movements, active assistive movements and active resistive movements. This group will take robotic hand therapy for 30-45 min, 5 days a week, and for 8 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

DHQ Hospital, Sheikhpura

Full name of responsible person

Dr. Imran Manzoor Bhatti

Street address

Lahore Sargodha road

City

Sheikhupura

Postal code

39350

Phone

+92 330 2746025

Email

pakeeza100@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Family Hospital Sheikhupura

Full name of responsible person

Pakeeza Bukhari

Street address

Khalid road

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Sheikhupura

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39350

Phone

+92 330 2746025

Email

Contact@familyhospital.info

Grant name

Research Fund

Grant code / Reference number

RF-2023

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Family Hospital Sheikhupura

Proportion provided by this source

30

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**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Riphah International University Lahore

Full name of responsible person

Sana Riaz

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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28-M, Quaid-e-azam Industrial Estate Kot Lakhat,
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Lecturer

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Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Family Hospital Sheikhupura

Full name of responsible person

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Position

Physiotherapy

Latest degree

Master

Other areas of specialty/work

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

To ensure the Privacy of patient's data because a signed consent was taken from them before becoming the part of the research.

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

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Clinical Study Report , through publishing it in a specific journal

When the data will become available and for how long

After July 2023 to onward

To whom data/document is available

Available for people working in academic institutions & Medical researchers

Under which criteria data/document could be used

Upon request.

From where data/document is obtainable

Email: pakeeza100@gmail.com

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

Through Email

Comments