Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, Sheikhupura.

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
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Pakistan
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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, Sheikhupura

Full name of responsible person
Dr. Imran Manzoor Bhatti
Street address
Lahore Sargodha road
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Sheikhupura
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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
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Khalid road
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39350
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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
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Person responsible for updating data

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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