

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Comparison of effects of Same Arm Movement Therapy (SAME) Vs Constraint Induced Movement Therapy (CIMT) to improve upper-limb function in chronic Stroke

Protocol summary

Study aim

To compare the effects of Same Arm Movement Therapy (SAME) Vs Constraint Induced Movement Therapy (CIMT) to improve upper-limb function in chronic Stroke.

Design

Randomized clinical trial.

Settings and conduct

Riphah Rehabilitation Center, Spine & Physiotherapy Rehab Centre

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Confirmed infarct or Hemorrhage by a neurologist using either MRI or CT scan. Age between 30-65. History of stroke 1-6 months prior to participation in the project. Patients who provided consents to participate in the study. Proper balance and safety while wearing the restraint Exclusion Criteria: Patients were not considered for participation in the trial if: They were discharged from hospital within 1 week. Patients with implants such as Neuro stimulator containing electric circuitry and implants generating electric sign. Patients with anxiety and claustrophobia with diagnosed psychological disorder. Patients undergoing chemotherapy. Alcohol dependency or evidence of substance abuse. Patients without any visual-perceptual problems. Patients without any communication barriers/language issue. Patients with no significant cognitive impairments

Intervention groups

Group A: SAME Therapy treatment protocol consists of 8 weeks of mental rehearsal of upper limb movements during 45-min supervised sessions three times a week and structured independent sessions twice a week. Group B: CIMT treatment protocol consists of 8 weeks of daily intensive training of the affected extremity for 2 hours per day, 5 days per week, and 8 weeks in association with restriction of the non-affected extremity for 10 hours a day.

Main outcome variables

Wolf motor function test, Action Research Arm test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047848N1**

Registration date: **2020-10-01, 1399/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-01, 1399/07/10**

Update count: **0**

Registration date

2020-10-01, 1399/07/10

Registrant information

Name

Alina Shaukat

Name of organization / entity

Riphah College of Rehabilitation & Allied Health Sciences

Country

Pakistan

Phone

+92 42 36610923

Email address

alinashaukat07@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-08, 1399/06/18

Expected recruitment end date

2020-11-08, 1399/08/18

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effects of Same Arm Movement Therapy (SAME) Vs Constraint Induced Movement Therapy (CIMT) to improve upper-limb function in chronic Stroke

Public title
Comparison of effects of Same Arm Movement Therapy (SAME) Vs Constraint Induced Movement Therapy (CIMT) to improve upper-limb function in chronic Stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed infarct or Hemorrhage by a neurologist using either MRI or CT scan Age between 30-65 History of stroke 1-6 months prior to participation in the project Patients who provided consents to participate in the study Proper balance and safety while wearing the restraint
Exclusion criteria:
They were discharged from hospital within 1 week Patients participating in any experimental rehabilitation on drug studies Patients with implants such as Neuro stimulator containing electric circuitry and implants generating electric sign Patients with anxiety and claustrophobia with diagnosed psychological disorder Patients undergoing chemotherapy Alcohol dependency or evidence of substance abuse Patients without any visual-perceptual problems Patients without any communication barriers/language issue Patients with no significant cognitive impairments

Age
From 30 years old to 65 years old

Gender
Both

Phase
2

Groups that have been masked
• Participant

Sample size
Target sample size: 22

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization by lottery method. Allocation concealment through sealed envelope

Blinding (investigator's opinion)
Single blinded

Blinding description
participant will be blinded

Placebo
Not used

Assignment
Parallel

Other design features

Non- Probability Convenient Sampling will be used to recruit the individuals for the study and then randomization will be done by lottery method to divide the individuals into 2 treatment groups. Sealed envelope will be used for allocation concealment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah College of Rehabilitation & Allied health Sciences

Street address

Madar-e-Millat Road, Quaid-e-Azam Industrial Estate

City

Lahore

Postal code

54770

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

RCRS-RE-MS-NMPT/FALL 19/026

Health conditions studied

1

Description of health condition studied

Chronic stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

upper limb strength

Timepoint

Total 8 week program and No followup. Primary outcome will be measured on 8th week.

Method of measurement

Wolf motor function test, Action Research Arm Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: SAME Therapy treatment protocols consist of 8 weeks of mental rehearsals of upper limb movements during 45-mins supervised sessions three

times a week and structural independent sessions twice a week.

Category

Rehabilitation

2

Description

Intervention group B: CIMT treatment protocol consists of 8 weeks of daily intensive training of the affected extremity for 2 hours per day, 5 days per week, and 8 weeks in association with restriction of the non-affected extremity for 10 hours a day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Riphah Rehabilitation Center, Lahore

Full name of responsible person

Alina Shaukat

Street address

28 Madar-e-Millat Road, Quaid-e-Azam Industrial Estate Quaid e Azam Industrial Estate, Lahore, Punjab 54760

City

Lahore

Postal code

54760

Phone

+92 42 32172454

Email

alinashaukat07@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Spine & Physiotherapy Rehab Centre

Full name of responsible person

Alina Shaukat

Street address

Al Fazal Hospital, 9-B, Board of Revenue Housing Society Johar Town, Lahore, Punjab 54000

City

Lahore

Postal code

54760

Phone

+92 42 32172454

Email

alinashaukat07@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Alina Shaukat

Street address

Madar-e-Millat Road, Quaid-e-Azam Industrial Estate

City

Lahore

Postal code

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Phone

+92 42 32172454

Email

alinashaukat07@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Riphah International 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University

Full name of responsible person

Alina Shaukat

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

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Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ripah International University

Full name of responsible person

Alina Shaukat

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

there is no further decision and information decided yet

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

Ripah International University

Full name of responsible person

Alina Shaukat

Position

Student

Latest degree

Master