

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Constraint-Induced Movement Therapy along with conventional therapy and conventional therapy alone on upper extremity spasticity in children with Cerebral Palsy.

Protocol summary

Study aim

To determine the effect of constraint-induced movement therapy along with conventional therapy and conventional therapy alone on upper extremity spasticity in children with cerebral palsy.

Design

Quasi-Experimental Study

Settings and conduct

Faisal Hospital Faisalabad Children Hospital Faisalabad Day Care Centre Faisalabad

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 4-12 years. Both genders. Children with diagnosed upper extremity spastic cerebral palsy. Children with minimum grade 1+ on modified Ashworth scale. Exclusion criteria: Children with Intellectual disability Children who had concomitant sight and hearing disabilities Children with previous six months history of hand surgery. Children with uncontrolled seizures Children with severe health problems not typically associated with CP Children with contractures that limit functional arm and hand use

Intervention groups

Treatment will be provided three times a week for 4 weeks. Group A will receive constraint-induced movement therapy along with conventional therapy.

Main outcome variables

Modified Ashworth Scale Quality of Life Questionnaire for Children (CP QOL-Child)

General information

Reason for update

Acronym

CIMTCP

IRCT registration information

IRCT registration number: **IRCT20220411054500N1**
Registration date: **2022-04-29, 1401/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-29, 1401/02/09**

Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

Name

Tehreem Jameel

Name of organization / entity

Government College University

Country

Pakistan

Phone

+92 313 8113973

Email address

tehreemclick123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-01, 1401/01/12

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Constraint-Induced Movement Therapy along with conventional therapy and conventional therapy alone on upper extremity spasticity in children with Cerebral Palsy.

Public title

Effect of Constraint-Induced Movement Therapy along with conventional therapy and conventional therapy alone on upper extremity spasticity in children with Cerebral Palsy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 4-12 years Both genders. Children with diagnosed upper extremity spastic cerebral palsy. Children with minimum grade 1+ on modified ashworth scale

Exclusion criteria:

□Children with Intellectual disability Children who had concomitant sight and hearing disabilities Children with previous six months history of hand surgery. Children with uncontrolled seizures□Children with severe health problems not typically associated with CP Children with contractures that limited functional arm and hand use

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee of Faisal Institute of Health Sciences

Street address

673-A, Peoples Colony, Canal Road, Faisalabad.

City

Faisalabad

Postal code

48395

Approval date

2022-03-20, 1400/12/29

Ethics committee reference number

FIHS/DR/DPT/292

Health conditions studied**1****Description of health condition studied**

Cerebral palsy (CP) is a disorder characterized by abnormal muscle tone, postural disabilities and movement disorders due to predominant motor syndrome. Constraint-induced movement therapy (CIMT) is referred to be an effective intervention that aid to improve motor functioning in hemiplegic cerebral palsy.

ICD-10 code

G80.9

ICD-10 code description

G80.9 is the ICD-10 code for Cerebral palsy.

Primary outcomes**1****Description**

The modified Ashworth scale will be used as the primary outcome variable to assess the level of spasticity.

Timepoint

3 timepoints including baseline measurement (week 0), 2nd week post treatment and 4th week post treatment.

Method of measurement

The modified Ashworth scale will be used to measure level of spasticity.

Secondary outcomes**1****Description**

Quality of Life Questionnaire for Children (CP QOL-Child) is a secondary outcome variable that is useful for evaluating Quality of Life.

Timepoint

Timepoint include 3 points including baseline measurement (week 0), 2nd week post treatment and 4th week post treatment.

Method of measurement

The CP QOL-Child is used to assess the quality of life of children aged 4-12 years

Intervention groups**1****Description**

Intervention group : Constraint Induced Movement Therapy and Conventional Therapy Group

Category

Rehabilitation

2**Description**

Control group: Conventional therapy group
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Faisal Hospital Faisalabad
Full name of responsible person
Dr. Rameesha Tahir
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2

Recruitment center

Name of recruitment center
Children Hospital & Institute of Child Health
Faisalabad
Full name of responsible person
Dr. Umair
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GC university,, Jhang road, New Campus Dr,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faisal Institute of Health Sciences
Full name of responsible person
Dr. Qurat ul Ain
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self financed
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
Faisal Institute of Health Sciences
Full name of responsible person
Dr. Tehreem Jameel
Position
Principle Investigator/Student
Latest degree
Medical doctor
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Physiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable