

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Registration timing: **registered_while_recruiting**

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.

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

Update count: **0**

Registration date

2022-04-29, 1401/02/09

Design

Quasi-Experimental Study

Registrant information

Name

Tehreem Jameel

Name of organization / entity

Government College University

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Pakistan

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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

Recruitment status

Recruitment complete

Funding source

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.

Expected recruitment start date

2022-04-01, 1401/01/12

Expected recruitment end date

2022-07-01, 1401/04/10

Main outcome variables

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

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Reason for update

Acronym

CIMTCP

IRCT registration information

IRCT registration number: **IRCT20220411054500N1**

Registration date: **2022-04-29, 1401/02/09**

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

Street address

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

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+92 41 8536999

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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

Street address

GC university,, Jhang road, New Campus Dr,

Faisalabad

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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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fihsfsd@outlook.com

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

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Tehreem Jameel

Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Faisal Institute of Health Sciences

Full name of responsible person

Dr. Tehreem Jameel

Position

Principle Investigator/Student

Latest degree

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Other areas of specialty/work

Physiotherapy

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City

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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