

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Expanded Constraint induced movement therapy on hand function in children with cerebral palsy: A Randomized Controlled trial

Protocol summary

Study aim

The aim of the study is to compare the effect of expanded constraint induced movement therapy (eCIMT) versus routine physical therapy in treating paretic arm of children with cerebral palsy

Design

Single blinded Randomized controlled trial

Settings and conduct

Data was collected from children hospital Lahore lottery method of randomization was used and was done by one of the research members who was not involve in recruitment or assessment or data analysis. Outcome assessor was also unaware of group assignment.

Participants/Inclusion and exclusion criteria

Age, Gender, spastic hemiplegic cerebral palsy, non use of more affected upper extremity, minimal ability to grasp the object known case of seizures ,anti epileptic drugs, visual problems, paretic hand surgery, cognitive or sensory disorder

Intervention groups

Two groups Experimental group Control group

Main outcome variables

Pediatric motor activity log scale(PMAL) Wolf motor function test(WMFT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210706051803N1**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **retrospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

wajeeha bakhat

Name of organization / entity

University of lahore

Country

Pakistan

Phone

+92 42 35918862

Email address

wajeehabakhat@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-04, 1399/09/14

Expected recruitment end date

2021-07-31, 1400/05/09

Actual recruitment start date

2020-12-25, 1399/10/05

Actual recruitment end date

2021-04-04, 1400/01/15

Trial completion date

2021-04-04, 1400/01/15

Scientific title

Effect of Expanded Constraint induced movement therapy on hand function in children with cerebral palsy: A Randomized Controlled trial

Public title

Effect of Expanded Constraint induced movement therapy on hand function in children with cerebral palsy: A Randomized Controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 5-12 years both female and male participants with diagnosis of spastic hemiplegic cerebral palsy as

diagnosed and reported in the medical history by a physician considerable nonuse of the more affected upper extremity minimal ability to actively grasp and stabilize an object with the more impaired hand

Exclusion criteria:

known case of seizure and on anti epileptic drugs visual problems interfering with treatment any surgery on the paretic hand with in past 1 year severe cognitive or sensory disorder, severe concurrent illness or disease not typically associated with CP, active medical conditions, and any major surgery or nerve blockage in the previous 6 months prior to the exposure to CP.

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized controlled trial was used. lottery method of randomization was used and was done by one of the research team members who was not involved in patient recruitment or assessment or data analysis.

Randomization assignments was kept in opaque sealed envelopes and unsealed by a researcher after baseline testing.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinded Randomized controlled trial

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The University of Lahore

Street address

House no 70,Ghazi block, Sector F, Bahria town
Lahore

City

Lahore

Postal code

53720

Approval date

2020-12-03, 1399/09/13

Ethics committee reference number

IRB-UOL-FAHS/792/2020

Health conditions studied

1

Description of health condition studied

cerebral palsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pediatric motor activity log scale (PMAL)

Timepoint

3 WEEKS

Method of measurement

22 ITEMS SCALE (HW) (HO)

Secondary outcomes

1

Description

WOLF MOTOR FUNCTION TEST (WMFT)

Timepoint

3 WEEKS

Method of measurement

16 ITEM SCALE CONSIST OF STRENGTH,FUNCTIONAL ABILITY AND TIME

Intervention groups

1

Description

Control group: Routine physical therapy

Category

Rehabilitation

2

Description

Intervention group: EXPANDED CONSTRAINT INDUCED MOVEMENT THERAPY(eCIMT)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children hospital Lahore
Full name of responsible person
Wajeeha bakhat
Street address
House no 70 Ghazi block, sector F bahria town lahore
City
Lahore
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Master
Other areas of specialty/work
Physiotherapy
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wajeehabakhat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Lahore
Full name of responsible person
Ashfaq Ahmed
Street address
UOL, Defence Road Lahore
City
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Postal code
53720
Phone
+92 42 35963424
Email
wajeehabakhat@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
University of Lahore
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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Lahore
Full name of responsible person
Wajeeha bakhat
Position
Student
Latest degree

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Lahore
Full name of responsible person
Wajeeha Bakhat
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

Contact

Name of organization / entity
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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

no further information

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