

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Modified Constraint Induced Therapy versus Developmental Exercises on Reaching Capacity in Hemiplegic Children

Protocol summary

Study aim

To study the effect of developmental exercise therapy after removal of mCIMT on controlling upper limb spasticity in hemiplegic CP children.

Design

Randomized controlled trial

Settings and conduct

The motion analysis lab (Biomechanics Lab, College of Applied Medical Science, Prince Sattam bin Abdulaziz University).

Participants/Inclusion and exclusion criteria

Fifty-two hemiplegic children, ranging in age from four to six years ($X \pm 6.4 \pm 3.5$ years) represented the sample of this study. They were selected from both sexes (26 females and 26 males) from the out-patient clinic of the Faculty of Physical Therapy, Cairo University, Egypt. The subjects enrolled in this study fulfilled the following criteria: [1] The degree of spasticity ranged from 1+ to 2 grades according to the modified Ashworth scale. [2] They were free from any associated disorders other than spasticity. [3] The affected upper limb was free from any structural deformities; however, patients demonstrated variable degree of tightness. [4] They had partial volitional control over the antispastic muscle groups. [5] They had normal superficial skin sensation of the affected upper limb. [6] All of them were within average IQ level.

Intervention groups

The children were divided randomly into two groups of equal number (I and II). Group I received developmental exercise therapy followed by a designed exercise program, while group II received mCIMT followed by the same exercise program given to group I.

Main outcome variables

Elbow extension and functional evaluation of reaching were measured before and after six months of the treatment program.

General information

Reason for update

Acronym

MCIT

IRCT registration information

IRCT registration number: **IRCT20210909052421N1**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **retrospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Nadia Radwan

Name of organization / entity

Prince Sattam Bin Abdulaziz University

Country

Saudi Arabia

Phone

+966 11 588 6500

Email address

n.radwan@psau.edu.sa

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2021-01-15, 1399/10/26

Actual recruitment start date

2020-02-16, 1398/11/27

Actual recruitment end date

2021-04-16, 1400/01/27

Trial completion date

2021-12-15, 1400/09/24

Scientific title

Modified Constraint Induced Therapy versus Developmental Exercises on Reaching Capacity in Hemiplegic Children

Public title

Effect of Modified Constraint Induced Therapy on reaching capacity in Hemiplegic Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hemiplegic children Ranging in age from four to six years
The degree of spasticity ranged from 1+ to 2 grades according to the modified Ashworth scale. They were free from any associated disorders other than spasticity
The affected upper limb was free from any structural deformities; however, patients demonstrated variable degree of tightness They had partial volitional control over the antispastic muscle groups. All of them were within average IQ level.

Exclusion criteria:

The degree of spasticity ranged from 3to4 grades according to the modified Ashworth scale.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **55**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. This technique maintains complete randomness of the assignment of a subject to a particular group. The method of simple randomization used is flipping a coin. For example, with two treatment groups (control versus treatment), the side of the coin (i.e., heads - control, tails - treatment) determines the assignment of each subject.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, care provider, and the data collectors are unaware of the treatment the participant receives.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Prince Sattam Bin Abulaziz university

Street address

ALmanifeia, Alraghi building

City

Alkharj

Postal code

00966

Approval date

2021-04-22, 1400/02/02

Ethics committee reference number

RHPT/021/010

Health conditions studied

1

Description of health condition studied

hemiplegic children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Elbow extension and upper limb kinematics (movement time, peak velocity, time-to-peak velocity, percent of reach-to-peak velocity, number of movement units, percent of time of first movement unit) were the outcome variables

Timepoint

Elbow extension and functional evaluation of reaching were measured before and immediately after six months of the treatment program.

Method of measurement

Electro-Goniometer and 3-Dimensional motion analysis system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: who received modified constraint movement therapy

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

King Khalid Hospital

Full name of responsible person

Radwa S. Abdul-Rahman

Street address

ALmanifeia, Alraghi building

City

Alkharj

Postal code

00966

Phone

+966 11 588 6556

Email

n.radwan@psau.edu.sa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Prince Sattam Bin Abdulaziz University

Full name of responsible person

Nadia L. Radwan

Street address

ALmanifeia, Alraghi building

City

Alkharj

Postal code

00966

Phone

+966 11 588 6500

Email

s.alrawaili@psau.edu.sa

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Prince Sattam Bin Abdulaziz University

Proportion provided by this source

100

Public or private sector

Public

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

Prince Sattam Bin Abdulaziz University

Full name of responsible person

Radwa Said

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

15- Nawal street

City

Madinat Naser

Province

Cairo

Postal code

002

Phone

+20 112 765 5396

Fax
Email

radwakku@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Cairo University

Full name of responsible person

Radwa Said

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

15 Nawal street

City

Madinat Naser

Province

Old Cairo

Postal code

002

Phone

+20 112 765 5396

Email

radwakku@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Cairo University

Full name of responsible person

Radwa Said

Position

Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Pediatrics
Street address
15 Nawal street
City
Madinat Naser
Province
Cairo
Postal code
002
Phone
+20 112 765 5396
Email
radwakku@gmail.com

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 information

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available