

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of hand arm bimanual intensive therapy with and without action observation training on upper extremity motor functions in children with spastic hemiplegic cerebral palsy

Protocol summary

Study aim

To compare the effects of hand arm bimanual intensive therapy with and without action observation training on upper extremity motor functions in children with unilateral spastic cerebral palsy.

Design

community based, Double blinded, Randomized control trial

Settings and conduct

Trial will be conducted at Ghurki Trust teaching hospital, Patients and assessor will be blinded through concealment of assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Spastic hemiplegic Cerebral Palsy diagnosed by Neurophysician. Aged 5-12 years Male and female Mini-mental state examination ≥ 24 Spasticity of grade ≤ 2 on Modified Ashworth scale Gross motor functional classification scale (GMFCS) III-IV Manual Ability Classification System (MACS) III- IV Sufficient cooperation and cognitive understanding to participate in the activities. No sensory impairments. No history of seizures Parents able to commit to an intensive therapy program. Exclusion criteria: Children with visual impairments Aphasic children Uncontrolled seizures Previous orthopedic surgery of upper limb. Severe spasticity and contractures that requires orthotic management. BoNT-A injection in the UL within 6 months prior to study entry.

Intervention groups

HABIT will be given for total 60 hours, 3 hour a day (1 hour home practice), 5 times per week for 4 weeks. AOT will be carried out for 30 minutes each day, 5 days a week, for 4 weeks. The total number of training sessions was 20 per subject.

Main outcome variables

Upper Extremity motor functions was assessed using Abilhand kids and Jebson taylor hand function Test.

General information

Reason for update

Acronym

HABIT & AOT

IRCT registration information

IRCT registration number: **IRCT20210225050494N1**

Registration date: **2021-02-28, 1399/12/10**

Registration timing: **prospective**

Last update: **2021-02-28, 1399/12/10**

Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

Zeeshan Saeed

Name of organization / entity

University of lahore

Country

Pakistan

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2641-10-19, 2020/07/27

Expected recruitment end date

2642-06-17, 2021/03/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of hand arm bimanual intensive therapy with and without action observation training on upper extremity motor functions in children with spastic hemiplegic cerebral palsy

Public title

Comparison of effects of hand arm bimanual intensive therapy with and without action observation training on upper extremity motor functions in children with spastic hemiplegic cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed spastic hemiplegic cerebral palsy Age 5- 12 years Mini mental state examination >24 Spasticity of grade <2 on modified ashworth scale Gross motor functional classification scale level III-IV Manual ability classification system level III- IV Sufficient cooperation and cognitive understanding to participate in the activities No sensory impairments no history of seizures parents able to commit to an intensive therapy program

Exclusion criteria:

Children with visual impairments Aphasic children uncontrolled seizures previous orthopedic surgery of upper limb severe spasticity or contractures that requires orthotic management BoNT- A injection in the UL within 6 months prior to study entry

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The basic strategy used for randomization will be the development of an ordered list with group assignments made in advance using random number table. As participants enter the study, they will be given consecutive numbers and assigned to the group indicated for each number.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be blinded for their group allocation. They will receive their allocated treatment without the knowledge of whether they belong to the control group or interventional group. The duration on treatment session will be same for both groups. The assessor will be physical Therapist who will have no role in the

treatment of the patients. The collected data will be analyzed by biostatistician who will be unaware of the group specification of data.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

University of Lahore

Street address

1 km, defence road, Off bhobatian chowk, lahore

City

Lahore

Postal code

54000

Approval date

2641-10-19, 2020/07/27

Ethics committee reference number

725-III

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

Spastic hemiplegic Cerebral palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

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

Upper extremity motor functions

Timepoint

Before intervention, 4th week at completion of intervention, at 8th week for follow up.

Method of measurement

ABILHAND KIDS questionnaire will be used to measure the manual ability of children. Questionnaire contains 21 activities which are rated by parents as impossible, easy, difficult. Jebson Taylor hand function test will be used to evaluate the speed of performance. It has 7 subsets of simulated daily activities and time score will be recorded for each activity.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Habit with AOT will be given. Therapy will be given for total 60 hours, 3 hours a day, 5 times per week for 4 weeks. AOT will be carried out for 30 min each day, 5 days per week for 4 weeks. Total training sessions will be 20 per subject

Category

Rehabilitation

2

Description

Control group: Habit without AOT will be given. Therapy will be given for total 60 hours, 3 hours a day, 5 times per week for 4 weeks. control group will receive visual stimulation and motor activities 30 mins per day, 5 times per week for 4 weeks. Total number of training sessions per subject will be 20.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghurki trust & teaching hospital lahore

Full name of responsible person

Hassan bin ikram

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Gt rd-burki road link, band road, jallo more lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Postal code

53401

Phone

+92 42 37392201

Email

marketing.ghurkihospital@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghurki trust & teaching hospital

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

University of Lahore

Full name of responsible person

Zeeshan Saeed

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)**

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

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