Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Phone
+92 42 35963424

Email address
zeeshans475@gmail.com

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 weather 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
Street address
Gt rd-burki road link, band road, jallo more lahore
City
Lahore
Postal code
53401
Phone
+92 42 37392201
Fax
Email
marketing.ghurkihospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghurki trust & teaching hospital
Full name of responsible person
Hassan bin ikram
Street address
Gt road- burki road link. band road, jallo more, lahore
City
Lahore
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
Street address
1 km, defence road, Off bhobatian chowk, lahore
City
Lahore
Province
punjab
Postal code
54000
Phone
+92 42 35322501
Email
zeeshans475@gmail.com

Person responsible for scientific 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
Street address
1 km, defence road, Off bhobatian chowk, lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35322501
Email
zeeshans475@gmail.com

Person responsible for updating data

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
Street address
1 km, defence road, Off bhobatian chowk, lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35322501
Email
zeeshans475@gmail.com

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