Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Upper-Lower extremity Intensive Functional Training (U-LIFT) with Hand-Arm Bimanual Intensive Training-Including Lower Extremities (HABIT-ILE) to improve Global Functional Performance in Hemiplegic Cerebral Palsy.

Protocol summary

Study aim

-To determine role of both treatment techniques to improve Global Functional Performance. -To determine the comparative balance improvement among the participants of both groups. -To determine the efficacy of the treatment techniques to improve functions of both upper and lower limb. Secondary Objective: -To assess the “Quality of Life” among participants of both groups.

Design

Randomized Control Trial (RCT) Double blind study. Study groups: U-LIFT and HABIT-ILE . Phase: N.A Sample size:30, Randomization: Simple random sampling technique is used by sealed envelop method. The study is double blinded as participants/caregivers and outcome assessors are blinded. Study center: Multi study centers.

Settings and conduct

The Children Complex Multan and CMH, Multan. All caregivers will be informed about the study and will sign written informed consent before interventions. Simple random sampling technique will be used by sealed envelop method. Study is double blinded as participants/caregivers and outcome assessors are blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: •Diagnosed hemiplegic Cerebral Palsy •Age 5-18 •Gross Motor Function Classification System score II-III • Manual Ability Classification System score II-IV •Ability to follow any 2-step instruction. Exclusion Criteria: •Cognitive Delay •Modified Ashworth score greater than 3 •Uncontrolled epilepsy •Any recent orthopedic surgery •Botulinum toxin injections within last 6 months •Visual or auditory impairments •Open wounds

Intervention groups

There are 2 interventional groups; Group A and B. Group A :Upper-Lower Extremity Functional Training (U-LIFT) group; Group B: Hand-Arm Bimanual Intensive Training-Including Lower Extremities (HABIT-ILE) group.

Main outcome variables

• ACTIVLIM-CP (Activity Limitations for Patients with Cerebral Palsy) • 1-Min Walk test • Pediatric Balance Scale • The Box and Block Test .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052835N5**
Registration date: **2022-03-24, 1401/01/04**
Registration timing: **prospective**

Last update: **2022-03-24, 1401/01/04**
Update count: **0**

Registration date

2022-03-24, 1401/01/04

Registrant information

Name
Fouzia Batool
Name of organization / entity
Shifa Tameer-e-Millat University
Country
Pakistan
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+92 51 8441752
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-31, 1401/01/11

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Upper-Lower extremity Intensive Functional Training (U-LIFT) with Hand-Arm Bimanual Intensive Training-Including Lower Extremities (HABIT-ILE) to improve Global Functional Performance in Hemiplegic Cerebral Palsy.

Public title

Comparison of Upper-Lower extremity Functional Training with Hand-Arm Bimanual Training to improve Performance in Hemiplegic Cerebral Palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed hemiplegic Cerebral Palsy. Age 5-18 Gross Motor Function Classification System (GMFCS) II-IIII Manual Ability Classification System (MACS) II-IV Ability to follow any 2-step instruction

Exclusion criteria:

Cognitive delay Modified Ashworth score greater than 3 Uncontrolled epilepsy Any recent orthopedic surgery Botulinum toxin injections within last 6 months Visual or auditory impairments Open wounds

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Participants will be allocated into both groups by using Sealed Envelope method. Random numbers will be written on index cards and placed in thick and opaque sealed envelops. After taking a written consent from the child's guardian and verbal consent from the child, an envelope is opened and the patient is then offered the allocated treatment regimen.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study participants, caregivers and outcome assessors will be blinded. So, it will be a double-blinded study. Prior to collecting data, children's guardian would be informed about details of treatment with its benefits and risks . Participants will be allocated into both groups by using Sealed Envelope method. Random numbers will be written on index cards and placed in thick and opaque sealed envelops. After taking a written consent from the child's guardian and verbal consent from the child, an envelope is opened and the patient is then offered the allocated treatment regimen. The group A or B belongs to which way of treatment is known to therapist but the patient/caregiver doesn't know about it. To make it a double blind, our primary outcomes 1MWT, PBS and AHA will be assessed by a blind assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board & Ethics Committee (IRB & EC) Shifa International Hospital Ltd. (SIH), Sh

Street address

Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

City

Islamabad

Postal code

44790

Approval date

2022-01-15, 1400/10/25

Ethics committee reference number

IRB#349-21

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
Global Functional Performance, Balance and Functional Upper and Lower Extremity Abilities.

Timepoint
Pre-Intervention at 0 week , Mid- Intervention after 2 weeks and Post-Intervention data after 4 weeks, will be taken.

Method of measurement
• ACTIVLIM-CP, 1 Min Walk Test, Box and Block Test and Pediatric Balance Scale.

Secondary outcomes

1

Description
Cerebral Palsy Quality of Life.

Timepoint
Pre-intervention, after 2 weeks and post intervention after 4 weeks.

Method of measurement
CP QOL (Cerebral Palsy Quality Of Life) - Child & Teen.

Intervention groups

1

Description
Interventional Group A: Group-A will receive “Upper - Lower Extremity Intensive Functional Training (U-LIFT)". For upper-limb training following exercises will be used; 1-Strengthening Exercises: Progressive resistance training will be incorporated by using resistance bands, squeeze stress balls or salt dough, paper scrunching and using minimal weights (15 repetitions x 3 sets/day). 2-Balancing and Coordination Exercises: By putting blocks into a bucket , putting coins into a money box, piling up cup, using a spoon, pouring water into a cup ,drinking the water and moving drink cans/bottles (7 repetitions each x 2 sets /day). For lower-limb training following exercises will be used; 1-Strengthening Exercises: Sit to stand, step ups, vertical jumping, stair climbing will be done (15 repetitions each x 3 sets). 2-Muscles Specific Exercises for Gait: Bridges and heel raises. (5 repetitions each x 2 sets). 3-Balance Exercises: Tandem walking, one-leg standing and standing on balance board. (5 repetitions each x 3 sets) 4-Coordination Exercises: Ball kicking, jumping jacks or hopscotch (5-repetitions each x 3 sets). All exercises will be focused towards the affected side with appropriate warm up, cool down and rest periods among sets. Pre-Intervention (Baseline), Mid-Intervention (Midline) and Post-Intervention (Final) data will be taken.

Category
Rehabilitation

2

Description
Interventional Group B: Group-B will receive “Hand- Arm Bimanual Intensive Training Including Lower Extremities HABIT-ILE: For Upper Limb: Motor Learning Techniques in which instructions will be given to achieve goals like; Gross Motor tasks/activities -Fine Motor Tasks - Manipulative Tasks -Functional Tasks -Art or Crafts -Card Games -Video Games. All these activities of upper limb will be combined and challenged progressively with postural and locomotor activities of the lower limb, e.g., walking while holding a glass, drawing while sitting on an exercise ball. For Lower Limb, the contribution of the LE in the different tasks will also be advanced from: 1) Sitting activities e.g., initially on a chair or a mat, potentially with a back support, progressing towards unsupported sitting and sitting on an unstable support, such us on a roller or a ball. 2) Transitions from lower to higher postures using the UE for support. 3) Static gross motor activities e.g. from standing with UE support to playing in standing without UE support. 4) Dynamic activities e.g. crawling, walking, running or jumping. Pre-Intervention (Baseline), Mid- Intervention (Midline) and Post-Intervention (Final) data will be taken.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military Hospital

Full name of responsible person
Shifa Saleem

Street address
Ghaus ul Azam Road، near Naseem Hayat Rd، Pia Colony, Multan, Punjab

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Phone

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2

Recruitment center

Name of recruitment center
Children's Hospital & The Institute of Child Health Multan.

Full name of responsible person
Shifa Saleem

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shifa Tameer-e-Millat University
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
Shifa Tameer-e-Millat University
Full name of responsible person
Fouzia Batool
Position
Assistant Professor
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Master
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Person responsible for updating data

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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

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Title and more details about the data/document

There is no such plan

When the data will become available and for how long

There is no such plan

To whom data/document is available

There is no such plan

Under which criteria data/document could be used

There is no such plan

From where data/document is obtainable

There is no such plan

What processes are involved for a request to access data/document

There is no such plan

Comments