

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Email address

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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-III 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 envelopes. 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 envelopes. 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 as 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

City

Multan

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60000

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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Sher Shah Road, Nawa Shehar Mohalla Qadirabad,
Multan, Punjab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer-e-Millat University

Full name of responsible person

Fouzia Batool

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Pitras Bukhari Road, Shifa Tameer-e-Millat University,
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fouzia_dpt.ahs@stmu.edu.pk

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

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Shifa Tameer-e-Millat University

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Position

Assistant Porfessor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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