

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Phone

+92 51 8441752

##### Email address

fouzia\_dpt.ahs@stmu.edu.pk

##### 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

#### **Postal code**

60000

#### **Phone**

#### **Email**

shifa59a@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

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

#### **Full name of responsible person**

Shifa Saleem

#### **Street address**

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

#### **City**

Multan

#### **Postal code**

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#### **Email**

shifa59a@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shifa Tameer-e-Millat University

**Full name of responsible person**

Fouzia Batool

**Street address**

Pitras Bukhari Road, Shifa Tameer-e-Millat University,  
H-8/4, Islamabad

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**Postal code**

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**Phone**

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**Email**

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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## Person responsible for scientific 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**

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## Person responsible for updating data

**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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## 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**