

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Functional changes induce by Hand-Arm Bimanual Intensive Therapy including lower extremities (HABIT-ILE) in preschool children with spastic cerebral palsy

#### Protocol summary

##### Study aim

To evaluate the effects of Hand arm bimanual intensive therapy including lower extremities (HABIT-ILE), in pre-school children with CP on functional parameters

##### Design

Randomized controlled trial

##### Settings and conduct

Hospitals of Faisalabad

##### Participants/Inclusion and exclusion criteria

Inclusion Both male and female Children will be considered Diagnosed children of Spastic Cerebral Palsy CP Child of Grade 3 and 4 aged between 3 to 6 years (corrected age if preterm birth), capable of following instructions and completing all necessary tests according to their Exclusion Limb fracture Uncontrolled epilepsy With any other congenital disease (e.g. Diabetes, Hyperthyroidism, Hypothyroidism etc.) Botulinum toxin injections or orthopedic surgery within the past 6 months. Have severe visual or cognitive impairments that could interfere with treatment/testing. Parents are unable/unwilling to provide consent for their child's participation

##### Intervention groups

Group A Interventional group consist of 25 participants will receive Early Hand arm Bimanual Intensive Therapy Including Lower Extremities (E-HABIT-ILE), while Group B will receive treatment through a Conventional Physical therapy. Both interventions will be given for 3 hours per day in hospital by dividing the both groups into sub groups

##### Main outcome variables

1. Five classification levels of the Gross Motor Functional Classification System (GMFCS) 2. Modified ACTIVLIM-CP Questionnaire 3. Pediatric Evaluation of Disability Inventory Questionnaire (PEDI-CAT)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220930056062N5**

Registration date: **2024-06-14, 1403/03/25**

Registration timing: **prospective**

Last update: **2024-06-14, 1403/03/25**

Update count: **0**

##### Registration date

2024-06-14, 1403/03/25

##### Registrant information

##### Name

Kaaynat Shafique

##### Name of organization / entity

The University of Faisalabad

##### Country

Pakistan

##### Phone

+92 334 6925051

##### Email address

kaaynatshafique@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-06-19, 1403/03/30

##### Expected recruitment end date

2024-07-29, 1403/05/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Functional changes induce by Hand-Arm Bimanual Intensive Therapy including lower extremities (HABIT-ILE) in preschool children with spastic cerebral palsy

### Public title

Hand-Arm Bimanual Intensive Therapy including lower extremities (HABIT-ILE) in preschool CP children

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Both male and female Children will be considered capable of following instructions and completing all necessary tests according to their age aged between 3 to 6 years (corrected age if preterm birth) CP Child of Grade 3 and 4 Diagnosed children of Spastic Cerebral Palsy

#### Exclusion criteria:

Limb fracture Uncontrolled epilepsy With any other congenital disease (e.g. Diabetes, Hyperthyroidism, Hypothyroidism etc.) Botulinum toxin injections or orthopedic surgery within the past 6 months Have severe visual or cognitive impairments that could interfere with treatment/testing Parents are unable/unwilling to provide consent for their child's participation

### Age

From **3 years** old to **6 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization through lottery method

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Patients will be blind in this clinical trial

### Placebo

Not used

### Assignment

Other

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Government College University Faisalabad

### Street address

Faisalabad

### City

Faisalabad

### Postal code

38000

### Approval date

2024-05-10, 1403/02/21

### Ethics committee reference number

GCUF/2024/0987

## Health conditions studied

### 1

#### Description of health condition studied

Cerebral palsy

#### ICD-10 code

G80

#### ICD-10 code description

Cerebral palsy

## Primary outcomes

### 1

#### Description

ACTIVLIM-CP Questionnaire and Pediatric Evaluation of Disability Inventory and Computer Adaptive Test Questionnaire (PEDI-CAT) will be solved on the basis of initial assessment of children. Five classification levels of the Gross Motor Functional Classification System (GMFCS) to measure the Grade of cerebral Palsy.

#### Timepoint

2

#### Method of measurement

ACTIVLIM-CP Questionnaire and Pediatric Evaluation of Disability Inventory and Computer Adaptive Test Questionnaire (PEDI-CAT) will be solved on the basis of initial assessment of children. Five classification levels of the Gross Motor Functional Classification System (GMFCS) to measure the Grade of cerebral Palsy.

## Secondary outcomes

### 1

#### Description

ACTIVLIM-CP Questionnaire and Pediatric Evaluation of Disability Inventory and Computer Adaptive Test Questionnaire (PEDI-CAT) will be solved on the basis of initial assessment of children. Five classification levels of the Gross Motor Functional Classification System (GMFCS) to measure the Grade of cerebral Palsy.

#### Timepoint

2

#### Method of measurement

ACTIVLIM-CP Questionnaire and Pediatric Evaluation of Disability Inventory and Computer Adaptive Test Questionnaire (PEDI-CAT) will be solved on the basis of

initial assessment of children. Five classification levels of the Gross Motor Functional Classification System (GMFCS) to measure the Grade of cerebral Palsy.

## Intervention groups

### 1

#### Description

Intervention group: Early Hand arm Bimanual Intensive Therapy Including Lower Extremities (E-HABIT-ILE)

#### Category

Rehabilitation

### 2

#### Description

Control group: Conventional treatment

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allied Hospital faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Street address

Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 9210092

##### Email

rafiaimtiaz@gcuf.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Government College University Faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Street address

Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 9210023

##### Email

rafiaimtiaz@gcuf.edu.pk

##### Grant name

##### Grant code / Reference number

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

No

#### Title of funding source

No funding was received

#### Proportion provided by this source

1

#### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Government College University Faisalabd

##### Full name of responsible person

Rafia Imtiaz

##### Position

Lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

Faisalabad

##### City

Faisalabad

##### Province

Punjab

##### Postal code

38000

##### Phone

+92 41 9200876

##### Email

rafiaimtiaz@gcuf.edu.pk

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Government College University Faisalabd

##### Full name of responsible person

Rafia Imtiaz

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Lecturer

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38000  
**Phone**  
+92 41 9200876  
**Email**  
rafiaimtiaz@gcuf.edu.pk

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Government College University Faisalabad  
**Full name of responsible person**  
Rafia Imtiaz  
**Position**  
Lecturer  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Faisalabad  
**City**  
Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 41 9200066  
**Email**  
rafiaimtiaz@gcuf.edu.pk

## 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

Privacy concerns

### 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

Yes - There is 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

### Title and more details about the data/document

Functional changes induce by Hand-Arm Bimanual Intensive Therapy including lower extremities (HABIT-ILE) in preschool children with spastic cerebral palsy

### When the data will become available and for how long

Data from this trial will not be made publicly available. However, it may be accessible upon request. For inquiries regarding data access, please contact rafiaimtiaz@gcuf.edu.pk.

### To whom data/document is available

Data from this trial will not be made publicly available. However, it may be accessible upon request. For inquiries regarding data access, please contact rafiaimtiaz@gcuf.edu.pk.

### Under which criteria data/document could be used

Data from this trial will not be made publicly available. However, it may be accessible upon request. For inquiries regarding data access, please contact rafiaimtiaz@gcuf.edu.pk.

### From where data/document is obtainable

Data from this trial will not be made publicly available. However, it may be accessible upon request. For inquiries regarding data access, please contact rafiaimtiaz@gcuf.edu.pk.

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

Data from this trial will not be made publicly available. However, it may be accessible upon request. For inquiries regarding data access, please contact rafiaimtiaz@gcuf.edu.pk.

### Comments