

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

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38000

Phone

+92 41 9210092

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rafiaimtiaz@gcuf.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Government College University Faisalabad

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?

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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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

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