Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Kaiynat Shafique

Name of organization / entity
The University of Faisalabad

Country
Pakistan

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+92 334 6925051

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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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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
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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 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
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