

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

EFFECTS OF 8 WEEKS FUNCTIONAL TRAINING PROGRAM IN POSTURE CONTROL AND FUNCTIONAL MOBILITY IN SPASTIC HEMIPLEGIC CEREBRAL PALSY

Protocol summary

Study aim

To find out effects of functional training vs conventional training on posture control and functional mobility in spastic hemiplegic cerebral palsy

Design

Randomized clinical trial

Settings and conduct

Rehab cure Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children diagnosed with cerebral palsy. Ages between 4 to 14 years. Children with gross motor functional classification system (GMFCS) level II or III. Children with no mental retardation. The degree of spasticity according to Modified Ashworth Scale between grade 1 to 3 Exclusion Criteria: Children who had orthopedic surgery or used Botulinum toxin injection. Children with severe visual defect. Children having auditory problems. Children having vestibular issues. Children with severe understanding problems. Parents of children who didn't want to participate in study

Intervention groups

Subjects will receive 8 weeks treatment 3 times a week. session will be of 45 mins to 1 hour. Group A will receive conventional training program consist on TENS, hot pack, ROMs, stretching, bridging, balance training, supine to sit exercise, diagonal pattern ex with resistance, lateral walk, step ups, gait training, sit to stand, stair climbing, single leg standing, weight shift, cat position Group B will receive functional training program consist on Gym ball exercises, ex with resistance bands, unilateral pelvic bridging, Bosu ball ex, trampoline jumping, resistance kneeling, Treadmill walk, squats, cycling, cat walk, back walk, stepper ex, stair climbing

Main outcome variables

Pediatric Balance scale, Trunk control measurement scale, Five Times Sit to Stand Test, Timed Up and Go

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200909048676N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **retrospective**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Aeysha Gulzar

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 42 35126110

Email address

ash.gul2012@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-15, 1399/06/25

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECTS OF 8 WEEKS FUNCTIONAL TRAINING PROGRAM IN POSTURE CONTROL AND FUNCTIONAL MOBILITY IN SPASTIC HEMIPLEGIC CEREBRAL PALSY

Public title

EFFECTS OF 8 WEEKS FUNCTIONAL TRAINING PROGRAM IN POSTURE CONTROL AND FUNCTIONAL MOBILITY IN SPASTIC HEMIPLEGIC CEREBRAL PALSY

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children diagnosed with cerebral palsy Ages between 4 to 14 years Children with gross motor functional classification system (GMFCS) level II or III Children with no mental retardation The degree of spasticity according to Modified Ashworth Scale ranged between grade 1 to 3

Exclusion criteria:

Children who have had orthopedic surgery or Botulinum toxin injection Children with severe visual defect Children having auditory impairment Children having vestibular problem Children with severe perceptual deficit. Parents of children who don't want to participate in study

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by lottery method. Allocation concealment through sealed envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be blinded

Placebo

Not used

Assignment

Parallel

Other design features

Non probability convenient sampling will be used to recruit the individuals for the study. Randomization will be done by lottery method to divide the individuals to 2 treatment groups. sealed envelope will be used for allocation concealment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah College of Rehabilitation & Allied health Sciences

Street address

Madar-e-Millat Road, Quaid-e-Azam Industrial Estate.

City

Lahore

Postal code

54770

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

RCRS-RE-MS-NMPT/FALL 19/026

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

Postural control and functional mobility

Timepoint

Total 8 week program and no follow up. Primary outcome will be measured on 8th week

Method of measurement

Pediatric Balance scale, Trunk control measurement scale, Five Times Sit to Stand Test , Timed Up and Go

Secondary outcomes

empty

Intervention groups

1

Description

Subjects will receive 8 weeks treatment 3 times a week. session will be of 45 mins to 1 hour. Group A will receive conventional training program consist on TENS, hot pack, ROMs, stretching, bridging , balance training, supine to sit exercise, diagonal pattern ex with resistance, lateral walk, step ups, gait training, sit to stand, stair climbing, single leg standing, weight shift, cat position

Category

Treatment - Other

2

Description

Intervention group: Subjects will receive 8 weeks treatment 3 times a week. session will be of 45 mints to 1 hour. Group B will receive functional training program consist on Gym ball exercises, ex with resistance bands, unilateral pelvic bridging, Bosu ball ex , trampoline jumping, resistance kneeling, Treadmill walk, squats, cycling, cat walk, back walk, stepper ex, stair climbing

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehab cure Lahore

Full name of responsible person

Aeysha Gulzar

Street address

Madar-e-Millat Road, Quaid-e-Azam Industrial Estate.

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Lahore

Postal code

54770

Phone

+92 42 35126110

Email

ash.gul2012@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Prof. Dr. Anis Ahmad

Street address

Madar-e-Millat Road Quaid e Azam Industrial Estate

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54770

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+92 42 35126110

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ash.gul2012@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Riphah International 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

Riphah International University

Full name of responsible person

Aeysha Gulzar

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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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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 decision and information decided yet

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

Undecided - It is not yet known if there will be 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