

# 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.

**City**

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

**City**

Lahore

**Postal code**

54770

**Phone**

+92 42 35126110

**Email**

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**

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

**City**

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**Province**

Punjab

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Aeysha Gulzar

**Position**

Student

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Riphah International University

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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