Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Proprioceptive Training and Partial Body Weight Supported Treadmill Training on Balance and Functional Mobility in Children with Spastic Diplegia: A Randomized Controlled Trial.

Protocol summary

Study aim
To improve balance and functional mobility in children with spastic diplegia by applying proprioceptive training and partial bodyweight supported treadmill training.

Design
Randomized controlled trial

Settings and conduct
Randomized controlled study was conducted in children hospital Faisalabad. Assessor was blinded.

Participants/Inclusion and exclusion criteria
Spastic diplegic cerebral palsy, Both gender, 11-13 years old, Spasticity of grade <2 according to the Modified Ashworth Scale, Level 2-3 (GMFCS), Intact cognitive status, Normal Vision and hearing status were included whereas patients with, Seizures, any surgical procedure 6 months ago, fixed Joint contractures, Bony deformity i.e. Scoliosis, windswept deformity, crouch knee deformity, Rocker Bottom deformity etc. Multiple medical concerns i.e. Any Cardiac issue and Asthma etc. Medicines to reduce spasticity were excluded.

Intervention groups
In Control Group patients practiced proprioceptive training in form special seven exercises. All the proprioceptive exercises was performed for 30 minutes per session with 5 minutes rest period in between for 3 days a week and continued for 12 weeks. whereas in Experimental group Patients were treated with proprioceptive exercises in addition of treadmill training program which was conducted 3 times/week for 12 successive weeks. Patients practiced one hour session of treatment including 30 minutes of Proprioceptive training and 30 minutes of treadmill training. A specialized Harness was used with treadmill training to ensure safety of a patient. Treadmill speed started at 0.5 km/h~1.0 km/h and increased gradually according to children's adaptability by 0.1 km/ h progressively to suit the child's speed.

Main outcome variables
Balance and Functional mobility was the main outcomes measure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210818052225N1**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date
2021-08-22, 1400/05/31

Registrant information

Name
Benish Shakoor
Name of organization / entity
University of Lahore
Country
Pakistan
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benishshakoor294@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-06, 1398/09/15

Expected recruitment end date
2019-12-11, 1398/09/20

Actual recruitment start date

2019-12-12, 1398/09/21

Actual recruitment end date

2019-12-28, 1398/10/07

Trial completion date

2020-03-28, 1399/01/09

Scientific title

Effects of Proprioceptive Training and Partial Body Weight Supported Treadmill Training on Balance and Functional Mobility in Children with Spastic Diplegia: A Randomized Controlled Trial.

Public title

Effects of Proprioceptive Training and Partial Body Weight Supported Treadmill Training on Balance and Functional Mobility in Children with Spastic Diplegia: A Randomized Controlled Trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Spastic diplegic cerebral palsy • Both gender 11-13 years old Spasticity of grade <2 according to the Modified Ashworth Scale Level II-III (Gross Motor Functional Classification System) Intact cognitive status (Mini Mental State Examination, level 9-20 will be included) Normal Vision and hearing status.

Exclusion criteria:

Seizures Patients who had gone through any surgical procedure related to spine and extremities 6 months ago Patients with fixed Joint contractures Bony deformity i.e. Scoliosis, windswept deformity, crouch knee deformity, Rocker Bottom deformity etc. Multiple medical concerns i.e. Any Cardiac issue and Asthma etc.• Medicines to reduce spasticity Patients already involve in Treadmill training at home

Age

From **11 years** old to **13 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

After fulfilling the inclusion criteria patients were divided randomly into experimental and control group. Patients were randomized individually. They were distributed by random numbers. Allocation was concealed in envelops. Researcher was unaware of treatment given to patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor was unaware about the patients from both groups. He was allowed to assess data before giving intervention and after the complete duration of twelve weeks. He was unaware of treatment given to participants.

Placebo

Not used

Assignment

Parallel

Other design features

Randomized controlled study design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review of Board of University of Lahore

Street address

Defence road Lahore

City

Lahore

Postal code

54590

Approval date

2020-12-03, 1399/09/13

Ethics committee reference number

IRB-UOL-FAHS/767/2020

Health conditions studied

1

Description of health condition studied

Spastic diplegic cerebral palsy

ICD-10 code

G80.1

ICD-10 code description

Spastic diplegic cerebral palsy

Primary outcomes

1

Description

Balance

Timepoint

before intervention and after twelve weeks of intervention

Method of measurement

Pediatric Balance scale

Secondary outcomes

1

Description

functional mobility

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

Timed Up and Go Test (TUG) was used to measure functional mobility.

Intervention groups

1

Description

Participants in control group were practiced proprioceptive training with specialized proprioceptive exercises. 1: Stair climbing up and down (regular 3 steps staircase).2: Standing with feet approximately shoulder-width apart with arm extending lower than shoulder then lifting the both heels from the floor an d maintain for 10 sec, followed by climbing regular steps3: One foot placed on inside of the opposing ankle and hold the position for 10 sec followed by climbing regular steps staircase.4: One leg standing with one foot raised to back and maintain this position for minimum 3 seconds. This procedure is performed with eyes closed also.5: Same procedure as described above with one foot raised to the front.6: Walking heel to toes.7: Rising from a standard chair 4 times without support. All proprioceptive exercises was performed for 30 minutes per session with 5 minutes rest period in between for 3 days a week and continued for 12 weeks.

Category

Rehabilitation

2

Description

Patients were treated with proprioceptive exercises in addition of treadmill training program which was conducted 3 times/week for 12 successive weeks. Patients practiced one hour session of treatment including 30 minutes of Proprioceptive training and 30 minutes of treadmill training. A specialized Harness was used with treadmill training to ensure safety of a patient. After Proprioceptive exercises treadmill training subdivided into 3 sets with 10 minutes each. During first and last 5 minutes, child walked at 60% maximal speed while during remaining 20 minutes, they performed walking at 80% maximal speed. 5 min rest after each set of training to prevent fatigue. Treadmill speed started at 0.5 km/h~1.0 km/h and increased gradually according to children’s adaptability by 0.1 km/ h progressively to suit the child’s speed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Hospital Faisalabad

Full name of responsible person

Dr. Faisal Rasool

Street address

Jhang road near eyoub research center

City

Faisalabad

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38000

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benishshakoor294@gmail.com

Web page address

https://www.marham.pk/hospitals/faisalabad/children-hospital-institute-of-child-health-faisalabad/gc-university-new-campus

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Dr. Filza Shaukat

Street address

Lahore Defense road near Bobatian Chowk

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54792

Phone

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anam.naz@uipt.uol.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Lahore

Proportion provided by this source

10

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

University of Lahore

Full name of responsible person

Benish Shakoor

Position

Student

Latest degree
Master
Other areas of specialty/work
Physiotherapy
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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 information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available