Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of functional progressive resistance exercise versus eccentric muscle control on muscle strength, dynamic balance, functional ability and muscle tone in children with spastic paraplegia.

Protocol summary

Study aim

To compare the effectiveness of functional progressive resistance exercise and eccentric muscle control on muscle strength, dynamic balance, functional ability and muscle tone in children with spastic paraplegia.

Design

Parallel group randomized clinical trial and Randomization will be achieved through computer generated random allocation software.

Settings and conduct

Syeda Khatoon-e-Jannat Trust Hospital and Special Education Centre, and Tanzeem-al-Lissan It will be assessor who will be blinded about the type of intervention. Treatment will be given by principal investigator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 6-13 years old, Gender: both male and female children, Children who follow the verbal instructions of the therapist, GMFCS between I and III, Male children having BMI range of 13.0-20.8, Female children havingBMI range of 12.7-21.8. Exclusion criteria: Surgical procedures on hamstrings or bilateral lengthening of triceps surae. Fixed deformity of lower limb, Visual or auditory impairments.

Intervention groups

Intervention group A: They will receive conventional physical therapy and functional progressive resistance exercises, which consist of sit-to-stand, half-kneeling standing, and side step-up exercises for 1-3 sets of 8–12 repetitions for 30 minutes. Exercises, repetitions, and weight will be gradually increased. Intervention group B: They will receive conventional physical therapy and eccentric muscle control exercises, which consist of stand-to-sit, standing and shifting weight anteriorly, sitting and returning to rock lying, and standing and kicking a large ball exercise for 10 sets, and each exercise will be performed five times for 30-minutes. The treatment duration for both groups will consist of three sessions per week for six weeks.

Main outcome variables

Muscle Strength, Dynamic Balance, Functional Ability and Muscle Tone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057434N8**
Registration date: **2024-03-13, 1402/12/23**
Registration timing: **prospective**

Last update: **2024-03-13, 1402/12/23**
Update count: **0**

Registration date

2024-03-13, 1402/12/23

Registrant information

Name

Zainab Sheraz

Name of organization / entity

Riphah International University, Faisalabad

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-15, 1402/12/25

Expected recruitment end date

2024-05-15, 1403/02/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of functional progressive resistance exercise versus eccentric muscle control on muscle strength, dynamic balance, functional ability and muscle tone in children with spastic paraplegia.

Public title
Effectiveness of two different techniques in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: 6-13 years old. Gender: both male and female children. Children who follow the verbal instructions of the therapist. Gross motor function classification system (GMFCS) level between I and III. Male children having normal BMI range of 13.0-20.8. Female children having normal BMI range of 12.7-21.8.

Exclusion criteria:
Surgical procedures on hamstrings or bilateral lengthening of triceps surae. Other surgical procedure of less than 1 year prior to participation in the study Botulinum toxin, type A injections in the lower limb less than 6 months before inclusion Fixed deformity of lower limb and musculoskeletal surgery Disorders such as visual or auditory impairments

Age
From **6 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done through a computer software "Random allocation software Version 2. The total sample size will be entered with required number of participants to be allocated in two groups. An automated randomization list will be achieved with attrition rate included. The program starts running with the default settings. Users may run the program with the default settings or set the number of groups, the name of participants in each group and the sample size. Clicking the 'Generate' button produces the random sequence. Before generating the random sequence, the option window will be displayed and different randomization settings can be entered.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be done on part of outcome assessor who will be an experienced therapist. Patients will be assessed by him at the end of treatment session. He will be blinded about the type of intervention patient will receive. Patients will also be blinded about the type of intervention they will receive.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Riphah International University Faisalabad

Street address
Riphah International University, Faisalabad

City
Faisalabad

Postal code
38000

Approval date
2024-03-01, 1402/12/11

Ethics committee reference number
RCRAHS/REC/24/06

Health conditions studied

1

Description of health condition studied
Spastic paraplegia

ICD-10 code
G82.2

ICD-10 code description
Paraplegia

Primary outcomes

1

Description
Muscle Strength

Timepoint
Assessment will be performed at 0 week (baseline) and at completion of 6 weeks treatment.

Method of measurement
Sit to stand test

Secondary outcomes

1

Description
Dynamic Balance
Timepoint
Assessment will be performed at 0 week (baseline) and at completion of 6 weeks treatment.
Method of measurement
Time up and go test

2

Description
Functional Ability
Timepoint
Assessment will be performed at 0 week (baseline) and at completion of 6 weeks treatment.
Method of measurement
Gross motor function measure 88

3

Description
Muscle Tone
Timepoint
Assessment will be performed at 0 week (baseline) and at completion of 6 weeks treatment.
Method of measurement
Modified Ashworth Scale

Intervention groups

1

Description
Intervention Group A (functional progressive resistance exercise) 32 children in Group A will receive functional progressive resistance exercise and a conventional physical therapy program. The conventional physical therapy program will be given to improve balance and stability through balance bar, single leg balance with bar, and stride line walking; gait training in both closed and open environments, which includes overcoming obstacles and walking on different types of floors; and walking up and downstairs. In addition, the functional progressive resistance exercises will consist of three circuit exercises. These are: In the sit-to-stand exercise, the child will be instructed to sit on the bench without a backrest. To start with, the child will be seated with their knees flexed at a 90-degree angle and their feet resting on the floor. From this position, the child will slowly stand up from the bench. In the half-kneeling standing exercise, the child will sit in a half-kneeling position without any external support. From this position, the child will be progressively push himself or herself forward to stand up while shifting weight forward on the front leg. In the side step-up activity, the child will climb a 15-cm staircase sideways. Each child will be given a rest period of 30 seconds to 1 minute in between each sets. Children with lower scores on the Gross Motor Function Classification System will be given more rest time to relieve stress. At the end of the protocol, each child will be given 2-minute cooling-down exercise, which includes range of motion, mobilization, and stretching. The treatment duration will consist of 3 sessions per week for 6 weeks, involving functional progressive resistance exercise with a gradual increase in intensity to improve lower limb muscle strength which directly leads to improvement in tone and functional ability as well. All exercises will be performed in 1-3 sets of 8–12 repetitions, with a rest period of 30 seconds to 1 minute in between each set. The session will last 25 minutes, followed by 5 minutes of warm-up and cool-down exercises. Each exercise session will start with a 5minutes warm-up that includes range of motion, mobilization, and stretching, followed by three types of exercises, and it will end with a 2 minutes cool-down session which comprise of range of motion, mobilization and stretching which will improve range of motion and decrease stiffness. The weight and repetitions of exercises will be increased based on the child's performance. The weight will gradually increase from 5% over 1-2 weeks to 10% over 3–4 weeks, and eventually to 35% over 5–6 weeks. Similarly, the repetitions will gradually increase from 5 times over 1-2 weeks to 10 times over 3–4 weeks, and eventually to 15 times over 5–6 weeks. Resistance will be increased, such as by using a weighted vest or ankle weights, to ensure the child reaches the required intensity level.
Category
Treatment - Other

2

Description
Intervention Group B (eccentric muscle control) 32 children in Group B will receive eccentric muscle control and conventional physical therapy. The conventional physical therapy program will be given in the form to improve balance and stability through balance bar, single leg balance with bar, and stride line walking; training gait in both closed and open environments, including overcoming obstacles and walking on different types of floor; and walking up and downstairs. In addition, the eccentric muscle control exercises will be designed to enhance muscle strength, dynamic balance and functional ability and will consist of four different exercises: Stand to sit: The child will stand straight with the neck in a neutral position, back erect, hand alongside the body, with knees extended, and feet flat on the floor. The therapist will instruct the child to sit on a chair with their back straight, knees flexed at a 90-degree angle, and feet flat on the floor. Standing and shifting weight anteriorly: The child will stand straight, and the therapist will instruct the child to shift weight anteriorly slowly. Sitting and returning to crock lying: The child will sit on the mat with the neck in a neutral position, the back erect, and the knees extended. The therapist will direct the child to return to the crock-laying position gradually. Standing and kicking a large ball: the child will position in front of a mirror; then, the therapist will instruct the child to kick a large ball backward slowly on a specific target and then return to the starting position. These exercises

will be given to each child for 30 minutes, three sessions per week for six weeks. The session will last 25 minutes, followed by 5 minutes of warm-up and cool-down exercises. These warm-up and cool-down exercises will consist of range of motion, mobilization, and stretching exercises to improve range of motion and decrease stiffness. Each exercise will be repeated five times, and 10 sets will be performed with rest intervals between each set.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Syeda Khatoon-e-Jannat Trust Hospital and Special Education Centre

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name
N/A

Grant code / Reference number
N/A

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
N/A

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
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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
Real patient is involved
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available