Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effects of Swiss Ball Stabilization Exercises on Trunk Control,Balance,Motor Skill in Spastic Diplegic Cerebral Palsy Children

Protocol summary

Study aim

The purpose of this study to check the effects of Swiss ball stabilization exercises on trunk control ,balance,motor skill in spastic diplegic cerebral palsy children and to evaluate the trunk control in children with spastic diplegic cerebral palsy and to measure the functional performance by using Pediatric berg balance scale. (PBBS).

Design

Randomized Clinical trial , Single Blinded, Parallel group

Settings and conduct

The Children Hospital & Institute of Child Health Faisalabad

Participants/Inclusion and exclusion criteria

inclusion • Child age with 3-10 years. • Both gender male and female. • Child able to follow verbal command. • Children with GMFS level (II, III, IV) • Children with Modified Ashworth scale (0-2) • Pediatric balance scale more than 20 score exclusion • Children who were uncooperative • Children who have visual and intellectual impairments • Use of anti-epileptic & anti-spasticity medications • CP include (Hemiplegic CP, Quadriplegic CP, Ataxic CP, Athetoid CP, Mixed CP, Hypotonic CP) • With any Hearing deficit • Sensory loss • Tumors • Children with severe mental abnormality • Any cardiac anomalies affecting exercise tolerance • Less than 4 months after undergoing orthopedic surgery • Usage of botulism toxins Injections • With any bony Malalignment and Contractures

Intervention groups

As a baseline treatment functional electrical stimulation was done. Then the Swiss ball stabilization exercises were applied. Swiss Ball Stabilization Exercises

Main outcome variables

The Trunk Control Gross Motor Function Scale-88 Pediatric Berg Balance Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240306061198N2**
Registration date: **2024-04-04, 1403/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-04, 1403/01/16**
Update count: **0**

Registration date

2024-04-04, 1403/01/16

Registrant information

Name

Syed Saqlain Babar

Name of organization / entity

The University of Faisalabad

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-17, 1402/11/28

Expected recruitment end date

2024-03-24, 1403/01/05

Actual recruitment start date

2024-02-17, 1402/11/28

Actual recruitment end date

2024-04-24, 1403/02/05

Trial completion date

2024-04-26, 1403/02/07

Scientific title
The Effects of Swiss Ball Stabilization Exercises on Trunk Control,Balance,Motor Skill in Spastic Diplegic Cerebral Palsy Children

Public title
Swiss Ball Stabilization Exercises with Trunk Control Spastic Diplegic Cerebral Palsy Children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
• Child age with 3-10 years • Both gender male and female • Child able to follow verbal command • Children with GMFS level (II, III, IV) • Children with Modified Ashworth scale (0-2) • Pediatric balance scale more than 20 score

Exclusion criteria:
• Children who were uncooperative • Children who have visual and intellectual impairments • Use of anti-epileptic & anti-spasticity medications • CP include (Hemiplegic CP, Quadriplegic CP, Ataxic CP, Athetoid CP, Mixed CP, Hypotonic CP) • With any Hearing deficit • Sensory loss • Tumors • Children with severe mental abnormality • Any cardiac anomalies affecting exercise tolerance • Less than 4 months after undergoing orthopedic surgery • Usage of botulism toxins Injections • With any bony Malalignment • Contractures

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **22**
Actual sample size reached: **21**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be done with the help of Chit & Draw method. Chit: A chit is a small piece of paper or token, often with a number or other identifier written on it. In randomization processes involving chits, each chit represents a specific outcome or option. Chits are typically placed into a container, such as a hat or a bowl, and then drawn at random to determine the outcome. This method ensures randomness because each chit has an equal chance of being selected. Draw: Drawing is the action of randomly selecting a chit or card from a container. In this method, a person reaches into the container without looking and selects one item (chit or card) at random. The selected item determines the outcome of the randomization process. Drawing is often used in situations where physical objects like chits, cards, or tokens are involved. Both chit and draw methods are straightforward and widely used for generating random outcomes in various contexts, from simple games to more complex decision-making processes. They provide a fair and unbiased way to select from a set of options without any predetermined

Blinding (investigator's opinion)
Single blinded

Blinding description
Single Blinded: outcome assessors are typically kept unaware of which participants received the experimental treatment and which received the comparative intervention. This blinding helps to prevent conscious or unconscious biases that could influence the assessment of study outcomes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and Ethics/ technical Committee for the University of Faisalabad

Street address
Faisal Town, West ,Canal Road, Faisalabad, Punjab

City
Faisalabad

Postal code
38000

Approval date
2024-01-05, 1402/10/15

Ethics committee reference number
TUF/Addl Reg/SB/656

Health conditions studied

1

Description of health condition studied
Spastic diplegic Cerebral Palsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Trunk Control

Timepoint
Baseline intervention and 5 weeks post intervention

Method of measurement
Gross motor function scale GMFS-88

2

Description
Gross Motor Function
Timepoint
Baseline intervention and 5 weeks post intervention
Method of measurement
GMFS-88

Secondary outcomes

1

Description
Balance
Timepoint
Baseline intervention and 5 weeks post intervention
Method of measurement
Pediatric berg balance scale

2

Description
Primitive Reflexes
Timepoint
Baseline intervention and 5 weeks post intervention
Method of measurement
Primitive Reflexes Screening evaluation form positive or negative

Intervention groups

1

Description
Intervention group 1: Functional Electrical Stimulation with Swiss Ball Stabilization Exercises As a baseline treatment, functional electrical stimulation was done. Then the Swiss ball stabilization exercises were applied. Swiss Ball Stabilization Exercises Each participant performed exercise using a Swiss ball for 25 minutes in two postures, prone and sitting. First, the prone posture will used one way, “To and FRO,” with sway accompanied volitional upper extremity extension like superman for 5 minutes. Second, the sitting posture will used to perform the “Up and Down,” “To and Fro,” and “Spinning” movements. Each session lasted 5 minutes, and the participants were instructed to perform rhythmical movements. Optimal arousal Swiss ball Make the child bounce, active/passive on the Swiss ball, slow/fast 5 times 5 sets .Combined frontal and transverse plane movements Swiss ball High sitting: one-handed weight bearing followed by trunk rotation to reach the toy on opposite side 5-7 times each side 1 set . Trunk activation activities Swiss ball High sitting foot placed on the ground: throwing the ball with both hands. 5 times, 1 set. Roll the ball maximum backward and hold for 10 seconds, keeping pelvis in neutral, knee in extension, and the foot in plantar flexion 5 times, 1 set 5. Dynamic trunk activities in sitting (transverse and frontal plane) Swiss ball Reaching the toy sideways with one hand by shifting the body weight toward the reaching side 5 times each one set Reaching the toy with both the hands kept a little back with trunk rotation toward the reaching side 5 times each side, 1 set .Prone posture was applied on way to & FRO & spinning with sway, accompanied by volitional upper extremity like Superman. 5 times, 1 set. Pressure time with a therapy ball Front & back pressure 3 times 1 set.
Category
Rehabilitation

2

Description
Control group: functional electrical stimulation with conservative physical therapy treatment
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Hospital & Institute of Child Health ,Faisalabad
Full name of responsible person
Dr.Syed Saqlain Babar; PT
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Sponsors / Funding sources

1

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

Yes

Title of funding source

The University of Faisalabad

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

The University of Faisalabad

Full name of responsible person

Dr.Gulraiz Ayub;PT

Position

Clinical Consultant Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Effects of Swiss Ball Stabilization Exercises on Trunk Control,Balance,Motor Skill in Spastic Diplegic Cerebral Palsy Children.Data was assembled with respect to muscle tone measured by Modified Ashworth Scale (Grade 0-2), Gross Motor Function Classification System (GMFCS) Grade (II, III, IV), a Gross Motor Function-88 Questionnaires to assessed trunk control and motor skill & balance assessed by PBBS more than 20 as outcome measure tools.

When the data will become available and for how long

15 days after publication

To whom data/document is available

15 days after publication

Under which criteria data/document could be used

Access to the data will be facilitated through a specified mechanism, such as a secure online portal or data sharing platform. Requests for access will be reviewed by a designated committee or entity responsible for ensuring that they meet the established criteria and comply with relevant regulations and guidelines. Additional supporting information and documents may be provided to assist requesters in understanding the available data and its potential applications.

From where data/document is obtainable

The University of Faisalabad 38000 https://tuf.edu.pk/ 0092 41 875 0971-5 Fax: +92 41 875 0970

What processes are involved for a request to access data/document

To receive the documents or data files, the process typically involves the following steps: 1. Request Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file transfer protocols, or a secure online portal. 7. Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that they have received the information they requested.

Comments