

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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

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Person responsible for updating data

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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