

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Phone

+92 41 87509715

##### Email address

2022-ms-pt-044@tuf.edu.pk

##### 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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Faisal Town, West ,Canal Road, Faisalabad, Punjab

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

The University of Faisalabad

#### **Full name of responsible person**

Dr.Zainab Boota PT

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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**  
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The University of Faisalabad  
**Full name of responsible person**  
Dr.Gulraiz Ayub;PT  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
Dr.Syed Saqlain PT  
**Position**  
HOD Clinical Physiotherapist Khadija Mahmood Trust  
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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**