# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on primitive reflexes in spastic diplegic cerebral palsy children

## Protocol summary

**Study aim**
The study investigate the of Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on primitive reflexes in spastic diplegic cerebral palsy children.

**Design**
Randomized Clinical trial , Single Blinded, Parallel group

**Settings and conduct**
The Children Hospital & Institute of child health Faisalabad

**Participants/Inclusion and exclusion criteria**
Children aged 3-10 years with a confirmed diagnosis of spastic diplegia and persistent primitive reflexes (Moro, ATNR, STNR, or Tonic Labyrinthine) are included. They must perform voluntary movements with minimal assistance, be at least 6 months post-surgery, have a stable medical regimen, follow verbal commands, and fall within GMFS levels II-IV and a Modified Ashworth Scale score of 0-2. Parental consent is required. Exclusions include cognitive impairments preventing participation, additional neurological conditions (epilepsy, severe autism), fixed contractures, recent Botox or surgery (within 6 months), uncontrolled seizures, uncooperative behavior, visual, intellectual, or hearing impairments, and other CP types or conditions affecting exercise tolerance.

**Intervention groups**
For Group A, functional electrical stimulation (FES) was applied as a baseline treatment, followed by Rood's Ontogenic Motor Patterns using inhibitory techniques. In Group B, FES was also administered as the baseline treatment, followed by Swiss ball stabilization exercises. Screening for primitive reflexes was conducted in both groups.

**Main outcome variables**
Primitive Reflexes chart

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240306061198N4**
Registration date: **2024-10-25, 1403/08/04**
Registration timing: **retrospective**

Last update: **2024-10-25, 1403/08/04**
Update count: **0**

**Registration date**
2024-10-25, 1403/08/04

**Registrant information**

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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**
2024-04-28, 1403/02/09

**Trial completion date**

2024-04-30, 1403/02/11

**Scientific title**
Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on primitive reflexes in spastic diplegic cerebral palsy children

**Public title**
Comparative Effects of Roods Ontogenic Motor Patterns and Swiss Ball Stabilization Exercises on Primitive Reflexes in Spastic Diplegic Cerebral Palsy Children

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Children with confirmed medical diagnosis of spastic diplegia. Children between 3 and 10 years old (as motor interventions may show significant results within this developmental range). Demonstration of persistent primitive reflexes such as the Moro reflex, ATNR (Asymmetrical Tonic Neck Reflex), STNR (Symmetrical Tonic Neck Reflex), or Tonic Labyrinthine reflex. Children who can perform voluntary movements with assistance or minimal assistance but have limited motor skills. At least 6 months post any surgery related to cerebral palsy or orthopedic corrections. Written informed consent from parents or guardians to allow their child's participation in the study Children on a stable medical treatment regimen without recent changes in anti-spasticity medication or other related treatments. 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)

**Exclusion criteria:**
Children with significant cognitive impairments that prevent them from following instructions or participating in the therapy sessions. Children with additional neurological conditions such as epilepsy, severe autism, or other progressive neurological disorders. Children with fixed contractures or severe musculoskeletal deformities that would limit their ability to perform the exercises or participate in motor pattern activities. Exclusion of children who have received Botox injections or undergone surgical procedures in the last 6 months, as this may influence muscle tone and reflexes. Children with a history of uncontrolled seizures, which might interfere with therapy participation or safety. Children who were uncooperative Children who have visual and intellectual impairments CP include hemiplegic CP, Quadriplegic CP, Ataxic CP, Athetoid CP, Mixed CP, and hypotonic CP. With any Hearing deficit Any Sensory loss Any history of Tumors and severe mental abnormality Any cardiac anomalies affecting exercise tolerance

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

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

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

**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**
No. TUF/DR/SA/MSPP/2024/405

## Health conditions studied

### 1

**Description of health condition studied**
spastic cerebral palsy children
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Trunk Control
**Timepoint**
baseline intervention and 5 weeks post intervention
**Method of measurement**
trunk measurement scale

## Secondary outcomes

### 1

**Description**
Primitive Reflexes
**Timepoint**
baseline intervention and 5 weeks post intervention
**Method of measurement**
Primitive reflexes Screening evaluation form Present & overcome

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: Functional Electrical Stimulation with Roods ontogenic motor pattern Group A Functional electrical stimulation before the treatment was done as a baseline treatment. Then, the Roods Ontogenic Motor patterns were applied. Roods Ontogenic Patterns These are normal developmental patterns which will used as a basis for therapy. These patterns have beneficial effects when combined with occupational engagement and can be used for inhibiting or facilitating by positioning in these patterns.1. Supine withdrawal (Supine flexion): Total flexion response toward the vertebral level of T10. this position is protective because flexion of the neck and crossing of the arms and legs protect the anterior surface of the body. this pattern is recommended for individuals dominated by extensor tone.2. Rollover (Toward side lying): Rollover is a mobility pattern for extremities and activates the lateral trunk musculature. it is encouraged for individuals who are dominated by tonic reflex patterns in the supine position.3. Pivot prone (prone extension): This position demands full range extension of neck, shoulders, trunk, and lower extremities. it is both a stability and mobility pattern. it plays an important role in preparation for stability of the extensor muscles in the upright position.4. Neck co-contraction (co-innervation): This action is thought to activate both flexors and deep tonic extensors of the neck. this position elicits tonic labyrinthine righting reaction and also promotes stability and extra ocular control.5. On elbows (prone on elbows): Bearing weight on elbows stretches the upper trunk musculature to influence stability of the scapular and gleno-humeral regions. this position is inhibitory to symmetrical tonic neck reflex.6. All fours (quadruped position): The lower trunk and lower extremities are brought into a co contraction pattern. The weight shifting is preparatory to equilibrium responses.7. Static standing: Assuming the bipedal position. this position brings about higher-level neurological integration, such as righting reactions and equilibrium reactions. 8. Walking: Walking includes stance phase, push off, swing, heel strike and stride length. it is a sophisticated process requiring coordinated movement patterns of various parts of body including weight shifting. 2sets 3-5 repitition
**Category**
Rehabilitation

### 2

**Description**
Intervention group: Functional Electrical Stimulation with Swiss Ball Stabilization Exercises Group BAs 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 of “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 instructing to perform rhythmical movements.1.Optimal arousal Swiss ball Make the child bounce, active/passive on the Swiss ball, slow/fast 5 times 5 sets .2. Combined frontal and transverse plane movements Swiss ball High sitting: one hand weight bearing followed by trunk rotation to reach the toy on opposite side 5-7 times each side 1 set 3. Trunk activation activities Swiss ball High sitting foot placing on the ground: throwing the ball with both the hands. 5 times 1 set 4.Roll the ball maximum backward and hold for 10s, keeping pelvis in neutral, knee in extension, 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 side 1 set 6.Reaching the toy with both the hands kept little back with trunk rotation toward the reaching side 5 times each side 1 set 7.Prone posture was applied on way to & FRO & spinning with sway accompanied by volitional upper extremity like super man 5 times 1 set 8. Pressure time with a therapy ball Front & back pressure 3 times 1 set

**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**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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## 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**
Comparative Effects Of Roods Ontogenic Motor Patterns And Swiss Ball Stabilization Exercises On Primitive Reflexes 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), and self administrated primitive reflexes chart as outcome measure tools.
**When the data will become available and for how long**
15 days after publication
**To whom data/document is available**
google scholar,pedro
**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**