Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on trunk control, balance, motor skill and 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 trunk control, balance, motor skill and 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

• 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 • 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

Intervention groups

Baseline Treatment with Functional Electrical Stimulation Group A Functional electrical stimulation before the treatment was done as a baseline treatment. Then, the Roods Ontogenic Motor patterns through inhibitory approaches were applied. Group B 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 Primitive Reflexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240306061198N1**
Registration date: **2024-04-03, 1403/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-03, 1403/01/15**
Update count: **0**

Registration date

2024-04-03, 1403/01/15

Registrant information

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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
Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on trunk control, balance, motor skill and primitive reflexes in spastic diplegic cerebral palsy children

Public title
Comparative effects of roods ontogenic motor patterns and swiss ball stabilization exercises on trunk control, balance, motor skill and primitive reflexes in 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
3
Groups that have been masked

- Participant

Sample size
Target sample size: **22**
Actual sample size reached: **20**
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
Spastic diplegic cerebral palsy gross motor function level pediatric berg balance scale gross motor function-88, modified Ashworth Scale

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
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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 Diplegic Cerebral Palsy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Trunk Control
Timepoint
baseline intervention and 5weeks post intervention
Method of measurement
gross motor function scale GMFS-88

2

Description
Gross motor function/ GMFMS LEVEL
Timepoint
baseline intervention and 5 weeks post intervention
Method of measurement
gross motor function scale 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: 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.
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

Name of recruitment center
Children Hospital & Institute of Child Health ,Faisalabad

Full name of responsible person
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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
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Latest degree
Master

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
Comparative Effects Of Roods Ontogenic Motor Patterns And Swiss Ball Stabilization Exercises On Trunk Control, Balance, Motor Skill And 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), 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
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