Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of roods ontogenic motor patterns on trunk control and balance in spastic diplegic cerebral palsy children

Protocol summary

Study aim
The purpose of this study to check the effects of Roods Ontogenic motor patterns on trunk control and balance in spastic diplegic cerebral palsy children.

Design
Non-Probability Consecutive sampling, single blinded , no phase

Settings and conduct
study was conducted at children hospital Faisalabad.

Participants/Inclusion and 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 children diagnosed with spastic cerebral palsy EXCLUSION CRITERIA Participants are excluded on following 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

Intervention groups
Baseline Treatment with Functional Electrical Stimulation then our intervention depands on Roods Ontogenic Motor patterns through inhibitory approaches were applied.

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: **IRCT20240306061198N3**
Registration date: **2024-04-17, 1403/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-17, 1403/01/29**
Update count: **0**

Registration date
2024-04-17, 1403/01/29

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 Effect of roods ontogenic motor patterns on trunk control and balance in spastic diplegic cerebral palsy children

Public title
The Effects of roods ontogenic motor patterns on trunk control and balance and motor skill and primitive reflexes among spastic diplegic cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Both gender male and female. Child age with 3-10 years. 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
1

Groups that have been masked

- Participant

Sample size
Target sample size: **22**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
non-probability consecutive sampling, 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 study was conducted to minimize the chance of biasness, this study design was used to allocate the members in comparable groups.This descriptions involve concealing details that could bias assessors when evaluating retrieval systems or algorithms. This ensures fair and unbiased evaluation of the systems' performance.

Placebo
Not used

Assignment
Parallel

Other design features
Spastic diplegic cerebral palsy gross motor function pediatric berg balance 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

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
G80.1

ICD-10 code description
Congenital spastic paralysis (cerebral) Spastic cerebral palsy NOS

Primary outcomes

1

Description
Trunk control

Timepoint
baseline intervention and 5weeks post intervention

Method of measurement
gross motor function scale

2

Description
Gross motor function
Timepoint
baseline intervention and 5 weeks post intervention
Method of measurement
Gross motor function scale

3

Description
balance
Timepoint
baseline intervention and 5 weeks post intervention
Method of measurement
pediatric berg balance scale

Secondary outcomes

1

Description
Modified Ashworth scale for spasticity
Timepoint
before and after 5 weeks of intervention
Method of measurement
Modified Ashworth scale

Intervention groups

1

Description
Intervention group: FES with Rood ontogenic motor pattern,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
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
Street address
GC University, Jhang road,New Campus Faisalabad, Punjab
City
Faisalabad
Postal code
38000
Phone
+92 41 9203065
Email
2022-ms-pt-044@tuf.edu.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Faisalabad
Full name of responsible person
Dr.Zainab Boota PT
Street address
Faisal Town, West ,Canal Road, Faisalabad, Punjab
City
Faisalabad
Postal code
38000
Phone
+92 335 7916317

Email
zainboota9698@gmail.com
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.Zainab Boota PT
Position
Clinical Consultant Physiotherapist
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Faisal Town, West ,Canal Road, Faisalabad, Punjab
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 335 7916317
Email
zainboota9698@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
The University of Faisalabad
Full name of responsible person
Dr.Wardah Jabbar
Position
Clinical Consultant Physiotherapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Faisal Town, West ,Canal Road, Faisalabad, Punjab
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
0092413138650848
Email
wardah.jabbar5@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The University of Faisalabad
Full name of responsible person
Dr.Syed Saqlain PT
Position
HOD Khadija Mahmood Trust Hospital Faisalabad
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
mohalla khalidabad #2 neighbanpura tower road, Faisalabad, Punjab
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
0092413156205017
Email
Syedsaqlain264@gmail.com

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 effect of Roods ontogenic motor pattern on trunk control and balance in spastic diplegic cerebral palsy. 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