STUDY PROTOCOL

Effectiveness of pelvis and trunk stabilization exercises over conventional physiotherapy to improve dynamic trunk balance in cerebellar ataxia: a randomized controlled trial

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Abstract

Cerebellar ataxia is caused by several hereditary or acquired aetiologies that eventually lead to abnormalities in the cerebellum. Patients with cerebellar ataxia may experience balance issues, eye movement abnormalities, limb incoordination, gait instability, and speech impairment as a result. The available treatment options for cerebellar ataxia are rather limited, causing many patients to struggle with daily activities. Although the success rate of a range of therapeutic interventions has been determined, evidence-based exercise guidelines for the treatment of balance disorders and associated problems in people with cerebellar ataxia are currently unavailable. Thus, physiotherapists must explore novel approaches to successfully manage the symptoms of ataxia and further improve the quality of life of patients. The current study protocol will provide new insight as no article available to date has looked at trunk and pelvis stabilization exercise programme as an intervention for treating cerebellar ataxia.

We hereby propose a study, which aims to investigate the impact of conventional exercises and trunk and pelvis stabilization exercises along with conventional exercises on subjects with Cerebellar ataxia in a two-arm randomized controlled trial on improving SARA, TIS, BBS, Barthel Index, WHOQOL. The total participants will be divided into two-arm parallel groups and the intervention will be given for complete 6
weeks, 5 days in a week. The outcome measure will be evaluated at baseline and the end of 6 weeks. The results will be evaluated after 6 weeks. If the hypothesis of our study proves to be effective, then this physiotherapy intervention could be included in the management of cerebellar ataxia

Keywords
Cerebellar ataxia, Proprioceptive Neuromuscular Facilitation, Balance, Physiotherapy interventions, randomized controlled trial, Quality of life., Trunk impairment scale, Severity of Ataxia Scale
Introduction

Cerebellar ataxia refers to a cluster of movement disorders caused by the vandalization of the cerebellum or its connections. The cerebellum oversees ensuring the precision and uniformity of actions required for centered motor action. The vestibular component of the cerebellum is crucial for coordinated movements. Cerebellar dysfunction is characterized by ataxia, hypotonia, asynergia, dysmetria, nystagmus, dysdiadochokinesia, tremor, and cognitive inabil-

ity. Hemorrhagic stroke, cerebellar stroke, medications (phenytoin, carbamazepine, lithium), meningitis, and abscesses are examples of acute causes of ataxia. Brain tumors, genetic ataxia, degenerative diseases, cerebellar atrophy, and cerebellar degeneration are examples of subacute and chronic causes. Patients report a significant loss of quality of life and a subsequent decrease in daily living activity performance. Varieties of ataxia are linked to decreased balance. Tumbles caused by impaired balance are common in people with cerebellar ataxia, with more than 70% experiencing at least one fall in the next 12 months.

To date, no effective pharmacological treatments have been available that have worked efficiently in decreasing or slowing the progression of pathology. Physiotherapy-centred rehabilitation exercises play a crucial role in controlling ataxia progression and improving patients’ functions. Rehabilitation strategies can aid in the abolition of balance and gait disorders, the decrease of fear of falling, and the increase of social participation, and independence in daily life activities. Moreover, to prevent secondary complications and promote the independence of the patient, exercises play a very vital role. Static cycling, biofeedback, treadmill training, gaze stimulation exercises and Opto-kinetic stimuli are known to improve balance and functional independence. Growing gait ataxia frequently results in decreased mobility and the ability to engage in everyday activities, thus negatively impacting the quality of life.

Despite the fact that the trunk is recognized as a significant variable in activity and is frequently affected in dysfunction of cerebellum, it is neglected routinely in rehabilitation. Pelvis is marked as a key structure that works to join the trunk to the lower limbs. The function it performs is to connect the trunk to the lower extremities, support the body’s weight, transferring its load onto the lower limbs, and bears the body’s weight and shifts its load to the lower limbs. Pelvic stability is defined as the ability of the lower trunk and proximal hip muscles to coordinate with their own activity while performing balance and mobility activities in which the pelvis supports dynamic balance in order to allow for effective lower limb mobility. A strong trunk allows for more regular movement in the rest of the body. Trunk stabilisation is required to support upper and lower extremity movements, meet loads, and protect the spinal cord. During kinetic chain activities, the trunk muscles act as a corset to provide both a stabilising and a mobilising function.

Trunk stabilization training intends to enhance the control of the muscles required to brace the trunk against internal as well as external forces. Although all abdominal muscles contribute to vertebral stability, rehabilitation programs have focused on the transversus abdominis muscle, for evaluation and training. Pelvic proprioceptive neuromuscular facilitation boosts joint proprioception, which enhances pelvic control, which is further important for maintaining control of the trunk, and balance. Techniques such as rhythmic initiation aid in the movement of the limb or body through the desired range of motion, beginning with passive motion and progressing to active resisted movement. There is a dearth of literature stating the impact of pelvis stabilization exercises and trunk stabilization exercises on achieving dynamic trunk control in patients with cerebral ataxia. Thus, there is a need to conduct a study on the independent effects of the pelvis and trunk stabilization exercises to achieve dynamic trunk balance in patients with cerebral ataxia.

The designed intervention aims to see the impact of the pelvis and trunk stabilization exercises over conventional physiotherapy exercises on dynamic trunk balance in patients with cerebellar ataxia in two-arm parallel/open-label equivalence randomized controlled trial in improving TIS, SARA, BBS, Barthel index, and WHOQOL on marginal difference.

Aim and objectives of the study

Primary objective:

1. To study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving severity of ataxia using the Severity of Ataxia Scale (SARA).
2. To study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving Trunk balance using the Trunk Impairment Scale (TIS).

3. To compare the effects of Pelvis and Trunk stabilization exercises over Conventional Physiotherapy exercises to improve Severity of ataxia, and trunk balance using Severity of ataxia scale and, Trunk impairment scale.

Secondary objective:

1. To study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving balance using Berg Balance Scale.

2. To study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving activity of daily living using the Barthel index.

3. To study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving quality of life using the World health related quality of life.

4. To compare the effects of Pelvis and Trunk stabilization exercises over Conventional Physiotherapy exercises to improve balance, activities of daily living and quality of life using Berg balance scale, Barthel index and World health related quality of life.

**Trial design**

Single-centric, two arm parallel open label equivalence, randomized controlled trial.

**Ethical considerations** – Approval was obtained from the Datta Meghe Institute of Higher Education and Research. **IEC no.** – DMIHER (DU)/IEC/2023/812 **IEC approval date** – 21/03/2023.

**Consent**

Patients will be explained about the study procedure in their native language. Informed written consent will be obtained from all study participants.

**Methods**

This is an interventional study, where participants will be recruited from Physiotherapy OPD of Acharya Vinoba Bhave Rural Hospital Sawangi, Meghe, Wardha, Maharashtra. After receiving an approval from institutional ethics committee of Datta Meghe Institute of Higher Education and Research. Study participants will be divided into Arm-A (Control group) and Arm-B (Interventional-group) with an intent to treat cerebellar ataxic population. A written consent form will be obtained from each patient. Participants will be assessed and screened using inclusion and exclusion criteria of the study. 1:1 allocation will be done with an intent to treat the cause. Randomization will be done using computer-generated system. The study is a parallel group-RCT with two arms for subject allocation. Arm-A will receive Conventional Physiotherapy exercises whereas, Arm-B will receive Trunk and pelvis stabilization exercises along-with physiotherapy exercises. The primary and secondary outcome measures used in the study will be quantified at baseline and at the end of the six-week treatment by a postgraduate resident in neuro-physiotherapy with similar expertise who is aware of the study but blind to the intervention. The design of study is visualized in (Figure 1). The study will be monitored PG guide, HOD, principal and chief advisor of research cell. The final dataset will be uploaded to institutional research website and will be accessible to concerned authorities.

**Eligibility criteria**

**Criteria for inclusion of subjects**

1. Patient diagnosed as Cerebellar Ataxia by Medical Doctor.

2. Both Male and Female gender.

3. Above 30-60 years of age.

5. Those willing to participate in the study.

6. Those having ability to understand and follow instructions.

Criteria for exclusion of subjects

1. Patients having musculoskeletal injury limiting ability to bear weight.

2. Conditions that impact lower limb mobility.

3. Subjects with unstable cardiovascular condition, as determined by the physician.

4. Patients having significant cognitive impairments, limiting ability to give informed consent.

5. Participants enrolled in another clinical trial.

Interventions

Group A (Conventional group): Participants in this group will undergo 60 minutes of conventional therapy. It will include strengthening, sensory stimulation, stretching, mobilising, and teaching functional mobility for the upper and lower limbs. It will be performed for six weeks, five days per week. Identification of weakened muscles will be done. Strengthening exercises for weakened trunk and lower limb at standing, sitting and supine position will be performed. Sensory stimulation will be provided through active ankle mobilisation. Active and functional training will be supplemented with passive mobilisation and stretching. Stretching for lower limb muscles will be done. The hold time for stretching will be 30 seconds with a rest duration of ten seconds. For functional ability, common mat activities will be incorporated.6
Group B (Interventional-group): Participants in this group will undergo trunk and pelvic stabilization exercises along-with Conventional physiotherapy exercises. Trunk stabilization exercise will include Trunk Proprioceptive neuromuscular Facilitation (PNF). Trunk PNF will include patterns like, Chopping, Lifting, Bilateral lower extremity flexion with knee flexion for lower trunk flexion, Bilateral lower extremity flexion with knee flexion for lower trunk extension, Trunk Lateral flexion, right lateral flexion with extension. Each exercise will be performed in ten repetition set with hold time being five to ten seconds and relaxation time being five seconds. Pelvis Stabilization exercise will include Pelvic Proprioceptive neuromuscular Facilitation (PNF). Pelvic motions like anterior elevation, posterior depression, posterior elevation, and anterior depression will be performed. Rhythmic initiation technique of PNF will be used to perform patterns with further progression into combinations of isotonics, dynamic reversal, stabilizing reversal followed by contract relax and hold relax technique. Each exercise will be performed for five repetitions, Sessions/Day three times, with a hold time of five seconds, rest time of two seconds.

Outcome measures
Primary outcome measures

1. **Change in Trunk impairment scale (TIS) Score**
   The trunk impairment scale totals the scores for static and dynamic sitting balance, as well as coordination. It is a 17-point scale. Its continued use in clinical practice and research is supported. To rate the quality of trunk movement, the scale can be used as a treatment guideline. The highest score is 23, the lowest is 0, and the total inter-observer reliability is 0.99.

2. **Severity of Ataxia Scale (SARA) Score**
   Schmitz-Hibusch developed this scale as a clinical assessment tool for calculating the severity of ataxia. It evaluates upper and lower limb ataxia, gait, and balance. It is divided into 8 categories, with a score ranging from 0 (no ataxia) to 40 (the most severe ataxia).

Secondary outcome measures

1. **Change in Berg Balance Scale Score**
   It is a performance tool that is based on balance. It is a 5-point scale, with each task scored between 0 and 4. The highest possible score is 56. It includes 14 tasks that are scored between 0 and 4. A participant’s maximum total score is 56.

2. **Change in Barthel Index Score**
   It is a 10-item assessment scale used to measure the performance of daily living activities. A lower score denotes more dependency.

3. **Change in World health-related quality of Life (WHO-QOL) score**
   It is a self-reported questionnaire consisting of 26 questions on patients’ health and well-being.

Sample size calculation
This study protocol will be an independent two-group study investigating the efficacy of trunk and pelvis stabilization exercises over conventional physiotherapy exercises to improve dynamic trunk balance in cerebellar ataxia. G. Power 3.15 software was used to determine the total participants.

Formula using mean difference

\[ n_1 = n_2 = \frac{2\left(Z_a + Z_b\right)^2 \sigma^2}{\delta^2} \]
Primary variable (Trunk Impairment Scale)
Mean ± SD. (Pre) result on Trunk Impairment Scale for experimental group = 5.17 (1.26)
Mean ± SD. (Post) result on Trunk impairment Scale for experimental group = 9.13 (1.72)
Difference = 3.96 (3.27 to 5.05). (As per reference Article)
Pooled standard deviation. = (1.26 + 1.72)/2 = 1.49
Clinically relevant superiority = 30% = (3.96 *30)/100 = 1.188
As per reference articles.
\[
N_1 = 2\left[\frac{(1.64 + 0.84)^2(1.49)^2}{(1.188)^2}\right] = 19.34 = 20
\]
Total samples required = 20 per Group.
Considering 10% dropout = 2
Total samples required (n1 = n2 = 20 per group)
The total sample size required (N) = 2*20 = 40
Notations:
\[
Z_\alpha = 1.64
\]
\[
\alpha = \text{Type I error at 5%}
\]
\[
Z_\beta = 0.84 (1 - \beta) = \text{Power at 80%}
\]
\[
\sigma = \text{std.dev}
\]
Reference Article: Effects of Pelvic Stability Training on Movement, Control, Hip Muscles Strength, Walking Speed, and Daily Activities after Stroke: A Randomized Controlled Trial.3

Discussion
People suffering from ataxia might regard physiotherapy as their “sole faith”. We intended to investigate the impact of the pelvis and trunk-stabilization exercises over conventional physiotherapy exercises on dynamic trunk balance in individuals suffering from cerebellar ataxia. Further, the study’s objective is to study the effect of pelvis and trunk stabilization over conventional physiotherapy in improving balance using the SARA, BBS, TIS, Barthel Index, and WHOOQL as outcome measures. The results of the study will be assessed at baseline and after 6 weeks of study. Mohammad Elshafey et al. (2022), carried out a study, to determine the impact of a core stability exercise program on coordination and balance in children with cerebellar ataxia.12 Winser et al. (2022), published a systematic review – meta-analysis to study the implications of therapeutic exercise on the severity of disease, balance, and functional independence in cerebellar ataxia patients.13

Further, Dubey et al. (2018), published an RCT concluding the positive impact of pelvis exercise on movement, and muscle strength of walking in stroke patients. Patients with cerebellar ataxia show greater trunk movements which reflect a lack of coordination between the segments of the body which impacts the spatiotemporal variables of gait local stability.14 According to Marimuthu et al (2022), trunk and neck-specific PNF exercises proved to be a useful intervention in improving balance and trunk control among patients.15 Cerebellar ataxia is associated with cerebellar dysfunction and various balance disorders.16 Further, Poor predictive control has been known to negatively impact the feed-forward part of the movement, which has been associated with the motor symptoms of cerebellar damage.17
The current study protocol will provide new insight as no article available to date has looked at trunk and pelvis stabilization exercise programs as an intervention for treating cerebellar ataxia.

**Analysis**

R studio software 4.3 version will be used to calculate the results. Descriptive statistics will be calculated on the quantitative assessment over the parameters for mean, standard deviation, maximum, minimum, and median for the variables (age, gender, hand dominance). For qualitative assessment frequency and percentage will be calculated over the variables (gender, hand dominance). All the results for the inferential statistics will be tabulated and tested for significance at a 5% level of significance (P < 0.05). The outcome variables (Primary variables: Trunk impairment scale for dynamic trunk balance, Severity of ataxia scale for calculating ataxia severity, and, Secondary variables: Berg balance scale for calculating balance, Barthel index for evaluating independence in activities of daily living and World health-related quality of life for evaluating the quality of life) will be evaluated for testing pre and post result using paired t-test. The outcome variables will be initially tested for normality using Kolmogorov-Smirnov Test for data testing. If data fails to follow normality will be attempted to transform in normal distribution using mathematical algorithm tests like Log Function, Inverse Function, Exponential function, or Boxcox transformation. If data persists with non-normal distribution then, Alternative non-parametric test will be used for the parametric test result. For the paired-t test, an alternative Wilcoxon sign t-test will be used. An unpaired t-test will be used to find significant differences over the mean for both primary and secondary variables between the control and interventional group. Alternate non-parametric Mann-Whitney will be used. Association analysis for finding sig for the unpaired t-test. The significance of cofounding parameters will be evaluated by using the Chi-squared test or Fisher’s exact test or by using multi-varient analysis.

**Study status**

Not started.

**Dissemination**

Planning to present my study protocol at the conference preceding.

**Data availability**

Not applicable as it’s a study protocol.

**Reporting guidelines**

Zenodo: SPIRIT_checklist.docx. DOI: https://doi.org/10.5281/zenodo.8013885

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**References**


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