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Research Article

Impact of a sitting training program for the improvement of independent sitting control in children with Cerebral Palsy and its association with the quality of life of their mothers – A Randomized Control Study Protocol

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ABSTRACT

Introduction: Children with Cerebral Palsy (CP) show sensory, motor, and perceptual impairments that may influence the development of trunk control and achievement of independent sitting control. This leads to the loss of other milestones that might affect the overall development of the child and increase the caretaking burden. Disabilities of children may burden their family members, especially their mothers, who are their long-term caregivers. The study outlines the protocol for a randomized controlled trial evaluating a sitting training programs efficacy in enhancing independent sitting control among children diagnosed with Cerebral Palsy. Furthermore, it aims to investigate the potential impact of improved sitting control on the quality of life (QoL) of their mothers.

Methods and analysis: Protocol for a prospective, double blinded, randomized, controlled trial. Seventy-two children with mild to moderate CP (Gross Motor Function Classification Scale – ER III & IV) aged between 3 years and 7 years along with their mothers will be recruited. Participants will be randomly allocated to two groups: sitting training group and conventional therapy group. The outcome measures will be Trunk control measurement scale (TCMS) and World Health Organization Quality Of Life (WHOQOL-BREF). The outcomes are assessed at baseline, 6 weeks and 8 weeks.

Ethics and dissemination: This study has approval from the institution ethics committee (ECR/677/Inst/PY/2014/RR-17). Results will be disseminated in journals, conference and among participants to complement their existing therapy.

Discussion: This study describes the background, hypotheses, rationale, and methodology of the protocol for a sitting training program for children with spastic cerebral palsy and will follow CONSORT and SPIRIT guidelines for reporting. The proposed sitting control training represents a novel approach to addressing core stability and sitting control in children with cerebral palsy. Improved sitting control promotes socialization, engagement in everyday activities, and the development of new motor skills that may provide valuable insights into the potential benefits of sitting control beyond the child's physical abilities, highlighting its potential to improve overall family well-being.

Key Words: Cerebral palsy, sitting control, quality of life, mothers, intervention

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Background

Cerebral palsy (CP) refers to a collection of permanent disorders of the development of movement and posture. These disorders result in activity limitation and are caused by non-progressive disturbances in the developing and maturing fetal or infant brain. The motor disorder is frequently accompanied by alterations and disruptions of sensation, cognition, communication, perception, behavior and by a seizure disorder, leading further to activity limitation and restricted participation [1,2]. Literature has documented the range of CP from 1.5 to 4 per 1000 live births globally but the prevalence range reported for India is higher ranging from 2.08 to 3.88 per 1000 live births [3,4].

Cerebral palsy (CP) is commonly diagnosed by evaluating motor function and postural deficits that manifest in early childhood and remain throughout an individual's life, hindering their ability to fulfill social tasks for both themselves and their parents [5, 6]. The ability to sit upright is a fundamental requirement for participating in daily activities and the earliest form of upright posture achieved during an individual's normal developmental stage. Children with CP have poor trunk control, due to postural, proprioceptive, somatosensory, perceptual motor dysfunctions, weak trunk muscles, altered neural control, and insufficient trunk core stability thus affecting their sitting control. A delay in the acquisition of neck and trunk control response affects the development of muscular strength and limits the overall activity of the child during sitting, playing, feeding, toileting, and other activities of daily living. This leads to the loss of other milestones that might negatively impact the overall quality of life of the child and increase the caregiver overload [7 - 15]. Mothers perform and function as the primary caregivers within most Indian families thus affecting the quality of life of mothers too [16]. Hence, this study aims to investigate the impact of sitting control training in children with cerebral palsy and to explore the relationship of independent sitting control on the Quality of Life (QoL) of their mothers

Objectives:

1. To evaluate the impact of independent sitting control among the children with cerebral palsy on the quality of life of their mothers as measured by the World Health Organisation Quality of Life Brief Questionnaire (WHO QOL BREF).

Research Hypothesis:

Based on the aforementioned objective, the following hypothesis is formulated;

The tailored sitting training program is expected to result in substantial enhancements in the independent control of sitting among children with Cerebral Palsy, consequently enhancing the quality of life for their mothers.

Theoretical Perspective

Postural control in sitting

Maintaining an upright body alignment in space is known as postural control. This entails regulating the body's position to achieve stability and orientation. Achieving stability and orientation requires integrating sensory input from the visual, vestibular, and somatosensory systems and motor output [17, 18]. Postural control involves a complex interplay of seven components: neuromuscular synergies, internal representations, adaptive mechanisms, anticipatory mechanisms, sensory strategies, individual sensory systems, and musculoskeletal components. This is explained by Motor Program theory, neural group selection theory (NGST), and Systems Control Theory [19-22].

Postural control dysfunction in children with cerebral palsy is caused by primary brain injury, resulting in deficits in motor, perceptual, and sensory networks. This leads to issues with sitting control and can cause perceptual and motor learning deficits. Children diagnosed with GMFCS - ER Level III – IV [23] cerebral palsy exhibit compromised trunk control, resulting in challenges in accurately modifying their basic direction-specific responses to environmental stimuli and adapting their postural muscular activity. These adjustments are contingent upon prior experiences and sensory input from the somatosensory, visual, and vestibular systems [24–26]. Failing to acquire these adjustments exacerbates postural instability during sitting.

Postural stability in sitting refers to the ability to control the center of mass of the body within the support base, which is crucial for preventing falls and controlling desired movements. Acquiring sufficient strength, power, and endurance in the core muscles is essential for maintaining spinal stability and producing functional movement. [27–30]. Individuals diagnosed with cerebral palsy experience challenges in effectively distributing their body weight during static balance and weight transfer [10–12,15]. Children with cerebral palsy experience a reduction in their ability to generate force, resulting in weakened core muscle strength. They may also have a diminished sense of their body's position and movement in relation to their surroundings. This leads to difficulty in coordinating the muscles involved in stabilizing the trunk, pelvis, and hips, which can ultimately affect their sitting control [25–30]. Therefore, poor core stability may lead to a decrease in a child's functional capabilities and lower gross motor skills level. This intervention focuses on using core muscle training exercises with sensory and perceptual feedback strategies to improve trunk function and independent sitting control in children with cerebral palsy.

Quality of life (QoL) of mothers

QoL is defined as "individual's perception of their position in life in the context of culture and value systems in which they live concerning their goals, expectations, standards and concerns". Health and well-being are influenced by various factors, including physical health, psychology, independence, social relationships, spirituality, beliefs, religion, and

environment [31,32]. The measurement of QoL is directly linked to the daily care practices of health services and has been used as an important indicator for assessing the effectiveness and impact of specific treatments for patients with several disabilities, including Cerebral Palsy (CP) [31].

Cerebral palsy is a condition that places a heavy burden on patients, their families, and the healthcare system. Although caregiving is a normal part of being the parent of a young child, this role takes on an entirely different significance when a child experiences functional limitations and possible long-term dependence [32]. Consequently, the task of caring for a child with complex disabilities at home might be challenging for caregivers. The provision of such care may prove detrimental to both the physical health and the psychological well-being of parents of children with chronic disabilities [32,33]. Poor caregiver health has negative implications for the child, the family, and the community as a whole, resulting in decreased work productivity and increased healthcare costs for the caregiver, as well as increased services and costs for the child [34]. Children with disabilities can have implications on their families, particularly their mothers who often act as their primary caregivers within Indian households [35]. Therefore, it is considered that mothers undertaking the most significant role in the rehabilitation and caring for the child, should be involved in the management of cerebral palsy children.

Scope of the study

Cerebral palsy presents significant challenges for patients, their families, and the public healthcare system. While caring for a young child is a common part of parenting, it takes on a different meaning when a child experiences functional limitations and potential long-term dependence [31]. A child's ability to sit is crucial for their development as it facilitates socialization, engagement in daily activities, and the development of motor skills. Poor sitting control in children with cerebral palsy can hinder their independence and participation in age-appropriate activities. Consequently, caregivers may struggle to support a child with complex disabilities at home [32, 33]. The presence of disabled children within families, can have far-reaching implications particularly on the mothers. Mothers who experience poor health often face a diminished quality of life, which in turn can have adverse effects on the well-being of the child, the family unit, and the broader community [31–33]. Therefore, we believe that mothers, who play a significant role in the care and rehabilitation of children with cerebral palsy, should be involved in their management. Mothers of children with cerebral palsy face specific challenges in providing care, managing their emotions, and experiencing disruptions in their quality of life [35]. This decreased QoL is often linked to the physical and emotional demands of caregiving, including challenges related to a child's limited mobility [31-35]. Hence the study protocol aimed to investigate the potential impact of improved sitting control among children with cerebral

palsy and its association with the quality of life of their mothers.

Method

Study design:

This is a prospective, parallel group, double-blinded randomized, two-arm clinical trial with equal arm allocation. This prospective community study will be conducted in Puducherry state, India. The target population is children with CP and their mothers. The study has been prospectively registered with the Clinical Trial Registry of India (CTRI/2022/10/046279)

Participants and recruitment

The study aims to recruit 72 children with mild to moderate cerebral palsy [Gross Motor Function Classification Scale – Extended Revised (GMFCS - ER) III – IV] aged between 3 years and 7 years old registered at the District Intervention Center, National Health Mission, Government of Puducherry as well as from the special schools in Puducherry. All children must have sufficient cognitive understanding to perform the tasks and with parental consent to participate in the study.

Inclusion criteria:

- Children with spastic cerebral palsy aged 3 to 7 years who can follow verbal commands with no cognitive impairment and categorized as level III - IV Gross Motor Function Classification System – Extended Revised (GMFCS - ER)
- Mothers having and living with cerebral palsied children

Exclusion criteria:

- Children who are uncooperative or have intellectual, visual, or hearing impairments.
- Children taking antiepileptic or antispasticity medications.
- Children with any cardiac abnormalities.
- Children who have undergone orthopedic surgery or botulinum toxin injections within the past four months.
- Other types of cerebral palsy
- Mothers having another patient or disabled individual along with the cerebral palsy child at home are excluded from the study

Sample size:

Sample size is estimated using the formula to compare two independent means. The planned study sample size has been estimated from a power calculation based on a previous literature data using minimum expected clinical significant difference in the TCMS score between the group as 10 with a standard deviation (S. D) of 15 at 5 % level of significance and 80% power, and accounting for a 10% dropout rate. Based on the formula a sample size of 72 (36 in each group) was estimated [36,37].

Randomisation and Allocation

Demographic information will be collected before randomisation. Participants will be randomly assigned to either the Sitting training group (Group I) or the

conventional therapy group (Group II) by block randomisation. Block randomisation using a computer-generated sequence will be done by independent research support staff to ensure equal distribution of subjects in each group. The process is blinded from the primary investigator and allocator and is set up in advance before the study. Allocation to Group I or II will be recorded on paper, folded, and placed in opaque sealed envelopes by an impartial staff member not connected with the study. After obtaining informed consent, participants will be irreversibly assigned to their respective groups by opening sealed envelopes containing their assignments.

Blinding

Therapists assessing outcomes and mothers of cerebral palsied children will be blinded to group allocation. If a child is unable to undergo the intervention for more than 4 weeks due to an unrelated adverse event, unmasking will be done and will be recorded and reported.

Retention

Participant retention will be promoted through consistent contact, counselling to parents, addressing their queries and by coordinating assessment and intervention sessions as per their needs and convenience.

Safety and Adverse Events

Adverse events from intervention and assessment are not anticipated. Adverse events if any will be reported to the Ethical committee and documented. Standard ICMR (Indian Council of Medical Research) COVID-19 protocol will be adhered. The ethical review process, conduct of the trial will be monitored by the Institution ethics committee.

Data Management

The principal investigator will preserve password protected data on the patient's unique ID, block number, block sizes and treatment versus control groups. Participants unique identification codes will be used to deidentify hardcopy and electronic files. Paper copies relating to assessment, consent form, results, and any other documents pertaining to the study will be deidentified and physically stored in a locked cabinet. Data will be made available while disseminating in journals but the confidentiality of the study participants will be preserved

Baseline measures

Demographic information regarding participant's socio – economic background, educational background, including gestational age, comorbidity will be obtained by interviewing the mother.

The assessment of sitting control will be done quantitatively by observation through Trunk control measurement scale (TCMS). The QoL is by face-to-face interview with mothers of cerebral palsied children in their mother tongue on the WHOQOL – BREF scale (Tamil version). All the outcome measure will be assessed for baseline characteristics and at the end 6

weeks to prevent attrition bias and to improve the design strength and 8 weeks of the intervention.

Intervention

The intervention for the Cerebral palsy child will be as per (Standard Protocol Items: Recommendations for Interventional Trials) SPIRIT guidelines (*Table 1*) [38,39]. Group 1 (Sitting control training group) participants will receive the conventional therapy comprising of range of motion exercise, strength training, passive stretching, functional training, coordination training, along with sitting control training. Group 2 (Conventional therapy group) participants will receive the conventional therapy comprising of range of motion exercise, strength training, passive stretching, functional training, and coordination training in the existing treatment setting itself.

Sitting control training are a set of tailored facilitating exercises done on an exercise ball, bolster or on a different textured surface, targeting the core muscles with facilitation, assistance and support wherever required with adequate rest period. The program is designed to enhance the interaction of children with their environment in an attempt to develop the perceptual motor attributes, balance, hand-eye coordination, ocular control, and gross motor coordination. The child will be trained on trunk activities targeting the core muscles. The therapist facilitate the child by hands to meet the requirements of the task by providing optimal alignment of the pelvis for the weight shifts at hips and elongation of the trunk toward the reaching side of the task. The child will be further challenged by activities through tactile, vestibular, proprioceptive, visual-spatial orientation of gross motor accommodation giving very light cues or assistance. The focus is on helping the child utilize forces to obtain a functional goal through their own movement strategy by engaging the core muscles. Each exercise session will be for one hour, three times per week for successive 8 weeks.

The conventional therapy given to the control group as per their own treatment setting consists of range of motion exercise, strength training, passive stretching, functional training, sitting balance, and coordination training. Each exercise session will be for one hour, three

times per week for successive 8 weeks.

Table 1: Study timeline according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

TIME PERIODS						
	Enrolment	Allocation	Post Allocation			Close-out
TIMEPOINT	-t ₁	0	Base line	6 weeks	8 weeks	t ₂
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Demographics	X					
GMFC –ER Classification	X					
Allocation		X				
INTERVENTIONS:						
Sitting training protocol						
Conventional Therapy						
ASSESSMENTS:						
Trunk control measurement (TCMS)			X	X	X	
World Health Organization Quality Of Life (WHOQOL-BREF)			X	X	X	

Outcome Measures

- 1. Trunk control measurement scale (TCMS):** The TCMS scale consists of two sections: static sitting balance and dynamic sitting balance. The second section is further divided into two subscales: selective movement control and dynamic reaching. The total scale contains 15 items, with the subscales consisting of five, seven and three items, respectively. All items are scored on an ordinal scale. The total score of the TCMS ranges from 0 to 58, with a higher score indicating a better performance. TCMS has an Internal consistency ($\alpha = 0.945$), ICC for intra rater reliability = 0.985, inter rater reliability 0.997, MDC (4.8 points) [36,37,40]
- 2. WHOQOL- BREF:** World Health Organization Quality Of Life (WHOQOL-BREF) self-assessment questionnaire derived from the WHOQOL-100. It contains 26 universal items addressing five domains of the QOL: (1) general health (two items), (2) physical health (seven items), (3) psychological health (six items), (4) social relationships (three items), and (5) environment (eight items). These domains and terms were agreed upon by the international consensus and adapted into a Tamil version. The domain scores were scaled in a positive direction ranging from 1–5 points, with higher scores denoting better QOL. Qualitative evaluation of the quality of life (English and Tamil version). Internal consistency ($\alpha = 0.92$), comparative fit index (0.90), inter rater reliability (0.66 for physical health, 0.72 for psychological health, 0.76 for social relationships and 0.87 for environment) [41,42,43]

Trial progress

The study is currently actively recruiting participants, after initial recruitment commenced in October 2022

Data analysis

Statistical methods

Analysis will be conducted on an intention-to-treat basis using SPSS and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement (Figure 1)[44,45]. Descriptive statistics [frequencies, means, standard deviation (SD) and 95% confidence interval (CI)s] will be used to describe the sample at baseline and data at different time points each outcome measure used will be summarised for both treatment groups. For skewed data, medians and interquartile ranges will be reported. The Kolmogorov Smirnov test will be used to analyse the homogeneity of the variables and based on the test corresponding parametric or non parametric statistical test will be used for the inter-group analysis, intra-group analysis and analysis of correlation between independent sitting control and maternal QoL. Missing data arising from incomplete observations and dropouts will be addressed at the analysis stage as per protocol analysis.

Ethical considerations

The present study complies with the principles of the Declaration of Helsinki and the Regulating Norms and Directives for Research Involving Human Subjects formulated by the Indian Council Medical Research. The study received approval from the ethics committee of the Indira Gandhi Medical College Hospital and Research Institute ECR/677/Inst/PY/2014/RR-17. Participating parents / legal guardians will receive a detailed explanation of the study process, after which written informed consent will be obtained. Voluntarily participating parents can withdraw their child from the study at any time without penalty, but their data will still be used in the final analysis. If they decide to withdraw, steps will be taken to assist the child in finding therapy options that match their preferences. The reasons for their withdrawal will be recorded and reported. Any changes to the study protocol will be reported and approved by the ethics committees

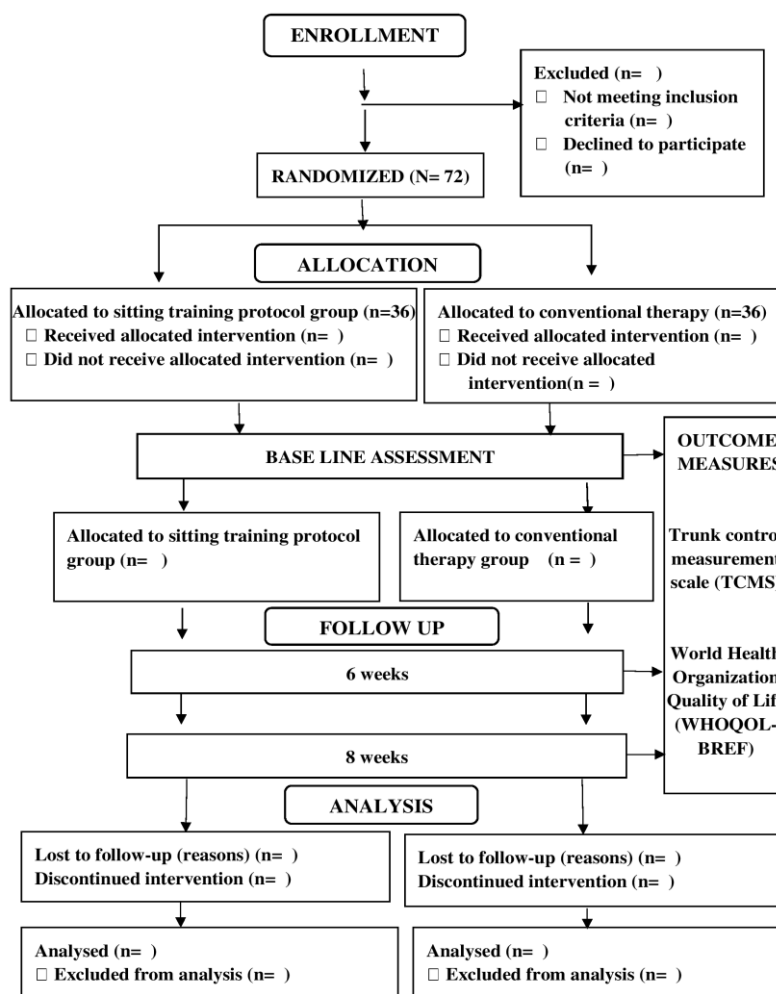
Patient and public involvement

Participants, families and the public were not involved in the design or recruitment of this study. Legal Guardians / Parents of the cerebral palsied child are informed of the study from the time of initial contact and are informed about all their rights.

Dissemination of results

Results of the study will be published/disseminated in (1) the trial registration database, (2) conference abstracts and presentations, (3) peer-reviewed articles in scientific journals. If a positive association is found between independent sitting control and maternal QoL, dissemination of these findings would assist children with CP by providing an easily accessible, cost-effective intervention that can be completed at home at the individual's own pace and help their mothers to cope up with the pressure of caregiving.

Figure 1: Study flow chart according to CONSORT – Guidelines for reporting of trial



Discussion

This protocol paper has reported the background, study design and methodology for a randomised controlled trial investigating the effectiveness of a sitting control training program for children with CP. This program has not previously been studied in this population. The dissemination of the results if found to be effective would assist children with CP and complement their ongoing therapy through the International classification of Function and Disability (ICF) introduced concept of Participation.

Intervention targeting specific sitting control can lead to substantial improvements in sitting behavior. Interventions focused on the child offer more flexibility and adaptability in developing this skill, potentially leading to easier overall motor development. Targeting the skill of sitting at a time when the child shows readiness for learning control at that level and providing more intense perceptual-motor training for a short term intervention may provide optimal motor learning adaptive control in sitting. The dedication of time and energy to this endeavor has the potential to enhance motor learning and adaptive control while in a seated position, which can positively influence multiple facets of everyday life. These include improved sitting balance, mobility, engagement in practical tasks, and decreased caregiving workload.

Conclusion:

Child-focused sitting training intervention provide greater flexibility and adaptability which may translate in achieving further motor development. We expect that these changes will influence the developmental curve of each child, improving functional ability, activity and participation in the short, mid and long terms and alleviating environmental stressors for both the child and their parents.

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Contributors

Rathish and Dr. Meena contributed to the conceptualisation of the topic and methodology of the

study. Both the authors developed and designed the intervention program. Rathish was involved in the writing of the article. Both the authors read and approved the final manuscript.

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Conflict of interests:

None declared.

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