

**“The effects of Neurodevelopmental Therapy on Feeding and Swallowing
Activities in Children with Cerebral Palsy”**

NCT04403113

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STUDY PROTOCOL

Scientific background:	<p>The trunk plays an important role in the organization of postural control and balance reactions because it holds the centre of all body mass and holds therefore, the centre of gravity. The trunk also provides stable attachment points to those muscles that control the head and neck regions. Neck and trunk stabilization exercises were the basis of static and dynamic balance abilities, and that increased neck and trunk stability might have had a positive effect thereon. To achieve the alignment of the head with the trunk, the pelvis must be stabilized. This has important consequences for the entire process of swallowing. If the head is not stable, then the fine movements of the jaw and tongue needed for feeding will be impaired. With feeding and oral-motor interventions and structured neck and trunk stabilization exercises, these parameters are positively affected.</p>
Objectives:	<p>Our study is planned to investigate the effects of neck and trunk stabilization exercises, which are structured from the principles of Neurodevelopmental Therapy Method-Bobath (NDT-B), added to feeding and oral motor intervention strategies (OMIS) and nutrition-related caregiver training (NRCT) on feeding and swallowing activities in children with cerebral palsy (CP).</p>
Design, Arm description:	<p>-Feeding and oral motor intervention strategies+structured neck and trunk stabilization exercises+caregiver training related to feeding (Study Group).</p> <p>-Feeding and oral motor intervention strategies+caregiver training related to feeding (Control Group).</p> <p>Intensive structured neck and trunk stabilization exercises based on Neurodevelopmental therapy method-Bobath concept principles. These exercises were performed for 6 weeks, 2 days a week, 45 minutes for a total of 12 sessions. Feeding and oral motor intervention strategies program were performed for 6 weeks, 2 days a week, 45 minutes for a total of 12 sessions. In caregiver training related to feeding; a) positioning and feeding technique during feeding, b) ensuring safety for aspiration, c)</p>

	using suitable containers and ingredients, d) adjusting (adapting) food consistency properly, e) preparing small amounts of high-calorie, balanced diet and f) reducing food spillage while feeding and how to ensure efficacy for shortening the feeding time, g) providing appropriate postural and physical support for self-feeding. All of these activities were continued for 6 weeks with a home program.
Sponsor:	Marmara University, Istanbul, Turkey
Measured Parameters:	<ul style="list-style-type: none"> -Gross Motor Functions, -The Eating and Drinking Ability, -The Mini-Manual Ability, -Trunk Functionally, -Oral-Motor Function in Children with Dysphagia, -The Quality of Life for Children with CP, - Fiberoptic Endoscopic Evaluation of Swallowing (FEES).
Study Center:	Marmara University Pendik Education And Research Hospital, Istanbul, Turkey
<p>All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval was obtained from the Marmara University Faculty of Medicine Clinical Research Ethics Committee protocol code 09.2018.278.</p>	