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RESEARCH ARTICLE

Electrophysiological and Functional Effects of Neuromuscular Electrical Stimulation Compared with Sham Stimulation in Children with Cerebral Palsy and Dysphagia: A Randomized Controlled Trial

Serebral Palsili ve Disfajili Çocuklarda Nöromüsküler Elektrik Stimülasyonunun Elektrofizyolojik ve Fonksiyonel Etkileri: Sham Stimülasyon ile Karşılaştırmalı Randomize Kontrollü Bir Çalışma

 Neslihan Altuntas Yılmaz¹,  Aynur Ayse Karaduman²,  Kayhan Ozturk³,  Omer Erdur⁴

¹Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya, Türkiye

²Lokman Hekim University, Faculty of Health Sciences, Ankara, Türkiye

³Karatay University, Medicana Hospital, Konya, Türkiye

⁴Selçuk University Faculty of Medicine, Department of Otorhinolaryngology, Alaeddin Keykubad Campus, Konya, Türkiye

ABSTRACT

Objective: To examine the functional and electrophysiological effects of NMES in children with cerebral palsy presenting with dysphagia.

Materials and Methods: This prospective, randomized, sham-controlled clinical trial was conducted in children with cerebral palsy presenting with oropharyngeal dysphagia. A total of 26 children (mean age: 7.02 ± 2.40 years) were randomly allocated to either the NMES group ($n = 16$) or the sham-NMES group ($n = 10$). Both groups received conventional swallowing rehabilitation. Outcome measures included the Pediatric Eating Assessment Tool (PEDI-EAT-10), Penetration-Aspiration Scale (PAS), Karaduman Chewing Performance Scale (KCPS), Swallowing Ability and Function Evaluation (SAFE), and electrophysiological assessment of suprahyoid activity during four consistencies. The trial was registered at ClinicalTrials.gov (Identifier: NCT07329387; registered September 30, 2025).

Results: PEDI-EAT-10 scores improved in both groups (NMES: $p = 0.001$, $d = 0.92$; sham-NMES: $p = 0.012$, $d = 0.71$) without a significant between-group difference ($p = 0.318$). PAS decreased in both groups (NMES: $p = 0.002$, $d = 0.88$; sham-NMES: $p = 0.021$, $d = 0.69$; between-group $p = 0.274$). The SAFE oral phase improved in both groups, whereas the pharyngeal phase improved only in the NMES group ($p < 0.001$, $d = 1.12$). KCPS improved only with NMES ($p = 0.043$, $d = 0.64$). Suprahyoid activation increased significantly with NMES during spontaneous, liquid, and solid swallowing, with the greatest improvement observed for solid swallowing. Swallowing duration favored NMES ($p = 0.013$ – 0.027).

Conclusion: Functional gains were similar between groups; however, NMES provided additional benefits in pharyngeal function and suprahyoid activation, particularly during solid swallowing.

Keywords: Cerebral Palsy, Dysphagia, Neuromuscular Electrical Stimulation, Suprahyoid Muscle

ÖZET

Amaç: Bu çalışmanın amacı, disfajisi olan serebral palsili çocuklarda NMES'in fonksiyonel ve elektrofizyolojik etkilerini incelemektir.

Gereç ve Yöntemler: Bu prospektif, randomize, sham kontrollü klinik çalışmaya orofaringeal disfajisi olan serebral palsili 26 çocuk (yaş ortalaması: 7.02 ± 2.40 yıl) dahil edildi. Katılımcılar NMES grubu ($n = 16$) ve sham-NMES grubu ($n = 10$) olarak randomize edildi. Her iki gruba da konvansiyonel yutma rehabilitasyonu uygulandı. Değerlendirmede Pediatric Eating Assessment Tool (PEDI-EAT-10), Penetrasyon-Aspirasyon Skalası (PAS), Karaduman Çiğneme Performans Skalası (KCPS), Swallowing Ability and Function Evaluation (SAFE) ve dört farklı besin kıvamında yutma sırasında suprahyoid kas aktivitesinin elektrofizyolojik değerlendirilmesi kullanıldı. Çalışma ClinicalTrials.gov veri tabanına kaydedildi (Kayıt Numarası: NCT07329387; kayıt tarihi: 30 Eylül 2025).

Bulgular: PEDI-EAT-10 skorları her iki grupta da anlamlı düzeyde iyileşti (NMES: $p = 0.001$; Sham: $p = 0.012$), ancak gruplar arasında anlamlı fark bulunmadı ($p = 0.318$). PAS skorlarında her iki grupta azalma gözlemlendi (NMES: $p = 0.002$; Sham: $p = 0.021$; gruplar arası $p = 0.274$). SAFE değerlendirmesinde oral faz her iki grupta iyileşirken, farengeal fazda anlamlı iyileşme yalnızca NMES grubunda saptandı ($p < 0.001$). KCPS skorlarında iyileşme yalnızca NMES grubunda görüldü ($p = 0.043$). Elektrofizyolojik değerlendirmede NMES grubunda spontan, sıvı ve katı yutma sırasında suprahyoid kas aktivitesinde anlamlı artış saptandı ve bu özellikle katı kıvamda daha belirgindi. Ayrıca yutma süresi NMES grubunda daha kısa bulundu ($p = 0.013$ – 0.027).

Sonuç: Her iki grupta fonksiyonel iyileşmeler gözlemlenmiş, NMES özellikle farengeal fonksiyon ve suprahyoid kas aktivasyonu açısından ek faydalar sağlamıştır. Bu etkiler özellikle katı kıvamlı besinlerin yutulması sırasında daha belirgin bulunmuştur.

Anahtar Kelimeler: Serebral Palsi, Disfaji, Nöromüsküler Elektrik Stimülasyonu, Suprahyoid Kas

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Corresponding Author: Neslihan Altuntas Yılmaz, Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya, Türkiye.

e-mail: nayilmaz@erbakan.edu.tr

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INTRODUCTION

Swallowing function consists of automatic and sequential processes involved in the passage of food from the oral cavity to the stomach (1). Dysphagia refers to an impairment in one or more phases of this process and is common in children with cerebral palsy (CP) (2). Among these comorbidities, oropharyngeal dysphagia (OPD) is highly prevalent, impacting up to 85% of children with CP and resulting in significant nutritional deficits (3). This condition negatively affects nutritional status and respiratory health and increases caregiver burden. Common clinical features include poor cervical control, inadequate lip closure, impaired bolus formation and propulsion, delayed swallowing reflex, insufficient laryngeal elevation, and laryngeal penetration or aspiration (4-5). Electrical stimulation is increasingly used in children with CP, although outcomes remain inconsistent. Electrical stimulation is thought to enhance muscle strength and facilitate the swallowing reflex via motor and sensory pathways and is commonly applied in neurological populations to improve muscle function and reduce atrophy (6). It induces muscle contraction and cortical activation through afferent input and has been associated with improved hyoid movement and reduced aspiration (7-8).

Suprahyoid muscles play a key role in laryngeal elevation; insufficient activation of these muscles compromises airway protection. Neuromuscular electrical stimulation (NMES) applied to the suprahyoid muscle group aims to enhance hyoid elevation and improve swallowing safety in patients with dysphagia. The effectiveness of NMES in dysphagia was first demonstrated in stroke patients by Freed et al. Although electrophysiological evaluations of suprahyoid muscle activity have been conducted in adults with various conditions and in healthy children, studies combining clinical and electrophysiological assessments in children with CP and dysphagia are lacking (7,9). To our knowledge, this is the first study to evaluate the effects of NMES on swallowing function in children with CP using electrophysiological analyses. This study aimed to investigate the effects of NMES on suprahyoid muscle activation, swallowing duration, and aspiration severity in children with CP and dysphagia. We hypothesized that NMES, in addition to conventional oromotor exercises and thermal-tactile stimulation, would result in greater improvements in both clinical and electrophysiological swallowing outcomes compared with conventional therapy alone.

MATERIALS AND METHODS

Design and Participants

This study was conducted at Necmettin Erbakan University. A total of 63 children with CP were screened for eligibility. The study was designed as a randomized controlled trial comparing neuromuscular electrical stimulation (NMES) plus conventional swallowing rehabilitation with sham-NMES plus conventional therapy.

Ethical Approval

The study protocol was approved by the Non-Invasive Clinical Research Ethics Committee of Selçuk University

(Decision No: 2017/22). The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from the parents or legal guardians of all participants, and assent was obtained from the children when appropriate, based on their age and cognitive status.

Participants and Data Collection

Participants were children with CP aged between 4 and 18 years who scored above 4 on the Turkish version of the Pediatric Eating Assessment Tool (Pedi-EAT-10) and were able to sit with or without support. A total of 63 children were screened for eligibility. Of these, 12 did not meet the age criteria, and 19 were unable to adhere to the treatment schedule and were therefore excluded. The remaining 32 children were included in the study. Six participants withdrew from the study, and a total of 26 patients completed the study (mean age: 7.02 ± 2.40 years), with 16 in the treatment group and 10 in the Sham-NMES group (Figure 1). Demographic, clinical, and feeding history data were collected through face-to-face interviews with the parents or caregivers.

Diagnostic Criteria

Dysphagia was diagnosed based on a clinical swallowing examination and videofluoroscopic swallowing study (VFSS). Electrophysiological evaluations were utilized for assessment rather than diagnosis. Dysphagia severity was evaluated using the Penetration-Aspiration Scale (PAS).

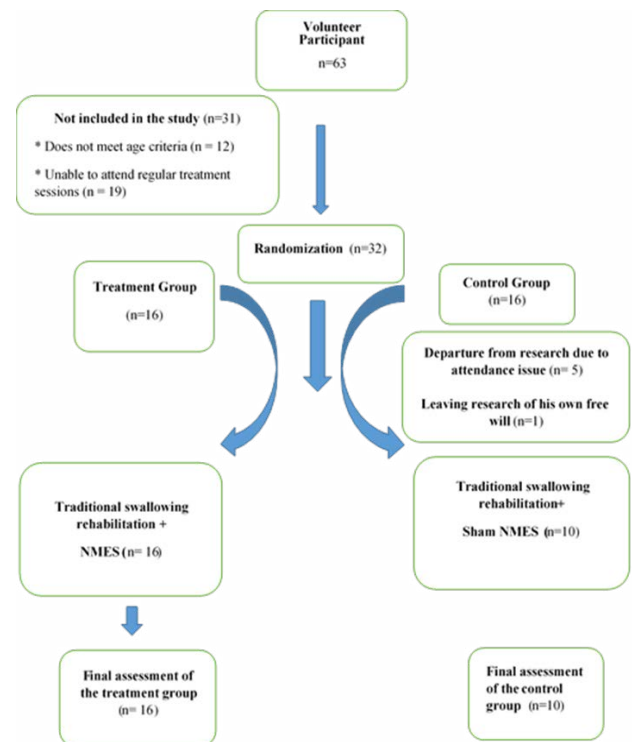


Figure 1. CONSORT flow diagram showing the enrollment, allocation, follow-up, and analysis of participants.

Clinical Assessment Tools

The Swallowing Ability and Function Evaluation (SAFE) was employed to assess the oropharyngeal phase of swallowing. Chewing performance was evaluated using the Karaduman Chewing Performance Scale (KCPS).

Inclusion Criteria

The inclusion criteria were: (1) a diagnosis of CP, (2) age between 4 and 18 years, (3) a Pedi-EAT-10 score > 4, and (4) the ability to sit with or without support.

Exclusion Criteria

Exclusion criteria included: history of maxillofacial, head, or neck surgery; recent botulinum toxin injection (within the last 3 months); structural oropharyngeal abnormalities; gastroesophageal reflux disease; history of previous medical or physical therapy interventions for dysphagia; severe cognitive, visual, auditory, or sensory impairments; current use of pharmacological treatment for spasticity; serious pulmonary or cardiac disease; and coagulation disorders.

Study Procedures

The study was conducted by independent experts blinded to treatment allocation. Physical examination, VFSS, and electrophysiological assessments were performed by an otorhinolaryngologist who was blinded to group allocation. Follow-up evaluations were conducted by a second otorhinolaryngologist who was blinded to group allocation four weeks after the intervention. This trial was prospectively registered at ClinicalTrials.gov (Identifier: NCT07329387).

Randomization

Randomization was performed by an independent researcher who was not involved in participant recruitment, assessment, or treatment. A computer-generated random allocation sequence was created using block randomization with a fixed block size of four to ensure balanced group allocation. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes prepared in advance. After baseline assessments were completed, participants were assigned to either the NMES group or the sham-NMES group according to the predefined randomization sequence. Six participants allocated to the control group discontinued the intervention due to poor adherence to the rehabilitation schedule and were excluded from the final analysis. These withdrawals occurred after randomization and are detailed in the CONSORT flow diagram.

Rehabilitation methods

All participants underwent a 4-week swallowing rehabilitation program (3 sessions per week, 12 sessions in total) administered by a physiotherapist with 10 years of clinical experience in pediatric rehabilitation and clinical expertise in dysphagia management. All rehabilitation practices were carried out with the primary caregiver, and after 12 sessions, the family was trained to continue the treatment as a home program. Conventional swallowing rehabilitation approaches were applied to both groups, including oral motor exercises such as tongue traction performed by the physiotherapist using a gloved finger or a tongue depressor, tongue protrusion against resistance, passive and/or active tongue movements

performed laterally and superiorly, lip closure exercises, and blowing exercises performed in front of a mirror. Each exercise was performed for 20 repetitions (10). For laryngeal mobilization, the larynx was moved in mediolateral (right-left) and superior (upward) directions for approximately 1 minute without causing discomfort or erythema, especially to facilitate laryngeal elevation during swallowing (11). For thermal-tactile stimulation, cold stimuli were applied to the anterior pharyngeal area with thermal stimulation probes in 5–6 contacts, which were considered one application, and 200 applications were performed on each side during each session (12). Gingival massage; Circular massage was performed digitally using a gloved finger from the front teeth towards the back on the upper and lower gums. Gum massage was applied for approximately 8–10 minutes in treatment sessions.

In addition to conventional therapy, the treatment group received NMES targeting the suprahyoid muscle group (80 Hz, 300–400 μ s pulse width) using VitalStim for 40 minutes per session, while the control group received sham NMES with identical electrode placement but with no current output. To address ethical considerations, NMES was offered to the sham group after data collection. NMES and surface electromyography (s-EMG) parameters were selected based on previously established safe and effective protocols in pediatric dysphagia and CP populations (9,13).

Data Collection

Demographic and clinical characteristics (including sex, birth history, gestational age, birth weight, Neonatal Intensive Care Unit (NICU) history, feeding history, Gross Motor Function Classification System (GMFCS) level, and clinical type of CP) were recorded via face-to-face interviews.

Clinical evaluation

Dysphagia severity was assessed using the PAS based on VFSS performed by experienced radiologists (14). Children were evaluated in a seated position while swallowing 3 mL of liquid three times, and bolus movement in the sagittal plane was scored on an 8-point scale. Chewing performance was assessed using the KCPS during consumption of a standard biscuit without physical or verbal assistance (15). Signs of respiratory distress (e.g., dyspnea, cyanosis, coughing, and voice changes) observed during feeding were recorded. Oral motor function was evaluated using the SAFE battery through inspection and palpation in a seated position (16). In children with cognitive impairment, verbal and visual cues were provided as needed. The sensory and cognitive evaluation subscales of SAFE were excluded from statistical analyses, as they were not considered essential for determining swallowing severity.

Electrophysiological evaluation

Prior to recording, the skin over the submental region was cleaned with alcohol to reduce impedance, and self-adhesive surface electrodes (1 × 2.5 cm) were placed over the submental region, symmetrically on either side of the midline. Electrodes and cables were secured with adhesive tape to minimize movement artifacts. Swallowing-related muscle activity was recorded using a dual-channel s-EMG system (Digital Swallowing Workstation Model 7245C, Kay Pentax,

Lincoln Park, NJ) integrated with Noraxon MyoResearch XP software. Signals were recorded in microvolts, band-pass filtered between 20 Hz and 2 kHz, and amplified with a gain of 200. Electromyographic recordings were obtained during four swallowing conditions: spontaneous swallowing, liquid (3 mL water), semi-solid (5 mL yogurt), and solid (biscuit); in children with chewing difficulties, the solid bolus was mechanically altered for safety. To standardize head position, participants wore a soft cervical collar. Each condition was recorded three times with 1-minute rest intervals, and the highest mean and peak values were analyzed. Assessments were performed before and after the 12-session intervention. Peak amplitude was defined as the maximum muscle contraction; baseline and resting amplitudes reflected resting muscle tone; and burst duration represented the total time of swallowing activity.

Sample size

The sample size was determined using an a priori power analysis (G*Power v3.1.9.2). An effect size of $d = 0.5$ was selected based on clinical relevance and previous literature (17). The analysis indicated that a minimum sample size of 32 participants would be required to achieve 90% power at an alpha level of 0.05.

Statistical Analysis

Statistical analyses were conducted using SPSS version 21.0 for Windows (IBM Corp., Armonk, NY, USA). The distribution of the data was assessed using the Shapiro–Wilk test. Descriptive data are presented as mean $\pm$ standard deviation (SD) for continuous variables and frequency (percentage) for categorical variables. To evaluate the effect of the intervention over time and to directly test the group $\times$ time interaction, linear mixed-effects models were applied. In these models, group (NMES vs. sham-NMES), time (pre- and post-treatment), and their interaction (group $\times$ time) were included as fixed effects, while subjects were treated as a random effect

to account for within-subject correlations. Within-group comparisons (pre–post treatment) were performed separately for each group using the Wilcoxon signed-rank test. Between-group comparisons were analyzed using the Mann–Whitney U test. Categorical variables were compared using the chi-square test or Fisher's exact test. Statistical significance was set at $p < 0.05$. Effect sizes and 95% confidence intervals were calculated for significant findings.

RESULTS

The study included a total of 26 participants, with 16 allocated to the NMES group and 10 to the sham-NMES group. At baseline, no significant differences were observed between the NMES and sham-NMES groups in PEDI-EAT-10 or PAS scores ($p > 0.05$), indicating baseline homogeneity regarding swallowing severity (Tables 1 and 2).

Clinical Outcomes

Linear mixed-effects analysis revealed no significant group $\times$ time interaction for PEDI-EAT-10 ($p = 0.421$, $\eta^2 = 0.037$), indicating that the change over time was similar in both the NMES and sham-NMES groups. Similarly, no significant group $\times$ time interaction was observed for PAS scores ($p = 0.362$, $\eta^2 = 0.048$). Following the 12-session intervention, no statistically significant between-group differences were found in PEDI-EAT-10 or PAS scores ($p > 0.05$). However, within-group analyses revealed significant post-treatment improvements in both groups for PEDI-EAT-10 and PAS scores ($p < 0.05$), demonstrating a large treatment effect (Tables 1 and 2). Although both groups demonstrated significant improvements, the magnitude of change did not differ significantly between the NMES and Sham-NMES groups. For SAFE scores, no significant group $\times$ time interaction was found for physical ($p = 0.118$, $\eta^2 = 0.09$), oral ($p = 0.482$, $\eta^2 = 0.03$), and pharyngeal phase evaluations ($p = 0.091$, $\eta^2 = 0.11$). No significant between-group differences

Table 1. Comparison of pre- and post-treatment PEDI-EAT-10 scores.

Pedi-Eat 10	Within-Group Changes		Mean Difference	95% CI	Between-Group Differences p	Group $\times$ Time
	NMES group (n=16) Mean $\pm$ SD / Median (Min–Max)	Sham-NMES group (n=10) Mean $\pm$ SD / Median (Min–Max)				
Pre-treatment	25.56 $\pm$ 9.69/ 25.50 (10–40)	19.10 $\pm$ 6.57/ 18.50 (8–40)	6.46	[–0.48, 13.40]	0.096**	P=0.421
Post-treatment	20.93 $\pm$ 8.9/ 20.00 (6–38)	17.00 $\pm$ 7.48/ 16.50 (7–38)	3.93	[–2.88, 10.74]	0.413**	$\eta^2 = 0.037$
Δ (Post–Pre)	–4.63 $\pm$ 6.20 /–4.00	–2.10 $\pm$ 4.80 /–2.00	–2.53	[–7.10, 2.04]	0.318**	
z	–3.073	–2.408				
p	0.002*	0.017*				
r	0.768	0.761				

CI: Confidence Interval, SD; Standard Deviation, * Wilcoxon test **Mann-Whitney U test, Δ (change score) was calculated as post-treatment minus pre-treatment values. The group $\times$ time interaction effect was evaluated using a linear mixed-effects model including group, time, and group $\times$ time interaction as fixed effects and subject as a random effect. Effect size (r) was calculated using the formula $r = z / \sqrt{N}$. Values of 0.1, 0.3, and 0.5 indicate small, medium, and large effects, respectively. Statistically significant p-values are presented in bold.

Table 2. Comparison of pre- and post-treatment Penetration-Aspiration Scale (PAS) scores.

PAS	Within-Group Changes		Mean Difference	95% CI	Between-Group Differences p	Group × Time
	NMES group (n=16) Mean ± SD / Median (Min–Max)	Sham-NMES group (n=10) Mean ± SD / Median (Min–Max)				
Pre-treatment	5.41±2.10/ 5.50 (2 – 8)	5.71±2.32/ 5.50 (2 – 8)	-0.30	[-2.14, 1.54]	0.096**	P= 0.362
Post-treatment	3.56±1.63/ 3.00 (1 – 7)	3.60±1.26/ 3.50 (2 – 7)	-0.04	[-1.18, 1.10]	0.213**	
Δ (Post–Pre)	-1.85 ± 1.50 / -2.00	-2.11 ± 1.40 / -2.00	0.26	[-1.10, 1.62]	0.274**	η ² = 0.048
Z	-3.073	-2.307				
P	0.002*	0.016*				
r	0.768	0.758				

CI: Confidence Interval, PAS: Penetration Aspiration Scale * Wilcoxon test **Mann-Whitney U test, Δ (change score) was calculated as post-treatment minus pre-treatment values. The group × time interaction effect was evaluated using a linear mixed-effects model including group, time, and the group × time interaction as fixed effects, with subject as a random effect. Effect size (r) was calculated using the formula $r = z / \sqrt{N}$. Values of 0.1, 0.3, and 0.5 indicate small, medium, and large effects, respectively. Statistically significant p-values are presented in bold.

Table 3. Comparison of pre- and post-treatment Swallowing Ability and Function Evaluation (SAFE) scores.

SAFE		Within-Group Changes (Pre- Post-treatment)		Between-Group Differences p	Group × Time
		NMES group (n=16)	Sham-NMES group (n=10)		
Physical Evaluation	Pre-treatment	68.50±12.29	68.00±9.68	0.369**	P= 0.118 η ² = 0.09
	Post-treatment	66.87±13.60	65.30±10.17	0.398**	
	z	-2.794*	-1.809*		
	p	0.005*	0.071*		
	r	0.698	0.272		
Oral Phase Evaluation	Pre-treatment	14.87±5.34	15.20±2.14	0.873**	p = 0.482 η ² = 0.034
	Post-treatment	16.50±5.46	16.20±2.09	0.208**	
	z	-3.125*	-2.368*		
	p	0.002*	0.018*		
	r	0.781	0.748		
Pharyngeal Phase Evaluation	Pre-treatment	12.93±3.71	14.60±4.24	0.958**	p = 0.091 η ² = 0.112
	Post-treatment	14.62±3.05	15.30±3.43	0.978**	
	z	-3.550*	-1.370*		
	p	p < 0.001 *	0.171*		
	r	0.887	0.433		

SAFE: Swallowing Ability and Functional Evaluation * Wilcoxon test **Mann-Whitney U test, The group × time interaction effect was evaluated using a linear mixed-effects model including group, time, and the group × time interaction as fixed effects, with subject as a random effect. Effect size (r) was calculated using the formula $r = z / \sqrt{N}$. Values of 0.1, 0.3, and 0.5 indicate small, medium, and large effects, respectively. Statistically significant p-values are presented in bold.

Table 4. Comparison of pre- and post-treatment Karaduman Chewing Performance Scale (KCPS) scores.

KCPS	Within-Group Changes *				Between-Group Differences **	
	NMES group (n=16)		Sham-NMES group (n=10)		Pre-treatment	Post-treatment
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	p	p
Level 1	2 (12.5%)	2 (12.5%)	1 (10%)	1 (10%)	0.585	0.085
Level 2	2 (12.5%)	5 (31.25%)	2 (20%)	3 (30%)		
Level 3	7 (43.75%)	6 (37.5)	5 (50%)	4 (40%)		
Level 4	5 (31.25%)	3 (18.75%)	2 (20%)	2 (20%)		
z	-3.004		-1.200			
p	0.043*		0.245			
r	0.751		0.379			

* Marginal homogeneity test ** Mann Whitney U test, Effect size (r) was calculated using the formula $r = z / \sqrt{N}$. Values of 0.1, 0.3, and 0.5 indicate small, medium, and large effects, respectively. Statistically significant p-values are presented in bold.

were observed in SAFE scores at baseline or post-treatment ($p>0.05$) (Table 3). Within-group analysis showed significant improvements in the NMES group in the oral ($p=0.002$) and pharyngeal phases ($p<0.001$), whereas the Sham-NMES group demonstrated a significant improvement only in the oral phase ($p=0.018$).

No significant between-group differences were found in KCPS scores at baseline or post-treatment ($p>0.05$) (Table 4). A significant within-group improvement was observed in the NMES group ($p=0.043$), while the change in the Sham-NMES group was not significant ($p=0.245$).

Maximum Activation Amplitude of Suprahyoid Muscle (Muscle Performance)

NMES led to a statistically significant increase in muscle performance for all consistencies except semi-solids (spontaneous: $p=0.004$; liquid: $p=0.003$; solid: $p=0.035$). Analysis of between-group differences revealed a significant difference only for solid consistency ($p=0.002$) (Table 5).

Suprahyoid Muscle Burst Duration

The activation amplitude of the suprahyoid muscle determined by the onset of laryngeal elevation was not significantly altered by either intervention. Differences in bolus

Table 5. Comparison of suprahyoid s-EMG parameters before and after treatment.

s-EMG			Within-Group Changes *			Between-Group Differences**		
NMES group (n=16)			z /p/r	Sham-NMES group (n=10))		z /p/r	Before p	After p
Pre-treatment	Post-treatment	Pre-treatment		Post-treatment				
Spontaneous								
MIN	11.10±8.15	9.57±6.05	z:-0.284 p:0.776 r: 0.071	9.62±6.92	7.68±6.23	z:-0.766 p:0.444 r: 0.242	0.895	0.476
MAX	39.91±12.25	57.23±19.61	z:-2.897 p:0.004 r: 0.724	50.90±17.42	46.55±10.78	z:-0.664 p:0.507 r: 0.210	0.206	0.091
TIME	645.22±117.95	516.12±67.81	z:-2.783 p:0.005 r: 0.696	570.67±41.21	559.54±57.32	z:-1.277 p:0.202 r: 0.404	0.235	0.027
Liquid								
MIN	10.75±6.93	8.07±4.74	z:-1.162 p:0.245 r: 0.290	10.80±4.71	12.74±5.78	z:-1.277 p:0.202 r: 0.403	0.890	0.080
MAX	42.68±13.5	60.83±25.25	z:-2.229 p:0.026 r: 0.557	46.49±14.70	59.28±16.33	z:-2.809 p:0.005 r: 0.888	0.174	0.978
TIME	620.95±91.7	561.13±94.66	z:-1.852 p:0.064 r: 0.463	582.10±25.00	478.00±21.58	z:-2.809 p:0.005 r: 0.888	0.421	0.013
Viscous								
MIN	11.01±8.86	10.23±6.60	z:-0.315 p:0.753 r: 0.078	9.94±4.40	10.80±4.33	z:-0.970 p:0.332 r: 0.306	0.930	0.334
MAX	57.80±20.60	64.13±21.81	z:-0.454 p:0.650 r: 0.656	51.89±10.35	52.55±15.29	z:0.357 p:0.721 r: 0.888	0.333	0.334
TIME	626.84±90.77	534.38±74.19	z:-2.622 p:0.009 r:0.655	578.37±20.05	483.08±31.42	z:-2.809 p:0.005 r:0.088	0.464	0.057
solid								
MIN	10.57±8.20	7.21±4.44	z:-1.401 p:0.161 r: 0.350	13.86±5.91	10.40±3.21	z:-1.123 p:0.261 r: 0.355	0.193	0.053
MAX	57.57±28.25	87.42±19.33	z:-2.103 p:0.035 r:0.526	59.10±17.33	54.24±14.09	z:0.000 p:1.000 r:0.000	0.809	0.002
TIME	645.14±127.81	473.53±51.30	z:-2.240 p:0.025 r:0.560	588.88±25.90	576.46±84.53	z:-0.140 p:0.888 r:0.044	0.736	0.017

Wilcoxon test **Mann-Whitney U test, Effect size (r) was calculated using the formula $r = z / \sqrt{N}$. Values of 0.1, 0.3, and 0.5 indicate small, medium, and large effects, respectively. Min: Resting amplitude, Max: Peak amplitude, Time; Swallow duration. Statistically significant p-values are presented in bold.

consistency did not significantly alter the amplitude required to initiate suprahyoid muscle activation ($p>0.05$) (Table 5).

Suprahyoid Muscle Activation Duration

In both groups, swallowing duration was reduced across all consistencies. However, this reduction was not statistically significant for all consistencies. In within-group analyses, NMES did not significantly alter the duration of liquid swallowing ($p>0.05$). Regarding between-group comparisons, a statistically significant difference was observed in swallowing duration for consistencies other than semi-solids (spontaneous: $p=0.027$; liquid: $p=0.013$; solid: $p=0.017$). The absence of a between-group difference after treatment for semi-solid consistency suggests that NMES did not affect the electrophysiology of swallowing for this bolus type (Table 5). Correlation analysis revealed a positive correlation between GMFCS level and dysphagia severity as well as aspiration-penetration risk, and a negative correlation with swallowing ability and function. No correlation was found between GMFCS level and post-treatment KCPS. A negative correlation was observed between GMFCS level and maximal suprahyoid muscle contraction amplitude during liquid swallowing.

In the Sham-NMES group, electrophysiological parameters did not show any statistically significant changes during dry and solid swallowing. In contrast, in the NMES group, a statistically significant difference was observed between groups in electrophysiological parameters during spontaneous and solid swallowing (spontaneous: $p=0.004$; solid: $p=0.035$) (Table 5). Therefore, NMES treatment resulted in significant electrophysiological improvements, particularly during spontaneous swallowing and solid food consumption.

DISCUSSION

NMES has increasingly been used as an adjunct to traditional dysphagia rehabilitation in children with CP (18). There are conflicting findings regarding the treatment efficacy of NMES for dysphagia (19,20). In many recent adult studies, NMES included in conventional dysphagia rehabilitation has been reported to yield superior electrophysiological results in the treatment of swallowing function compared to either NMES alone or conventional dysphagia rehabilitation alone (21,22). To our knowledge, this study is the first randomized controlled trial in a pediatric CP population to simultaneously evaluate both clinical swallowing outcomes and electrophysiological suprahyoid muscle activation parameters in a sham-controlled design. By integrating instrumental VFSS-based clinical assessment with surface electromyographic analysis, this study provides a more comprehensive evaluation of NMES effects in children with dysphagia. While NMES did not demonstrate superiority over sham stimulation in overall clinical swallowing scales, it resulted in significantly greater improvements in maximal suprahyoid muscle activation during spontaneous and solid swallowing. These findings suggest that electrophysiological gains may precede or exceed measurable clinical scale improvements in pediatric populations. Although between-group differences were not significant for several clinical scales, the within-group improvements observed

in PEDI-EAT-10, PAS, and SAFE scores may still have clinical relevance. The decrease in PEDI-EAT-10 scores may reflect reduced caregiver-perceived swallowing difficulties during daily feeding. Similarly, improvements in PAS scores may indicate safer swallowing with a lower risk of penetration and aspiration. Improvements in SAFE scores, particularly in the oral and pharyngeal phases, may suggest better bolus control and improved swallowing function. Therefore, these findings may have practical implications for feeding safety and daily swallowing performance in children with cerebral palsy.

Previous research has indicated that the prevalence of oropharyngeal dysphagia increases markedly with higher GMFCS levels in children with CP (23). In addition, Ma et al. demonstrated that NMES treatment in children with CP and dysphagia classified as GMFCS levels IV and V reduced the risk of aspiration by decreasing PAS scores for both solid and liquid consistencies (13). Unlike previous research, our sample included children across all GMFCS levels. Our analysis revealed a positive association between GMFCS level and both PAS and PEDI-EAT-10 scores after treatment. Consistent with the findings of Benfer et al., increased functional limitation was associated with greater swallowing impairment and reduced treatment benefit. No significant relationship was observed between GMFCS level and chewing performance after treatment, which may be attributable to the lack of stratification based on baseline chewing ability. Oral and pharyngeal phases are closely linked in swallowing function. Therefore, the improvement of oral functions will facilitate the reflex phase of swallowing. Song et al. reported that NMES application to the suprahyoid muscle in children with CP and dysphagia significantly improved functions related to the oral phase compared to the Sham group. In contrast, using the modified SAFE battery to evaluate the oral phase, we found that both groups benefited from the treatment, with no significant difference between them. This may be attributed to the administration of oral exercises in both groups.

Chewing and swallowing are integral components of the stomatognathic system. Therefore, the muscles involved in these two functions are interrelated. Giannas et al. reported that they treated sleep apnea by applying NMES to the masticatory muscles in 13 adult CP patients, hypothesizing that it enhanced muscle activation and motor unit recruitment in the upper respiratory tract (24). The results of the present study offer reciprocal support for this hypothesis. There was no difference between the effects of the treatments applied to both groups on masticatory function. Although no significant between-group difference was observed in masticatory function, within-group analysis indicated significant improvement in the NMES group. As hypothesized by Giannas et al., it can be suggested that the increase in motor units or sensory gain from NMES in muscles related to the hyolaryngeal complex outside the target muscle may have contributed to the improvement in chewing function. Mishra et al. reported that children with CP exhibited significantly more suprahyoid muscle activity during the ingestion of semisolid and solid foods compared to healthy children. This is attributed to the increased demand

for muscle contraction and additional muscle strength during the chewing and swallowing of solids (25). In our study, as the viscosity of food increased before and after treatment, peak muscle amplitude increased in both groups. Xia et al. reported that NMES administration in combination with conventional dysphagia rehabilitation in adult hemiplegic dysphagia patients was significantly superior in both FEES assessment results and electrophysiological outcomes compared to NMES or conventional rehabilitation alone (26). Our study also found that NMES administration increases muscle contraction performance during spontaneous swallowing and the ingestion of liquid and solid boluses, consistent with these findings. When examining the effect of NMES on maximum muscle contraction performance between the two groups, we found that it was significantly greater only during solid food swallowing. Accordingly, we can conclude that strengthening the suprahyoid muscle with electrical stimulation in solid foods may be beneficial.

During voluntary muscle contraction, type I motor units, specifically slow-twitch fibers, are recruited first, whereas type II motor units are activated only when greater force is required. In contrast, NMES recruits motor units in a non-physiological reverse order, contrary to Henneman's size principle (7). Therefore, potential improvements in muscle activation or strength may not fully translate into significant functional swallowing performance. For this reason, evaluating the effectiveness of NMES requires assessment of both myoelectric activity and functional swallowing outcomes. The pharyngeal phase of swallowing lasts approximately 500–600 ms, and prolonged suprahyoid muscle activation has been reported in dysphagia (27). Vaiman et al. demonstrated that in healthy children aged 4–12 years, swallowing duration increases with bolus consistency and is longer than in adults, indicating slower swallowing patterns (27). In the present study, activation duration decreased across all consistencies in both groups; however, NMES did not demonstrate superiority for semi-solid boluses. Christiaanse et al. reported that NMES application had no significant therapeutic effect in their study on pediatric dysphagia patients (28). However, these results were assessed using the functional oral intake level. In our study, aspiration risk was assessed by a blinded radiologist, while other clinical parameters were evaluated by independent researchers to minimize bias. The use of objective instrumental assessment (VFSS) and blinded evaluators in our study strengthens the validity and reliability of the results. Nevertheless, the interpretation of these findings should take into account the relatively small final sample size and the participant attrition that occurred after randomization, particularly in the sham-NMES group. Although the sample size was determined through an a priori power analysis, the target sample size could not be fully achieved due to withdrawals related to difficulties in adhering to the rehabilitation schedule. This reduction in sample size may have decreased the statistical power of the study and limited the detection of additional between-group differences in some clinical outcomes. Therefore, larger randomized controlled trials with adequate sample sizes are

needed to confirm the present findings.

Recent studies have reported electrophysiological analyses of the submental muscle in adult patient populations and in healthy children (1,2,6–8); however, no study has combined clinical and electrophysiological evaluations in children with CP. To our knowledge, this is the first study to assess the effectiveness of NMES in children with CP and dysphagia using electromyographic analysis, making the evaluation of both clinical dysphagia outcomes and submental muscle EMG parameters particularly important. A primary strength of this study is its novelty as the first randomized controlled trial to show the effect of NMES on submental muscle performance and clinical dysphagia evaluation parameters by comparing it with conventional oromotor exercises in dysphagia rehabilitation. Second, the evaluation techniques chosen to assess clinical dysphagia and suprahyoid muscle activations are all valid and reliable, and the study was conducted using a single-blind design. Third, sham-NMES was administered to the control group to control for potential placebo effects and standardize sensory input between groups. Another strength is the baseline homogeneity of the groups regarding clinical involvement, type, GMFCS levels, head control values, dysphagia scores, chewing scores, penetration-aspiration levels, and swallowing ability and function assessment scores, which supports the robustness of group comparisons.

Study Limitations: One limitation of this study is the lack of a control group receiving NMES alone, which restricts the ability to isolate the effects of NMES on swallowing and electrophysiological outcomes. Additionally, for safety reasons, mechanically altered solid food was used in some children with inadequate lip closure and chewing ability, which may have altered physiological chewing mechanics and affected suprahyoid muscle activation during solid swallowing. Therefore, EMG findings for solid consistencies should be interpreted with caution. Another limitation is the relatively small final sample size. Although the sample size was estimated through an a priori power analysis, the planned sample size was not fully achieved because several participants withdrew after randomization, particularly in the sham-NMES group. This attrition may have reduced the statistical power of the study and limited the ability to detect significant between-group differences for some outcomes.

CONCLUSION

The findings of this study suggest that adding NMES to conventional swallowing rehabilitation did not result in additional significant improvements in overall swallowing function. However, NMES appears to provide electrophysiological benefits, particularly in children who experience difficulty in solid food consumption. These patients often exhibit prolonged spontaneous swallowing durations during solid bolus management. Therefore, NMES may be considered an adjunctive modality of swallowing rehabilitation in this population.

DECLARATIONS

Conflict of Interest: The authors declare no conflicts of interest.

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Address correspondence to: Neslihan Altuntas Yilmaz, Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya, Türkiye
e-mail: nayilmaz@erbakan.edu.tr

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