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Original Article

Combined Thermal and Neuromuscular Stimulations for Stroke-Related Dysphagia: A Pilot Randomized Clinical Trial

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ABSTRACT

Background: The incidence of stroke escalates with age in both genders, with nearly 50% and 30% of cases reported in individuals over the ages of 75 and 85 years, respectively. This pilot randomized clinical trial was designed to explore the effects of combined thermal and neuromuscular stimulations on dysphagia improvement. It also aimed to identify the most efficient dysphagia management plan for acute stroke patients.

Methods: In this pilot randomized clinical trial study, twelve acute stroke patients were randomly and concurrently allocated into two groups. The control group received routine medical treatment without speech therapy counseling, while the intervention group underwent superficial and deep thermal neuromuscular stimulations. In the intervention group, one patient received treatment for two weeks, three patients for three weeks, and two patients for five weeks (five times a week). Patients in the intervention group were re-evaluated each week after five days of therapy using the Motility Function (MF) and Mann's Assessment of Swallowing Ability (MASA) tests to monitor consistent improvement. Based on the cutoff point of the MASA test, treatment was either continued or terminated. Accordingly, different follow-up periods were considered for the patients: one received treatment for two weeks, three for three weeks, and two for five weeks.

Results: The results indicated a significant difference between the two groups regarding the mean MASA score after a 21-day intervention. The intervention group scored 166.5±3.53, while the control group scored 163±10.02 after 35 days (P=0.03). Furthermore, the intervention group reached the cutoff MASA score in the sixth MASA assessment after a 35-day intervention.

Conclusion: According to the protocol proposed by speech-language pathologists, it is recommended to perform stimulations for approximately 21-35 days. Given the significant results obtained from this preliminary study, it is suggested that this protocol be implemented in a larger sample size.

Introduction

The incidence of stroke escalates with age in both men and women, with nearly 50% and 30% of cases reported in individuals over the ages of 75 and 85 years, respectively [1]. Stroke ranks among the top five causes of mortality and is the leading cause of disability in adults [2]. The global incidence of stroke is 258 per 100,000 population each year, a rate that increases annually with population aging [3]. Post-stroke dysphagia (PSD) is an underestimated complication of stroke, reported in almost half of stroke survivors [4]. PSD can lead to

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malnutrition and dehydration in persistent cases, as well as aspiration pneumonia in patients with acute stroke. Moreover, it is associated with a longer hospital stay [5], a higher annual cost ($4,510) [6], and a higher mortality rate [7] compared to stroke patients without PSD.

Some cases of PSD may recover spontaneously, while others may suffer from related complications, require tube placement, or succumb due to related complications. Therefore, effective management strategies are essential [8]. Treatment approaches for PSD traditionally include prevention of aspiration through diet and fluid modifications or positional changes and improvement of swallowing ability through exercise and maneuvers, depending on the patient's condition and the physician's experience [9]. Alternative or adjunctive treatment strategies have also been proposed for PSD to enhance cortical neuroplasticity via sensory input from peripheral receptors [10]. Evidence suggests that thermal, tactile stimulation, and massage, as types of sensory stimulation [11], can have various cortical and behavioral effects and can improve dysphagia and oral movement disorders in patients with subacute PSD [12, 13]. Moreover, oropharyngeal sensorimotor training with an oral IQoro screen appears to have favorable long-term effects on PSD [14]. Myofascial and orofacial exercises, as a type of massage, can also be effective against dysphagia by improving the orofacial muscle strength and response rate [15].

Massage stroke is a technique that comprises six components: depth, speed, rhythm, duration, direction, and frequency. The depth of a stroke can range from light to moderate or deep. Initially, the depth of the massage is fairly light, with more moderate or deeper pressure applied as the tissue warms and the massage progresses. The speed at which a stroke is performed depends on the desired outcome, i.e., a slow speed is used to relax the muscles, while a fast speed is used to stimulate them. Massage strokes are typically performed under stable conditions for a specific duration. Generally, each stroke is performed at least three times before transitioning to another stroke or body area. This ensures adequate distribution of the lubricant, warming of the tissues, and delivery of a final stroke. On the extremities, the movement is always centripetal towards the heart or in the direction of venous flow. However, for the torso and the back, the direction is not necessarily towards the heart [16].

Generally, swallowing therapy services in Iran do not include intensive treatments for acute stroke patients. As a result, dysphagia treatment often involves symptom management rather than direct rehabilitation of swallowing function [17]. No study has investigated the depth, rhythm, and duration of head and neck massages for stroke patients with swallowing disorders in the acute phase. Therefore, there is a need to explore more dysphagia management plans. The present study investigated the depth, speed, rhythm, duration, direction, and frequency of massage techniques for patients with acute PSD. This was compared to a control group after five weeks of combined thermal and neuromuscular stimulations to determine the effectiveness of this treatment on the face, neck, and intraoral areas in improving swallowing disorders. Additionally, this study aimed to determine this therapeutic approach's shortest and most effective duration.

Methods

Study Sample

This pilot randomized clinical trial, with a parallel-group design, was conducted on patients with PSD from February 2021 until April 2021. The aim was to evaluate the effects of thermal and neuromuscular stimulations on improving oral movements and swallowing function in stroke patients. The patients who were in the acute phase of stroke (within the first 30 days), had dysphagia and were on various medications were divided into an intervention group and a control group. Participants were selected from individuals referred to the neurology unit of Namazi Hospital in Shiraz, Iran.

Two previous studies employed a method most similar to the present study [18, 19]. According to a similar study [18], G*Power version 3.1.9.2 was used to calculate the sample size. With an effect size of two, an alpha risk of 0.05, and a beta risk of 0.2 in a two-sided test, a sample size of six patients per group was calculated. Consequently, a total sample size of 12 was selected for this study.

The inclusion criteria for the study were as follows: being in the acute phase of stroke (i.e., the first 30 days after a stroke); being aged between 18 and 90 years; having PSD in the oral and pharyngeal phases; and having a normal level of consciousness. Conversely, patients were excluded from the study if they were unwilling to participate (i.e., due to non-cooperation or non-attendance) or could not cooperate in the swallowing examination due to low consciousness or comprehension. Another exclusion criterion was the recurrence of stroke or the incidence of other neurological disorders affecting dysphagia.

The control group received only routine hospital treatments, which included medical management of stroke, but did not receive any counseling or speech therapy to treat swallowing disorders. In contrast, the intervention group performed protocol-based exercises and received routine medical treatments. Medical treatments for stroke patients typically include pharmacotherapy. They are often categorized into three groups: drugs to address the primary cause of the stroke, drugs to prevent stroke recurrence, and complementary drugs based on the patient's blood test results. The medical treatment continued in both the control and intervention groups when the intervention treatment was introduced to the experimental group.

All the patients encountered psychosocial issues during meals. They exhibited one or more of the following symptoms: drooling, food spillage, choking accompanied by coughing, difficulties swallowing, prolonged mealtimes, stiffness or weakness of the face, tongue, and lips, movement disorders of the tongue and lips, problems with chewing, and the presence of a nasogastric (NG) tube (Table 1) [18].

Table 1: The dysphagia symptoms of the participants

Symptoms	Intervention group	Control group
Drooling	3	3
Food spillage down the chin	1	2
Choking accompanied by coughing	3	2
Difficulty swallowing	1	2
Long mealtimes	4	2
Stiffness of the face, tongue, and lips	1	1
Weakness of the face, tongue, and lips	3	4
Movement disorders of the tongue and lips	6	6
Chewing problems	5	4
Having an NG tube*	5	3

*Nasogastric tube (NG tube)

Randomization

Participants were recruited for this study using a simple random sampling method. The randomization sequence was created using the Random Allocation Software Version 2.0 and stratified in our center by a non-clinically involved person, with a 1:1 allocation ratio and a random block size of two. A statistician used this software to create a table of random numbers and coded the participants accordingly; the order of the blocks was determined in this table. For allocation concealment of the generated codes, a blinded nurse interviewed the patients' family members. If the inclusion criteria were met, after obtaining written informed consent, the participants were allocated into groups A or B, using prepared sealed envelopes. Group A was the intervention group, and group B was the control group. The nurse was not familiar with the groups. Finally, the participants were allocated into the intervention and control groups. After the assignment to the groups, the intervention was performed for the intervention group. Written informed consent was obtained from all the intervention and control group participants.

In this study, the investigator who measured the outcomes, the investigator who implemented the protocol, and the statistical analyst were all blinded to the group allocations. The patients in the intervention group were aware of their treatment, while the patients in the control group were blinded to the treatment. It was impossible to blind the patients in the intervention group, as they received an intervention different from what they had previously received. The researcher ensured blinding for other individuals involved in this study, such as the nurse interviewing the patient's family members, the investigator measuring the outcomes and implementing the protocol, and the statistical analyst.

The Kolmogorov-Smirnov test was used to determine the normal distribution of data. The mean±standard deviation (SD) was calculated to present quantitative data. Due to the small sample size, the Wilcoxon signed-rank test was used to analyze intragroup differences, and the Mann-Whitney test was used for between-group comparisons. An intraclass correlation test was performed to evaluate the agreement between the two examiners. This test represented the degree of agreement between two raters and the agreement of repeated administrations by a single rater. Since this study was a pilot trial and the number of participants in each group was limited, no comparison was made between the patients and their follow-ups. All statistical analyses were performed using SPSS version 16 (SPSS Inc., Chicago, IL, USA).

This study was registered in the Iranian Registry of Clinical Trials (IRCT) under the IRCT code IRCT20190618043938N1. It also received approval from Shiraz University of Medical Sciences, with the ethics code IR.SUMS.REHAB.REC.1398.006. Written informed consent was obtained from all intervention and control group participants.

Measurements

Before the onset of treatment, each patient (in both groups) was evaluated using three scales: a demographic information questionnaire, the Motility Function (MF) test, and Mann's Assessment of Swallowing Ability (MASA) [20]. After five weeks, the severity of dysphagia was re-evaluated using the MF and MASA tests. One of the study's goals was to determine the shortest effective duration for the intervention. To achieve this, patients in the intervention group were re-evaluated each week after five days of therapy using the MF and MASA tests to monitor consistent improvement. The two tests took about 45 minutes to complete. Based on the cutoff point of the MASA test, treatment was either continued or terminated. In the intervention group, one patient who achieved the MASA cutoff point received treatment for two weeks, three for three weeks, and two for five weeks. Accordingly, different follow-up periods were considered for the patients. There were no changes in the trial outcomes after the trial commenced.

1. Demographic Information Questionnaire

Participants' general information was collected through this questionnaire.

2. MF Test

This test was based on the motility function test introduced by Hägg [18]. However, to enhance its performance, some details were modified. As per these modifications, the scoring scale was changed from a four-point to a two-point scale, representing the existence or non-existence of movement. The patient, lying or sitting on a chair or bed, was asked to perform 31 different movements across five sections, representing the motor function of their mouth. These movements encompassed the head, facial muscles, lips, jaws, tongue, and soft palate. The scores for the items were zero (indicating "lack of movement") and one (indicating "having movement"),

with the total score amounting to 31 (Appendix 1).

3. MASA

MASA, which consists of 24 items (Appendix 2), is a valid tool for diagnosing swallowing disorders [20]. The primary outcome of this study was to examine swallowing disorders using MASA, while the secondary outcome was to assess mouth motor function using the Motility Function (MF) test.

Intervention

The treatment protocol of this study consisted of 10 different stimulations for various body parts performed without medical gloves. These stimulations were prioritized as follows:

1) Thermal stimulation of the facial area [21]: This was performed using a bag of hot water placed on one-half of the patient's face for 15 seconds. The same procedure was performed for the other side of the face and repeated for five cycles.

2) Superficial stroking of the face [16]: The therapist's palm was placed on one half of the face and moved down from the hairline (reaching the mandible bone) for one minute. The same procedure was performed for the other side of the face and repeated for three cycles.

3) Thermal stimulation of the neck area [21]: This stimulation was performed using a hot water bag on one side of the neck. The bag covered the neck from the mandible to the clavicle bone for 15 seconds. The same procedure was applied to the other side of the neck and repeated for five cycles. During the 15 seconds of stimulation, care was taken to ensure the water temperature did not lead to rubefaction.

4) Superficial stroking of the neck [16]: The therapist's palm was placed on one half of the neck and moved from the mandible bone to the clavicle for one minute. The same procedure was performed for the other side of the neck and repeated for three cycles.

5) Tapping on the suprahyoid triangle of the neck [16]: The neck was gently tapped with four fingertips for one minute. There was a 30-second break between the sets, and the procedure was repeated for three cycles.

6) Deep stroking of the anterior belly of the digastric muscle [16]: The therapist kept the pad of their index finger in contact with the origin of the anterior belly of the digastric muscle and moved it along the muscle fiber (reaching the sternocleidomastoid muscle) on each side of the neck for 30 seconds. This procedure was repeated for the other side of the neck and performed for three cycles.

7) Superficial stroking of the lips [16]: The therapist placed the index finger pad perpendicularly at the corner of the upper lip and moved it from left to right for 30 seconds. The same procedure was applied to the lower lip and repeated for three cycles.

8) Tapping on the lip area [16]: The therapist placed the index finger pad perpendicularly at the corner of the upper lip and tapped from left to right for 30 seconds. The same procedure was applied to the lower lip and repeated for three cycles.

9) Intraoral superficial stroking stimulation [16]: A tongue blade was used to stimulate six intraoral surfaces for about one minute without touching the surrounding structures. These surfaces included the tongue (stroked from back to front before triggering a gag reflex), palate (stroked from back to front depending on the palatine reflex threshold), cheeks (stroked from inside out), and vestibule (stroked from left to right) of the upper and lower lips.

10) Facial nerve (FN) stimulation: This treatment has two stages. In FN1, the therapist stroked five pathways on the face with a piece of ice (Figure 1) for 30 seconds in all directions. A similar procedure was applied to the other side of the face. FN2 involved deep stroking of the face [16]. The therapist's index finger pad was placed at the starting point of each pathway and moved to the endpoint on both sides of the face simultaneously for 30 seconds. The same procedure was applied to the other pathways.

All treatments were performed by a speech and language pathologist, who was an expert in dysphagia treatment and was trained on how to apply the protocol. The treatments were performed at the hospital until discharge and continued at the participant's home after discharge once a day, five times per week. After the onset of the trial, three participants in the intervention group showed absent gag reflexes for the MASA test. Therefore, three stimulations were added to the abovementioned protocol for these patients:

1) Stimulation of the posterior pharyngeal wall [16]: A tongue blade was used to gently stimulate the posterior pharyngeal wall without touching the surrounding structures. This stimulation continued until a gag reflex response was observed.

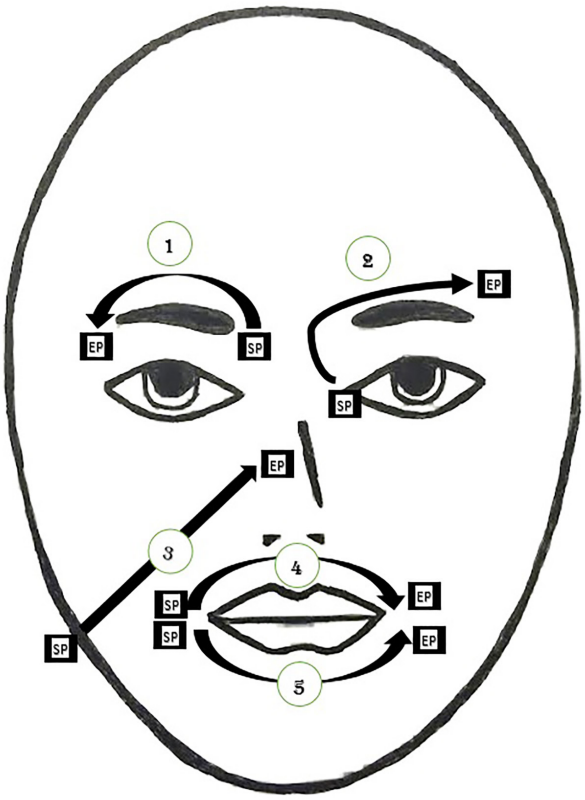

Figure 1: Pathways of facial nerve stimulation. SP: Starting point of pathway; EP: End point of pathway

2) Depression of the root of the tongue [22]: For this stimulation, a tongue blade was used to gently depress the root of the tongue without touching the surrounding structures. This stimulation continued until a gag reflex response was observed.

3) Elevation of the soft plate [22]: A tongue blade was used to gently elevate the soft plate without touching the surrounding structures for 30 seconds.

After observing the reflex response, we terminated the three stimulations. This exercise was only administered to a subset of patients in the intervention group. It's important to note that this vital reflex is inherent in all humans. However, its stimulation can be unpleasant for healthy individuals and patients whose reflex is not damaged; thus, we refrained from stimulating it or administering treatment. The treatment protocol was consistent for all patients, with the last three exercises relating to the gag reflex. However, some patients whose reflexes were not damaged did not perform these exercises due to discomfort and unpleasantness. Additionally, we evaluated the contraindications of massage strokes, such as infection, burning, and wounds at the site of the strokes, both before and after the intervention. An observer recorded adverse effects, such as skin redness or lesions, in a checklist.

Results

Fifteen stroke patients were initially recruited for this study. However, the final sample size was 12, comprising six women and six men, with a mean age of 72.42±10.66 years, ranging from 54 to 85 years. The intervention and control groups each consisted of three men and three women. Three participants were excluded from the study due to secondary stroke during the study period and unwillingness to continue. These included one patient from the intervention group and two from the control group. Consequently, the study was completed with 12 conscious stroke patients (six females and six males). Statistical analysis was performed on these 12 participants (n=6 per group). The study spanned a maximum duration of five weeks. One patient reached the intended cutoff point after two weeks, three patients after three weeks, and two patients after five weeks (in the sixth examination) (Figure 2)

The participants had a mean age of 72.42 years (SD=10.66). All neuroimaging data were collected from computed tomography (CT) scans. These scans revealed that 11 patients (91.65%) had suffered an ischemic stroke, while one patient (8.65%) had experienced a hemorrhagic stroke. Furthermore, eight patients (66.6%) exhibited non-fluent speech patterns, such as slurred speech or mutism, while four (33.3%) demonstrated fluent speech. The tests were conducted within an average of 10.75 (SD=6.35) days post-onset.

In the initial assessment (before the intervention), there was no significant difference between the intervention group (mean=110.50, SD=12.021) and the control group (mean=143, SD=18.011) in terms of the MASA score (P=0.2). Similarly, no significant difference was observed between the intervention group (mean=9, SD=7.071) and

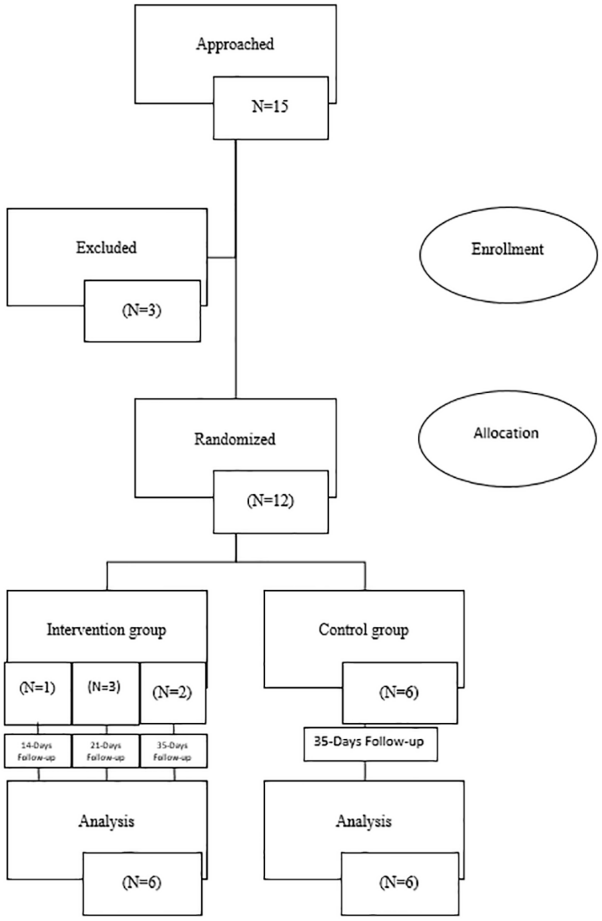

Figure 2: The CONSORT flow diagram

the control group (mean=18.50, SD=5.01) regarding the oral MF score (P=0.1). The main demographic and clinical characteristics of the participants in both groups are presented in Table 2.

According to the statistical analysis, the MASA score significantly improved in the intervention group after a 35-day intervention (P=0.02). There was also an improvement in the MF score of the intervention group compared to the first day (P=0.02). Significant progress was observed in the MASA score in the control group (P=0.028). Furthermore, the improvement level in these patients' MF scores showed a significant difference from the first day to day 35 (P=0.027).

Based on the findings, there was no significant difference in the mean MASA score (P=0.5) after seven days of intervention in the intervention group (133.50±14.84) compared to after 35 days in the control group (163±10.02). However, a significant difference was observed between the groups in terms of the mean MASA score (P=0.03) after 21 days of intervention in the intervention group (166.5±3.53) compared to after 35 days in the control group (163±10.02).

A significant difference was also noted in the mean MF scores (P=0.05) after seven days of intervention in the intervention group compared to after 35 days in the control group (P=0.02). However, this difference was insignificant after 35 days of intervention (P=0.4).

The most significant mean difference in the MASA scores between the initial assessment (before intervention) and the subsequent assessments (second, third, fourth,

Table 2: The demographic information of the participants

Groups	Intervention group (n=6)	Control group (n=6)
	Mean±SD	Mean±SD
Age (years)	72±10.25	72.83±12.02
Duration (days)	9.3±4.58	12.17±4.58
Sex		
Male	3 (50%)	3 (50%)
Female	3 (50%)	3 (50%)
Stroke type		
Ischemic stroke	6 (100%)	5 (83.3%)
Hemorrhagic stroke	0 (0%)	1 (16.7%)
Neuroimaging		
CT scan	6 (100%)	6 (100%)
Speech type		
Non-fluent	4 (66.6%)	4 (66.6%)
Fluent	2 (33.3%)	2 (33.3%)

Duration: Interval between the stroke and the first bedside examination.

Table 3: The intra- and intergroup comparisons of the intervention and control groups

	Intervention			Control			Between-group comparisons		Effect size
	Before (n=6)	After (n=6)	P-value^{w}	Before (n=6)	After (n=6)	P-value^{w}	Before (n=6)	After (n=6)	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		P-value^{b}	P-value^{a}	
MASA[1] score	110.50±12.02	177.50±7.07	P=0.02	143±18.01	163.00±10.02	P=0.028	P=0.2	P=0.03*	1.67
MF[2] score	9.00±7.07	22.50±6.36	P=0.02	18.50±5.01	25.50±2.88	P=0.027	P=0.1	P=0.4**	0.61

P-value^{w}: Within-group comparison in the intervention and control groups. P-value^{b}: Between-group comparison before the intervention. P-value^{a}: Between-group comparison after the 21-day intervention. *After 21 days of intervention in the intervention group and after 35 days in the control group. **After 35 days of intervention in the intervention group and after 35 days in the control group. 1-Mann's Assessment of Swallowing Ability (MASA); 2- Motility Function (MF)

fifth, and sixth assessments) was observed in the sixth assessment in the intervention group (67±11.31). Furthermore, patients in the intervention group reached the cutoff MASA score in the sixth MASA assessment (after 35 days of intervention).

Moreover, a gag reflex response was observed in three patients from the intervention group who initially did not exhibit a gag reflex response. This response was observed in two patients after one week of treatment and in one patient after two weeks. Further details on group comparisons can be found in Table 3.

The intra-rater agreement for the MASA and MF tests was perfect, with a score of one at a 95% confidence interval (CI) of 0.998-1.000 and 0.997 at a 95% CI of 0.976-1.000, respectively. The inter-rater agreement for the MASA and MF tests was also high, with scores of 0.969 at a 95% CI of 0.799-0.996 and 0.895 at a 95% CI of 0.434-0.985, respectively.

Discussion

This study aimed to ascertain how the rhythm, depth of technique, and duration of thermal and neuromuscular stimulations influence PSD. The current findings revealed a significant difference in the mean swallowing disorder scores after 21 days of intervention in the intervention group compared to after 35 days in the control group. A significant difference was also observed in the mean MF scores after seven days of intervention in the intervention group compared to after 35 days in the control group. These findings suggest that individual movements, as assessed by the MF test, showed a spontaneous and gradual improvement over 35 days.

However, the improvement in swallowing function, a complex cognitive function, was not as significant as the spontaneous improvement observed in individual movements. This discrepancy may be attributed to the differences between individual and complex movements. Generally, complex movements necessitate the simultaneous engagement and organized control of intricate temporal (e.g., rhythm) and ordinal motor processes. Furthermore, complex movements activate the basal ganglia for timing and the cerebellum for sequential ordering [23]. In contrast, simple movements of individual body parts primarily activate the primary motor cortex [24].

The intervention implemented in this study encompassed combined thermal and superficial stroking stimulations on the face, neck, and intraoral areas. The current findings align with previous neuroplasticity findings related to the tongue and face sensorimotor cortex, suggesting their contributions to the control of chewing and swallowing [25]. In this context, Regan et al. reported that sensory stimulation improved swallowing in individuals with PSD. If neurological damage is present in the efferent swallowing system, sensory stimulation can alter the motor output for swallowing. This could be achieved through stimulations such as thermal stimulation of facial arches, which are among the areas of the oral cavity and pharynx. These areas have been identified as indirect projections of the brainstem swallowing pathway, contributing to improved pharyngeal deglutition [26].

Hägglund and Hagg concluded that oral neuromuscular training led to long-term improvements in swallowing for individuals who had impaired swallowing following a stroke. Recovery was observed in all participants. This recovery appears due to the motion pattern expressing the sensory-motor reflex arc. This arc is actuated by sensory

stimulation through the afferent path and returns as an impulse in the efferent motor path [18].

One specific aspect of this study's intervention protocol involves stimulating the face and neck to enhance swallowing. Previous findings have shown that thermal and superficial stroking stimulation of the face and neck can affect swallowing and MF. According to other studies, the face sensorimotor cortex plays a significant role in chewing and deglutition [25]. Therefore, stimulating the face and neck may provide additional benefits in improving swallowing.

Furthermore, this study suggests that combined thermal and neuromuscular stimulations of the face, neck, and intraoral areas can significantly improve stroke patients' oral motility and swallowing function. This can be explained by the fact that the areas of the brain triggered by oral temperature include the insular taste cortex (identified by glucose taste stimuli), a part of the somatosensory cortex, the orbitofrontal cortex, the anterior cingulate cortex, and the ventral striatum. These areas can contribute to the improvement of oral motility and swallowing function. Multimodal inputs, such as taste and oral temperature, were essential for the oral aspects of touch, with somatosensory inputs enhancing the texture and mouthfeel of food [27]. It appears that combining thermal and neuromuscular stimulations increases the activation of the somatosensory cortex more than neuromuscular stimulation alone, thereby altering oral motility and swallowing function.

The most effective component of the protocol above was the intraoral superficial stroking stimulation. On the one hand, due to various challenges with oral somatosensory stimulation, such as the stable fixation of electrodes in the oral cavity, particularly on the tongue [28], superficial neuromuscular stimulation may be the optimal choice for managing neurogenic oral-motor disorders. On the other hand, the six intraoral surfaces for superficial stroking could facilitate movement initiation in patients with a neurogenic oral motor disorder. This is because self-touch in the somatic sensory system is largely regulated by activities such as scratching, stroking, and grooming. In essence, the oral somatosensory function arises from self-touch [29]. These sensory contributions are typically produced by the active movement of oral tissues [30]. Due to the absence of self-touch, neurogenic oral motor disorder patients are deprived of these sensory inputs. Therefore, the lack of self-touch, another consequence of neurogenic oral motor disorder, appears to result in oral somatosensory dysfunction. However, six intraoral stroking surfaces may compensate for this deprivation and enhance the oral somatosensory function."

Another finding of this study is the one-minute duration of thermal and neuromuscular stimulations. This one-minute stimulation can activate certain mechanoreceptors during tongue movements, in addition to regulating the masticatory force. This is because slowly adapting mechanoreceptors, located more deeply within the tongue muscle, are active during tongue movements and regulate the masticatory force.

Moreover, the proposed intervention involves stimulating the middle part of the tongue from back to front before triggering a gag reflex. Stimulating the middle and anterior parts of the tongue may be more effective in individuals with an active or hypersensitive gag reflex, as these areas are more sensitive than the posterior and lateral parts [29]. However, for individuals with an absent gag reflex, tongue stroking should commence from the posterior tongue, as the activation of the primary somatosensory area is higher following the stimulation of the posterior part than the anterior part. Furthermore, since tongue stimulation is perceived in the hemispheres both contralaterally and ipsilaterally [31], PSD is at least partially initiated by damage to functional connectivity within the deglutition network, leading to reduced activation of both injured and undamaged hemispheres [30]. Therefore, this midline stimulation may activate cortical lesions and the healthy side and is suggested for both unilateral and bilateral lesions [31]. This study had several limitations. Infections that occurred before or during the intervention posed a challenge. Given the patients' status (old age and acute phase of stroke), videofluoroscopy and endoscopic procedures were not performed. Data collection and follow-up of treatments were also challenging, and similar to previous studies, the sample size was small [18, 19]. Due to the small sample size, we could not match participants for severity of stroke, severity of dysphagia, age, and time post-stroke onset. Therefore, we did not consider excluding these differences and only assessed statistically significant improvements. Furthermore, due to the small sample size, this study lacked sufficient statistical power to generalize the findings.

In this pilot study, due to several reasons (such as the non-cooperation of patients to participate in the treatment and continue the 5-week treatment process), we could not exclude people who had an active gag reflex or perform a separate analysis for these two groups (people who had active and absent gag reflex). For future studies, it is suggested that these techniques be investigated separately for these two groups. In people with an active gag reflex, the three techniques (in the posterior pharyngeal wall, soft palate, and tongue root) that stimulate gag reflex movement should not be performed.

Another limitation of this study was the lack of blinding in the intervention group. It was not possible to blind the patients in the intervention group, as they received a different intervention from what they had routinely received before. However, blinding was performed for other individuals involved in this study, such as the nurse interviewing the patient's family members, the investigator who measured the outcomes, the investigator implementing the protocol, and the statistical analyst.

Conclusion

Based on the current results, a combination of thermal and neuromuscular stimulations can serve as a safe and effective treatment for patients with PSD, helping to alleviate their swallowing problems. Both thermal and neuromuscular stimulations significantly improved swallowing and the motor function of the mouth, with effects becoming apparent immediately after a 21-day

intervention. Consequently, these stimulations were identified as a safe and effective strategy to shift treatment from compensation to the recovery of swallowing function in elderly patients with PSD. To enhance MF and PSD, the proposed protocol recommends these stimulations for approximately 21-35 days. Overall, this study offered promising insights into clinical swallowing rehabilitation and laid the groundwork for a large-scale trial. It's worth noting that there were no adverse treatment effects, and all patients found the treatment tolerable.

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