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Direct effects of Facio-Oral Tract Therapy® on swallowing frequency of non-tracheotomised patients with acute neurogenic dysphagia

Jürgen Konradi[1,2], Annekatrin Lerch[2], Marilena Cataldo[1] and Thomas Kerz[3]

Abstract

Objectives: The aim of this study was to investigate the direct effect of Facio-Oral Tract Therapy® on swallowing frequency of non-tracheotomised patients with acute neurogenic dysphagia.

Methods: Within a pre-, post-/during and follow-up study design, 19 non-tracheotomised dysphagic patients were included consecutively and treated according to three specific preselected Facio-Oral Tract Therapy stimulation techniques.

Results: The primary outcome was the direct effect of the three different Facio-Oral Tract Therapy stimulation techniques on the number of swallows. We found a significant effect of Facio-Oral Tract Therapy on swallowing frequency as compared to baseline with an increase by 65.63% and medium effect size of D = 0.62. No significant difference could be demonstrated when comparing baseline to follow-up.

Conclusion: For the first time, this positive therapy effect could be demonstrated on a population of non-tracheotomised patients. Facio-Oral Tract Therapy seems to be an appropriate means for improving effectiveness and safety of swallowing. Since improvement was not long lasting, it appears to be reasonable to apply therapy frequently during the day with the plausible result of minimising the amount of aspirated saliva and thereby reducing the risk of aspiration pneumonia. Further studies may consider choosing a randomised controlled trial design to demonstrate that change in swallow frequency is related to the target intervention only.

Keywords

Facio-Oral Tract Therapy, deglutition, deglutition disorders, dysphagia therapy, neurogenic dysphagia, swallowing saliva

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Introduction

The treatment of neurogenic dysphagia is of high clinical importance, since patients suffering from swallowing disorders are at high risk of developing aspiration pneumonia,[1] with strong converging evidence.[2–7] Existing therapies for patients with swallowing disorders after head and neck surgery origin in the work of Logemann,[8] which became extended to patients with neurogenic swallowing disorders building the empirical basis of the functional swallowing therapy.[9–15] The application of these techniques relies on patients with adequate vigilance and cooperation. Therefore, Kay Coombes developed a new concept, Facio-Oral Tract Therapy® (FOTT),[16] which is based on the Bobath concept,[17] and has already been defined and described for rehabilitation.[18] Within the FOTT-framework, there are four interacting major areas of interest: swallowing of saliva and eating, breathing/voice/speech articulation, facial expressions, and

[1]Institute for Physical Therapy, Prevention and Rehabilitation, University Medical Centre of the Johannes Gutenberg University Mainz, Mainz, Germany
[2]Department for Health Care & Nursing, Catholic University of Applied Sciences, Mainz, Germany
[3]Department of Neurosurgery, University Medical Centre of the Johannes Gutenberg University Mainz, Mainz, Germany

Corresponding author:
Jürgen Konradi, Institut für Physikalische Therapie, Prävention und Rehabilitation, Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Langenbeckstrasse 1, D-55131 Mainz, Germany.
Email: juergen.konradi@unimedizin-mainz.de

oral hygiene. Additionally, the FOTT-concept distinguishes four phases of swallowing: the pre-oral (preparation and transportation of food to the mouth), the oral (forming and transport of bolus through the oral cavity), the pharyngeal (safe transport of bolus from the oral cavity through the pharynx into the oesophagus, initiation of the swallowing reflex), and the oesophageal phase (transport of bolus through the oesophagus into the stomach).

In our study, we focus mainly on the first area, precisely swallowing of saliva by targeting the oral and the pharyngeal phase by means of three specifically chosen stimulation techniques. It can be assumed that FOTT stimulation techniques targeting the oral and pharyngeal phases of swallowing as relevant phases for swallowing saliva[18] may have the benefit of decreasing the risk for acquiring aspiration pneumonia[1] by improving the effectiveness and safety of swallowing.[18] The notion behind this claim is that if (pooled) saliva is swallowed safely, there will be less saliva that might become aspirated therefore reducing the probability for aspiration pneumonia. This claim does not imply that by improving saliva swallowing only there will be an expectancy of effective safe swallowing of food stimuli. The neurophysiological idea is to place tactile stimuli for sensory stimulation and prevention of sensory deprivation. Furthermore, the facilitation of movements and movement directions derived from physiological processes shall lead to a stimulation of the motor system,[19] causing a motor response of the structures involved, and at best triggering a swallowing process.[16]

Even though there is 'no EBM-data',[20] FOTT is already in widespread use across many neurological rehabilitation units in Germany, Austria, Switzerland and Scandinavia.[16] In a first pre-/post-intervention group study[21] including 10 tracheotomised patients with severe neurological impairments, no statistically significant change in swallowing frequency during the treatment as a direct effect of the FOTT intervention could be detected. Rather, there was a significant decrease in swallowing frequency between completion of the treatment session and repositioning of the patient. Swallowing frequency after repositioning increased slowly and after 90 min had re-attained the pre-treatment level. The increase in swallowing frequency over the entire therapy period of 15 days (1 h per day) and protection of the lower respiratory tract were indeed statistically significant but can also be attributed to spontaneous recovery due to the chosen study design.[22]

Furthermore, regarding the conduction of FOTT studies and its evidence, it can be noted that indeed there are concrete principles of FOTT, but concrete instructions of how to perform therapy are still lacking, which makes it difficult to conduct research and compare studies.[23]

Taken together, it seems reasonable to start testing FOTT on a more basic level, before evaluating the whole framework at once.

The aim of this study was to evaluate the direct therapy effect of FOTT on swallowing frequency (primary outcome) in a larger and non-tracheotomised population suffering from acute neurogenic dysphagia.

Methods

The study was carried out in a pre- (A), post-/during (B) and follow-up (A) study design with consecutive inclusion of patients during a predefined period of 6 months (September 2012 until February 2013) with clear signs of dysphagia after clinical examination and dysphagia screening[24] as the key inclusion criteria. A total of 19 non-tracheotomised patients (13 male, mean age = 63.59, standard deviation (SD) = 13.13, range = 26–81 years), 2 before and 17 after neurosurgery of the head (mean = 8.24, SD = 7.24 days post-onset) for various reasons (see Table 1) were included.

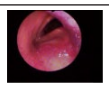
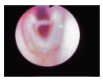
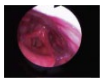
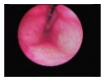
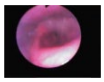
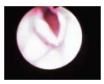
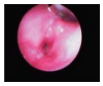
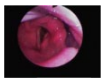
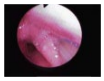
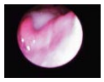
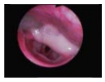
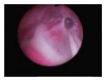
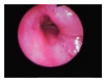
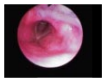
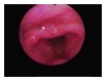
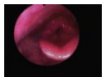
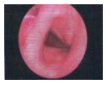
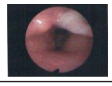
Neurogenic dysphagia was diagnosed using endoscopic evaluation (Rhino-Laryngofiberscope Olympus ENF Type GP, 3.4/3.6 mm diameter, rp-Szene; Rheder und Partner Medizintechnik, Hamburg, Germany) according to the Langmore protocol[25] for Fiberoptic Endoscopic Evaluation of Swallowing (FEES) together with the Penetration and Aspiration Scale (PAS) of Rosenbek[26] for the severity of the swallowing disorder for saliva. Patients with either severely decreased consciousness or patients that have already shown relevant aspiration of saliva during the FEES did not receive boluses. As a measure for consciousness, the Glasgow Coma Scale (GCS)[27] was used. All assessments were carried out during the same day the intervention took place (Table 2).

Diagnostics and therapy were conducted at the Department of Neurosurgery, University Medical Centre of the Johannes Gutenberg University Mainz as part of the necessary daily routine as an observational study for which no formal vote of the ethics committee is mandatory. The trial was conducted according to the principles of International Conference on Harmonization–Good Clinical Practice (ICH-GCP), legal regulations, and the Declaration of Helsinki in its latest accepted version. All patients, their relatives or legal representatives gave their informed consent. The study protocol was approved by the responsible and competent authorities (i.e. acceptance as an observational study by the ethics committee of the Federal Chamber of Physicians of Rhineland-Palatinate; approval by the Clinical Director of the Department for Neurosurgery and by the Head of the Institute for Physical Therapy, Prevention and Rehabilitation) before start of the trial. Serious adverse events had not been expected.

Design and primary outcome

As shown in Figure 1, the swallowing frequency as the primary outcome was measured via palpation of the larynx within three conditions for 6 min each: patient in upright sitting position (baseline), during application of FOTT and after a rest period of 5 min still in upright sitting position (follow-up).

Table 1. Full characteristics of 19 patients.

Nr	Sex	Age	Aetiology	Days postop	GCS score	FEES	Rosenbek scale
1	M	66	ICH, Leukaemia	32	3		8
2	M	69	Sphenoid wing meningioma (left side)	15	11		7
3	F	61	Craniopharyngioma grade I	15	4		8
4	M	76	Non-obstructive hydrocephalus	7	15		2
5	M	26	Epidural haematoma after craniectomy	10	6		3
6	M	68	Non-obstructive hydrocephalus after subarachnoid haemorrhage	4	14		8
7	F	81	Right frontal ICH	6	3		6
8	M	73	Left parietal ICH after stroke and intravenous lysis	2	12		5
9	M	57	CSF-fistula after operation of meningeoma	8	13		3
10	F	69	Posterior fossa ICH right-sided	9	14		8
11	F	68	Malignant melanoma with cerebral metastases	N/A	13		7
12	M	53	MCA-aneurysm left side with intraventricular bleed	3	13		8
13	M	72	Obstructive hydrocephalus after SAH from ICA-aneurysm	5	5		8
14	M	44	Aneurysm, SAH, ICH right frontally, high ICP	3	13		8
15	F	65	Malignant melanoma with cerebral metastases	2	15		3
16	M	61	Acoustic neurinoma right side	6	12		4
17	F	72	Skull defect after craniectomy for SAH and ICH	7	10		1
18	M	77	Acute subdural haematoma right side	6	11		7
19	M	71	Bifrontal intracranial tumour	N/A	15		8

GCS: Glasgow Coma Scale; FEES: Fiberoptic Endoscopic Evaluation of Swallowing; ICH: intracranial haemorrhage; CSF: cerebrospinal fluid; MCA: middle cerebral artery; SAH: subarachnoid haemorrhage; ICA: internal carotid artery; ICP: intracranial pressure.

Table 2. Patients and values.

Patients	Values
Sex	13 male, 6 female
Age	Mean = 63.59, SD = 13.13, range = 26–81 years
Aetiology	Cerebral blood flow disorders and non-traumatic intracranial bleeding (n = 11), brain tumour and brain pressure change (n = 8), cranio-cerebral injury (n = 1)
GCS[a]-score	Mean = 10.63, SD = 4.22, range = 3–15
PAS[b]-score	Median = 7, range = 1–8

SD: standard deviation; GCS: Glasgow Coma Scale; PAS: Penetration/Aspiration Scale.
[a]Teasdale and Jennett.[27]
[b]Rosenbek et al.[26]

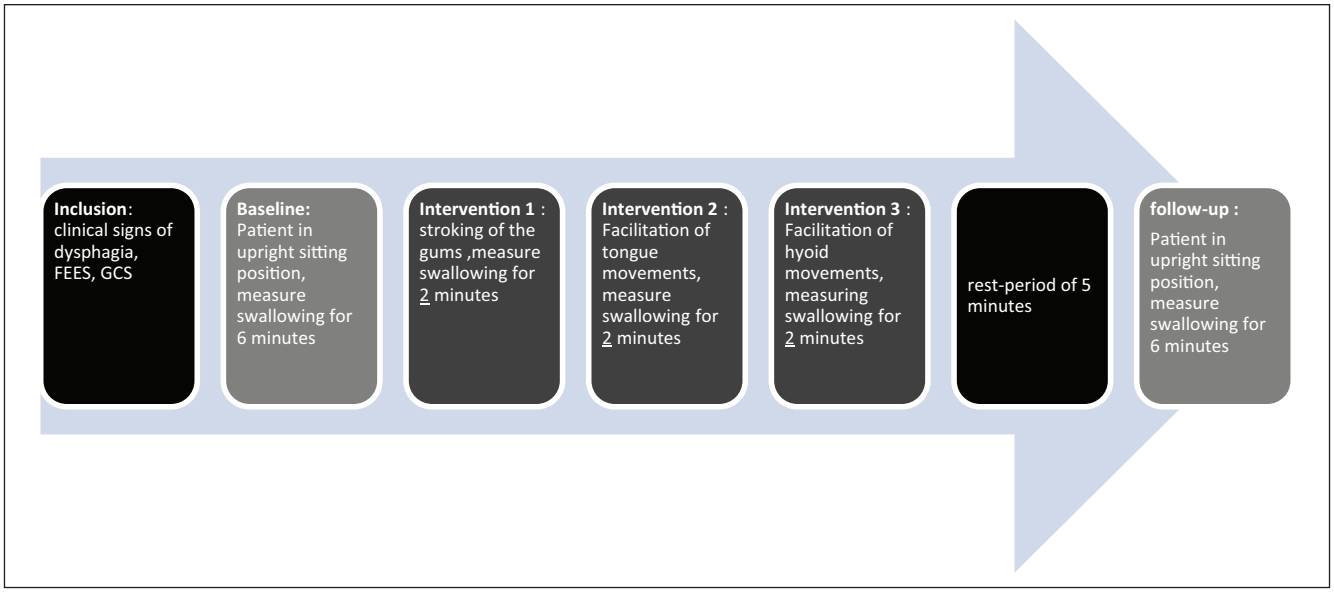


Figure 1. Course of the study.

Detailed description of the application of FOTT

Patients were treated according to three specific preselected FOTT stimulation techniques targeting the oral and pharyngeal phases of swallowing as relevant phases for swallowing saliva[18] with the possible benefit of decreasing the risk for acquiring aspiration pneumonia[1] by improving the effectiveness and safety of swallowing.[18]

Before the measurements started, the patients were mobilised according to the chosen therapy concept and brought in the best possible physiological posture for swallowing, an upright sitting position of approximately 70°.[28–30] Although this is already an integral part of the FOTT-concept, essential to increasing vigilance and heightening awareness, we chose to do so since we were interested in testing the stimulation techniques only and since it may lead to severe methodological problems as occurred in the study of Seidl et al.[21] when there was a significant decrease in swallowing frequency between completion of the treatment session and repositioning of the patient.

Baseline. Before the intervention phase, a 6-min baseline measurement of the spontaneous swallowing frequency was taken. The measurement of swallowing frequency, both in the baseline period as well as in all other phases, was done by visually observing the laryngeal elevation and by tactile palpation of laryngeal elevation with the tip of the index finger. A full laryngeal elevation beyond the tip was counted as a sufficient swallow (for methods of bias prevention, see below).

Immediately after the baseline measurement, the intervention phase started. In the intervention phase, the following three FOTT stimulation techniques were applied in a sequential order, imitating the natural way of the bolus: oral preparation, oral–pharyngeal transition, and pharyngeal phase with triggering of the swallowing reflex.

Intervention 1. Starting with targeting the oral phase, there was a 2-min oral stimulation, the so called quadrant stimulation.[31] It consists of a massaging stimulation with the finger tip of the therapist's little finger within the oral cavity of the patient. It is carried out along the gums from the front to the

rear and back within all quadrants of the mouth and is concluded with the elongation of the respective inner cheek. Since bite reflexes could not be excluded in all patients, the next step of the usual FOTT-concept, the stimulation of the tongue and the hard palate, was omitted to achieve uniformity in conducting the study.

Intervention 2. Targeting the oral phase at the transition to the pharyngeal phase of swallowing, the base of the mouth was stimulated for 2 min via a massaging motion with a cranial direction of movement.[32]

Intervention 3. Addressing the pharyngeal phase of swallowing, the patient's hyoid bone movement was facilitated via a cranio-ventrally executed stimulation along the physiological direction of movement.[32]

Follow-up. The intervention phase was followed by a rest period of 5 min, after which a further 6-min measurement of swallowing was carried out to investigate if possible therapy derived effects were maintained.

Considerations, measures of safety and bias prevention

As common for a pre–post design, the investigation was carried out without blinding of participants or the therapist. However, the rating of swallowing was blinded as follows: during baseline, the measurement was done by the therapist (rater A). During intervention, the therapist conducted therapy (Interventions 1–3) and the counting of swallows was done by rater B. Finally, during the follow-up measure, the calculation of swallows was performed by rater C. All three rating persons (authors of this article) were blinded for the previous outcome measure, are experienced therapists and are familiar with the treatment and diagnostics of neurogenic dysphagia. Additionally, in order to achieve uniformity in measuring, all raters rated five healthy subjects (two male) simultaneously within three pairwise blocks (subjects 1–5/raters A&B; subjects 1–5/raters A&C; subjects 1–5/raters B&C) for 2 min each. Inter-rater reliability was calculated by Intraclass Correlation Coefficients (ICC) with Statistical Package for the Social Sciences (SPSS) Version 19 (two-way mixed, absolute agreement) for average measures of the three pairs of raters. The ICC for raters A&B was 0.98, for raters A&C 1.0, and for raters B&C 1.0. Therefore, we argue that it is highly unlikely that bias was prominent in our measures of the primary outcome.

Data analysis

Statistical analyses were carried out using the statistics software package SPSS Version 19, IBM Germany, and Microsoft Office Excel 2010. To describe the effects on swallowing, the arithmetic mean and SD were used.

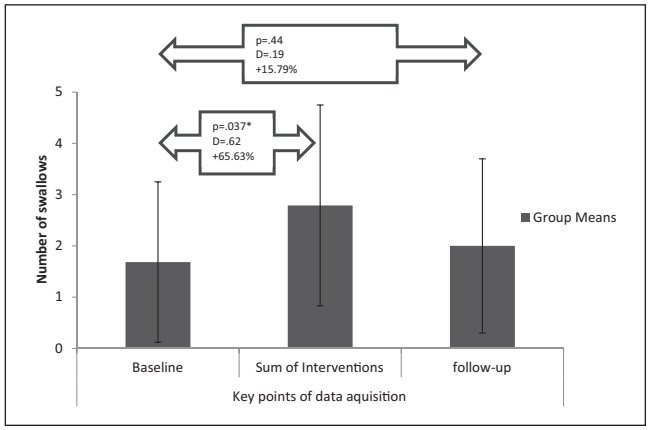


Figure 2. Main results of intervention. Means, standard deviations, effect sizes and percentage of improvement across the measurement points of the study.

Spearman rank-order correlations were used to determine the correlation between the measured parameters and swallowing ability. For testing significant differences, the Wilcoxon signed-rank test was performed. All tests were performed two-tailed.

Results

The primary outcome was the direct effect of the three different FOTT stimulation techniques on the number of swallows. The therapy effect is expressed via the difference of the number of swallows between the baseline and sum of swallows across all interventions. Both measured swallowing for 6 min.

As can be seen in Figure 2, the mean swallowing frequency during baseline was 1.68 (SD = 1.57) and 2.79 (SD = 1.96) during FOTT intervention, meaning an increase by 65.63%, a medium effect size of 0.62 according to Cohen's D, and a significant difference revealed by Wilcoxon signed-rank test ($Z = 2.081$, $p = .037$). A total of 14 (73.68%) participants showed positive reactions, 3 (15.79%) worsened, and 2 (10.53%) remained unaffected by FOTT. Comparing baseline and follow-up measures, the therapy effect diminishes. The mean swallowing frequency during follow-up was 2 (SD = 1.70), constituting only a small effect size of D = 0.19, with no significant difference by Wilcoxon signed-rank test ($Z = 0.77$, $p = .44$).

For comparison, within the control measures of healthy subjects the mean swallowing frequency of the employed surveillance window of 2 min was 5.6 (SD = 2.13).

When comparing the three stimulation techniques, an interesting pattern emerges. First, stimulation of the gums has a descriptively lesser effect on swallowing frequency (M = 0.79, SD = 0.92) than the two other types of stimulation (M = 1, SD = 0.94; Mean = 1, SD = 1.11) (Figure 3), and second, nine participants (47.37%) showed no reaction at all on this type of stimulation.

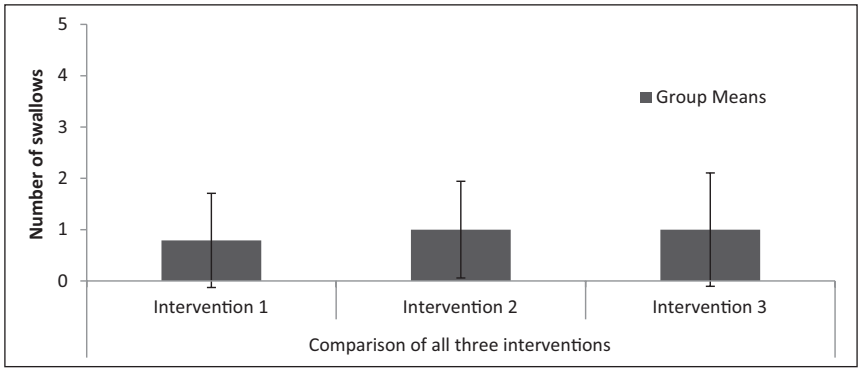


Figure 3. Means and standard deviations of all three interventions.

Table 3. Means, standard deviations and correlations for all variables.

Spearman-rho	M	SD	1	2	3	4	5	6	7	8	9	10	11
1. Age	63.59	13.13	1	−.07	−.08	−.14	−.25	.19	.10	.11	.17	.13	.32
2. D.a.s./p-o	8.24	7.24		1	−.45	−.00	.01	−.22	−.18	−.05	−.15	.09	−.17
3. GCS	10.63	4.22			1	−.05	−.10	**.47***	−.08	−.09	.10	−.11	.08
4. PAS	7	1–8				1	.21	−.04	.14	.04	.09	.04	−.07
5. Baseline	1.68	1.57					1	.16	.05	.15	.23	.38	−.44
6. I1	0.79	0.92						1	.15	−.11	.43	.08	.23
7. I2	1.00	0.94							1	**.52***	**.77****	.11	**.63****
8. I3	1.00	1.11								1	**.77****	.43	**.59****
9. Sum I1–I3	2.79	1.96									1	.36	**.67****
10. Follow-up	2.00	1.69										1	.11
11. Diff. Su-Ba.	1.11	1.91											1

SD: standard deviation; D.a.s./p-o: days after surgery/post-onset; GCS: Glasgow Coma Scale; PAS: Penetration/Aspiration Scale (Median/Range); I1: Intervention 1; I2: Intervention 2; I3: Intervention 3; Sum I1–I3: sum of Interventions 1–3; Diff. Su-Ba.: difference between sum of interventions and baseline. Signifcant values are boldfaced.
*$p < .05$; **$p < .01$ (two-tailed).

Additionally, Spearman rank-order correlations were calculated for all variables as can be seen in Table 3.

There were three types of significant correlations. First of all, there was a significant positive relation ($r = .47$, $p = .04$) between the GCS score and the reaction on the stimulation of the gums, signifying that the higher the state of consciousness the better the effect on swallowing frequency by this FOTT technique was. The second type consists of positive relations between Interventions 2 and 3, and between Interventions 2 as well as 3 and the sum of all interventions. The third type of significant positive relation can be found between the interventions and the difference between baseline and the sum of interventions.

Discussion/conclusion

As shown, there was a direct effect of FOTT stimulation on triggering swallowing reflexes with a medium effect size and an increase of 65.63%. Nearly three-quarters of the study population could profit from the stimulation. This result has various implications. First of all, it underpins the usefulness of FOTT and therefore its clinical relevance in the treatment of patients suffering from neurogenic dysphagia. FOTT seems to be an appropriate means for improving the effectiveness and safety of swallowing. Although a reduction in the risk of aspiration could not be detected with this study setting, it nevertheless appears to be a plausible result since it can be assumed that the initiation of swallowing reflexes would reduce the amount of pooled saliva in the hypopharynx. The fact that the improvement was not long lasting makes it reasonable to apply therapy frequently during the day in order to achieve a reduction of the amount of aspirated saliva and thus reducing the risk of aspiration pneumonia.

Furthermore, the results show that the supposed effect mechanisms of the three specifically selected FOTT stimulation techniques targeting the oral and pharyngeal phases of swallowing hold true. The neurophysiological concept to place tactile stimuli for sensory stimulation as well as the facilitation of movements and movement directions derived from physiological processes led to a stimulation of the motor system,[19] caused a motor response of the structures involved and triggered swallowing processes.[16]

Unfortunately, the therapy effect diminished to a small effect size of D = 0.19 when comparing baseline and follow-up, although the follow-up measurement was performed after a rest period of only 5 min. Further studies may consider lengthening the therapy phases in order to prolong the therapy effect.

Potential limitations arise from methodological issues. Since this trial was conducted as an observational study within the daily routine, there is no control group, receiving no intervention or a different but comparable kind of intervention. Future studies may consider choosing a randomised controlled trial (RCT) design with either no intervention or any kind of tactile stimulation to the face and/or neck area as possible control conditions. Our design shows that the chosen stimulation techniques contribute to an increase in swallowing frequency; a further RCT design might be able to demonstrate that change in swallow frequency is related to the target intervention only. Another limitation arises from the predefined data acquisition period of 6 months resulting in only 19 participants, which limits the external validity of the findings. We chose to do so since before our study there were no data available for a reliable formal estimation of an optimal sample size. But now, subsequent studies may consider our effect sizes as a basis for calculation.

Additionally, Interventions 1–3 were carried out consecutively without pausing in between. Thus, cross-over effects of the single interventions cannot be excluded. Furthermore, as demonstrated, there were statistically significant relationships between two of the three interventions. In order to make statements about the effectiveness of isolated interventions, they would have to be rated separately, with enough resting time in between, or they would have to be carried out in alternating order. However, this would have led to new difficulties, since this sequence of treatment was chosen deliberately due to being based on physiological conditions and the sequence of swallowing. So changes in order or timely separation of the interventions, although methodologically feasible, would have violated the idea of following the physiological swallowing process. Nonetheless, there was one technique with the lowest impact on the preferred outcome, that is, the stimulation of the gums. The fact that stimulation of the gums has no effect in 47.37% of the patients and that it is significantly positively correlated with the patients' vigilance, makes it clear that this technique is not primarily targeting the swallowing process and makes its suitability questionable for patients with reduced consciousness since its efficacy seems to rely on good vigilance. This is an interesting finding that needs to be considered by therapists when choosing the appropriate stimulation techniques.

A different interpretation of the findings would be to attribute the effects of techniques 2 and 3 to the massaging effect of the submandibular salivary glands increasing salivation, and subsequently reflexive swallowing, and not by tactile stimulation, or facilitation of movement and movement directions. Nevertheless, this notion lacks an explanation why the first intervention has no immediate effect, which we showed it does not have for nearly half of our participants. Since, if it increases salivation and has the strong potential to influence the latter Interventions 2 and 3, why does it have no immediate effect? Would it not be more plausible to expect that it would lead to more swallowing in the first place with a subsequent ongoing but becoming lesser effect afterwards?

Although there was no explicit monitoring of the medication (i.e. dehydrating agents or potent vasoconstrictors) and even if in some patients the reason for a reduced swallowing rate was a medical induced reduced production of saliva, this is not of primary relevance because in our statistical analyses we did not focus on the absolute amount of swallows but on the difference between baseline (pre) and post/follow-up. If there would have been effects of medication, they would have affected all relevant phases of the study with a levelling influence. Furthermore, we documented all patients' swallowing disorder with FEES showing relevant pooling, penetration and aspiration of saliva.

Taken together, these results underline the usefulness of FOTT and therefore its clinical relevance in the treatment of patients suffering from neurogenic dysphagia. For the first time, this positive therapy effect could be demonstrated on a population of non-tracheotomised patients suffering from neurogenic dysphagia.

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