Masterthesis Clinical Language Speech and Hearing Sciences

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Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life.

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Abstract

Objective: This study compares the effects of traditional logopedic dysphagia treatment versus NMES on quality of life in patients with Parkinson's disease and oropharyngeal dysphagia.

Material and method: 89 patients were randomized over three treatment groups: traditional logopedic dysphagia treatment or logopedic treatment combined with NMES at sensory or motor stimulation levels. Patients received 12 up to 15 sessions during three to five weeks. Three times (pre- and post treatment, plus three months following treatment), two quality of life questionnaires (Swal-QOL, MD Anderson Dysphagia Inventory) and a single item dysphagia severity scale were scored. The Functional Oral Intake Scale (FOIS) was applied to assess the dietary intake.

Results: After therapy all groups showed significant improvement on quality of life. Minimal group differences were found. These effects can still be measured three months following treatment. No significant correlation was found between the dietary intake and quality of life.

Conclusion: Logopedic dysphagia treatment results in an increased quality of life in patients with Parkinson's disease. Logopedic treatment combined with NMES shows similar results compared to solely logopedic treatment.

Introduction

Oropharyngeal dysphagia is a common finding in patients with Parkinson's disease. It is estimated that up to 80% of all patients will suffer from oropharyngeal dysphagia during the first stages of the disease. In later stages of the disease, the incidence of dysphagia can increase up to 95%. (Bird et al., 1994; Bushmann et al., 1989; Leopold et al., 1997; Mari et al., 1997; Nagaya et al., 1998; Robins et al., 1986; Wintzen et al., 1994). Literature describes the main etiology of dysphagia in patients with Parkinson's disease in terms of rigidity and bradykinesia of the swallowing function. Incomplete cricopharyngeal relaxation, reduced cricopharyngeal opening, and delayed initiation of the swallowing reflex have been suggested as possible mechanisms of dysphagia in this patient population (Ali et al.,1996; Nagaya et al., 2000). Furthermore, delayed oropharyngeal transition time, reduced muscle strength, as well as aspiration are common findings in dysphagic Parkinson patients. (Ertekin et al., 2002; Johnston et al., 1995; Nagaya et al., 2000).

Dysphagia is associated with malnutrition, dehydration, aspiration pneumonia and sudden death (Kirshner,1989; Marik et al., 2003; Martin et al., 1993). Dysphagia is also associated with severe consequences for the Quality of Life of patients (Gustafsson & Tiblin, 1991). In patients with Parkinson's disease these consequences become more prominent than in patients without Parkinson's disease, as quality of life will progressively decrease when the disease becomes more invalidating. (Ekberg et al., 2002; Tibbling et al., 1991; Marik et al. 2003; McHorney et al. 2000)

Currently, the treatment of dysphagia in patients with Parkinson's disease exists of traditional dysphagia treatment by a speech therapist. Usually, this treatment is provided once or twice a week, for several months or years. Oral motor exercises, airway protecting manoeuvres, and postural correction to facilitate bolus transition and thermotactile stimulation are included in this therapy (Crary et al., 2003). The literature regarding randomized controlled trials on the outcomes of speech therapy for swallowing dysfunction in patients with Parkinson's disease is scarce (Baijens et al., 2009). Nagaya et al. (2000) and Sharkawi et al. (2002) describe a positive effect of speech therapy on patients with Parkinson's disease and dysphagia, but methodological issues arise.

Neuromuscular electrical stimulation (NMES) is a therapeutic adjunct to known interventions in the treatment of dysphagia (Bogaardt et al., 2009; Baijens et al., 2006; Chetney et al., 2004; Freed et al., 2001; Leelamanit et al., 2002). The rationale of NMES is a stimulation of muscle fibres by stimulating the nerve and the motor-end-plate of the nerve, resulting in a re-education of the functional muscle-contraction-patterns (Freed et al.,2001; Leelamanit et al., 2002; Park et al., 1997). NMES has not been investigated in Parkinson patients with dysphagia yet. In this study, therefore, a randomized controlled trial was set up in which traditional therapy was compared to therapy with NMES in patients with Parkinson's disease and oropharyngeal dysphagia. It was hypothesized that NMES would not only contribute to a significant improvement of the swallowing function, but would also contribute to an increased quality of life in these patients.

Methods

Design

A three-arm open randomized trial was set-up to evaluate the hypotheses. For this study, approval of the medical ethical committee of the university medical centre was obtained. Following approval, the purpose of the study and inclusion criteria were sent to neurologists and ENT-specialists in the Netherlands asking for possible eligible patients to participate in this study. Furthermore, the Dutch Parkinson patient society was informed about the ongoing study. Prior to inclusion, patients were seen at the Maastricht University Medical Centre by an ENT-specialist and a speech language pathologist to evaluate definite eligibility for this study. The neurological diagnosis was confirmed by the patient's neurologist. Informed consent was obtained from all patients prior to participation.

Patient inclusion and exclusion criteria

For inclusion in this study the following criteria had to be met:
(1) diagnosis of idiopathic Parkinson's disease as confirmed by a neurologist;
(2) patient's physical condition considered as in a 'stable' course of Parkinson's disease;
(3) age between 40-80 years old.;
(4) presence of oropharyngeal dysphagia with preservation of the swallowing reflex;
(5) high motivation for dysphagia treatment (because of the frequency and the high intensity of the treatment).

Excluded were the following patients:
(1) patients with known other neurogenic diseases (such as ALS or MS);
(2) patients with severe mental depression or severe cognitive degeneration
(3) patients with deep brain stimulation or malignancies, extensive surgery or radiotherapy of the head and neck region;
(4) patients with severe cardiopulmonary diseases, epilepsy, carotis sinus syndrome or dermatological diseases of the head and neck;
(5) patients who received dysphagia treatment during the last six months prior to randomization.

Sample size and randomization

After a conservative sample size calculation, three intervention groups were formed. A minimum of 30 patients in each arm was set, leading to a total of 90 included patients, minimally. Patients were randomized to one of the three arms using a block randomization. Every block contained three patients, of whom each one was assigned to a different one of the three arms.

Treatment groups and treatment intensity

Patients were randomly assigned to the three treatment groups. Group 1 received traditional dysphagia treatment (Group TT) by a speech therapist. This treatment consisted of oral motor exercises, airway protecting manoeuvres and postural compensation . Group 2 and Group 3 received the same treatment as Group 1 combined with neuromuscular electrical stimulation of the suprahyoidal musculature. In this study, Vitalstim© equipment was used (VitalStim® Therapy; frequency 80 Hz, pulse width 700 microseconds; Chattanooga Group, Chattanooga, TN, USA). Stimulation time was one minute, with a rest period of one second. NMES consisted of transcutaneous electrical stimulation by positioning electrodes bilaterally on the neck in order to facilitate contraction of the suprahyoidal muscles. Group 2 and 3 differed in the applied current intensity of the NMES. The neuromuscular electrical stimulation of Group 2 (Group NMES-M) was set to stimulate at a motor level, to an extend that contractions of the underlying musculature were visible in combination with the subjective 'grabbing sensation' of the patient. Spasm of the musculature was avoided. Group 3 (Group NMES-S) received NMES on a sensory level only (Ludlow et al., 2007). Therapies were administered at the patient's residence by speech and language pathologists trained in dysphagia management. Therapists received additional training and information on NMES at the Maastricht University Medical Centre according to the manual of the manufacturer. All three groups received 12 to15 dysphagia treatment sessions of half an hour each, on five consecutive days per week within a period of three weeks. If required the food consistency was adapted, to ensure a safe intake of food.

Evaluation Measurements

Baseline characteristics

The following tools (or scales) were used to describe the patient characteristics; The Mini Mental State Examination (MMSE) was scored to ensure an intact cognition (Folstein et al. 1975). The Hoehn and Yahr Scale was used to judge the severity of Parkinson's disease (Hoehn et al. 1967). All baseline characteristics were determined by an experienced physician.

Pre-, Post- and Follow-up treatment evaluation.

As dietary evaluation the Functional Oral Intake Scale (FOIS) (Crary et al., 2005) was used to measure a functional improvement in swallowing or a difference in oral intake. Two questionnaires on quality of life related to oropharyngeal dysphagia were used in this study: the SWAL-QOL (McHorney et al., 2002) and the MD Anderson Dysphagia Inventory (MDADI) (Chen et al., 2001). The SWAL-QOL judges specifically the quality of life affected by dysphagia. The Dutch translation of the SWAL-QOL, translated and validated by Bogaardt et al. (2009), was used to determine the quality of life in oropharyngeal dysphagia. The 44-item analysis is a highly valid instrument in evaluating the quality of life concerning dysphagia. In addition, the SWAL-QOL has a very reliable short-term reproducibility. Its eleven subscales represent the different aspects of quality of life. The minimum and maximum score per subscale are zero and 100, indicating extremely impaired quality of life versus no impairment as experienced by the individual. The MDADI consists of 20 items and is composed of a global assessment (a single question) and three subscale: the emotional, the functional, and the physical subscale. It uses a five-point scale with a minimum of 20 and maximum score of 100. The original scoring uses a reversed coding in two items. In the Dutch translation (Speyer et al., 2010)all items are rated the same, thus, rewriting two questions. All three measurement tools were used to evaluate swallowing function at three time points: pre-treatment, post-treatment and at a three months follow-up.

In addition, a visual analogue scale, the Dysphagia Severity Scale (DSS), was used to evaluate difficulties in swallowing. Using the DSS, the patient self-reports his swallowing function with a score from 0 to 100 by rating a single question: 'How do you qualify your swallowing today?' (0 = Can't swallow at all; 100 = Normal swallow). The

DSS was filled in after every treatment session. Therefore, the DSS had a maximum of 15 measurement moments; The first two measurements were averaged as a baseline and the last two as a post therapy result.

Statistical analysis

All statistical analyses were based both on the intention-to-treat principle as well as the treatment-per-protocol principle. All data were formally tested for normality with the Kolmogorov-Smirnoff test prior to further analysis. The distribution of the data was not sufficiently normal to allow parametric statistics. Descriptive statistics of baseline and effect data were determined (median, 25^{th} and 75^{th} percentile). Differences between post-therapy and baseline data, as well as between follow-up- and post-therapy data, were tested for significance by a Wilcoxon Signed Rank Test. Group differences were tested using a Mann-Whitney *U* test. Associations between measurements were calculated using Pearson's correlation coefficients. All statistical analyses were performed using SPSS 15.0. (SPSS Inc., Chicago, IL).

Results

After applying inclusion and exclusion criteria, a total of 109 subjects were included in this study. All patients were diagnosed with idiopathic Parkinson's disease and oropharyngeal dysphagia. All patients were assigned to one of the three treatment groups as described previously. During the period of intervention, 21 subjects were excluded because of diverse reasons (change of medication 17x, dental surgery 2x, other reasons 2x). The excluded subjects had experienced no adverse effects from therapy. Furthermore, no significant differences in baseline data were present between the group of excluded subjects and the group of included subjects.

Finally, a total of 88 patients (65 males, 23 females) did accomplish the full period of therapy and provided enough data for further analysis. The averaged age of this group was 68 years old, with an age range of 42 to 81 years. The MMSE ranged from 22 to 30 points (mean 27), whereas the Hoehn and Yahr scores ranged from 1 to 4. No differences were found between the baseline characteristics of the three treatment groups. In Table 1 the patients' characteristics for each treatment group separately as well as for all groups combined, are presented.

Improvement on the Dysphagia Severity Scale during the treatment period is presented in Table 2. Table 2 presents the descriptive statistics of the baseline and the effect data (post- minus pre-treatment data) of the Dysphagia Severity Scale: the median, the 25th and the 75th percentile of a patient's self-evaluation of dysphagia. The median progress on the DSS is 14 points (range -33 to 70). The effect data have been tested for significance (Wilcoxon Signed rank test). All groups show a significant positive therapeutically effect. However, no statistically significant differences in effect data were found between the three treatment groups (Mann-Whitney *U* test).

Tables 3 to 6 show the descriptive statistics of two quality of life measurement tools: the SWAL-QOL, and the MDADI. For each group separately as well as for the total group, data are presented. Table 3, 4 and 5 contain, respectively, descriptive statistics of the baseline data, the effect data, and the follow-up minus post-therapy data of the SWAL-QOL. A Wilcoxon signed rank test was used to test for significant changes between baseline and post-therapy measurements (Table 4). In table 4 and 5, only dysphagia-concerning subscales are given. Applying a Bonferoni correction, both the total group

and the TT group show a significant change on the Symptom Index. The total group also presents a significant effect on the Burden scale. No other statistically significant results are found. Because of the minimally increased medians (Table 5), no tests were performed to test for significant differences in the post- and follow-up data.

Table 6 shows the descriptive statistics of the baseline data, the effect data and the follow-up data minus the post-therapy data for the MDADI and its subscales. A Wilcoxon signed rank test was used to test for significant changes between baseline and post-therapy measurements. After Bonferoni correction, significant therapy effects were found for the total group on the total score, the global assessment and both the physical and emotional subscales. None of the groups reached significance on the functional subscore. The only other significant effects were found for the TT group and the NMES_M group on, respectively, the global assessment score and the Total score. No obvious group differences were found. After three months follow-up measurement, ignorable median changes were present in all treatment groups. Only total group changes were tested for significance and indicated at a minor deterioration of the global assessment score. The Interclass Correlation Coefficients between the repeated measurements showed a reliable range ($0,7 < r < 0,9$).

Descriptive statistics of baseline data and of the differences in effect data and follow-up minus post therapy data of the Functional Oral Intake Scale are given in Table 7.

Discussion

The aim of this study was to investigate the effects of neuromuscular electrical stimulation in patients with Parkinson's disease and oropharyngeal dysphagia compared to traditional therapy with Health Related Quality of Life (HRQOL) as primary outcome measure.

A patient group of in total of 109 subjects was randomly assigned to one of three different treatment groups. All groups showed significant therapy effects on the Dysphagia Severity Scale, SWAL-QoL and MDADI. Only slight differences between groups were found. Additionally, in this study no significant correlation was found between the dietary intake and Quality of Life.

Interestingly, this study underlines the positive effects of dysphagia therapy in patients with Parkinson's Disease as found in other studies [Baijens et al., 2009]. However, the hypothesis that electrical stimulation would provide a better outcome on HRQOL could not be confirmed. Clinimetrical and methodological issues arise in our study design.

Although a proper sample size calculation was made prior to this study, one might suggest that the available information on the effects of electrical stimulation in this patient group is rather scarce. This might lead to an underpowering of our study; a larger sample-size might provide a clearer outcome. Also one might suggest that the baseline characteristics of our patient group, with a larger proportion having a maximum score on the FOIS, will make it difficult to detect any progress. From a clinimetrically point of view one might even suggest that the outcome measures used in this study (SWAL-QoL, MDADI) are not sensitive enough for detecting differences in HRQOL in this specific patient group. Further research on the clinimetrical aspects of these outcome tools, would provide more information on the sensitivity of these instruments.

In our study we have been rather conservative regarding statistical analyses; the large number of statistical tests has led to a major impact of the Bonferroni-correction on our data. When applying these strict rules of statistical analysis on our data set, the danger arises that our study is underpowered as the initial sample-size calculation was based on a power of 0.80 and a significance level of 0.05. Therefore regarding our data, a Type II-error cannot be ruled out.

Another form of bias in our study might be attributed to the fact that all patients received standard therapy with or without electrical stimulation. This might introduce different forms of exercises, provided by different therapists. A very large sample size would correct for these influences, but the number needed in such a study would immediately lead to questions on the feasibility. Another solution to correct for this type of bias, is introducing a control group which would receive a sham-treatment. However, this was considered to be unethical by the Medical Ethical Board, because of severity of complications related to the underlying dysphagia.

As a consequence of the medical ethical committee all treatment groups had to receive traditional treatment, because it was unethically due to complications related to the dysphagia. A sham-group or non-treatment group, concerning the additional treatment (NMES), could exclude this factor and differentiate the effects of the different interventions.

The use of neuromuscular electrical stimulation in dysphagia therapy is primarily aimed enhancing muscle power in specific muscles involved in swallowing [Bogaardt et al, 2009]. Although sensory effects of this type of electrical stimulation is reported [Oh et al, 2009], this adjunct to traditional dysphagia therapy is considered to be a motor treatment [Bogaardt, 2008]. The question arises whether all treated patients had motor problems in respect to their dysphagia. In Parkinson's Disease one might argue, the swallowing problems would be more based on the neurological control of swallowing and not to muscle weaknesses. Therefore, one might also suggest that neuromuscular electrostimulation is less appropriate for these patients compared to other patient groups. When taking in account that a large proportion of our patient group was already on an oral diet (and thus might not have an disuse atrophy of the muscles involved in swallowing), the possible effect of electrical stimulation on dysphagia in these patients might be too small again to be detected on a HRQOL-level.

We recommend therefore, that future research in this patient group should be primarily focussed on surrogate outcome measurements as laryngeal excursion (as measured by videofluoroscopy) and other parameters, and less on 'softer' outcome measurements as HRQOL.

However, as stated previously, our study shows the potential benefits of dysphagia therapy in patients with Parkinson's Disease. Also, based on some parameters a possible positive effect of neuromuscular electrical stimulation is suggested by our data, although methodological issues arise. Most important, a detrimental effect of neuromuscular electrical stimulation was not found; this would support our recommendations for a future study with a larger patient group.

Based on our data, we conclude that NMES might have a positive effect on HRQOL in patients with Parkinson's Disease, but a larger study is needed to support our preliminary findings.

Conclusion

This study is one of the first attempts to evaluate the effects of NMES in patients with Parkinson's Disease with dysphygia by conducting a randomized controlled trial. In our study some significant differences were found on Quality of Life between the three treatment groups (TT, NMES-M and NMES-S) as measured by to general HRQOL related questionnaires (SWAL-QoL, MDADI). This would suggest an overall positive effect op dysphagia therapy in this patient group. Methodological and clinimetrical issues arise from our study design and subsequent study outcomes.

Based on our data, however, we conclude that NMES might have a positive effect on HRQOL in patients with Parkinson's Disease, but a larger study is needed to support our preliminary findings.

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Table 1. Patient characteristics.

Descriptive statistics of patient characteristics for each group separately as well as for all groups combined.

Group[a]	Gender (N_{Male}; N_{Female})	Age (years)		MMSE		H&Y scale	
		Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.
Group TT (N=28)	22;7	69	62;74	28,0	26,0;29,0	2	1,0;4,0
Group NMES-M (N=27)	20;9	65	60;74	28,0	26,0;29,5	2	1,0;3,0
Group NMES-S (N=30)	23;9	66	60;69	28,0	26,5;29,0	2	1,5;3,0
Total Group (N=85)	65;23	68	60;73	28,0	26,0;29,0	2	1,0;3,0

[a] TT = traditional therapy, NMES-M = neuromuscular electrostimulation at a motor level, NMES-S = neuromuscular electrostimulation at a sensory level.

Table 2. Dysphagia Severity Scale (DSS).

Descriptive statistics of the baseline data and the effect data (post- minus pre-treatment data), the number of patients per treatment group, and the level of significance of the difference between post-therapy data compared to baseline data for all groups (Wilcoxon Signed rank test).

Group[a]	Baseline data[b]			Effect data			
	Median	25';75'perc.	N	Median	25';75'perc.	N	P-value
Group TT	59	41;88	28	19	3;44	28	0,000
Group NMES-M	72	52;88	27	10	0;31	27	0,000
Group NMES-S	74	49;87	30	6	-2;24	30	0,005
Total Group	67	49;88	85	14	0;30	85	0,000

[a] TT = traditional therapy, NMES-M = neuromuscular electrostimulation at a motor level, NMES-S = neuromuscular electrostimulation at a sensory level.

[b] The maximum score of the scale is 100.

Table 3. SWAL-QOL.

Descriptive statistics of the baseline data and the number of patients per treatment group.

SWAL-QOL [a]	Baseline Data	Burden		Food selection		Eat duration		Eat desire		Fear		Sleep		Fatigue		Communcation		Mental Health		Social effects		Symptom	
Group[a]	N	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.
Group TT	30	57	38;75	75	75;100	50	25;75	83	67;100	100	81;100	75	38;88	67	33;77	63	38;75	80	68;86	75	54;81	64	54;70
NMES-M	29	50	25;88	75	75;94	38	13;69	83	54;100	88	75;100	50	38;82	58	46;75	63	44;88	75	60;95	75	58;95	59	41;68
NMES-S	29	63	31;82	75	50;88	38	25;63	88	63;100	88	75;100	75	25;94	75	46;79	63	38;75	75	65;85	75	65;85	59	48;71
Total group	88	63	38;75	75	66;88	44	25;63	83	67;100	94	81;100	69	38;88	67	42;75	63	38;75	80	60;90	75	60;90	61	50;70

[a] The maximum score of each scale is 100.

[b] TT = traditional therapy, NMES-M = neuromuscular electrostimulation at a motor level, NMES-S = neuromuscular electrostimulation at a sensory level.

Table 4. SWAL-QOL.

Descriptive statistics of the effect data (post- minus pre-treatment data), the number of patients per treatment group, and the level of significance of the difference between post-therapy data compared to baseline data for all groups (Wilcoxon Signed rank test).

SWAL-QOL [a]	Effect data	Burden			Food selection			Eat duration			Eat desire			Social effects			Symptom		
Group[b]	N=	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value [b]
Group TT	14	0	-13;9	N.S.	0	0;25	N.S.	6	-15;12	N.S.	0	-8;0	N.S.	0	0;6	N.S.	10	1;19	0.004
NMES-M	17	0	0;25	N.S.	0	-6;13	N.S.	12	0;25	N.S.	0	-8;4	N.S.	0	-3;15	N.S.	4	-2;10	N.S.
NMES-S	18	6	0;37	N.S.	0	-16;0	N.S.	12	-3;37	N.S.	0	-8;17	N.S.	0	-8;16	N.S.	4	-5;11	N.S.
Total group	49	0	0;25	0,009	0	-12;6	N.S.	12	0,25	N.S.	0	-8;8	N.S.	0	0;15	N.S.	5	0;11	0,001

[a] The maximum score of each scale is 100.

[b] TT = traditional therapy, NMES-M = neuromuscular electrostimulation at a motor level, NMES-S = neuromuscular electrostimulation at a sensory level.

Table 5. SWAL-QOL.

Descriptive statistics of the difference between the follow up data and the post-therapy data and the number of patients per treatment group.

SWAL-QOL[a]	Post minus Pre data	Burden		Food selection		Eat duration		Eat desire		Social effects		Symptom	
Group[b]	N=	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.
Group TT	6	19	9;53	-13	-31;6	-12	-19;3	0	-2;2	0	-9;6	10	-22;14
NMES-M	6	0	-12;6	-19	-38;0	0	-16;25	0	0;6	0	-4;5	-4	-12;-2
NMES-S	7	0	-25;0	0	0;12	-13	-25;0	0	-41;0	0	-25;5	0	-4;2
Total group	19	0	0;12	0	-25;0	-12	25;0	0	0;0	0	-10;5	-2	-10;7

[a] The maximum score of each scale is 100.

[b] TT = traditional therapy, NMES-M = neuromuscular electrostimulation at a motor level, NMES-S = neuromuscular electrostimulation at a sensory level.

Table 6. MD Anderson Dysphagia Inventory (MDADI).

Descriptive statistics of the baseline data, the effect data (post- minus pre-treatment data), and the follow-up minus post-therapy data, the number of patients per treatment group, and the level of significance of the difference between post-therapy data compared to baseline data for all groups as well as the level of significance of the difference between follow-up data compared to post-therapy data for all groups combined.

MDADI[a]	Group[b]	Baseline data			Effect data				Follow-up minus post-therapy data			
		Median	25';75 perc.	N	Median	25';75' perc.	N	P-value	Median	25';75' perc.	N	P-value
Global assessment	Group TT	3	2;4	29	0	0;2	29	0,012	0	-1,0	17	
	NMES-M	4	2;4	29	0	0;1	28	N.S.	0	0;0	13	
	NMES-S	4	2;5	27	0	0;1	27	N.S.	0	-1;0	13	
	Total Group	4	2;4	85	0	0;1	84	0,000	0	-1;0	43	0,011
Functional subscale	Group TT	21	19;22	27	0	-2;3	25	N.S.	0	-1;3	16	
	NMES-M	21	18;22	29	0	-2;4	27	N.S.	0	-5;0	11	
	NMES-S	20	18;24	25	0	-1;2	25	N.S.	1	-2;2	13	
	Total Group	21	18;23	81	0	-2;4	77	N.S.	0	-2;2	40	N.S.
Physical subscale	Group TT	28	24;31	28	2	-1;5	24	N.S.	0	-5;3	15	
	NMES-M	26	22;30	29	1	-2,7	28	N.S.	0	-3;2	13	
	NMES-S	28	22;32	25	2	-5;6	25	N.S.	-2	-5;1	12	
	Total Group	28	23;30	82	2	-1;6	77	0,000	-1	-4;2	40	N.S.
Emotional subscale	Group TT	21	18;24	27	1	-3;3	27	N.S.	0	-3;2	16	
	NMES-M	21	17;24	28	2	0,4	26	N.S.	-1	-4;2	13	
	NMES-S	20	18;24	27	1	-1;3	26	N.S.	-2	-5;2	12	
	Total Group	21	18;24	82	1	-1;3	79	0,002	-1	-3;2	41	N.S.
Total score	Group TT	72	63;80	26	2	-4;8	22	N.S.	1	-4;6	13	
	NMES-M	69	63;81	28	7	2,13	25	0,007	-3	-10;3	11	
	NMES-S	74	65;82	24	4	-1;9	23	N.S.	-2	-11;3	11	
	Total Group	72	64;81	78	4	-1;11	70	0,000	0	-10;3	35	N.S.

[a] The range of the Total Score, the Global Assessment, and the Emotional, Functional, and Physical subscale is, respectively, 20 to 100, 1 to 5, 6 to 30, 5 to 25 and, 8 to 40

[b] TT = traditional therapy, NMES-M = neuromuscular electrostimulation on a motor level, NMES-S = neuromuscular electrostimulation on a sensory level.

Table 7. Functional Oral Intake Scale (FOIS).

Descriptive statistics of baseline data and effect data (differences in post- minus pre-therapy) and follow-up minus post therapy data.

Functional Oral Intake Scale[a]	Baseline Data			Post- minus pre-treatment data			Follow-up minus post data		
	Median	25';75' perc.	N	Median	25';75' perc.	N	Median	25';75' perc.	N
Group TT	7	6;7	29	0	0;0	29	0	0;0	17
Group NMES-M	7	6;7	29	0	0;0	29	0	-1;0	13
Group NMES-S	7	6;7	29	0	0;0	29	0	0;0	13
Total group	7	6;7	87	0	0;0	87	0	0;0	43

[a] The maximum score of the scale is 7.

[b] TT = traditional therapy, NMES-M = neuromuscular electrostimulation on a motor level, NMES-S = neuromuscular electrostimulation on a sensory level.