NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults

Oropharyngeal dysphagia is when people have difficulty starting to swallow. It can cause coughing, choking and a sense of food being stuck. This procedure involves electrically stimulating nerves in the throat or neck using electrodes placed on the skin, while the person swallows. The aim is to strengthen the muscles involved in swallowing.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety

and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in November 2017.

Procedure name

- transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults

Specialist societies

- Royal College of Speech and Language Therapists
- British Society of Gastroenterology
- British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)
- British Society of Rehabilitation Medicine.

Description of the procedure

Indications and current treatment

Difficulty in swallowing (dysphagia) can be caused by neurological impairment affecting the muscles of the oropharynx. It can happen because of a stroke, traumatic brain injury, disorders of cerebral development, neurodegenerative conditions and major head and neck surgery (for example, to remove cancer). Dysphagia may lead to malnutrition, dehydration and aspiration pneumonia.

Treatment options depend on the cause and severity of the dysphagia. Conservative treatments involve swallowing therapy to help the patient relearn swallowing techniques and strengthen oropharyngeal muscles. In severe cases nasogastric tubes or percutaneous endoscopic gastrostomy tubes may be used to provide nutritional support.

What the procedure involves

Transcutaneous neuromuscular electrical stimulation (NMES) is usually used as well as traditional swallowing therapy for treating oropharyngeal dysphagia. Swallowing therapy uses exercises to improve muscle function. The aim of NMES is to increase the effectiveness of swallowing therapy by strengthening the muscles involved in swallowing. It also promotes recovery of cortical control of swallowing.

NMES is usually done by a speech and language therapist after appropriate diagnosis and patient selection. Therapists need appropriate training to use the procedure. The speech and language therapist places electrodes in selected positions on the patient's neck. Small electrical currents are then passed through the electrodes to stimulate the peripheral nerve supply of the pharyngeal or laryngeal muscles. Stimulus intensity may be at a low sensory level, or at a higher motor level to trigger muscle contractions. Under the supervision of the therapist, the patient exercises their swallowing muscles while having concurrent electrical stimulation. Treatment duration recommendations vary by device, but can be up to 1 hour. The mild electrical stimulation can produce feelings ranging from tingling and warmth to a 'grabbing' sensation.

The position of the electrodes and levels of current used vary from patient to patient. There is a range of NMES devices that use different electrode designs, positions and stimulus intensities. At an initial assessment, videofluoroscopy or clinical observation may be used to optimise the placement of treatment electrodes and to determine an appropriate stimulus intensity.

Outcome measures

Functional dysphagia scale

The functional dysphagia scale (FDS) is a 100-point scale that evaluates oral and pharyngeal phases of swallowing semi-objectively by using videofluoroscopic swallowing study (VFSS, lower scores indicate a better ability to eat).

Functional oral intake scale

The Functional Oral Intake Scale (FOIS) is a 7-point ordinal scale that is used to describe the amount and types of food or liquid that patients can safely ingest on a consistent basis. The scale has been shown to have strong validity and reliability specific to patients with dysphagia caused by strokes.

FOIS levels:

1. No oral intake.

2. Tube dependent with minimal or inconsistent oral intake.

3. Tube supplements with consistent oral intake.

4. Total oral intake of a single consistency.

5. Total oral intake of multiple consistencies needing special preparation.

6. Total oral intake with no special preparation, but must avoid specific foods or liquid items.

7. Total oral intake with no feeding restrictions.

Rosenbek Penetration-Aspiration Scale (PAS)

The Rosenbek Penetration-Aspiration Scale (PAS) is an 8-point scale and is used during videofluoroscopy to evaluate the presence and severity of any penetration/aspiration of contrast. The scores represent the worst-rated swallow attempt for boluses given of each viscosity attempted during assessment.

The scores are:

1. Material does not enter airway.

2. Material enters the airway, remains above the vocal folds, and is ejected from the airway.

3. Material enters the airway, remains above the vocal folds, and is not ejected from the airway.

4. Material enters the airway, contacts the vocal folds, and is ejected from the airway.

5. Material enters the airway, contacts the vocal folds, and is not ejected from the airway.

6. Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway.

7. Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.

8. Material enters the airway, passes below the vocal folds, and no effort is made to eject.

Swallowing-related Quality of Life scale

The Swallowing-related Quality of Life (SWAL-QOL) scale is designed to objectively measure a patient's perspective of the effect of dysphagia on their quality of life. The instrument has been validated and has favourable psychometric properties, including high internal consistency, reliability and reproducibility. It consists of 44 questions that evaluate 11 domains: swallowing as a burden, desire to eat, eating duration, frequency of symptoms, food selection, communication, fear of eating, mental health, social function, sleep and fatigue. SWAL-QOL domains are scored from 0 to 100, with higher scores indicating better quality of life.

Swallow Function Scoring System

The Swallow Function Scoring System (SFSS) is an assessment tool that measures the severity of dysphagia by identifying the consistency of liquid a patient can swallow without aspiration. The outcome measure consists of an ordinal scale ranging from 0 to 6. A score of 0 indicates severe dysphagia where no solid or liquid is safe to swallow. A score of 6 indicates no swallowing deficit so that all liquids are tolerated.

Swallowing performance status scale

The swallowing performance status scale is a 7-point scale which assesses the swallowing function.

The scores are:

1. Normal swallowing.

2. Within functional limits.

3. Mild impairment.

4. Mild-moderate impairment.

5. Moderate impairment.

6. Moderate-severe impairment.

7. Severe impairment.

Efficacy summary

Swallowing function and dysphagia

A systematic review and meta-analysis of 12 studies, including 578 patients with stroke or traumatic brain injury, treated by neuromuscular electrical stimulation (NMES, n=344) or traditional dysphagia therapy (TDT, n=234) reported a statistically significant overall pooled standardised mean difference of 1.14 (95% confidence interval [CI] 0.941 to 1.338, p<0.001) in favour of NMES for the improvement in subjective swallowing function. This was done by pooling mean changes in the following dysphagia severity scales: FOIS, swallow score, the American Speech-Language-Hearing Association National Outcomes Measurement System (ASHA-NOMS), visual analogue scale (VAS) and standardized swallowing assessment (SSA) scores. The heterogeneity between the 10 selected studies was statistically significant, indicating inconsistency among the results (I^2= 81%, 95% CI: 66% to 89%, p<0.0001). [1]

In a randomised controlled trial (RCT) of 60 patients with post-stroke dysphagia treated by NMES with swallowing training (n=30) or swallowing training alone (n=30), the dysphagia scores (range 0 to 10 with lower scores indicating severe dysphagia) improved statistically significantly in both groups (3.92±1.04 before treatment to 8.01±1.20 at 10 days, p<0.01 for the NMES group and 3.83±1.18 to 5.31±1.10, p<0.05 for the control group). The improvement was statistically significantly better in the NMES group than in the control group (p<0.01). In the same study, the treatment efficacy was evaluated by improvement of dysphagia as follows: cured, dysphagia improved to Grade 7, with a total score of 9 to 10; effective, dysphagia improved by 3 to 5 grades but did not reach Grade 7, with a total score increase by 6 to 8; fair, dysphagia improved by 1 to 2 grade but did not reach Grade 7, with a total score increase by 3 to 5; and ineffective, no obvious improvement of the dysphagia, and a score increase by 0 to 2. In the NMES group, after 10 days, dysphagia was ''cured'' in 57% (17/30) of patients, treatment was ''effective'' in 20% (6/30), treatment was ''fair'' in 20% (6/30), and treatment was ''ineffective'' in 3% (1/30) of patients. In the control group, dysphagia was ''cured'' in 30% (9/30) of patients, treatment was ''effective'' in 10% (3/30), treatment was ''fair'' in 23% (7/30), and treatment was ''ineffective'' in 37% (11/30) of patients (p=0.022 for the comparison between groups). [4]

In an RCT of 132 patients with brain injury and dysphagia treated with electrical stimulation therapy (EST) applied on the suprahyoid muscle (SM, n=66) or on the suprahyoid and infrahyoid muscles (SI, n=66), the statistically significant before-after improvements in functional dysphagia scale (FDS) scores observed within both groups from 41.2 ± 20.9 to 34.5 ± 20.3 in the EST-SM group and from 44.3 ± 19.1 to 35.7 ± 20.5 in the EST-SI group (p<0.001, intention-to-treat [ITT] analysis) were not statistically significantly different between groups. In the same

study, the statistically significant within-group improvements in swallow function scores (SFS) (from 3.3 ± 1.6 to 3.9 ± 1.6 in the EST-SM group and from 2.8 ± 1.9 to 3.6 ± 2.0 in the EST-SI group ($p<0.001$, intention-to-treat [ITT] analysis) were also not statistically significantly different between groups.[5]

In an RCT of 82 patients with medullary infarction and dysphagia treated by NMES acting on the sensory input (sensory approach, SA) combined with swallowing therapy (n=28) or NMES acting on the motor muscle (motor approach, MA) combined with swallowing therapy (n=27) or traditional swallowing therapy (TT) alone (n=27), the water swallow test (WST), the standardised swallowing assessment (SSA), and the FOIS scores were all statistically significantly improved 1 month after starting the treatment in all the 3 groups ($p\leq0.01$ for the differences within groups); the SA group showed statistically significantly greater improvement than the other 2 groups, and the MA group showed statistically significantly greater improvement than the TT group ($p<0.05$). [6]

In an RCT of 30 patients with post-stroke dysphagia treated with NMES in combination with swallow exercise (n=15) or usual speech and language therapy dysphagia care (n=15), mean FOIS scores increased from 3.5 at baseline to 5.3 after 1 month post-treatment in the NMES group and from 4.3 to 5.1 in the control group (difference between groups adjusted for baseline was not statistically significant [95% CI]: 0.59 [−0.98 to 2.15]).[7]

In a retrospective comparative study of 95 patients with head and neck cancer which retrospectively compared patients treated with at least 10 sessions of NMES (n=41) with those who had received fewer than 10 sessions of NMES (n=54), the mean FOIS score decreased in both groups, indicating worsening function. The decrease was statistically significantly less in the NMES group (from 6.195 at baseline to 5.732 at mean 4.5 months) compared with the control group (from 5.981 to 4.593), $p<0.015$. In the same study, the mean swallowing performance status scale score worsened in both groups 4.5 months after treatment (from 2.902 to 3.415 in the NMES group and from 2.815 to 4.074 in the control group). [8]

In a small UK prospective case series of 10 patients with dysphagia of neurological origin, patients were initially given 5 weeks of traditional therapy, followed by 5 weeks of NMES therapy. There was no statistically significant improvement in the mean FOIS score ± SD between the start (1.6±1.1) and the end of the 5 weeks of traditional therapy (1.7±1.3, $p<0.05$) but there was a statistically significant improvement in the FOIS score between the start of the NMES + traditional therapy (1.7±1.3) and the end of the NMES + traditional therapy (3.4±2.0, $p<0.01$).[9]

Penetration/ aspiration

The systematic review and meta-analysis of 12 studies reported a statistically significant overall pooled standardised mean difference of -0.845 (95% CI -1.169 to -0.521, p<0.001) in favour of NMES for the reduction of penetration/aspiration. The heterogeneity between the 6 selected studies was statistically significant (I^2= 90%, 95% CI: 81% to 95%, p<0.0001). [1]

In an RCT of 170 patients with head and neck cancer treated by NMES combined with swallow exercise (n=116) or sham NMES combined with swallow exercise (n=54), the mean penetration-aspiration scale (PAS) scores for NMES remained unchanged after 13-week treatment (PAS scores of 5.13 at baseline and 5.14 at 13 weeks) and the mean PAS scores for sham NMES improved from 5.48 at baseline to 4.91 at 13 weeks. Adjusting for differences in baseline, this resulted in a difference of 0.52 on PAS (95% CI 0.06 to 0.98, p=0.027) indicating statistically significantly greater improvement in the sham NMES group.[2]

In the RCT for 132 patients, 53% of patients in the EST-SM group and 56% of patients in the EST-SI group had improvement in penetration and aspiration after the treatment (p=0.687). [5]

In the RCT of 30 patients, mean PAS scores for the fluids decreased from 6.4 at baseline to 4.3 after treatment in the NMES group and from 5.2 to 3.4 in the control group (difference between groups adjusted for baseline [95% CI]: 0.40 [−2.13 to 2.92]). The PAS scores for the diet decreased from 4.6 at baseline to 2.5 after treatment in the NMES group and from 2.5 to 1.8 in the control group (difference between groups adjusted for baseline [95% CI]: −0.62 [−2.77 to 1.54]). 58% (7/12) of patients in the NMES group made progress on fluids compared with 50% (6/12) of patients in the control group. On diet, 58% (7/12) of patients in the NMES group made progress compared with 17% (2/12) of patients in the control group. [7]

In the retrospective comparative study of 95 patients, the mean PAS score increased in the group who had more than 10 sessions of NMES from 2.927 to 3.073 and in the group who had fewer than 10 sessions of NMES from 3.056 to 4.315. The difference between groups was not statistically significant. [8]

Oral and pharyngeal transit times

The systematic review and meta-analysis of 12 studies reported a statistically significant overall pooled standardised mean difference of -0.856 (95% CI -1.167 to -0.546, p<0.001) in favour of NMES for the reduction of pharyngeal transit time. The heterogeneity between the 4 selected studies was statistically significant (I^2= 77%, 95% CI: 39% to 92%, p=0.004). [1]

In an RCT of 108 post-stroke patients with dysphagia treated with transcutaneous electrical nerve stimulation (TENS, n=54) with orofacial rehabilitation (OFR) or OFR only (n=54), there was a statistically significant difference for the change in oral transit time (OTT) after 4 weeks of therapy between the group who had TENS (mean 0.55 seconds ± 0.01) and the control group (mean 0.29 seconds± 0.03) (p=0.01). The difference was also statistically significant between groups for the change in pharyngeal transit time (PTT) after 4 weeks of therapy: mean 0.37 seconds ± 0.02 for the TENS group and mean 0.15 seconds ± 0.02 for the control group (p=0.009).[3]

Quality of life

In the RCT of 170 patients, the head and neck cancer inventory (HNCI) scores were not statistically significantly different between the group who had NMES and the group who had sham NMES after 13 weeks of treatment. The performance status scale (PSS) scores were also not statistically significantly different between the group who had NMES and the group who had sham NMES after 13 weeks of treatment. [2]

In the RCT of 82 patients, the SWAL-QOL scale score was statistically significantly increased 1 month after starting the treatment in all the 3 groups from 43.6 to 77.4 in the SA group, from 42.8 to 63.5 in the MA group and from 43.6 to 52.7 in the TT group (p≤0.01 for the differences within groups); the SA group showed statistically significantly greater improvement than the other 2 groups, and the MA group showed statistically significantly greater improvement than the TT group (p=0.04). [6]

In the RCT of 30 patients, the mean SWAL-QoL scores increased from 107 at baseline to 128 after 1 month post-treatment in the NMES group and from 118 to 121 in the control group (with a statistically significant difference between groups adjusted for baseline [95% CI]: 20.5 [4.2–36.7]). One month after the end of the treatment, both groups showed continued improvement, with 100% (12/12) of patients in the NMES group reporting improved SWAL-QoL scores compared with 42% (5/12) of patients in the control group. [7]

In the prospective case series of 10 patients, there was no statistically significant improvement in the mean SWAL-QOL and in the mean Eating Assessment Tool 10 (EAT-10) scores ± SD between the start (106±49 and 34.6±7.0 respectively) and the end of the 5 weeks of traditional therapy (109±51 and 32.7±9.1, p<0.05) but there was a statistically significant improvement in both scores between the start of the NMES + traditional therapy (109±51 and 32.7±9.1) and the end of the NMES + traditional therapy (136±56 and 32.7±9.1, p<0.01).[9]

Safety summary

Skin reaction

Skin redness or allergic reaction at the electrode site were reported in 11% (3/28) of patients in the group who had the NMES sensory approach combined with traditional swallowing therapy and in 15% (4/27) of patients in the group who had the NMES motor approach combined with traditional swallowing therapy in the RCT of 82 patients. This disappeared soon after the cessation of the electrical stimulation, and no patient dropped out because of the skin reaction [6]

Skin irritation or soreness beneath the electrodes was reported in 2 patients and skin irritation or soreness and a burning sensation beneath the electrodes was reported in 1 patient in the case series of 10 patients. This was resolved by repositioning the electrodes.[9]

A burning sensation was reported in 50% (3/6) of patients during sessions in a case series of 6 patients. In the same study, skin irritation was reported in 33% (2/6) of patients at the site of electrodes. [10]

Neck or jaw pain

Neck or jaw pain was reported in 1 patient in the case series of 10 patients. This was resolved by repositioning the electrodes.[9]

Neck soreness at the site of electrodes was reported in 17% (1/6) of patients in the case series of 6 patients.[10]

Sensation of gastric fullness

The sensation of gastric fullness was reported in 33% (2/6) of patients in the case series of 6 patients. [10]

Coughing and expectoration

Coughing and expectoration were reported during 22% of NMES sessions in the case series of 6 patients. [10]

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse events: worsening of dysphagia. They

considered that the following were theoretical adverse events: chemical burn due to electrode paste application, electrical or heat burn due to current intensity, electric shock, spread of infection from muscle-pumping effect, muscle pain after prolonged use, laryngospasm, muscle spasm, haematoma, bleeding, arrhythmia and hypotension.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults. The following databases were searched, covering the period from their start to 14 November 2017: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Adults with oropharyngeal dysphagia.
Intervention/test	Transcutaneous neuromuscular electrical stimulation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 1,263 patients from 1 systematic review and meta-analysis[1], 6 RCTs[2-7], 1 comparative study[8] and 2 case series[9,10].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in the appendix.

Table 2 Summary of key efficacy and safety findings on transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults

Study 1 Ding R (2016)

Details

Study type	**Systematic review and meta-analysis**
Country	USA
Recruitment period	Date of search: 01/01/2001 to 31/03/2016
Study population and number	n= **578 (344 NMES versus 234 TDT) patients** with stroke or traumatic brain injury from 12 studies (8 RCTs and 4 quasi-experimental trials)
Age and sex	See below
Patient selection criteria	Study inclusion criteria: 1) RCTs or quasi-experimental studies published in the English language that compared NMES versus TDT for treatment of adult patients with acute neurological impairments, mainly stroke and traumatic brain injury; 2) The NMES intervention was placed on the surface of the neck or submental area; 3) a validated outcome measurement on swallow function was available.
Technique	NMES or TDT which included posture and diet changes, oral motor exercises, and thermal-tactile stimulation or swallow manoeuvres.
Follow-up	**Maximum 3 years (see below for each study included)**
Conflict of interest/source of funding	None

Analysis

Study design issues:

- The authors said that ''One of the limitations in reviewing these studies is the lack of a uniform measurement to assess swallow function. Therefore, a mixture of outcome measures was included in the present analysis.''
- The FOIS was used in 6 of the selected 12 studies so it was chosen to estimate the effects size.
- In the studies for which FOIS was not used, a measuring scale of swallowing function similar to FOIS was chosen for estimating the effect size.
- The standardized mean difference (SMD) was used as a summary statistic
- The meta-analysis was done separately for studies using subjective measures and for studies using objective measures.
- A SMD less than 0.5 was considered small, between 0.5 and 0.8 medium, and greater than 0.8 large. SMD of medium or above was considered clinically meaningful.

Study population issues:

- Study #5 and 12 consisted of both stroke and TBI patients, and the rest included only stroke patients. Four studies exclusively focused on stroke in hemispheric region (Study # 2, 9, 10, and 11), one on stroke in

supratentorial region (Study #8), the remaining studies consisted of multi-location strokes. More than half of the studies investigated the effect of NMES on dysphagia treatment in the acute phase of stroke or TBI (Study # 4, 5, 6, 7, 8, and 10).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **578 (344 NMES versus 234 TDT)**

Summary of the studies included in the meta-analysis

Study	Authors & year	Age (years) NMES/TDT	Sample size (NMES/ TDT)	Diagnoses (location)	Time since onset	Study design (intervention type)	Traditional Therapy	NMES Frequency/ Duration	Assessment interval
1	Freed et al. 2001	75.7/78.1	99 (63/36)	stroke (brainstem, hemispheric, multiple strokes)	not reported	quasi-experimental (NMES vs TDT)	TTS	in-patients 1h/day out-patients 1h/day 3d/week until swallow score of 6 or no more progress	0 and final Follow-up time up to 3 years
2	Bulow et al. 2008	70.0/71.0	25 (12/13)	stroke (hemispheric)	>3 month	RCT (NMES vs TDT)	diet modification, exercises	1-hour session, 5 sessions a week, for 3 weeks	0 and 3 weeks
3	Lim et al. 2009	67.8± 8.1/ 60.8 ±12.3	28 (16/12)	infarction, hemorrhage (hemisphere, subarachnoid)	13 < 6 months, 3 >6 months/9 <6 months, 3 >6 months	RCT (NMES +TDT vs TDT)	TTS	1-hour sessions, 5 sessions a week, for 4 weeks	0 and 4 weeks
4	Permsirivanich et al. 2009	64.5±8.8/ 64.3±9.4	23 (12/11)	stroke	average 24 days	RCT (NMES vs TDT)	Compensatory, TTS, exercises, maneuvers	1-hour session, 5 sessions a week, for 4 weeks	0 and 4 weeks
5	Beom et al. 2011	66.1±19.5/ 68.5±12.5	28 (7/21)	stroke and TBI (Cortex, subcortex, brainstem)	2.4±2.1/ 1.3±1.0 (months)	quasi-experimental (NMES+TDT vs TDT)	Compensatory, maneuvers, and TTS	30-minute sessions, 5 sessions a week, for 4 weeks	0 and 4 weeks
6	Kushner et al. 2013	19-89 (range)/ 49-91	92 (65/27)	stroke (hemispheric, intracerebral hemorrhage, brainstem)	<16 days	quasi-experimental (NMES+TDT vs TDT)	Compensatory, exercises, maneuvers, and TTS	1-hour session, 5-6 sessions a week, for an average of 18 days	0 and averaged 18 days (SD=3)
7	Huang et al. 2014	68.9±9.8/ 64.5±14.4/ 67.0±10.1	29 (10/8/9)	Stroke (hemispheric)	<3 months	RCT (NMES+TDT vs NMES vs TDT)	Compensatory, exercises, maneuvers, and TTS	1-hour session, 3 sessions a week, for 10 sessions	0 and 3 weeks
8	Lee et al. 2014	63.4±11.4/ 66.7±9.5	57 (31/26)	ischemic stroke (supratentorial)	10 days or less	RCT (NMES+TDT vs TDT)	exercises, manoeuvres, and TTS	30-minute sessions, 5 sessions a week, for 3 weeks	0,3,6, 12 weeks
9	Li et al. 2014	66.7±14.6/ 65.8±13.2/ 66.4±13.1	118 (40/38/40)	stroke (hemispheric)	>3 months	RCT (NMES+TDT vs NMES vs TDT)	compensatory and exercises	1-hour session, 5 sessions a week, for 4 weeks	0 and 4 weeks

10	Lim et al. 2014	66.3±15.4/ 62.5±8.2	33 (18/15)	stroke (hemispheric)	<3 months	RCT (NMES+TDT vs TDT)	Compensatory, exercises, manoeuvres and TTS	30-minute session, 5 sessions a week, for 2 weeks	0, 2, 4 weeks
11	Toyama et al. 2014	63.6 ± 21.4/ 67.2 ± 13.7	26 (12/14)	brain injury (hemispheric)	25.2 ± 25.9/14.7 ± 10.6 (weeks)	quasi-experimental (NMES+TDT vs TDT)	TTS with dry swallow	40-min sessions, 5 days per week, for 8 weeks	0, 8 weeks
12	Terre et al. 2015	46/51	20 (10/10)	stroke and traumatic brain injury	subacute	RCT (NMES+TDT vs TDT)	diet change, exercises and manoeuvres	1-hour session, 5 sessions a week, for 4 weeks	0, 4 weeks, 3 months

Subjective swallowing function changes post-treatment from baseline (SMD)

		NMES			Control						
Source	**Measurement**	**n**	**Mean change**	**SD**	**n**	**Mean change**	**SD**	**SMD**	**SE**	**95% CI**	**P**
Freed et al., 2001	Swallow score	63	3.76	1.40	36	0.64	1.17	2.34	0.27	1.815 to 2.870	
Bulow et al., 2008	VAS	12	2.90	2.30	12	2.50	1.78	0.19	0.40	-0.632 to 1.007	
Permsirivanich et al., 2009	FOIS	12	3.17	1.27	11	2.46	1.04	0.59	0.41	-0.269 to 1.443	
Toyama et al., 2013	FOIS	12	1.40	1.19	14	0.60	0.51	0.87	0.40	0.0468 to 1.697	
Kushner et al., 2013	FOIS	65	4.40	1.90	27	2.40	2.70	0.92	0.24	0.447 to 1.388	
Huang et al., 2014	FOIS	10	3.70	1.19	11	3.00	1.03	0.61	0.43	-0.293 to 1.505	
Lee et al., 2014	FOIS	31	1.40	1.00	26	0.50	0.70	1.01	0.28	0.454 to 1.572	
Lim et al., 2014	ASHA NOMS	18	1.10	0.80	15	1.00	0.75	0.13	0.34	-0.571 to 0.822	
Li et al., 2015	SSA	45	17.70	5.60	45	7.90	5.26	1.79	0.25	1.296 to 2.281	
Terre et al., 2015	FOIS	10	2.60	1.19	10	1.00	1.19	1.29	0.47	0.291 to 2.284	
Total (fixed effects)		**278**			**207**			**1.14**	**0.10**	**0.941 to 1.338**	**<0.001**

Test for heterogeneity: I^2 (inconsistency) 80.82%; 95% CI for I^2 65.69 to 89.28, $p < 0.0001$.

Penetration/aspiration changes post-treatment from baseline (SMD)

		NMES			Control						
Source	**Outcome measurement used in analysis**	**n**	**Mean change posttreatment from baseline**	**SD**	**n**	**Mean change posttreatment from baseline**	**SD**	**SMD**	**SE**	**95% CI**	**p**
Bulow et al., 2008	Misdirection	12	-0.58	2.00	11	-1.00	2.22	0.192	0.403	-0.647 to 1.031	

Beom et al., 2010	VDS	7	-11.90	10.60	21	-12.60	6.30	0.0904	0.424	-0.781 to 0.962	
Toyama et al., 2013	VDS	12	-21.40	13.47	14	-5.20	4.90	-1.6	0.441	-2.510 to -0.690	
Lim et al., 2014	PAS	20	-2.63	1.46	20	2.00	1.00	-3.627	0.51	-4.660 to -2.593	
Huang et al., 2014	PAS	8	-1.30	1.19	11	-1.50	1.48	0.14	0.444	-0.798 to 1.077	
Lee et al., 2016	PAS	25	-1.36	1.50	25	-0.20	0.50	-1.021	0.297	-1.617 to -0.425	
Total (fixed effects)		**84**			**102**			**-0.845**	**0.164**	**-1.169 to -0.521**	**<0.001**

Test for heterogeneity: I^2 89.87%; 95% CI for I^2 80.66 to 94.70; $p < 0.0001$

Pharyngeal transit time changes post-treatment from baseline (SMD)

		NMES			Control						
Source	**Outcome measurement used in analysis**	n	**Mean change posttreatment from baseline**	**SD**	**n**	**Mean change posttreatment from baseline**	**SD**	**SMD**	**SE**	**95% CI**	**p**
Lim et al., 2009	PTT (liquid)	16	-0.10	0.17	12	-0.02	0.08	-0.558	0.378	-1.335 to 0.219	
Lim et al., 2014	PTT (liquid)	20	-0.06	0.16	20	-0.05	0.11	-0.0714	0.31	-0.699 to 0.556	
Li et al., 2015	PTT (liquid)	45	-0.10	0.16	45	0.10	0.11	-1.444	0.235	-1.911 to -0.977	
Terre et al., 2015	PTT	10	-0.11	0.33	10	0.40	0.82	-0.781	0.446	-1.718 to 0.155	
Total (fixed effects)		**91**			**87**			**-0.856**	**0.157**	**-1.167 to -0.546**	**<0.001**

Test for heterogeneity; I^2 (inconsistency) 77.47%; 95% CI for I^2 38.82 to 91.70, p= 0.0040

Abbreviations used: ASHA NOMS: The American Speech-Language Hearing Association National Outcomes Measurement System; CI, confidence interval; FOIS, functional oral intake scale; NMES, neuromuscular electrical stimulation; PAS, penetration-aspiration scale; PTT, pharyngeal transit time; SMD, standardised mean difference; SSA, Standardized Swallowing Assessment; TDT, traditional dysphagia therapy; TTS, thermal-tactile stimulation; VAS, visual analogue scale; VDS, videofluoroscopic dysphagia scale.

Study 2 Langmore S E (2016)

Details

Study type	**Double-blinded RCT**
Country	USA (16 centres)
Recruitment period	2009-12
Study population and number	n= **168 (116 NMES + swallow exercise versus 54 sham NMES + swallow exercise)** patients with head and neck cancer with dysphagia
Age and sex	Mean 62 years; 14% (24/168) female
Patient selection criteria	Eligible patients were over 21 years old, cancer free, had completed a full dose (≥50Gy) of radiation therapy or chemoradiotherapy at least 3 months before enrollment, and demonstrated moderate-severe dysphagia on a modified barium swallow (MBS) study defined as Penetration-Aspiration Score (PAS) ≥4 on at least 1 bolus. Key exclusion criteria: history of dysphagia unrelated to head and neck cancer, prior use of electrical stimulation, neurologic disease, presence of pacemaker/defibrillator, floor of mouth resection, or inability to follow the study protocol.
Technique	The NMES device used was the BMR NeuroTech (NT) 2000 (Galway, Republic of Ireland). The sham device looked and performed identically to the real device, but the internal current carrying wires were disabled. A visual bar and audio tone were activated when the stimulation was supposedly being transmitted, identical to the active device. Electrodes were placed in a bipolar fashion, above the hyoid, beneath the mandible. Electrical stimulation was delivered to the submental region to stimulate the supra-hyoid muscles. Patients in the Active NMES group were able to set the amplitude to a level where they felt a comfortable contraction. The treatment time was 20 min or longer if needed twice a day, 6 days a week, for 12 weeks.
Follow-up	**12 weeks of treatment**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- Of 488 screened patients, 170 were randomised into the study. 116 patients were randomly assigned to the Active NMES + exercise group while 54 were assigned to the Sham NMES + exercise group.
- 91 patients in the Active NMES group and 36 patients in Sham NMES group were included in the primary analyses. Drop-out was not statistically significantly different between the treatment groups (Fisher's exact test p=0.394).
- 84 patients in the NMES group and 34 patients in the sham group completed follow-up.
- The patients returned to the clinic every 3 weeks to assess competence and compliance. Repeat MBS studies, diet assessments [Performance Status Scale (PSS)] and quality of life assessments [Head Neck Cancer Inventory (HNCI)] were done mid-way through the treatment (week 7) and at completion of treatment (week 13).

Study design issues:

- The primary outcome measure was swallowing function as measured by the Penetration-Aspiration Score (PAS).
- Two other swallow measures, Oropharyngeal Swallow Efficiency (OPSE), and hyoid excursion (in mm), were secondary outcome measures. Diet, measured by the PSS and Quality of Life, measured by the HNCI were other secondary outcomes.
- Patients and research staff were blinded from the results.
- The randomisation used a 2:1 experimental to control treatment arm scheme.

Study population issues:

- The initial criteria required a PAS ≥ 6, but low enrollment prompted an easing in this requirement.
- Patients in the 2 arms were not statistically significantly different for any patient variables of interest at time of entry.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **127 (91 NMES + swallow exercise versus 36 sham NMES + swallow exercise)**

Difference between the groups at week 13 for primary and secondary outcome measures, adjusted for baseline differences

Outcome Measure	Difference between the 2 groups: NMES-Sham (95%CI) n=127	p-value
Primary Outcome		
PAS Total	0.52 (0.06 to 0.98)	**0.027**
PAS Thin	0.81 (0.29 to 1.33)	**0.002**
PAS Thick	−0.13 (−0.96 to 0.71)	0.767
PAS Pudding	0.23 (−0.57 to 1.04)	0.570
PAS Banana	0.03 (−0.78 to 0.84)	0.943
PAS Saltine	0.11 (−0.76 to 0.98)	0.806
Secondary Outcomes		
OPSE Total	−2.75 (−8.63 to 3.14)	0.361
Hyoid Anterior Total	0.22 (−1.03 to 1.47)	0.732
Hyoid Superior Total	−1.30 (−3.63 to 1.03)	0.274
PSS Total	2.30 (−3.10 to 7.69)	0.404
PSS Diet	0.37 (−7.48 to 8.22)	0.926
PSS Public	6.20 (−3.40 to 15.81)	0.206
PSS Speech	−0.20 (−4.65 to 4.25)	0.929
HNCI Speech	−3.37 (−9.81 to 3.06)	0.304
HNCI Eating	1.41 (−5.28 to 8.10)	0.679
HNCI Aesthetics	0.49 (−7.98 to 8.95)	0.910
HNCI Social Disruption	−3.11 (−10.28 to 4.05)	0.395

Raw Scores at Baseline and 13 weeks (end of treatment) in selected outcome variables

Variable	Treatment group	n	Baseline	Week 13	Change
PAS Total	NMES	90	5.13	5.14	0.01
	Sham	35	5.48	4.91	−0.57
OPSE	NMES	81	41.47	41.81	0.34
	Sham	30	35.88	40.72	4.84
Hyoid Anterior Total	NMES	76	7.05	6.42	−0.62
	Sham	32	6.57	5.86	−0.71
Hyoid Superior Total	NMES	76	16.81	15.94	−0.87
	Sham	32	16.91	17.31	0.4
% Residue in Pharynx	NMES	85	30.81	30.55	−0.26
	Sham	34	35.84	31.74	−4.1
PSS Total	NMES	91	60.73	66.98	6.25
	Sham	35	58.38	62.9	4.52
HNCI Eating	NMES	86	32.54	38.85	6.31
	Sham	34	24.18	30.93	6.74

Compliance

The Active and Sham NMES groups were similarly "compliant" defined as performing 10 or more sessions per week. 57% of the Active NMES group and 48% of the Sham NMES group were deemed compliant, yielding a non-significant chi square p-value of 0.2958.

Change over time for primary and secondary outcome measures in the 2 groups

Outcome Measure	Active NMES: Change per month (95%CI) n=116	p-value	Sham NMES: Change per month (95%CI) n=54	p-value	Overall (combined groups) Change per month (95%CI) n=170	p-value
Primary Outcome						
PAS Total	0.01 (−0.07,0.08)	0.879	−0.20 (−0.31,−0.09)	**<0.001**	−0.05 (−0.11,0.01)	0.084
PAS Thin	0.02 (−0.07,0.11)	0.671	−0.28 (−0.41,−0.14)	**<0.001**	−0.06 (−0.14,0.01)	0.097
PAS Thick	−0.01 (−0.15,0.13)	0.897	0.03 (−0.19,0.25)	0.780	0.00 (−0.12,0.12)	0.967
PAS Pudding	0.00 (−0.15,0.15)	0.973	−0.14 (−0.37,0.09)	0.232	−0.04 (−0.17,0.09)	0.540
PAS Banana	−0.07 (−0.21,0.08)	0.376	−0.13 (−0.35,0.09)	0.249	−0.08 (−0.21,0.04)	0.173
PAS Saltine	−0.04 (−0.20,0.12)	0.600	−0.25 (−0.50,−0.01)	**0.043**	−0.10 (−0.24,0.03)	0.131
Secondary Outcomes						
OPSE Total	0.27 (−0.75,1.29)	0.601	1.43 (−0.17,3.04)	0.080	0.60 (−0.26,1.46)	0.168
Hyoid Anterior Total	−0.25 (−0.48,−0.01)	**0.038**	−0.24 (−0.60,0.11)	0.177	−0.25 (−0.44,−0.05)	**0.014**
Hyoid Superior Total	−0.27 (−0.71,0.17)	0.230	0.01 (−0.66,0.67)	0.988	−0.19 (−0.55,0.18)	0.314
PSS Total	1.96 (1.06,2.86)	**<0.001**	1.42 (0.02,2.81)	**0.046**	1.81 (1.06,2.57)	**<0.001**
PSS Diet	1.87 (0.62,3.12)	**0.003**	2.25 (0.32,4.19)	**0.023**	1.99 (0.94,3.03)	**<0.001**
PSS Public	2.75 (1.06,4.45)	**0.002**	1.05 (−1.57,3.67)	0.430	2.28 (0.86,3.70)	**0.002**
PSS Speech	1.18 (0.29,2.06)	**0.009**	1.05 (−0.32,2.43)	0.132	1.15 (0.41,1.89)	**0.003**
HNCI Speech	1.29 (0.24,2.35)	**0.016**	2.93 (1.28,4.58)	**0.001**	1.75 (0.86,2.64)	**<0.001**
HNCI Eating	2.22 (1.19,3.24)	**<0.001**	2.44 (0.86,4.01)	**0.003**	2.28 (1.43,3.14)	**<0.001**
HNCI Aesthetics	0.40 (−1.09,1.90)	0.596	1.30 (−1.05,3.65)	0.276	0.66 (−0.59,1.92)	0.300
HNCI Social Disruption	1.14 (−0.07,2.34)	0.065	2.31 (0.43,4.19)	**0.016**	1.46 (0.45,2.48)	**0.005**

Abbreviations used: HNCI, head and neck cancer inventory; MBS, modified barium swallow; NMES, neuromuscular electrical stimulation; OPSE, oropharyngeal swallowing efficiency; PAS, penetration-aspiration scale; PSS, performance status scale.

Study 3 Konecny P (2017)

Details

Study type	**RCT**
Country	Czech Republic
Recruitment period	2013-16
Study population and number	n= **108 (54 TENS + orofacial rehabilitation [OFR] versus 54 OFR only)** post-stroke patients with dysphagia
Age and sex	TENS: Mean 70 years; 52% (28/54) female Control: Mean 69 years; 43% (23/54) female
Patient selection criteria	Dysphagia in the early stage after stroke, ability of active cooperation and negative watertest (excluding aspiration).
Technique	TENS: electrical stimulation of the suprahyoid muscles by mean of TENS currents with a frequency of 60 Hz and intensity of the motor threshold was applied in the study group for 20 min a day, five days a week. Standard OFR was done in both groups once a day 5 days a week.
Follow-up	**4 weeks**
Conflict of interest/source of funding	None

Analysis

Study design issues:

- Swallowing was evaluated at the beginning of the study and at the end, by videofluoroscopy – measuring the time for oral and pharyngeal phases.
- Measured values for OTT and PTT times before and after the therapy and differences between the study group and the control group were statistically evaluated using ANOVA.

Study population issues:

- In the TENS group, 50 patients had ischemic stroke and 4 patients had haemorrhagic stroke. Brainstem damage with bulbar palsy was present in 7 patients. Cortical-subcortical damage with pseudobulbar palsy was present in 47 patients.
- In the control group, 49 patients had ischemic stroke and 5 had haemorrhagic stroke. Ten patients with brainstem lesion suffered bulbar palsy and 44 developed pseudobulbar palsy due to cortical-subcortical brain lesion.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 108 (54 TENS + OFR versus 54 OFR only)

Transit times before and after therapy (seconds)
<table>
<tr><th></th><th>TENS + OFR group (n=54)</th><th>OFR only group (n=54)</th><th>p</th></tr>
<tr><td>OTT before therapy (SD)</td><td>1.55 (±0.21)</td><td>1.56 (±0.25)</td><td>NS</td></tr>
<tr><td>OTT after 4 weeks of therapy (SD)</td><td>1.00 (±0.20)</td><td>1.29 (±0.29)</td><td>p<0.05</td></tr>
<tr><td>PTT before therapy (SD)</td><td>1.05 (±0.15)</td><td>1.06 (±0.17)</td><td>NS</td></tr>
<tr><td>PTT after 4 weeks of therapy (SD)</td><td>0.68 (±0.13)</td><td>0.91 (±0.19)</td><td>p<0.05</td></tr>
</table>
Statistically significant difference in OTT and PTT after therapy between groups.

Statistically significant difference in OTT and PTT before and after treatment within group for both groups:
-TENS: difference in OTT was 0.55 ± 0.01, p=0.0009 and the difference in PTT was 0.37 ± 0.02, p=0.0001
-OFR only: the difference in OTT was 0.29 ± 0.03, p=0.01 and the difference in PTT was 0.15 ± 0.02, p=0.009)

Differences between groups after therapy: statistically significant changes for the OTT value (p=0.01) and for the PTT value (p=0.009).</td><td>No safety events were reported.</td></tr>
<tr><td colspan="2">Abbreviations used: NS, not statistically significant; OFR, orofacial rehabilitation; OTT, oral transit time; PTT, pharyngeal transit time; SD, standard deviation; TENS, transcutaneous electrical nerve stimulation; VFSS, videofluoroscopic swallowing study</td></tr>
</table>

Study 4 Jing Q (2016)

Details

Study type	**RCT**
Country	China
Recruitment period	2013-14
Study population and number	n= **60 (30 NMES versus 30 control)** patients with post-stroke dysphagia
Age and sex	NMES: Mean 68 years; 37% (11/30) female Control: Mean 69 years; 47% (14/30) female
Patient selection criteria	1) Patients who met the China diagnostic criteria of cerebrovascular diseases; 2) patients whose condition had been diagnosed with cerebral infarction and cerebral haemorrhage by computerised tomography or MRI scans; 3) dysphagia found within 1 to 3 days after the episode of stroke; 4) patients with the grade of dysphagia ≤5; 5) patients who had never received rehabilitation training; 6) patients with stable vital signs; and 7) patients who had signed informed consent.
Technique	Both groups received swallowing training and conventional medical treatment. Additionally, the patients in the treatment group received NMES therapy using the Vitalstim device. The electrical stimulation therapy used 2 channels with the following parameters: bi-directional square wave, wave width of 700 ms, and intensity of electrical stimulus of 6 to 21 mV (±10%). The surface electrodes were placed on the surface of swallowing muscles. The treatment mode was selected according to the result of dysphagia evaluation. The intensity of stimulation was adjusted until the patients felt itching. The patients in each group were treated continuously for 10 days.
Follow-up	**10 days**
Conflict of interest/source of funding	None

Analysis

Study design issues:

- The following outcomes were evaluated: curative effects, swallowing function, aspiration, laryngeal elevation, food residue, and food intake scores.
- Data on admission and after treatment of the patients were double-blindly evaluated by the same trained rehabilitation therapist.
- Patients with dysphagia were evaluated according to Rattans dysphagia classification criteria. A rehabilitation nurse was asked to record the food intake of the patients, including time and type of food intake, bucking, aspiration, and amount of food intake.
- The Mann-Whitney test was used for the comparison of efficacy between the 2 groups. Quantitative data were described by mean and standard deviation and compared with t-test, whereas qualitative data were described by rates and compared with $\chi 2$ test.

Study population issues: The distribution of age, sex, disease course, and type of stroke were compared between the 2 groups and no statistically significant difference was found.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **60 (30 NMES versus 30 control)**

Treatment efficacy

Group	n	Cured	Effective	Fair	Ineffective
NMES	30	57% (17/30)	20% (6/30)	20% (6/30)	3% (1/30)
Control	30	30% (9/30)	10% (3/30)	23% (7/30)	37% (11/30)

Data were compared with Mann-Whitney test; u=119.5, p=0.022.

Treatment efficacy was evaluated by improvement of dysphagia as follows:
cured: dysphagia improved to Grade 7, with a total score of 9 to 10; effective, dysphagia improved by 3 to 5 grades but did not reach Grade 7, with a total score increase by 6 to 8; fair, dysphagia improved by 1 to 2 grade but did not reach Grade 7, with a total score increase by 3 to 5; and ineffective, no obvious improvement of dysphagia, and a score increase by 0 to 2.

Dysphagia scores

Dysphagia was classified as follows: scores 0 to 2 show severe dysphagia, 3 to 5 moderate dysphagia, 6 to 8 mild dysphagia, and 9 to 10 normal. The lower scores indicate severe dysphagia.

Group	n	Before treatment	After treatment	t	p
NMES	30	3.92±1.04	8.01±1.20	12.67	<0.01
Control	30	3.83±1.18	5.31±1.10	4.184	<0.05
T			7.39		
P			<0.01		

At 10 days after the treatment, **the swallowing function, aspiration, and laryngeal elevation scores** were statistically significantly higher in the treatment group than in the control group (p<0.05); however, the food residue and food intake scores were not statistically significantly different between the 2 groups.

Safety

No safety events were reported.

Abbreviations used: NMES, neuromuscular electrical stimulation.

Study 5 Beom J (2015)

Details

Study type	**RCT**
Country	Korea (2 centres)
Recruitment period	Not reported
Study population and number	n= **132 (66 EST on the suprahyoid muscles [SM] versus 66 EST on suprahyoid muscle and infrahyoid muscle [SI])** brain-injured patients with dysphagia
Age and sex	SM group: Mean 64 years; 50% (33/66) female SI group: Mean 60 years; 33% (22/66) female
Patient selection criteria	Major inclusion criteria were (1) stroke, traumatic brain injury, or brain tumour over 1 week prior; (2) hemiplegia caused by a hemispheric lesion as confirmed by CT or MRI; (3) dysphagia diagnosed by a videofluoroscopic swallowing study (VFSS), showing aspiration or penetration and decreased laryngeal elevation; and (4) responses to pain. Exclusion criteria: patients who (1) did not have potential for neurological or functional recovery; (2) could not communicate because of aphasia or severe speech problems; or (3) had contraindications for hyolaryngeal NMES due to cardiac pacemaker, cochlear implant, malignancy, neck surgery, skin wound, infection, or other acute medical conditions.
Technique	SM group: hyolaryngeal NMES of the suprahyoid muscles only with the Stimplus device (Cyber-medic Corp., Iksan, Republic of Korea) SI group: electrical stimulation of the suprahyoid muscle with 1 pair of electrodes and of the infrahyoid muscle with another pair of electrodes using the Vitalstim device. All patients had 10–15 sessions of electrical stimulation during the period of 2–3 weeks. Electrical stimulation was applied for 30 min at intensity increased by 1 mA. The stimulation level when patients felt the sense of electricity was defined as the 'threshold intensity' (sensory threshold). When patients noted they could not tolerate pain or discomfort, the intensity just below that level was defined as the 'stimulation intensity' (pain threshold). In addition to NMES, the patients also received conventional swallowing therapies, such as chin tuck, effortful swallowing, multiple swallowing, or Shaker's exercise depending on VFSS results and clinical symptoms.
Follow-up	**Within 1 week of the last treatment session**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- A total of 158 patients were assessed for eligibility, and 132 patients were randomly assigned to 2 groups. Among the 132 patients enrolled in the study, 38 did not meet treatment or follow-up criteria due to insufficient number of treatment sessions (n=5 in the SM group and 4 in the SI group), failure to receive follow-up evaluation (n=14 in each group), or death (n=1 in the SM group).
- The VFSS was conducted before electrical stimulation and within 1 week after the last session with the same protocol in each hospital.

Study design issues:

- The functional dysphagia scale (FDS), swallow function score (SFS), supraglottic penetration, and subglottic aspiration were measured using videofluoroscopic swallowing study.
- Hyolaryngeal NMES was carried out by 3 experienced occupational therapists.
- Patients received 11.2 ± 3.4 sessions of electrical stimulation in the SM group and 11.9 ± 3.4 sessions in the SI group.

Study population issues:

- There were no statistically significant differences between the 2 groups in gender, age, time from initial VFSS to follow-up VFSS, number of electrical stimulation session, and location of brain lesions.
- Stimulation threshold and intensity in the SM group were statistically significantly lower than those in the SI group ($p<0.001$, respectively).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **132 (66 EST-SM versus 66 EST-SI)**

Functional Dysphagia Scale (FDS)

	SM group		SI group	
	Before EST	**After EST**	**Before EST**	**After EST**
FDS (per-protocol analysis)*	42.0 ± 19.1	32.3 ± 17.8	44.8 ± 17.4	32.9 ± 18.8
FDS (intention-to-treat analysis)*	41.2 ± 20.9	34.5 ± 20.3	44.3 ± 19.1	35.7 ± 20.5

***p<0.001 for the differences within groups**

The changes in the FDS score after EST were not statistically significantly different between the SM and the SI groups in both per-protocol and intention-to-treat analyses (p = 0.451 and 0.398 respectively).

Swallow Function Score (SFS)

	SM group		SI group	
	Before EST	**After EST**	**Before EST**	**After EST**
SFS (per-protocol analysis)*	3.3 ± 1.8	4.2 ± 1.6	2.8 ± 1.8	4.0 ± 1.8
SFS (intention-to-treat analysis)*	3.3 ± 1.6	3.9 ± 1.6	2.8 ± 1.9	3.6 ± 2.0

***p<0.001 for the differences within groups**

The changes in the SFS after EST were not statistically significantly different between the SM and SI groups in both per-protocol and intention-to-treat analyses (p = 0.311 and 0.278 respectively).

The proportions of patients who showed improved SFSs after electrical stimulation were 56.5 % in the SM group and 54.2 % in the SI group, which were comparable between the two groups (p = 0.165).

Penetration and Aspiration

	SM group	**SI group**	**p value**
Proportion of patients who showed improvement in penetration and aspiration after NMES	52.5%	55.9%	0.687

Safety

One patient (68-year-old female) in the SM group died probably from the rupture of a giant cerebral aneurysm that was not related to electrical stimulation therapy.

There were no complications or serious adverse effects that were related to electrical stimulation.

Abbreviations used: EST, electrical stimulation therapy; NMES, neuromuscular electrical stimulation; SI, suprahyoid muscle and infrahyoid muscle; SFS, swallow function score; SM, suprahyoid muscle; VFSS, videofluoroscopic swallowing study

Study 6 Zhang M (2016)

Details

Study type	**RCT**
Country	China
Recruitment period	2012-15
Study population and number	n= **82 (28 sensory approach combined with traditional swallowing therapy versus 27 motor approach combined with traditional swallowing therapy versus 27 traditional swallowing therapy)** patients with dysphagia with medullary infarction
Age and sex	Mean 62 years; 37% (30/82) female
Patient selection criteria	Inclusion criteria: (1) a primary diagnosis of medullary infarction with brain CT or MRI; (2) disease onset <1 month previously; (3) presence of oropharyngeal dysphagia confirmed by videofluoroscopic swallowing study, including different levels of water choke to cough, choking, prolonged eating time, difficulty with swallowing, and nasal regurgitation after swallowing; (4) age within the range of 40 to 80 years; (5) no severe cognitive degeneration that could restrict cooperation with the checks and treatment, with a Mini-Mental State Examination (MMSE) score≥21; and (6) 30-mL water swallow test (WST) level of 3, 4, or 5. Exclusion criteria: (1) unstable vital signs caused by highly inflammatory, severe cardiopulmonary disease or carotid sinus syndrome; (2) a cardiac pacemaker or other electrically sensitive implanted stimulator; (3) dysphagia caused by structural lesions; (4) skin lesions of the area to be treated or implants containing metal parts within the area of treatment; (5) a history of epilepsy, malignancies, or other neurologic disease; (6) pregnancy; or (7) spastic paralysis.
Technique	Traditional swallowing therapy involved compensation strategies to augment the impaired aspects of oropharyngeal swallowing. The electrical stimulations were done for 20 minutes per session, twice a day, 5d/week, for 4 weeks. Sensory approach: this approach used a vocaSTIM-Master device and a pair of 2 surface electrodes. The cathode was placed on the submental region, and the anode was placed on the occipital skin. The intensity of the electrode stimulation ranged from 0 to 15mA, increasing the intensity gradually up to a sensory input level expected to lead to swallowing. Motor approach: this approach used a multifunctional nerve rehabilitation and treatment system and a pair of 2 surface electrodes. The cathode and anode were placed in parallel on the skin of the anterior belly of the digastric muscle in the submental region above the hyoid bone. The intensity of electrode stimulation ranged from 0 to 60mA, increasing the intensity gradually to a level expected to elicit a contraction of the target muscle.
Follow-up	**1 month after starting the treatment**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 97 patients were originally recruited, 5 patients were excluded, and 2 declined to participate; 8 patients dropped out for personal reasons unrelated to the intervention.

Study design issues:

- All treatments were done by an occupational therapist.
- Swallowing function was evaluated by the water swallow test and standardized swallowing assessment, oral intake was evaluated by the functional oral intake scale, quality of life was evaluated by the swallowing-related quality of life (SWAL-QOL) scale, and cognition was evaluated by the mini-mental state examination (MMSE).

Study population issues: There were no statistically significant differences between the groups in age, sex, duration, MMSE score, or severity of the swallowing disorder.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **82 (28 sensory approach combined with traditional swallowing therapy versus 27 motor approach combined with traditional swallowing therapy versus 27 traditional swallowing therapy)**

Comparisons before and after treatment (Wilcoxon signed-rank test, median [interquartile range])

	Before treatment			After treatment			p		
Assessment	**SA+TT**	**MA+TT**	**TT**	**SA+TT**	**MA+TT**	**TT**	**SA+TT**	**MA+TT**	**TT**
WST	4.5 (1)	4 (1)	4 (1)	2 (1)	3 (1)	4 (2)	≤0.01	≤0.01	≤0.01
SSA	37 (6.5)	36 (5)	35 (5)	25 (3.8)	28 (3)	32 (8)	≤0.01	≤0.01	≤0.01
FOIS	1 (1)	2 (1)	2 (1)	6 (2)	4 (3)	3 (3)	≤0.01	≤0.01	≤0.01
SWAL-QOL	43.6 (8.1)	42.8 (9.1)	43.6 (7.4)	77.4 (26.5)	63.5 (23.9)	52.7 (18.9)	≤0.01	≤0.01	≤0.01

The total score for the SSA is in the range of 18 to 46 points, with higher scores indicating worse swallowing function.

Comparisons of treatment effect (mean rank)

Assessment	**SA+TT**	**MA+TT**	**TT**	**H**	**p**
WST	59.43	38.93	25.48	37.96	0.01
SSA	19.29	45.83	60.204	42.19	0.01
FOIS	61.77	36.93	25.06	35.26	0.02
SWAL-QOL	59.43	38.93	25.48	28.40	0.04

Safety

No significant side effects were observed.

Only a few patients (11% [3/28] in the sensory approach combined with traditional swallowing therapy group and 15% [4/27] in the motor approach combined with traditional swallowing therapy group) had **local skin redness or allergic reaction at the electrode site**; this disappeared soon after the cessation of the electrical stimulation, and no patient dropped out because of the skin reaction.

Abbreviations used: FOIS, functional oral intake scale; MA, motor approach; MMSE, mini-mental state examination; SA, sensory approach; SSA standardised swallowing assessment; SWAL-QOL, swallowing-related quality of life; TT, traditional swallowing therapy; WST, water swallow test.

Study 7 Sproson L (2018)

Details

Study type	**RCT**
Country	England (3 NHS trusts)
Recruitment period	Not reported
Study population and number	n= **30 (15 NMES with swallow-strengthening exercises versus 15 usual speech and language therapy dysphagia care)** patients with post-stroke dysphagia
Age and sex	NMES: Mean 73 years; 33% (5/15) female Control: Mean 81 years; 40% (6/15) female
Patient selection criteria	Inclusion criteria: medically stable; dysphagia incorporating reduced laryngeal elevation; more than 1 month post-stroke; and no other neurological disease. Exclusion criteria: under 18 years of age; pacemaker or other serious cardiac disease; severe cognitive or communication difficulties; and lesions or infections in the treatment site.
Technique	NMES: Ampcare Effective Swallowing Protocol (ESP) with 30 minute-treatment 5 days/week for 4 weeks. During pulses of stimulation, patients were asked to do 3 sets of exercises (10 min for each exercise in each treatment session). The rate and degree of the increase of the electrical stimulation was tailored according to each participant's tolerance. Control: Usual care varied from periodic reviews primarily focusing on posture and diet modification to weekly visits with home-practise regimes. These regimes included exercises and postural adaptations based on videofluoroscopy findings.
Follow-up	**1 month after the end of the treatment**
Conflict of interest/source of funding	Ampcare LLC contributed a small percentage of funding; however, the authors guarantee complete study independence and integrity of study design, data analysis and interpretation.

Analysis
Follow-up issues:

- Assessments were conducted at baseline (FOIS, PAS and SWAL-QOL), after the 4-week treatment (FOIS and PAS were repeated, plus a questionnaire on treatment tolerability) and 1 month after the end of the treatment (FOIS and SWAL-QoL).
- The overall attrition rate was 20%. In the NMES group, data analysis was done on 12 patients (3 were lost to follow-up as 1 patient died, 1 became unwell due to secondary diagnosis of cancer and 1 was unable to complete treatment due to deterioration in a pre-existing mental health condition). In the control group, 14 patients were analysed according to the data gathered (1 patient died and 2 patients reached different time points on the study).

Study design issues:

- A team of 3 experienced speech and language therapists (SLTs) did the clinical assessments, and a blinded SLT assessor and radiographer did the videofluoroscopy assessments.
- Outcome measures included: the Functional Oral Intake Scale (FOIS), the Rosenbek Penetration-Aspiration Scale (PAS) and patient reported outcomes (Swallow Related Quality of Life—SWAL-QOL).
- The patients were allocated using a randomised block design. Randomisation was done using a computer algorithm selecting the cohort consecutively from date of referral. The sample size of 15 per group struck a balance between pragmatism and sufficient sample size to provide estimates of effect size and variability for the power calculation for a future fully powered RCT.
- All results were presented by intention to treat. For the patients who withdrew before completing the full protocol, all data were included up to the point at which they withdrew. For some patients, data on some but not all the outcome measures were available at the end of study and/or 1 month follow-up.

Study population issues: Patients in the intervention group tended to be further post-stroke than the usual-care group.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **30 (15 NMES with swallow-strengthening exercises versus 15 usual speech and language therapy dysphagia care)**

FOIS

	NMES + exercises			Control			Difference between groups, adjusted for baseline (95% CI)
	n	mean	(SD)	n	mean	(SD)	
Baseline	15	3.5	(2.0)	15	4.3	(1.8)	
After treatment	13	5.1	(2.0)	14	5.1	(1.9)	0.50 (−0.72 to 1.72)
1 month post-treatment	12	5.3	(1.9)	14	5.1	(2.2)	0.59 (−0.98 to 2.15)

75% (9/12) of patients from the NMES group had better scores on the FOIS 1 month after the end of the treatment compared with 57% (8/14) of the control group. None of the intervention group showed deterioration in FOIS scores either posttreatment or at 1 month follow-up compared with 14% (2/14) of the control group.

Rosenbek PAS

	NMES + exercises			Control			Difference between groups, adjusted for baseline (95% CI)
	n	mean	(SD)	n	mean	(SD)	
Fluids Baseline	15	6.4	(2.3)	15	5.2	(2.7)	
After treatment	12	4.3	(3.0)	12	3.4	(2.7)	0.40 (−2.13 to 2.92)
Diet Baseline	15	4.6	(3.1)	15	2.5	(2.4)	
After treatment	12	2.5	(2.6)	12	1.8	(2.1)	−0.62 (−2.77 to 1.54)*

*A negative difference indicates a change in favour of the intervention.

58% (7/12) of patients in the NMES group made progress on fluids compared with 50% (6/12) of patients in the control group.

On diet, 58% (7/12) of patients in the NMES group made progress compared with 17% (2/12) of patients in the control group.

SWAL-QoL

	NMES + exercises			Control			Difference between groups, adjusted for baseline (95% CI)
	n	mean	(SD)	n	mean	(SD)	
Baseline	14	107	(17.8)	13	118	(22.8)	
After treatment	13	115	(15.1)	13	119	(23.6)	9.7 (−0.9 to 20.3)
1 month post-treatment	12	128	(14.3)	12	121	(24.9)	20.5 (4.2–36.7)

1 month after the end of the treatment, both groups showed continued improvement, with 100% (12/12) of patients in the NMES group reporting improved SWAL-QoL scores compared with 42% (5/12) of patients in the control group.

Qualitative data

All patients in the NMES group reported that the treatment was tolerable. None found it disruptive to their lifestyle, however 1 patient would have preferred the treatment slightly less intensively, preferring 3 times per week rather than 5.

Safety

There were no adverse events.

Abbreviations used: CI, confidence interval; FOIS, functional oral intake scale; NMES, neuromuscular electrical stimulation; PAS, penetration-aspiration scale; SD, standard deviation; SLT, speech and language therapist; SWAL-QoL, swallow related quality of life.

Study 8 Bhatt A D (2015)

Details

Study type	**Retrospective comparative study**
Country	USA
Recruitment period	2006-11
Study population and number	n= **95 (41 NMES [consecutive patients] versus 54 control)** patients with locally advanced head and neck cancer
Age and sex	NMES: Mean 62 years; 15% (6/41) female Control: Mean 59 years; 26% (14/54) female
Patient selection criteria	Inclusion criteria: use of definitive chemoradiotherapy, availability of a premodified barium swallow (MBS) and post-MBS and/or fibre-optic endoscopic evaluation of swallowing, and TNM stages III and IV. The post-MBS study was typically done at or shortly after completing chemoradiotherapy, usually within a 2-week period. Exclusion criteria: treatment with radiotherapy alone, definitive surgery alone, TNM stages I and II, recurrent disease, only 1 or no MBS done, prior neck surgery, including a tracheostomy.
Technique	NMES: Patients who had at least 10 treatment sessions with the Vitalstim device. The most common electrode placement was neck nodal level (3a/3b). Therapy involved administration of at least 5 mA current, 80 Hz frequency with phase duration of 300 microseconds given 3 times a week beginning at the first week of chemoradiotherapy. Each session lasted about 45 to 60 minutes. All patients were offered therapeutic exercises, compensatory strategies, and diet modification, as deemed necessary by the speech language pathologist, in addition to the NMES. NMES was routinely offered to patients who exhibited some degree of dysphagia during the initial pre-treatment evaluation by a speech language pathologist. Control: Patients who had less than 10 treatment sessions or none with the Vitalstim device.
Follow-up	**Mean 4.5 months**
Conflict of interest/source of funding	Not reported

Analysis
Study design issues: The purpose of this study was to investigate the role of NMES therapy in maintaining swallowing function during chemoradiation for locally advanced head and neck cancer.
Study population issues:

- There was a retrospective definition of 'intervention' and 'control' groups with 'intervention' group being those patients who had received 10 or more treatments (as recommended), and the 'control' group those who had received fewer than 10 treatments. The reasons for receiving fewer than 10 treatments included: lack of significant dysphagia on initial evaluation (n=20), patient refusal (n=15), hospitalisation during treatment resulting in premature discontinuation (n= 7), severe skin toxicity or additional toxicity resulting in patient discontinuation (n=8), insurance denial (n= 2), and unknown reason (n= 2).
- Patients receiving 1 to 9 applications had statistically significantly similar mean scores on baseline measures of swallowing function to those receiving zero applications ($p > 0.05$).
- The 2 groups were well balanced for baseline patient characteristics, and this was confirmed by non-statistically significance in independent samples t tests comparing group differences.
- The median number of NMES treatments were 14 (range, 10–38) in the treatment group and 0 (range, 0–9) in the control group.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **95 (41 NMES [consecutive patients] versus 54 control)**

	Treatment group (n=41)		Control group (n=54)		Results	
	Baseline (mean±SD)	**Follow-up (mean±SD)**	**Baseline (mean±SD)**	**Follow-up (mean±SD)**	**F**	**p value**
FOIS	6.195±1.382	5.732±1.566	5.981±1.380	4.593±2.311	6.122*	**0.015**
8-point PAS	2.927±2.494	3.073±2.514	3.056±2.543	4.315±2.590	2.445	0.121
Swallowing Performance Status Scale	2.902±1.530	3.415±1.658	2.815±1.738	4.074±2.222	0.736†	0.393

* Analysis adjusted for race.

† Analysis adjusted for nodal status.

Logistic regression analysis of predictive factors for outcome

''No NMES intervention'' was statistically significant for predicting poorer scores on the FOIS (OR 5.895, 95% CI 1.126 to 30.859, p=0.036) and on the Swallowing Performance Status Scale (OR 0.169, 95% CI 0.032 to 0.881, p=0.036) after chemoradiotherapy treatment.

Safety

No safety events were reported.

Abbreviations used: CI, confidence interval; FOIS, functional oral intake scale; NMES, neuromuscular electrical stimulation; OR, odds ratio; PAS, penetration-aspiration scale; SD, standard deviation; TNM, tumour, node and metastasis;

Study 9 Frost J (2018)

Details

Study type	**Prospective case series**
Country	UK
Recruitment period	2015-16
Study population and number	n= **10** patients with dysphagia of neurological origin
Age and sex	Mean 64 years; 10% (1/10) female
Patient selection criteria	All patients had previously had traditional swallowing therapy for dysphagia for a minimum of 6 months. However, all had achieved only limited oral intake of foods and fluids, corresponding to a score of 4 or less on the FOIS scale. In addition, patients must have had no interventions or changes in therapy in the 5 weeks before recruitment, and no planned interventions or changes in therapy during the study period.
Technique	The full study period for each patient was 10 weeks, divided into two 5-week phases. In the first phase of the study, traditional therapy alone was delivered in 3 separate sessions a week for 5 weeks, in which each session lasted 30 min. Traditional therapy was also delivered for a prestudy period of 5 weeks. The type of traditional therapy was determined by the speech and language therapist. In the second phase of the study, a combination of traditional therapy and NMES was delivered in 3 separate sessions a week for 5 weeks, in which each session lasted 30min. The two-channel VitalStim stimulator was used to deliver NMES to the submental musculature. The stimulator delivered biphasic current pulses at a fixed rate of 80Hz. One pair of electrodes was placed submentally and connected to 1 channel of the stimulator. Electrodes placed adjacent to the thyroid cartilage (either side of the larynx) formed the second pair of electrodes, and these were connected to the second channel of the stimulator.
Follow-up	**10 weeks from the start of traditional therapy**
Conflict of interest/source of funding	The authors reported no conflicts of interest. The study was supported by VitalStim as they lent the stimulation units. The authors have no financial connection with VitalStim.

Analysis

Follow-up issues: The patients were assessed at 3 time points: initially at the start of the 10-week study period to provide a baseline, at the end of the first phase (the 5-week period of traditional therapy) and finally at the end of the second phase (5-week period of combined traditional and NMES therapy).

Study design issues:

- The primary aim of the study was to determine whether patients who had received traditional swallowing therapy but still had limited oral food and fluid intake could improve their oral intake following a course of treatment combining traditional swallowing therapy with NMES.
- The swallowing function was assessed using the FOIS. To allow comparisons between the results of this study and other studies using different assessment scales, the Eating Assessment Tool 10 (EAT-10) (a patient-based self-assessment based on 10 questions) and the SWALQOL self-assessment were also recorded for each patient.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 10

Functional Oral Intake Scale, Quality of Life in Swallowing and Eating Assessment Tool 10 scores
<table>
<tr><th>Factor</th><th>Start conventional therapy</th><th>End of conventional therapy/start NMES</th><th>End NMES therapy</th></tr>
<tr><td>FOIS median±IQR (mean±SD)</td><td>1.0±0.8 (1.6±1.1)</td><td>1.0±0.8 (1.7±1.3)</td><td>3.0±0.8 (3.4±2.0)</td></tr>
<tr><td>SWAL-QOL median±IQR (mean±SD)</td><td>102±53 (106±49)</td><td>102±80 (109±51)</td><td>144±93 (136±56)</td></tr>
<tr><td>EAT-10* median±IQR (mean±SD)</td><td>35.0±6.8 (34.6±7.0)</td><td>34.5±7.8 (32.7±9.1)</td><td>26.5±9.0 (23.5±11.8)</td></tr>
</table>
* A decrease in value indicates an improved swallowing performance.

There was no statistically significant improvement in the FOIS, SWAL-QOL and EAT-10 scores between the start and the end of the 5 weeks of traditional therapy (p<0.05).

There was a statistically significant improvement in the FOIS, SWAL-QOL and EAT-10 scores between the start of the NMES + traditional therapy and the end of the NMES + traditional therapy (p<0.01).

Of the 10 patients, 3 had an improved quality of voice following the use of NMES+traditional therapy.</td><td>Minor adverse reactions to the NMES were reported in 4 patients on 4 occasions. This gives an incidence of adverse reactions of 1.3% (4/300) in terms of electrode pair placements.

- One patient had both skin irritation/ soreness and a burning sensation beneath the electrodes
- 2 patients had skin irritation or soreness beneath the electrodes
- 1 patient had neck or jaw pain.

In each case, the problem was resolved by repositioning the electrodes.</td></tr>
<tr><td colspan="2">Abbreviations used: EAT-10, Eating Assessment Tool 10 scores; FOIS, Functional Oral Intake Scale; IQR, interquartile range; SWAL-QOL, Quality of Life in Swallowing.</td></tr>
</table>

Study 10 Carnaby-Mann GD (2008) *[Study reported in the previous overview]*

Details

Study type	**Case series**
Country	USA
Recruitment period	Not reported
Study population and number	n= **6** patients with chronic pharyngeal dysphagia due to stroke, treatment of head and neck cancer or brain trauma.
Age and sex	Mean 64 years; 33% female
Patient selection criteria	Inclusion criteria: patients aged ≤90 years with at least 6 months' swallowing impairment (confirmed by videofluoroscopy), Mini-mental State Examination score ≥23, FOIS score of ≤5. Exclusion criteria: patients who received swallowing therapy within 3 months of participation.
Technique	NMES delivered using electrodes placed on the anterior neck. NMES was delivered with an electrical current that had a frequency of 80 Hz and pulse width of 700 μs. Patients received 1 hour NMES session each day, 5 days per week for a maximum of 15 sessions or until they attained a FOIS score of 6.
Follow-up	**6 months**
Conflict of interest/source of funding	Supported by a research grant from the manufacturers of the NMES device.

Analysis
Follow-up issues:

- 1 patient who suffered an unrelated adverse event was withdrawn from the study.
- 1 patient was lost to follow-up due to advancing primary disease.

Study design issues:

- 2 speech-language pathologists who administered NMES were blinded to baseline assessments.
- Outcome assessors blinded to swallowing status and progress of patient.
- Patients received 2 pre-treatment sessions to familiarise them with the procedure and avoid 'anticipatory bias'.
- MASA scale assesses swallowing ability and recovery time. The highest possible score is 200, with higher scores indicating better swallowing abilities.
- VAS assessed a patient's perspective on their swallowing ability with 0 indicating the inability to swallow and 100 indicating no swallowing deficit.

Other issues:

- Percentages of patients who experienced coughing or expectoration (22%) in addition to neck soreness (17%) do not correlate with 6 patients as a denominator.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 6

Changes in outcome measures (refer to comments column to examine direction of outcome measures)
<table>
<tr><td>Outcome</td><td>Pre-treatment</td><td>After treatment [a]</td><td>6-month follow-up [d]</td></tr>
<tr><td>MASA[b] (Mean±SD)</td><td>160.5±17.4</td><td>181.8±8.5</td><td>191.7±5.6</td></tr>
<tr><td>FOIS[c] Mean (range)</td><td>4 (2-5)</td><td>6 (3-7)</td><td>6 (6-7)</td></tr>
<tr><td>Weight (lb) (Mean±SD)</td><td>144.0±21.2</td><td>145.8±27.6</td><td>138.0±31.3</td></tr>
<tr><td>VAS of patients' perception of swallowing (Mean±SD)</td><td>20.5±17.8</td><td>59.8±21.0</td><td>70.2±19.6</td></tr>
</table>
[a] Statistically significant differences between the pre- and after treatment measurements for MASA (p<0.04), FOIS (p<0.02), weight change (p<0.03) and patients' perception of swallowing (p<0.04).
[b] 4/5 patients achieved an increase of 10 or more points on the MASA scale, which was considered a clinically meaningful improvement.
[c] In 5/6 patients, FOIS scores increased by at least 2 points, which was considered a clinically meaningful improvement.
[d] Changes were sustained over time because no statistically significant differences were observed between post-treatment and follow-up scores for all outcomes (p>0.05).</td><td>Minor complications
• 1 patient was withdrawn due to unrelated seizure activity.
• A burning sensation was reported in 50% (3/6) of patients during sessions.
• Skin irritation was reported in 33% (2/6) of patients at the site of electrodes.
• The sensation of gastric fullness was reported in 33% (2/6) of patients
• Neck soreness at the site of electrodes was reported in17% (1/6) of patients.
• Coughing and expectoration were reported during 22% of NMES sessions</td></tr>
<tr><td colspan="2">Abbreviations used: FOIS, Functional Oral Intake Scale; MASA, Mann assessment of swallowing ability; VAS, visual analogue scale.</td></tr>
</table>

Validity and generalisability of the studies

- The systematic review and meta-analysis (Study 1) showed large heterogeneity and many of the included studies were small. The authors concluded that future large scale randomised clinical trials with objective measures were warranted.
- Most of the included studies assessed the efficacy of NMES in patients with dysphagia after a stroke or a brain injury[1, 3-7, 9].
- Only 2 of the included studies assessed the efficacy of NMES in patients who had dysphagia after the treatment of head and neck cancers[2, 8].
- The longest follow-up reported was a maximum of 3 years for 1 of the studies included in the systematic review and meta-analysis[1].
- Different devices were used in the studies with different methods and different electrode shape, different electrode placement, and different current intensity setting.
- The efficacy of the NMES intervention was either assessed on its own or in combination with swallowing exercises.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia. NICE interventional procedures guidance 550 (2016). Available from https://www.nice.org.uk/guidance/ipg550

- Flexible endoscopic treatment of a pharyngeal pouch. NICE interventional procedure guidance 513 (2015). Available from http://www.nice.org.uk/guidance/IPG513
- Endoscopic stapling of pharyngeal pouch. NICE interventional procedure guidance 22 (2003). Available from http://www.nice.org.uk/guidance/IPG22

NICE guidelines

- Stroke rehabilitation in adults. NICE clinical guideline 162 (2013). Available from http://guidance.nice.org.uk/CG162
- Improving outcomes in head and neck cancers. NICE cancer service guidance (2004). Available from http://www.nice.org.uk/Guidance/CSGHN

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. 4 Specialist Advisor Questionnaires for transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent 4 companies who manufacture a potentially relevant device for use in this procedure. NICE received 2 completed

submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

There were no on-going trials.

References

1. Ding R, Ma F (2016) Effectiveness of Neuromuscular Electrical Stimulation on Dysphagia Treatment in Patients with Neurological Impairments– A Systematic Review and Meta-Analysis. Ann Otolaryngol Rhinol 3(12): 1151.
2. Langmore S E, McCulloch T M, Krisciunas G P et al. (2016) Efficacy of electrical stimulation and exercise for dysphagia in patients with head and neck cancer: A randomized clinical trial. Head and Neck 38 (pp E1221-E1231).
3. Konecny P, and Elfmark M (2017) Electrical stimulation of hyoid muscles in post-stroke dysphagia. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub
4. Jing Q, Yang X, and Reng Q (2016) Effect of neuromuscular electrical stimulation in patients with post-stroke dysphagia. Medical Science Technology 57(pp 1-5)
5. Beom J, Oh B M, Choi K H et al. (2015) Effect of Electrical Stimulation of the Suprahyoid Muscles in Brain-Injured Patients with Dysphagia. Dysphagia 30(4), 423-9
6. Zhang M, Tao T, Zhang Z Bet al. (2016) Effectiveness of Neuromuscular Electrical Stimulation on Patients With Dysphagia With Medullary Infarction. Archives of Physical Medicine & Rehabilitation 97(3), 355-62
7. Sproson L, Pownall S, Enderby P et al. (2018) Combined electrical stimulation and exercise for swallow rehabilitation post-stroke: a pilot randomized control trial. International Journal of Language and Communication Disorders;53(2):405-417.
8. Bhatt A D, Goodwin N, Cash E et al. (2015) Impact of transcutaneous neuromuscular electrical stimulation on dysphagia in patients with head and neck cancer treated with definitive chemoradiation. Head and Neck 37(7), 1051-1056.
9. Frost J, Robinson HF, Hibberd J (2018) A comparison of neuromuscular electrical stimulation and traditional therapy, versus traditional therapy in patients with longstanding dysphagia. Current Opininion in Otolaryngology and Head and Neck Surgery. 26(3):167-173.
10. Carnaby-Mann GD, Crary MA (2008) Adjunctive neuromuscular electrical stimulation for treatment-refractory dysphagia. Annals of Otology, Rhinology, and Laryngology 117 (4): 279-287

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	14/11/17	Issue 11 of 12, November 2017
HTA database (Cochrane Library)	14/11/17	Issue 11 of 12, November 2017
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	14/11/17	Issue 10 of 12, October 2017
MEDLINE (Ovid)	14/11/17	1946 to November Week 1 2017
MEDLINE In-Process (Ovid)	13411/17	November 13 2017
EMBASE (Ovid)	13/11/17	1974 to 2017 Week 46
PubMed	14/11/17	n/a
BLIC	15/11/17	n/a

Trial sources searched 8th November 2017

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched 8th November 2017

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 Transcutaneous Electric Nerve Stimulation/
2 Electric Stimulation Therapy/
3 Electric Stimulation/
4 (Electr* adj4 (stimulat* or therap*)).tw.
5 (NMES or TENS or FES).tw.
6 Electrostimul*.tw.

7 Electrotherap*.tw.
8 or/1-7
9 exp Deglutition Disorders/
10 (swallow* or oropharyngeal* or pharyngeal* or deglutit*).tw.
11 dysphag*.tw.
12 (deglutit* adj4 disorder*).tw.
13 or/9-12
14 8 and 13
15 VitalStim.tw.
16 empi.tw.
17 Spectramed.tw.
18 The guardian way.tw.
19 eSwallow USA.tw.
20 Freedom stim.tw.
21 madison oral strengthening theraputic device.tw.
22 or/15-21
23 14 or 22
24 Animals/ not Humans/
25 23 not 24
26 limit 25 to ed=20121201-20171130

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Baijens LWJ, Speyer R et al. (2012). The effect of surface electrical stimulation on swallowing in dysphagic parkinsons patients. Dysphagia: 27(4): 528-537	n=10 dysphagic Parkinson's patients Follow-up: immediately during treatment	No significant differences in laryngeal vestibule duration (seconds) and duration of horizontal hyoid motion were observed between 2 of 3 electrode placement configurations.	Study assessed the effect of 3 electrode placement configurations: suprahoidal, infrahoidal and bilateral.
Baijens LW, Speyer R, Passsos VL, Pilz W, van der Kruis J, Haarmans S, Desjardins-Rombouts C. 2013. Surface electrical stimulation in dysphagic Parkinson patients. Laryngoscope. 123 (11): E38-E44	n=90 (NMES vs TT) Follow-up: 2 weeks	Using proportional odds models (POMs), some of the visuoperceptual ordinal outcome variables showed significant improvement in all groups following treatment. Following 15 days of NMES of the submental region, few significant effects were found, suggesting a therapy effect of traditional logopedic dysphagia treatment without any additional influence of NMES.	This study assessed the same patients that have been included in a previous article, by the same co-authors. The previous study was included in table 2 of the previous overview (Heijnen 2012). Furthermore, this study utilises proportional odds models to assess the efficacy of the procedure over a short, 2 week, follow-up period.
Beom J, Kim S J, and Han T R (2011) Electrical Stimulation of the Suprahyoid Muscles in Brain-injured Patients with Dysphagia: A Pilot Study. Annals of Rehabilitation Medicine 35(3), 322-7	Comparative study n=28 brain-injured patients with dysphagia (7 NMES + conventional dysphagia management [CDM] versus 21 conventional	Although repetitive NMES of the suprahyoid muscles did not further improve the swallowing function of dysphagia patients with reduced laryngeal elevation, more	This study is included in the Ding (2016) systematic review and meta-analysis which is included in Table 2.

	dysphagia management) FU= 4 weeks	patients in the NMES group showed improvement in the ASHA level than those in the CDM group. Further studies with concurrent controls and a larger sample group are required to fully establish the effects of repetitive NMES of the suprahyoid muscles in dysphagia patients.	
Bogaardt H, van Dam D et al (2009) Use of Neuromuscular electrostimulation in the treatment of dysphagia in patients with multiple sclerosis. Annals of Oncology, Rhinology and Larynology: 118 (4): 241-246	n=25 Follow-up: 3 weeks	A significant decrease in pooling of saliva in the pyriform sinuses was seen in 6 patients (p=0.03). Significantly less aspiration during swallowing of thin liquids was observed in 9 patients (p<0.01). All patients reported improved swallowing.	Bigger studies reporting the same outcome measures were included in table 2.
Blumenfield L, Hahn Y (2006) Transcutaneous electrical stimulation versus traditional dysphagia therapy: a nonconcurrent cohort study. Otolaryngology – head and neck surgery. 135: 754-757	n=80 (NMES vs TT) Follow-up: not reported	Both NMES and TT groups exhibited improved swallowing scores. He NMES group exhibited significantly greater improvements compared to the TT group (p=0.002)	Other studies were available that reported more outcome measures.
Bulow M (2008) Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysphagia. Dysphagia: 33 (3): 302 - 309	n=25 (NMES vs TT) Follow-up: After 15 NMES sessions	No statistically significant differences were between NMES and TT group were observed in Videoradiographic Evaluation of swallowing scores, Actual Nutrition scale and Oral Motor Function test scores.	This study was included in Appendix A in the previous overview and is also included in the Ding (2016) systematic review and meta-analysis.
Byeon H (2016) Effect of the Masako manoeuvre and neuromuscular	Comparative study	The Masako manoeuvre and	Studies with more patients or

electrical stimulation on the improvement of swallowing function in patients with dysphagia caused by stroke. Journal of Physical Therapy Science 28(7), 2069-71	n=47 (24 NMES versus 23 Masako Manoeuvre) FU=after 4 weeks of therapy	neuromuscular electrical stimulation each showed significant effects on the improvement of swallowing function for the patients with dysphagia caused by stroke, but no significant difference was observed between the 2 treatment methods.	longer follow-up are included.
Byeon H, and Koh H W (2016) Comparison of treatment effect of neuromuscular electrical stimulation and thermal-tactile stimulation on patients with sub-acute dysphagia caused by stroke. Journal of Physical Therapy Science 28(6), 1809-12	RCT n=55 (27 NMES versus 18 thermal tactile oral stimulation) FU= after 3 weeks of therapy	Analysis of pre-post values of videofluoroscopic studies of the NMES and thermal tactile oral stimulation groups using a paired t-test showed no statistically significant difference between the 2 groups despite both having decreased mean values of the videofluoroscopic studies after treatment.	Studies with more patients or longer follow-up are included.
Calabro R S, Nibali V C, Naro A, Floridia D, Pizzimenti M, Salmeri L, Salviera C, and Bramanti P (2016) Is non-invasive neuromuscular electrical stimulation effective in severe chronic neurogenic dysphagia? Reporton a post-traumatic brain injury patient. Neurorehabilitation 38(1), 53-7	Single case report FU= after 6 weeks of treatment	The patient did not report any side-effect either during or following both the intensive rehabilitation trainings. We observed an important improvement in swallowing function only after Vitalstim training. In fact, the patient was eventually able to safely eat even solid food.	Studies with more patients or longer follow-up are included.
Carnaby-Mann GD. (2007) Examining the evidence on neuromuscular electrical stimulation for swallowing: A meta-analysis.	n=255 Follow-up: not reported	Pooled Hedges g was 0.66, in favour of NMES.	A more recent systematic review was included in Table 2.

Chen Y W, Chang K H, Chen H C et al. (2016) The effects of surface neuromuscular electrical stimulation on post-stroke dysphagia: a systemic review and meta-analysis. Clinical Rehabilitation 30(1), 24-35	Systematic review and meta-analysis n=8 RCTs and quasi RCTs 1/NMES+swallow treatment versus swallow treatment alone 2/ NMES versus swallow treatment Search up to 31/12/2014	- For the comparison "swallow treatment with neuromuscular electrical stimulation vs. swallow treatment without neuromuscular electrical stimulation'': standardized mean difference (SMD) = 1.27 (95% confidence interval (CI)= 0.51-2.02, p=0.001) with significant heterogeneity (I^2=85%). - The meta-analysis for the comparison of neuromuscular electrical stimulation alone and swallow therapy demonstrated a non-significant SMD of 0.25 (95% CI= -0.16-0.65, p=0.23) without significant heterogeneity (I^2=16%).	A more recent systematic review was included in Table 2.
Cheung SM, Chung CJ. (2010) Effect of neuromuscular electrical stimulation in a patient with Sjorgens syndrome with dysphagia: A real time videofluoroscopic swallowing study. Chang gung medical journal: 33: 338-345	n=1 Follow-up: 46 NMES sessions	Following NMES, improved hyoid elevation, laryngeal elevation, tongue retraction, and swallowing reflexes were observed. No hypernasality, drooling or choking was observed following NMES.	Bigger studies with better outcome measures were available
Choi J B (2016) Effect of neuromuscular electrical stimulation on facial muscle strength and oral function in stroke patients with facial	Case series n=9	Subjects showed significant improvement in cheek and lip	Studies with more patients or

palsy. Journal of Physical Therapy Science 28(9), 2541-2543	FU=after 4 weeks of treatment	strength and oral function after the intervention.	longer follow-up are included.
Christiaanse ME, Mabe B et al (2011) Neuromuscular stimulation is no more effective than usual care for the treatment of primary dysphagia in children. Paediatric pulmonology 46: 559-565	n=95 children (NMES vs TT) Follow-up: 10 weeks	Both groups showed improvements in FOIS scores ($p<0.01$); however, no significant differences between groups ($p=0.11$).	Study included patients with non oropharyngeal dysphagia.
Clark H, Lazarus C, Arvedson J, Schooling T, Frymark T. (2009) Evidence-based systematic review: effects of neuromuscular electrical stimulation on swallowing and neural activation. American Journal of Speech-Language Pathology. 18(4):361-75	n=14 studies Follow-up: 14 articles	Out of 899 citations initially identified 14 articles relating to NMES qualified for inclusion. Most of the studies (10/14) were considered exploratory research, and many had significant methodological limitations. High-quality controlled trials were needed to provide evidence of efficacy.	This study was labelled as a systematic review; however, it is actually a narrative review highlighting key papers related to NMES.
El-Tamawy M S, Darwish M H, El-Azizi H S et al. (2015) The influence of physical therapy on oropharyngeal dysphagia in acute stroke patients. Egyptian Journal of Neurology, and Psychiatry and Neurosurgery 52(3), 201-205	RCT n=30 (15 medical treatment + physical therapy including NMES versus 15 medical treatment only) patients with acute stroke FU=after 6 weeks of treatment	Before treatment, there were no statistically significant differences in different variables between the study group and the control group. After treatment there was a statistically significant improvement in all variables in the study group compared with the control group, as measured by digital fluoroscopy.	Studies with more patients or longer follow-up are included.
Freed ML, Freed L, Chatburn RL et al. (2001) Electrical stimulation for swallowing disorders caused by stroke. Respiratory care 46 (5): 466–474	Non-randomised comparative study n=110 (NMES vs TTS. Numbers allocated to each group not reported) Follow-up: up to 3 years	NMES appears to be a safe and effective treatment for dysphagia due to stroke and results in better swallow function than conventional TS treatment.	This study was included in Table 2 in the previous overview and is also included in the Ding (2016) systematic review and meta-analysis.

Gallas S. (2010) Sensory Transcutaneous Electrical Stimulation Improves Post-Stroke dysphagic patients. Dysphagia: 25(4): 291-297	n=7 Follow-up: 1week	Questionnaire results revealed significant improvements in symptoms, videofluoroscopy measurements, pharyngeal residue and swallowing reaction time (p values<0.05)	Short-term follow-up of 1 week and small sample size.
Geeganage C, Beavan J, Ellender S, Bath PMW. Interventions for dysphagia and nutritional support in acute and subacute stroke. Cochrane Database of Systematic Reviews 2012, Issue 10. Art. No.: CD000323. DOI: 10.1002/14651858.CD000323.pub2.	Systematic review and meta-analysis n=33 studies (6779 participants) but only 1 study on NMES	NMES did not alter dysphagia at the end of one small trial (t = 1; n = 22; OR 0.43; 95% CI 0.07 to 2.50). Data on other outcomes were not available.	There was only 1 study included for the NMES therapy (Lim 2009) and this study is included in the systematic review and meta-analysis included in Table 2 (Ding 2016).
Guillen-Sola A, Messagi Sartor, M, Bofill Soler, N et al. (2017) Respiratory muscle strength training and neuromuscular electrical stimulation in subacute dysphagic stroke patients: a randomized controlled trial. Clinical Rehabilitation 31(6), 761-771	RCT n=62 (20 standard swallow therapy [SST] +inspiratory/expiratory muscle training [IEMT] + NMES versus 21 SST + IEMT versus 21 SST) dysphagic patients with stroke FU=3 months	Adding IEMT to SST was an effective, feasible, and safe approach that improved respiratory muscle strength. Both IEMT and NMES were associated with improvement in pharyngeal swallowing security signs at the end of the intervention, but the effect did not persist at 3-month follow-up and no differences in respiratory complications were detected between treatment groups and controls.	Studies with more patients or longer follow-up are included.
Gupta H, and Banerjee A (2014) Recovery of Dysphagia in lateral medullary stroke. Case Reports in Neurological Medicine Print 2014, 404871	Single case report FU=6 months	Despite being diagnosed with a severe form of dysphagia followed by late treatment intervention, the patient had complete recovery of the swallowing function.	Case report with no complications reported.

Heijnen BJ, Speyer R, Baijens LW et al. (2012) Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life. Dysphagia 27 (3): 336-345	RCT n=85 (27 NMES motor level versus 30 NMES sensory level versus 28 traditional therapy) patients with Parkinson's disease and oropharyngeal dysphagia FU=3 months after treatment	All groups showed statistically significant therapy effects on the Dysphagia Severity Scale and restricted improvements on the SWAL-QOL and the MD Anderson dysphagia inventory. However, only slight nonsignificant differences between groups were found.	This study was included in Table 2 in the previous overview.
Huang K L, Liu T Y, Huang Y C et al. (2014) Functional outcome in acute stroke patients with oropharyngeal Dysphagia after swallowing therapy. Journal of Stroke & Cerebrovascular Diseases 23(10), 2547-53	RCT n=29 (10 NMES + traditional swallowing [TS] versus 8 NMES versus 11 TS) acute stroke patients with oropharyngeal dysphagia FU= post treatment	TS therapy and combined therapy both had statistically significant swallowing improvement after therapy according to the FOIS and 8-point PAS ($p < 0.05$). When comparing the results of the VFS among the 3 groups, the results showed statistically significant improvements in patients eating cookies and thick liquid after combined NMES/TS therapy ($p < 0.05$).	This study is included in the systematic review and meta-analysis included in Table 2 (Ding 2016).
Kiger M, Brown CS (2006) Dysphagia management: An analysis of patient outcomes using Vitalstim therapy compared to traditional swallowing therapy. Dysphagia 21 (4): 243 - 253	n=22 Follow-up: Not reported	Results of Chi-square analysis revealed no statistically significant difference in outcomes between experimental and control groups.	Included patients with varying aetiologies of dysphagia (including non oropharyngeal dysphagia) but did not stratify. Inconsistent numbers of NMES courses were administered to patients. NMES group: mean =8.72, TT group: mean = 3.36.

Kim H, Park J W, and Nam K (2017) Effortful swallow with resistive electrical stimulation training improves pharyngeal constriction in patients post-stroke with dysphagia. Journal of Oral Rehabilitation 44(10), 763-769	Case series n=19 patients with post-stroke dysphagia FU=after 4 weeks of treatment	Effortful swallow with resistive electrical stimulation training increases pharyngeal constriction. It can be used as a treatment to improve pharyngeal constriction in patients with dysphagia.	Studies with more patients or longer follow-up are included.
Krisciunas G P, McCulloch T M, Lazarus C L et al. (2015) Impact of compliance on dysphagia rehabilitation outcomes: Results from a multi-center clinical trial evaluating the efficacy of electrical stimulation for dysphagia. Dysphagia Conference, 23rd Annual Meeting of the Dysphagia Research Soci	n=153 head and neck patients with compliance data from the Langmore (2015) study FU=after 12 weeks of therapy	The addition of estim to swallowing exercises resulted in worse swallowing outcomes than exercises alone, even in compliant patients. Since neither compliant nor non-compliant patients benefitted from therapy, the proper dose and/or efficacy of swallowing exercises must be questioned.	This study is a secondary analysis of the Langmore (2015) study on compliance. The Langmore (2015) study is included in Table 2.
Kushner DS, Peters K, Eroglu ST et al. (2013) Neuromuscular electrical stimulation efficacy in acute stroke feeding tube-dependent dysphagia during inpatient rehabilitation. American Journal of Physical Medicine & Rehabilitation 92 (6): 486-495	Non-randomised comparative study n=92 (65 NMES+TT+PRT vs 27 TT+PRT) Follow-up: not reported	This study suggests that NMES with TDT/PRT is statistically significantly more effective than TDT/PRT alone during inpatient rehabilitation in reducing feeding tube-dependent dysphagia in patients who have had an acute stroke.	This study was included in Table 2 in the previous overview and is also included in the Ding (2016) systematic review and meta-analysis.
Lee D H, Park J S, Lee S W et al. (2017) Effects of electrical stimulation combined with dysphagia therapy in elderly individual with oropharyngeal dysphagia: a case study. Journal of Physical Therapy Science 29(3), 556-557	Single case report FU=after 4 weeks of treatment	The results suggest that electrical stimulation and conventional dysphagia therapy were effective in improving the swallowing function in an elderly individual with dysphagia.	Single case report with no reported complications.

Lee H Y, Hong J S, Lee K C et al. (2015) Changes in hyolaryngeal movement and swallowing function after neuromuscular electrical stimulation in patients with Dysphagia. Annals of Rehabilitation Medicine 39(2), 199-209	Case series n=15 patients with dysphagia of various aetiologies FU=not reported	Immediate hyolaryngeal movement was paradoxically depressed after NMES on both submental and throat regions with significant reductions in the NIH-SSS but not the PAS, suggesting improvement in pharyngeal peristalsis and cricopharyngeal functions at the oesophageal entry rather than decreased aspiration and penetration. The results also suggested that patients with dysphagia should be carefully screened when determining motor-level NMES.	Studies with more patients or longer follow-up are included.
Lee K W, Kim S B, Lee J H et al. (2014) The effect of early neuromuscular electrical stimulation therapy in acute/subacute ischemic stroke patients with Dysphagia. Annals of Rehabilitation Medicine 38(2), 153-9	RCT n=57 (31 NMES + traditional dysphagia therapy [TDT] versus 26 TDT only) dysphagic stroke patients FU=12 weeks	Both groups showed a statistically significant improvement on the FOIS after treatment. The FOIS score was statistically significantly more improved at 3 and 6 weeks after baseline in the NMES/TDT group than in the TDT group ($p<0.05$).	This study is included in the systematic review and meta-analysis included in Table 2 (Ding 2016).
Lee S Y, Yang H E, Yang H S et al. (2012) Neuromuscular Electrical Stimulation Therapy for Dysphagia Caused by Wilson's Disease. Annals of Rehabilitation Medicine 36(3), 409-13	Single case report Patient with Wilson's disease and dysphagia. FU=after 2 weeks of treatment	After 10 sessions of NMES for 1 hour per day, decreased amount of residue was observed in the valleculae during the pharyngeal phase on the follow-up VFSS.	Case report with no reported complications.

Leelamanit V. Limsakul C. et al (2002) Synchronized electrical stimulation in treating pharyngeal dysphagia. The laryngoscope: 112: 2204-2210	n=23 patients with reduced laryngeal elevation Follow-up: up to 33 months but mainly reported outcomes after initial course of NMES	20/23 patients exhibited marked improvements at the first course of NMES therapy (4 hours a day for 2 to 4 days). Patients in the NMES group were able to take adequate regular diet orally without aspiration (Videofluoroscopy pictures shown but no numbers reported).	This was a mainly descriptive study that reported outcomes using videofluoroscopy pictures did not use employ any statistical tests apart from Kaplan-Meier analysis which revealed that severity and age were significant predictive variables for improvements in dysphagia.
Li L, Yin J, Shen Y, Qiao B et al. (2012) The value of adding transcutaneous neuromuscular electrical stimulation (VitalStim) to traditional therapy for post-stroke dysphagia: A randomized controlled study. Revista Ecuatoriana de Neurologia 21(1-3), 37-42	RCT n=118 (38 NMES versus 40 NMES + TST versus 40 TST) FU=4 weeks of treatment	Data suggest that NMES coupled with traditional swallowing therapy may be beneficial for post-stroke dysphagia.	This study is included in the systematic review and meta-analysis included in Table 2 (Ding 2016).
Lim K B, Lee H J, Yoo J, et al. (2014) Effect of Low-Frequency rTMS and NMES on Subacute Unilateral Hemispheric Stroke With Dysphagia. Annals of Rehabilitation Medicine 38(5), 592-602	RCT n=47 (18 NMES versus 15 conventional dysphagia therapy [CDT] versus 14 repetitive transcranial magnetic stimulation [rTMS]) FU=4 weeks	The results indicated that both low-frequency rTMS and NMES could induce early recovery from dysphagia; therefore, they both could be useful therapeutic options for dysphagic stroke patients.	This study is included in the systematic review and meta-analysis included in Table 2 (Ding 2016).
Lim KB, Lee HJ, Lim SS et al. (2009) Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomised controlled trial. Journal of rehabilitation medicine 41: 174-178	RCT n=36 (NMES+TTS vs TTS). Numbers randomised not reported Follow-up: 4 weeks	The results suggested that neuromuscular electrical stimulation combined with thermal-tactile stimulation is a better treatment for patients with swallowing disorders after stroke than thermal-tactile stimulation alone.	This study was included in Table 2 in the previous overview and is also included in the Ding (2016) systematic review and meta-analysis.

Lin PH, Hsiao TY, Chang YC, Ting LL, Chen WS, Chen SC, Wang TG. (2011) Effects of functional electrical stimulation on dysphagia caused by radiation therapy in patients with nasopharyngeal carcinoma. Support Care Cancer;19(1):919.	n=20 (NMES vs Home rehabilitation vs treatment) Follow-up: after 15 sessions	Significant improvements in quality of life score, duration of movement of thin barium through the hyoid, the speed of movement of paste barium through the hyoid and the pyriform sinus stasis area of barium paste were observed in the NMES group. The degree of improvement in the movement speed of the hyoid bone in the thin barium and the Penetration and Aspiration Scale of barium paste were statistically significantly greater in the NMES group than in the HRP group.	Bigger studies reporting the same outcome measures were included in table 2.
Long YB, and Wu XP (2013) A randomised controlled trial of combination therapy of neuromuscular electrical stimulation and balloon dilatation in the treatment of radiation-induced dysphagia in nasopharyngeal carcinoma patients. Disability and rehabilitation. Disability and Rehabilitation. 35(6):450-4	n=60 (NMES+balloon dilatation+TT vs TT-alone) Follow-up: 4 months	NMES group showed significant improvements in swallowing function (oral transit time, swallowing reaction times, pharyngeal transit times and laryngeal closure duration) compared with the control group	Combination therapy: NMES +balloon dilatation+TT was compared with TT-alone. Hence, it is unclear if the effect was due to NMES or balloon dilatation. Furthermore, outcome measures included oral transit times, swallowing reaction times, pharyngeal transit times and laryngeal closure duration.
Ludlow CL, Humbert I et al. (2007) Effects on surface electrical stimulation both at rest and during swallowing in chronic pharyngeal dysphagia. Dysphagia. 22(1):1-10	n=11 Follow-up: immediate	Significant hyoid depression occurred during NMES	Study assessed biophysical characteristics of muscle contractions. More relevant outcome

			measures were used.
Meng P, Zhang S, Wang Q et al. (2018) The effect of surface neuromuscular electrical stimulation on patients with post-stroke dysphagia. Journal of back and musculoskeletal rehabilitation. 31(2):363-370	RCT n=30 (10 TDT + surface NMES on the suprahyoid region versus 10 TST + surface NMES on both suprahyoid and infrahyoid regions versus 10 TDT only) patients with post-stroke dysphagia FU=after 2 weeks of treatment	Swallowing function in the patients with post-stroke dysphagia was statistically significantly improved using TDT combined with NMES. Stimulating electrodes placed at the suprahyoid region or on both suprahyoid and infrahyoid regions resulted in no difference of effect. However, NMES on suprahyoid region could further improve the moving distance of hyoid bone anteriorly.	Studies with more patients or longer follow-up are included.
Oh DH, Park JS and Kim WJ (2017) Effect of neuromuscular electrical stimulation on lip strength and closure function in patients with dysphagia after stroke. Journal of physical therapy science.29(11):1974-1975	Case series n=8 patients with dysphagia after stroke FU=after 4 weeks of treatment	Lip strength showed significant improvement and lip closure function showed a significant decrease.	Studies with more patients or longer follow-up are included.
Park J S, Oh D H, Hwang N K et al. (2016) Effects of neuromuscular electrical stimulation combined with effortful swallowing on post-stroke oropharyngeal dysphagia: a randomised controlled trial. Journal of Oral Rehabilitation 43(6), 426-34	RCT n=50 (25 NMES versus 25 sham) patients with oropharyngeal dysphagia after stroke FU=after 6 weeks of treatment	The experimental group revealed a statistically significant increase in anterior and superior hyoid bone movement and the pharyngeal phase of the swallowing function. This intervention can be used as a novel remedial approach in dysphagic stroke patients.	Studies with more patients or longer follow-up are included.
Park JW, Kim Y, Oh JC, Lee HJ. (2012) Effortful swallowing training combined with electrical stimulation in post-stroke dysphagia: a randomized controlled study. Dysphagia. 27(4):521-7	n=20 Follow-up: 4 weeks	In the experimental group, the maximal vertical displacement of the larynx was increased significantly after the intervention ($p<0.05$). The maximal vertical displacement of the hyoid bone and the	Study assessed biophysical characteristics of muscle contractions. More relevant outcome measures were used.

		maximal width of the UES opening increased but the increase was not found to be significant (p=0.066).	
Permsirivanich W, Tipchatyotin S, Wongchai M et al. (2009) Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study. Journal of the medical association of Thailand 92 (2): 259-265	RCT n=28 (15 NMES vs 13 TT) Follow-up: not reported	While both rehabilitation swallowing therapy and NMES therapy showed a positive effect in the treatment of persistent dysphagia in stroke patients, NMES was statistically significantly superior.	This study was included in Table 2 in the previous overview and is also included in the Ding (2016) systematic review and meta-analysis.
Restivo DA, Casabona A et al (2013) Pharyngeal electrical stimulation for dysphagia associated with multiple sclerosis: A pilot study. Brain stimulation: 6: 418-423	n=20 multiple sclerosis patients (NMES vs Sham stimulation) Follow-up: 4 weeks	Patients who received NMES showed significant improvements in all swallowing outcome measures: PAS, Electromyographic measures of laryngeal transductor excursion, duration of EMG of suprahyoid muscles and the duration of inhibition of cricopharyngeal cortical motor thresholds.	Larger studies were available that reported PAS scores.
Rice LK (2012) Neuromuscular electrical stimulation in the early intervention population: A series of five case studies. The internet journal of allied health sciences and practice: 10 (3)	n=5 children Follow-up: up to 63 NMES sessions	Participants showed moderate to marked improvements in their swallowing capabilities.	Bigger studies were available.
Rofes L, Arreola V, López I, Martin A, Sebastián M, Ciurana A, Clavé P. (2013) Effect of surface sensory and motor electrical stimulation on chronic poststroke oropharyngeal dysfunction. Neurogastroenterology and Motility. 25(11): 888-e701	n=42 Follow-up: 5 days after last treatment.	After sensory stimulation, the number of unsafe swallows was reduced by 66.7% (p<0.001), the laryngeal vestibule closure time by 22.94% (p=0.027) and maximal vertical hyoid extension time by 18.6% (p=0.036).	Larger studies with longer follow-up periods were included in table 2. Furthermore, the study assessed biophysical characteristics of muscle contractions: more relevant outcome

		After motor stimulation, the number of unsafe swallows was reduced by 62.5% (p=0.002), the laryngeal vestibule closure time by 38.26% (p=0.009) and maximal vertical hyoid extension time by 24.8% (p=0.008). Moreover, the motor stimulus reduced the pharyngeal residue by 66.7% (p=0.002), the upper esophageal sphincter opening time by 39.39% (p=0.009), and increased bolus propulsion force by 211.1% (p=0.008). No serious adverse events were detected during the treatment.	measures used in studies that were included in table 2.
Ryu JS, Kang JY, Park JY et al. (2009) The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer. Oral oncology 45(8): 665-668	RCT n=46 (21 NMES vs 25 sham stimulation) Follow-up: not reported	NMES combined with traditional swallowing training is superior to traditional swallowing training alone in patients suffering from dysphagia following treatment for head and neck cancer.	This study was included in Table 2 in the previous overview.
Scarponi L, Mozzanica F, De Cristofaro V, et al. (2015) Neuromuscular Electrical Stimulation for Treatment-Refractory Chronic Dysphagia in Tube-Fed Patients: A Prospective Case Series. Folia Phoniatrica et Logopedica 67(6), 308-14	Prospective case series n=11 patients with dysphagia FU=after 4 weeks of treatment	NMES as adjunctive treatment to TT may offer a new possibility for the management of tube-fed patients who are refractory to TT.	Studies with more patients or longer follow-up are included.
Shaw GY, Sechtem PR et al. (2007) Transcutaneous Neuromuscular Electrical stimulation (Vtalstim) Curative Therapy for severe dysphagia: Myth or reality? Annals of Oncology, Rhinology and Laryngology: 116(1): 36-44	n=18 Follow-up: 21 months	61% (11/18) patients experienced some improvement in swallowing. 33% (6/18) no longer	Heterogeneity in study population: dysphagia was caused by stroke, Parkinson's Disease, traumatic brain

		required a feeding tube	injuries and radiotherapy. Patient groups were not stratified according to dysphagia type.
Soon K S, Lee M Y, Tsai W W, et al. (2013) Development of a swallowing electrical stimulation system for treatment of dysphagia in stroke patients. Journal of Medical and Biological Engineering 33(5), 497-503	Case series n=11 patients with dysphagia after stroke FU=post-treatment	The results indicated that restoring swallowing function by strengthening muscles via swallowing electrical stimulation system facilitated improvement in the treatment of dysphagia.	Studies with more patients or longer follow-up are included.
Sun SF, Hsu CW, Lin HS, Sun HP, Chang PH, Hsieh WL, Wang JL. 2013. Combined Neuromuscular Electrical Stimulation (NMES) with Fiberoptic Endoscopic Evaluation of Swallowing (FEES) and Traditional Swallowing Rehabilitation in the Treatment of Stroke-Related Dysphagia. Dysphagia: 28(4):557-566.	n=29 Follow-up: 2 years	Statistically significant improvements in Functional Oral Intake Scale (FOIS), Fibreoptic Endoscopic Evaluation of Swallowing (FEES) and Visual Analogue Scale (VAS) scores were observed at 6-month and 2-year follow-up.	Larger studies with similar outcome measures were available.
Tan C, Liu Y, Li W et al. (2013) Transcutaneous neuromuscular electrical stimulation can improve swallowing function in patients with dysphagia caused by non-stroke diseases: a meta-analysis. Journal of oral rehabilitation 40 (6): 472-480	Systematic Review and Meta-analysis n=7 studies: 291 patients (175 NMES vs 116 TT) Follow-up: not reported	NMES is more effective for treatment of adult dysphagia patients of variable aetiologies than traditional therapy. However, in patients with dysphagia post-stroke, the effectiveness was comparable. No studies reported complications of NMES.	This study was included in Table 2 in the previous overview.
Terre R, and Mearin F (2015) A randomized controlled study of neuromuscular electrical stimulation in oropharyngeal dysphagia secondary to acquired brain injury.	RCT n=20 (10 NMES + conventional swallowing therapy [CST] versus 10 sham	NMES statistically significantly accelerated swallowing function improvement in patients with	This study is included in the Ding (2016) systematic review and meta-analysis which is

European Journal of Neurology 22(4), 687-e44	NMES + CST) patients with neurological oropharyngeal dysphagia FU=3 months	oropharyngeal dysphagia secondary to acquired brain injury.	included in Table 2.
Thakkar D R, and Malarvizhi D (2016) Effectiveness of transcutaneous eletrical neuromuscular stimulation along with exercisces manoeuver in Dysphagia: Case series. International Journal of Pharma and Bio Sciences 7(4), B753-B756	Case series n=3 FU=after 6 days of treatment	Transcutaneous Neuromuscular Electrical Stimulation along with Exercise Manoeuvre improved oral intake ability and improved the quality of life in Dysphagia patients.	Studies with more patients or longer follow-up are included.
Toyama K, Matsumoto S, Kurasawa M et al.(2014) Novel neuromuscular electrical stimulation system for treatment of dysphagia after brain injury. Neurologia Medico-Chirurgica 54(7), 521-8	Comparative study n=26 (12 NMES + conventional treatment versus 14 conventional treatment) patients with dysphagia after brain injury. FU=after 8 weeks of treatment	The results suggested that NMES combined with conventional treatment is superior to conventional treatment alone in patients with dysphagia following treatment for brain injury. Further investigations are necessary to examine the effects of NMES in patients with more varied types of diseases.	This study is included in the Ding (2016) systematic review and meta-analysis which is included in Table 2.
Xia W, Zhen C, Lei Q et al. (2011) Treatment of post-stroke dysphagia by vitalstim therapy coupled with conventional swallowing training. Journal of Huazhong University Science Technology Medical Sciences 31 (1): 73-76	RCT n=120 (40 NMES-alone vs 40 NMES+TT vs 40 TT-alone) Follow-up: after 4 weeks of treatment	NMES therapy coupled with conventional swallowing training was conducive to recovery of post-stroke dysphagia.	This study was included in Table 2 in the previous overview.
Zhao J W, Wang Z Y, Cao W Z, Zhang Y W et al. (2015) Therapeutic efficacy of swallowing neuromuscular electrical stimulation combined with acupuncture for post-stroke dysphagia. World Journal of Acupuncture Moxibustion 25(1), 19-23	RCT n=120 (62 NMES + acupuncture versus 58 acupuncture only) patients with dysphagia after stroke.	The swallowing neuromuscular electrical stimulation combined with acupuncture treatment has a better clinical effect when compared	Studies with more patients or longer follow-up are included. The efficacy of the treatment was only assessed with the Kubota's water test.

	FU=2 weeks	with ordinary acupuncture.	