

Stroke rehabilitation in adults (update)

[I] Evidence reviews for interventions to support oral feeding in adults after a stroke

NICE guideline <number>

*Evidence reviews underpinning recommendations 1.11.2 to 1.11.7 and recommendations for research in the NICE guideline
April 2023*

Draft for Consultation

*This evidence review was developed by the
Guideline Development Team at NICE*

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1. Interventions and adaptations to support oral feeding

1.1. Review question

In people after stroke, what is the clinical and cost-effectiveness of interventions to support oral feeding compared with alternative interventions or usual care to reduce/improve difficulties with oral feeding?

1.1.1. Introduction

Dysphagia, or difficulties with oral feeding is common post stroke and 11-50% will have persistent dysphagia at six months (Smithard et al 1996 & Mann et al 2000). Stroke survivors with dysphagia have an increased risk of pneumonia and death (Cohen 2016). Longer term impacts of post stroke dysphagia include tube feeding, risk of malnutrition (Smithard et al 1997, Serra-Prat et al 2012) and reduced quality of life (Ekberg et al 2002).

To reduce these risks the first line of action in current practice is to compensate or adapt to the dysphagia and may require a period nil by mouth with nasogastric or gastrostomy tube feeding, if oral feeding can be offered, recommendations are made for different strategies cups or cutlery during eating and drinking, or modifications to the volume and consistency of the foods or drinks. Alongside adaptation, swallow rehabilitation is also important to improve difficulties with swallowing. In current practice these are usually behavioural approaches including motor exercises and sensory stimulation in some services peripheral neurostimulation techniques are emerging (Eltringham et al 2022). Research into the effectiveness of all these interventions has increased significantly in recent years therefore it is important to summarise the latest evidence in efforts to reduce the negative consequences of dysphagia on health and wellbeing.

1.1.2. Summary of the protocol

Table 1: PICO characteristics of review question

Population	<p>Inclusion:</p> <ul style="list-style-type: none">• Adults (age ≥ 16 years) who have had a first or recurrent stroke (including people after subarachnoid haemorrhage) <p>Exclusion:</p> <ul style="list-style-type: none">• Children (age < 16 years)• People who had a transient ischaemic attack• People with mechanical dysphagia• People with other pre-existing neurological conditions causing dysphagia
Interventions	<p>Interventions for oropharyngeal dysphagia:</p> <ul style="list-style-type: none">• Acupuncture/electroacupuncture• Behavioural interventions e.g. CTAR, Massako exercises, biofeedback, strength & skill training, effortful swallows, EMST• Drug interventions, including:<ul style="list-style-type: none">○ Metoclopramide○ Glyceride trinitrate patches• Neuromuscular electrical stimulation (NMES)• Pharyngeal electrical stimulation (PES)• Physical stimulation (such as flavours, thermal or tactile)

	<ul style="list-style-type: none"> • Transcranial direct current stimulation (tDCS) • Transcranial magnetic stimulation (TMS) <p>Interventions specifically for oesophageal dysphagia:</p> <ul style="list-style-type: none"> • Drug intervention <ul style="list-style-type: none"> ○ Erythromycin ○ Metoclopramide ○ Domperidone ○ Prucalopride <p>Adaptations for oral feeding:</p> <ul style="list-style-type: none"> • Thickened fluids • Modifying bolus volume/mode of delivery • Modified diet • Swallow strategies (such as chin tuck, head turn, supraglottic swallow, bolus hold etc.) • Carbonation • Positioning • Free water protocol • Combinations of the above <p>Where studies include a mixture of the above categories studies will be included if at least 80% satisfy the criteria for one category. If <10% of participants are in a different category (for example: 9% receive tongue exercises, 91% receive carbonated water), this study will be included in the majority category without downgrading for indirectness. If 10-20% are in a different category, this study will be included in the majority category and downgraded for intervention indirectness.</p>
Comparisons	<ul style="list-style-type: none"> • Placebo/sham therapy • Usual care • No treatment <p>These groups will be analysed separately.</p>
Outcomes	<p>All outcomes are considered equally important for decision making and therefore have all been rated as critical:</p> <p>At time period...</p> <ul style="list-style-type: none"> • <3 months • ≥3 months <ul style="list-style-type: none"> • Mortality (dichotomous outcomes) • Person/participant generic health-related quality of life (continuous outcomes will be prioritised [validated measures]) • Carer generic health-related quality of life (continuous outcomes will be prioritised [validated measures]) • Occurrence of chest infections (dichotomous outcomes) • Occurrence of aspiration (continuous outcomes will be prioritised) • Dysphagia present/Return to normal diet (dichotomous outcomes) • Discharge to residential service (dichotomous outcomes) • Length of hospital stay (continuous outcome will be prioritised)

	<ul style="list-style-type: none">• Re-admission (dichotomous outcomes)• Swallowing ability (continuous outcomes will be prioritised)• Nutrition (continuous outcomes will be prioritised)• Hydration (continuous outcomes will be prioritised)
Study design	<ul style="list-style-type: none">• Systematic reviews of RCTs• Parallel RCTs• Cluster randomised trials• Cluster randomised crossover trials (unit of randomisation = stroke unit)• Crossover studies (for people after chronic stroke only)• Non-randomised studies (if insufficient RCT evidence is available)<ul style="list-style-type: none">○ Prospective cohort studies○ Retrospective cohort studies

1 For full details see the review protocol in Appendix A.

2 **1.1.3. Methods and process**

3 This evidence review was developed using the methods and process described in
4 [Developing NICE guidelines: the manual](#). Methods specific to this review question are
5 described in the review protocol in Appendix A and the methods document.

6 Declarations of interest were recorded according to [NICE's conflicts of interest policy](#).

7

1 **1.1.4. Effectiveness evidence**

2 **1.1.4.1 Included studies**

3 One systematic review⁶ and in total eighty-two randomised controlled trials (ninety-two
4 papers) studies were included in the review;<sup>1-3, 7, 11, 12, 16, 17, 19, 21, 22, 25, 26, 28, 29, 31, 33, 35, 40, 41, 43-46,
5 49, 51-62, 64-66, 68-70, 75-77, 79-81, 89, 91, 92, 95-100, 103, 104, 107, 108, 110, 113-116, 118, 120-124, 127-131, 133-136</sup> these are
6 summarised in Table 2 below. Evidence from these studies is summarised in the clinical
7 evidence summary below (Table 3).

8 Evidence was identified for the following comparisons:

- 9 • Interventions for people with oropharyngeal dysphagia after stroke
- 10 ○ Acupuncture/electroacupuncture compared to:
- 11 – Placebo/sham therapy - One study¹³⁵
- 12 – Usual care – Six studies^{35, 40, 41, 70, 108, 127}
- 13 ○ Behavioural interventions compared to:
- 14 – Placebo/sham therapy – Two studies^{26, 96}
- 15 – Usual care – Eighteen studies^{17, 33, 43, 49, 53, 54, 59, 79, 80, 89, 91, 92, 97, 107, 121, 131, 134, 136}
- 16 ○ Drug interventions compared to placebo, including:
- 17 – Metoclopramide – One study¹²⁴
- 18 – Domperidone – One study*² (This study includes a mixed population of people with
19 oropharyngeal and oesophageal dysphagia)
- 20 – Lisinopril – One study⁶⁰
- 21 – Nifedipine – One study¹⁰⁰
- 22 ○ Neuromuscular electrical stimulation (NMES) compared to:
- 23 – Placebo/sham therapy – Six studies^{12, 62, 76, 95, 96, 115}
- 24 – Usual care – Twelve studies^{3, 12, 19, 33, 46, 61, 65-67, 77, 114, 127, 132}
- 25 ○ Pharyngeal electrical stimulation (PES) compared to placebo/sham therapy – 6
26 studies^{7, 25, 44, 111, 118, 130}
- 27 ○ Physical stimulation compared to:
- 28 – Placebo/sham therapy – One study²⁹
- 29 – Usual care – Two studies^{120, 123}
- 30 ○ Transcranial direct current stimulation (TDCS) compared to:
- 31 – Placebo/sham therapy – Ten studies^{1, 28, 55, 57, 58, 103, 104, 110, 122, 129}
- 32 – Usual care – Two studies^{64, 75}
- 33 ○ Transcranial magnetic stimulation (TMS) compared to:
- 34 – Placebo/sham therapy – Eight studies^{16, 22, 51, 52, 68, 69, 99, 113}
- 35 – Usual care – Three studies^{45, 67, 116}
- 36 • Interventions for people with oesophageal dysphagia after stroke
- 37 ○ Drug interventions (domperidone) compared to placebo/sham therapy– One study*²
38 (This study includes a mixed population of people with oropharyngeal and oesophageal
39 dysphagia)
- 40 • Adaptations to support people with dysphagia after stroke
- 41 ○ Diet modification compared to usual care – Two studies^{21, 133}
- 42 ○ Free water protocol compared to usual care – Two studies^{31, 81}
- 43 ○ Combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
44 compared to usual care – One study¹¹

45 No relevant clinical studies comparing the following were identified:

- 1 • Drug interventions compared to usual care
- 2 • Pharyngeal electrical stimulation (PES) compared to usual care
- 3 • Drug interventions for oesophageal dysphagia (other than domperidone to placebo) to any
- 4 comparison
- 5 • Adaptations to oral feeding compared to placebo/sham therapy
- 6 • Swallow strategies, carbonation and positioning compared to usual care
- 7 • Any intervention compared to no treatment

8 See also the study selection flow chart in Appendix C, study evidence tables in Appendix D,
9 forest plots in Appendix E and GRADE tables in Appendix F.

10 1.4.1.2 Excluded studies

11 See the excluded studies list in Appendix J.

12 1.1.5. Summary of studies included in the effectiveness evidence

13 1.1.5.1. Oropharyngeal dysphagia

14 **Table 2: Summary of studies reporting interventions for oropharyngeal dysphagia**
15 **included in the evidence review**

Study	Intervention and comparison	Population	Outcomes	Comments
Ahn 2017 ¹	<p>Transcranial direct current stimulation (TDCS) (n=13) 10 sessions of 20 minutes using 1mA stimulation (5 times per week for 2 weeks).</p> <p>Placebo/sham therapy (n=13) The same protocol was applied, except that the 1mA current was delivered for only 30s, producing an initial tingling sensation but no significant changes in cortical excitability.</p> <p>Concomitant therapy: All people simultaneously had dysphagia therapy, consisting of diet modification, appropriate positioning, behavioural manoeuvres, oromotor exercise and thermal tactile stimulation.</p>	<p>People after a first or recurrent stroke Mean age (SD): 64.0 (10.7) years N = 26</p> <p>Severity of dysphagia: Mixed Time after stroke: Chronic (>6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>	Swallowing ability at <3 months	<p>Setting: Inpatients from outpatient services in the Republic of Korea</p> <p>Funding: Supported by Mid-career Researcher Program through the National Research Foundation of Korea funded by the Ministry of Science, ICT & Future Planning (NRF-2014R1A2A2A01002501).</p>

Study	Intervention and comparison	Population	Outcomes	Comments
Arreola 2021 ³	<p>Neuromuscular electrical stimulation (NMES) (n=60) Pooled results of two groups (following the approach used in the Cochrane review to classify both motor and sensory electrical stimulation as NMES). Group 1 (n = 30) received TENS at 100% intensity at the motor threshold. Group 2 (n = 30) received TENS at the sensory level, 75% of the motor threshold.</p> <p>Usual care (n=29) Usual care only</p> <p>Concomitant therapy: Standard compensatory clinical care including adaptation of fluids with thickening agents, texture-modified diet, oral hygiene recommendations, postural changes if necessary (chin down and head rotation to the affected side) and nutritional advice.</p>	<p>People after a first or recurrent stroke Mean age (SD): 74.1 (11.6) years N = 89</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Chronic (>6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>	<p>Mortality at ≥3 months Person/participant generic health-related quality of life at ≥3 months Occurrence of chest infection at ≥3 months Occurrence of aspiration at ≥3 months Dysphagia present/return to normal diet at ≥3 months Nutrition at ≥3 months</p>	<p>Setting: Outpatient follow up in Spain</p> <p>Funding: This study was supported by a research grant from DJO Global. Financial support was also received by grants from Fondo de Investigaciones Sanitarias Instituto de Salud Carlos III (14/00453, 18/00241); Proyectos de Investigacion Clinica Independiente, Instituto de Salud Carlos III; and Programa de Estabilizacion de Investigadores y de Intensificacion de la Actividad Investigadora en el Sistema Nacional de Salud (INT15/00026, INT16/00111).</p>
Bath 2016 ⁷ Subsidiary papers: Love 2012 ⁷¹	<p>Pharyngeal electrical stimulation (PES) (n=87) An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference between the threshold and tolerance levels. Treatment was given daily for 3 days.</p>	<p>People after a first or recurrent stroke Mean age (SD): 74.4 (11.2) years N = 162</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months)</p>	<p>Mortality at <3 months Person/participant generic health-related quality of life at <3 months Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months Discharged to residential service at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in the United Kingdom, Spain, Germany, Denmark and France.</p> <p>Funding: This trial was sponsored and funded by Phagenesis, Ltd. (Manchester, UK).</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Placebo/sham therapy (n=75) The same procedure but when the levels were established, had the stimulation turned off.</p> <p>Concomitant therapy: Treatment was given in addition to standard stroke care, including thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of antihypertensives (all people), oral antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic stroke) were recommended for secondary prevention as per each site's local practice.</p>	<p>People requiring enteral feeding support: Mixed Around 60% of people required enteral feeding support. Type of stroke: Mixed</p>	<p>Nutrition at <3 months</p>	
Carnaby 2020 ¹²	<p>Neuromuscular electrical stimulation (NMES) (n=18) Neuromuscular electrical stimulation applied daily for one-hour over a consecutive 3-week period (anticipated total of 15 hours or until discharge if earlier than 3 weeks).</p> <p>Placebo/sham therapy (n=18) The device delivered 3 minutes of active stimulation at onset, followed by 20% incremental declinations over a further 3 minutes. After the ramp down period, the electrodes remained no stimulating, until the</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.9 (13.4) years N = 53</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Type of stroke: Mixed</p>	<p>Mortality at <3 months Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in the United States of America.</p> <p>Funding: Supported by a grant from NIH/NCMRR: NIH-R21HD054752.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>unit was switched off for >5 minutes.</p> <p>Usual care (n=17) Behavioural swallowing intervention only.</p> <p>Concomitant therapy: A standardized behavioural swallowing intervention was provided to everyone. This included treatment strategies and manoeuvres that are commonly used.</p>			
Cheng 2017 ¹⁶	<p>Transcranial magnetic stimulation (TMS) (n=14) Repetitive transcranial magnetic stimulation. 30 100-pulse trains of 5Hz rTMS, with inter-train interval of 15s per day for 10 days over 2 weeks.</p> <p>Placebo/sham therapy (n=7) The same procedure but when the levels were established, had the stimulation turned off.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 64.5 (8.2) years N = 21</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Chronic (>6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Swallowing ability at <3 months and ≥3 months	<p>Setting: Outpatient follow up in Hong Kong, China.</p> <p>Funding: Funded by the Early Career Scheme, University Grants Council, Hong Kong.</p>
Choi 2017 ¹⁷	<p>Behavioural intervention (Shaker exercise) (n=16) Shaker exercises in addition to conventional dysphagia therapy. Shaker exercises included isometric and isokinetic movements.</p> <p>Usual care (n=15)</p>	<p>People after a first or recurrent stroke Mean age (SD): 60.6 (10.7) years N = 31</p> <p>Severity of dysphagia:</p>	<p>Occurrence of aspiration at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Inpatients in the Republic of Korea.</p> <p>Funding: This research was carried out without funding.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Conventional dysphagia therapy only.</p> <p>Concomitant therapy: Conventional dysphagia therapy was provided to all which comprised orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory manoeuvres for 30 minutes a day, 5 days a week for 4 weeks.</p>	<p>Not stated/unclear</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>		
Cola 2021 ¹⁹	<p>Neuromuscular electrical stimulation (NMES) (n=6) Traditional therapy combined with neuromuscular electrical stimulation. A biphasic symmetrical rectangular pulse waveform was applied with a stimulation frequency of 80 Hz and a phase duration of 250 microseconds. Care was provided (with concomitant therapy) for 40 minute sessions, 5 days per week over 3 weeks.</p> <p>Usual care (n=2) Usual care only.</p> <p>Concomitant therapy: Everyone received a traditional therapy using tactile thermal stimulus program, using sour taste and cold temperature in the oral cavity region. Voluntary swallowing maneuvers were also used, including the Mendelsohn maneuver and effortful swallowing maneuver. Hearing, tactile and</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 64.5 years N = 8</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Mixed</p> <p>People requiring enteral feeding support: Mixed</p> <p>Type of stroke: Not stated/unclear</p>	Occurrence of aspiration <3 months	<p>Setting: Inpatients in Brazil</p> <p>Funding: No additional information</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	visual support were offered to the person.			
Du 2016 ²²	<p>Transcranial magnetic stimulation (TMS) (n=28) Combination of two groups. Group 1) 3Hz rTMS (n = 15). Group 2) 1Hz rTMS (n = 13). Each person received rTMS daily for 5 consecutive days.</p> <p>Placebo/sham therapy (n=12) The same stimulation parameters as the 1Hz rTMS group, except the coil was rotated 90 degrees away from the scalp (producing the same noise and local stimulation, but no effect beyond this).</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 58.3 (2.9) years N = 40</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed</p> <p>Type of stroke: Mixed</p>	Swallowing ability at ≥3 months	<p>Setting: Inpatients at China.</p> <p>Funding: Partly supported by grants from the National Natural Science Foundation of China (Nos. 81201078 and 81100870) and Jiangsu Province Foundation of China (BK20141373).</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
<p>Dziewas 2018²⁵</p> <p>Subsidiary papers: Dziewas 2017²⁴</p>	<p>Pharyngeal electrical stimulation (PES) (n=35) Treatment was given daily for 3 days. An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference between the threshold and tolerance levels.</p> <p>Sham therapy (n=34) Sham therapy using the same procedure, but no current was applied.</p>	<p>People after a first or recurrent stroke Mean age (SD): 64.2 (12.0) years N = 69</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Type of stroke: Not stated/unclear</p>	<p>Mortality at <3 months</p> <p>Occurrence of aspiration at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Inpatient at 7 acute care hospitals and 2 rehabilitation facilities, Germany, Austria and Italy.</p> <p>Funding: Sponsored by Phagenesis Ltd., Manchester, UK.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Concomitant therapy: No additional information.</p>			
Eom 2017 ⁷	<p>Behavioural interventions (resistance expiratory muscle strength training) (n=13) Treatment was given daily for 3 days. An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference between the threshold and tolerance levels.</p> <p>Placebo (n=13) The placebo group was trained by using a sham expiratory muscle strength training device with no loading device. Its exterior is the same as that of an expiratory muscle strength training device for the experiment group, but it is a non-functional device with little effect of physiologic load on targeted muscles.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 69.7 (3.9) years N = 26</p> <p>Severity of dysphagia: Severe Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>	<p>Occurrence of aspiration at <3 months Swallowing ability at <3 months</p>	<p>Setting: Republic of Korea.</p> <p>Funding: No additional information</p>
Farpour 2022 ²⁸	<p>Transcranial direct current stimulation (TDCS) (n=24) Transcranial direct current stimulation applied for 20 minutes for five days (one</p>	<p>People after a first or recurrent stroke Mean age (SD): 68.0 (16.6) years N = 44</p>	<p>Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months Nutrition at <3 months</p>	<p>Setting: Inpatients in Iran.</p> <p>Funding: Support from Kerman Neuroscience Research Center, Institute of</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>session in a day). Intensity was 2mA.</p> <p>Placebo/sham therapy (n=24) Sham transcranial direct current stimulation (same procedure but the current was only applied for 30 s at the beginning and end of the period).</p> <p>Concomitant therapy: During stimulation, all people received behavioural therapy according to their condition. The techniques consisted of different passive and active rehabilitative techniques and swallow maneuvers. After each session, the people/caregivers received 10 minutes consultation with the speech therapist about the food modification (if applicable), positioning and the behavioural techniques which were used for the person.</p>	<p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Acute (72 hours - 7 days)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Mixed</p>		<p>Neuropharmacology, Kerman University of Medical Sciences, Kerman, Iran (No. 99000137).</p>
Feng 2012 ²⁹	<p>Physical stimulation (Tongyan Spray) (n=61) Tongyan Spray composed of ginger and clematis radix (producing a heat sensation and using flavours). Spray applied to the pharynx on both sides and the middle part once respectively for each time, three times a day. The spray was applied 30 minutes before meals for people who were able to take food.</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 70.9 (10.4) years N = 122</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Not stated/unclear</p> <p>People requiring</p>	<p>Dysphagia present/return to normal diet at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Outpatient and inpatients in China.</p> <p>Funding: Supported by the Project of Beijing Traditional Chinese Medicine Scientific Program (No. JJ2007-010).</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Placebo/sham therapy (n=61) Same procedure but using a placebo spray.</p> <p>Concomitant therapy: Conventional treatment was given to all and included maintaining water and electrolyte balance, controlling blood pressure and blood sugar matched with acupuncture therapy (exclusive of the head, face or neck acupoints).</p>	<p>enteral feeding support: Mixed Type of stroke: Not stated/unclear</p>		
Guillen-Sola 2017 ³¹	<p>Behavioural interventions (inspiratory and expiratory muscle training) (n=20) Respiratory muscle exercises, 5 sets of 10 respirations followed by 1 minute of unloaded recovery breathing off the device, twice a day, 5 days per week for 3 weeks.</p> <p>Neuromuscular electrical stimulation (NMES) (n=21) Same as the first group, but also receive NMES to the suprahyoid muscle at 80Hz for 40 minute sessions (5 days per week for 3 weeks).</p> <p>Usual care (n=21) Standard swallow therapy alone.</p> <p>Concomitant therapy: Everyone received an educational intervention, oral exercises and</p>	<p>People after a first or recurrent stroke Mean age (SD): 69.1 (8.8) years N = 62</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection <3 months and ≥3 months Occurrence of aspiration at <3 months and ≥3 months</p>	<p>Setting: Tertiary subacute care hospital in Barcelona (Catalonia, Spain)</p> <p>Funding: The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Partially supported by grants from: ISCIII (P110/01560)/FEDER</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	compensatory techniques.			
Han 2004 ³⁵	<p>Acupuncture/electroacupuncture (both) (n=34) Scalp and neck acupuncture with electroacupuncture with standard Western medical treatment</p> <p>Usual care (n=32) Standard Western medical treatment only</p> <p>Concomitant therapy: No additional information</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 66</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Dysphagia present/return to normal diet at <3 months	<p>Setting: China</p> <p>Funding: No additional information.</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Hongling 2006 ⁴⁰	<p>Acupuncture/electroacupuncture (acupuncture) (n=40) Acupuncture for 3 cycles. Two courses were given with each course taking 12 days (with 12 treatments) with a 2 day break between courses (26 days in total). They also received the rehabilitation exercises provided to usual care.</p> <p>Usual care (n=32) Basic rehabilitation with Logemann JA exercise and Mendelsohn exercise; tongue exercises; respiratory control training and feeding exercises.</p> <p>Concomitant therapy:</p>	<p>People after a first or recurrent stroke Mean age: 55.1 years N = 72</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear. Type of stroke: Not stated/unclear</p>	Dysphagia present/return to normal diet at <3 months	<p>Setting: China.</p> <p>Funding: No additional information.</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶. This study is referred to as Jia 2006a.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	Regular internal treatments for cerebrovascular diseases were conducted in both groups.			
Huang 2010 ⁴¹	<p>Acupuncture/electroacupuncture (acupuncture) (n=32) No additional information</p> <p>General swallowing therapy (n=30) No additional information</p> <p>Concomitant therapy: No additional information</p>	<p>People after a first or recurrent stroke Mean age (SD): No additional information N = 97</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Dysphagia present/return to normal diet <3 months	<p>Setting: China</p> <p>Funding: No additional information</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Jang 2019 ⁴³	<p>Behavioural interventions (mechanical inspiration and expiration exercise) (n=21) Ten sessions of mechanical inspiration and expiration exercise were conducted for the study group once a day, 5 days a week, for 2 weeks, with each session lasting 30 min.</p> <p>Usual care (n=20) Conventional swallowing rehabilitation therapy only.</p> <p>Concomitant therapy: Conventional dysphagia</p>	<p>People after a first or recurrent stroke Mean age (SD): 71.15 (8.61) years N = 41</p> <p>Severity of dysphagia: Very severe Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Rehabilitation centre of a university hospital in the Republic of Korea</p> <p>Funding: No additional information</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	rehabilitation consisted of oral motor and sensory stimulation, neuromuscular electrical stimulation of the suprahyoid muscle, and oral and lingual exercises. Twenty sessions of conventional swallowing rehabilitation therapy were conducted twice a day, 5 days a week, for 2 weeks, with each session lasting 30 min.			
Jayasekera n 2010 ⁴⁴	<p>Pharyngeal electrical stimulation (PES) (n=17) Electrical stimulation of the pharynx (at 0.2ms pulses, 280V) was delivered at a set frequency (5Hz), intensity (75% of maximal tolerated) and duration (10 minutes). Therapy was delivered once daily for 3 consecutive days. Follow up was at 2 weeks.</p> <p>Sham therapy (n=14) Sham stimulation using the same method. However, on commencement of stimulation, the constant current generator was switched off and the intraluminal pharyngeal catheter was left in situ in the subject for the duration of intervention.</p> <p>Concomitant therapy: No additional information</p>	<p>People after a first or recurrent stroke Mean age (SD): 75 (2) years N = 31</p> <p>Severity of dysphagia: Mixed Time after stroke: Not stated/unclear People requiring enteral feeding support: Mixed Type of stroke: Mixed (TACS or PACS)</p>	<p>Mortality at <3 months Occurrence of chest infection at <3 months Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months</p>	<p>Setting: Inpatients in the United Kingdom</p> <p>Funding: Supported by the Health Foundation, Medical Research Council, Research into Aging, and the National Institute of Health Research/Research for Patient Benefit. The study was sponsored by the University of Manchester, UK.</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Jiao 2022 ⁴⁵	<p>Transcranial magnetic stimulation (TMS) (n=32) rTMS (3 Hz) was used daily. The stimulation</p>	<p>People after a first or recurrent stroke</p>	<p>Dysphagia present/return to normal diet at <3 months</p>	<p>Setting: Inpatients in China.</p> <p>Funding: This study was supported by</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>frequency was 3 Hz, with intensity of 80% motion threshold. The stimulation time should be 3s, with an interval of 20s. The treatment lasts for 20 minutes, once each day. The person can rest for 2 days after 5-day treatment and then move on to the next course. There were two courses of treatment in total (14-day period).</p> <p>Placebo/sham therapy (n=29) People in the control group received the basic treatment of rehabilitation training. One course of treatment lasts 1 week, and two courses in total.</p> <p>Concomitant therapy: All people were routinely treated with anti-platelet aggregation and statins, supported with nutrition, and corrected water and electrolyte disorder. When people's vital signs were stable and showed no progress during 48 hours, they were given swallowing rehabilitation.</p>	<p>Mean age (SD): 58.6 (10.0) years N = 61</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Swallowing ability at <3 months</p>	<p>Medical Science and Technology Foundation of Guangdong Province (A2018389).</p>
<p>Jing 2016⁴⁶</p>	<p>Neuromuscular electrical stimulation (NMES) (n=30) Electrical stimulation therapy performed using 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 people in each</p>	<p>People after a first or recurrent stroke Mean age (SD): 68.3 (12.0) years N = 60</p> <p>Severity of dysphagia: Not stated/unclear</p>	<p>Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients, Department of Neurology, Qinghai People's Hospital, Xining in China.</p> <p>Funding: None.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>group were treated continuously for 10 days.</p> <p>Usual care (n=30) Usual care only.</p> <p>Concomitant therapy: Usual care available to all. Routine drug therapies, including haemostasis, reducing intracranial pressure or dilating blood vessels, and using neurocyte activators, as well as swallowing function training, including exercise training to improve mouth and facial muscle function, sensory stimulation and exercise training to improve tongue function, vocal cord training, chew training and therapeutic feeding.</p>	<p>Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed (Around 60% of people required enteral feeding support). Type of stroke: Mixed</p>		
Kang 2012 ⁴⁹	<p>Behavioural interventions (additional bedside exercise training) (n=25) An additional exercise program for dysphagia treatment was conducted under nursing intervention for at least 1 hour a day, by an average during the 2-month study period. The exercise program was composed with oral, pharyngeal, laryngeal and respiration exercises.</p> <p>Usual care (n=25)</p> <p>Concomitant therapy: Both the experimental and control groups visited the occupational therapy</p>	<p>People after a first or recurrent stroke Mean age (SD): 67.5 (6.4) years N = 50</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Swallowing ability at <3 months</p>	<p>Setting: Department of Rehabilitation Medicine, Gwangju Veterans Hospital, Republic of Korea.</p> <p>Funding: No additional information.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	room for 30 minutes a day, 5 days a week for two months to carry out a tactile-thermal stimulation.			
Khedr 2009 ⁵¹	<p>Transcranial magnetic stimulation (TMS) (n=14) Transcranial magnetic stimulation applied in 10 trains of 3-Hz stimulation for 10 minutes every day for five consecutive days.</p> <p>Placebo/sham therapy (n=12) Sham rTMS applied using the same parameters, but with the coil held so that the edge was in contact with the head while the remainder was rotated 90 degrees away from the scalp in the sagittal plane to reproduce the noise of the stimulation as well as some of its local sensation.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 57.7 (12.6) years N = 26</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Mortality at <3 months	<p>Setting: United Kingdom.</p> <p>Funding: No additional information.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Khedr 2010 ⁵²	<p>Transcranial magnetic stimulation (TMS) (n=11) Transcranial magnetic stimulation applied in 10 trains of 3-Hz stimulation for 10 minutes every day for five consecutive days.</p> <p>Placebo/sham therapy (n=11) Sham therapy was applied using the same parameters but with the coil held so that the edge was in contact with the head, while the remainder was rotated 90 degrees away from the scalp in the sagittal plan to</p>	<p>People after a first or recurrent stroke Mean age (SD): 57.8 (14.1) years N = 22</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding</p>	Mortality at <3 months Swallowing ability at <3 months	<p>Setting: Inpatients in Egypt</p> <p>Funding: No additional information.</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	reproduce the noise of the stimulation as well as some of its local sensation. Concomitant therapy: No additional information.	support: Not stated/unclear Type of stroke: Posterior circulation stroke (POCS) (Either lateral medullary infarction or other brainstem infarction.)		
Kim 2011 ⁵⁵	Transcranial direct current stimulation (TMS) (n=20) Two groups: Group 1 = 5 Hz, Group 2 = 1Hz. Therapy for 20 minutes, five days a week for 2 weeks. Placebo/sham therapy (n=10) Sham stimulation applied using the protocol employed for high-frequency stimulation, but the coil was rotated through 90 degrees. Concomitant therapy: All people received swallowing training comprised of oral and facial sensory training, oral and pharyngeal muscle training, compensatory techniques and neuromuscular electrical stimulation on pharyngeal muscles during rTMS.	People after a first or recurrent stroke Mean age (SD): 68.1 (11.2) years N = 30 Severity of dysphagia: Not stated/unclear. Time after stroke: Subacute (7 days - 6 months). People requiring enteral feeding support: Not stated/unclear. Type of stroke: Not stated/unclear.	Occurrence of aspiration at <3 months Swallowing ability at <3 months	Setting: Inpatients in the Republic of Korea. Funding: No additional information. This study was included in the Cochrane review, Bath 2018 ⁶ .
Kim 2017 ⁵⁴	Behavioural interventions (tongue-to-palate resistance training) (n=21) Tongue-to-palate resistance training. 30 exercise repetitions for the anterior and posterior regions five times per week for 4 weeks.	People after a first or recurrent stroke Mean age (SD): 60.8 (10.7) years N = 41	Occurrence of aspiration at <3 months	Setting: Inpatients in the Republic of Korea. Funding: This research was carried out without funding.

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Usual care (n=20) Conventional therapy only.</p> <p>Concomitant therapy: Both groups received conventional dysphagia therapy including thermal tactile stimulation, facial massage and various manoeuvres.</p>	<p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>		
Kim 2019 ⁵³	<p>Behavioural interventions (Modified chin tuck against resistance with standard care) (n=12) The experimental group performed the mCTAR exercise using a PhagiaFLEX-HF (Alternative Speech and Swallowing Solutions, Inc). The intervention was delivered 5 days a week, for 6 weeks.</p> <p>Usual care (n=13) Usual care.</p> <p>Concomitant therapy: Both groups received traditional dysphagia treatment (TDT) by skilled occupational therapists (30 min/d). TDT included oral facial massage, thermal-tactile stimulation and various compensatory trainings.</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 64.4 (5.9) years N = 25</p> <p>Severity of dysphagia: Severe</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: People requiring enteral feeding support at baseline</p> <p>Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p> <p>Dysphagia present/return to normal diet at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Department of Occupational Therapy, Semyung University, Jecheon in the Republic of Korea</p> <p>Funding: Semyung University Research Grant of 2018, Grant/Award Number: NA. This paper was supported by the Semyung University Research Grant of 2018.</p>
Kumar 2011 ⁵⁷ Subsidiary papers:	<p>Transcranial direct current stimulation (TDCS) (n=7) Anodal tDCS (2 mA for 30 minutes) was applied daily to the</p>	<p>People after a first or recurrent stroke</p>	<p>Swallowing ability at <3 months</p>	<p>Setting: Inpatient stroke service in the United States of America.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
Kumar 2010 ⁵⁶	<p>non-lesional hemisphere for 5 consecutive days.</p> <p>Placebo/sham therapy (n=7) Sham therapy was applied daily to the non-lesional hemisphere for 5 consecutive days for 30 mins.</p> <p>Concomitant therapy: Standardized swallowing manoeuvres were used for effortful swallowing.</p>	<p>Mean age (SD): Not stated/unclear N = 14</p> <p>Severity of dysphagia: Mixed Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		<p>Funding: Authors receive academic or government grants.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Kumar 2022 ⁵⁸	<p>Transcranial direct current stimulation (TDCS) (n=27) An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference between the threshold and tolerance levels. Treatment was given daily for 3 days.</p> <p>Placebo/sham therapy (n=15) The sham group received sham stimulation twice daily.</p> <p>Concomitant therapy: All stimulation sessions were conducted concurrently with standardized effortful swallowing exercises.</p>	<p>People after a first or recurrent stroke Mean age (SD): 71.0 (13.6) years N = 42</p> <p>Severity of dysphagia: Mixed Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Mortality at <3 months Occurrence of aspiration at <3 months Swallowing ability at <3 months Nutrition at <3 months</p>	<p>Setting: Beth Israel Deaconess Medical Center (BIDMC) in Boston, MA, USA.</p> <p>Funding: This trial was funded Grant support from the National Institute on Deafness and Other Communication Disorders of the National Institutes of Health (NIH) under Award Number R01DC012584 (PI: Kumar). GS acknowledges support from NINDS (U01NS102353) and NIMH (R01MH111874).</p>

Study	Intervention and comparison	Population	Outcomes	Comments
Lan 2013 ⁵⁹	<p>Behavioural interventions (balloon dilatation) (n=15) Modified balloon dilatation therapy and regular therapy. The procedure was repeated five to eight times per sessions, around 30 minutes for each process time once a day for 5 consecutive days per week. All dilatations were performed without radiographic or endoscopic guidance.</p> <p>Usual care (n=15) Usual care only.</p> <p>Concomitant therapy: Everyone received 30 minutes of supervised regular therapy, twice a day, 5 days a week. Several techniques for improving swallowing function were implemented by treating therapists. Programs progressed as indicated to meet the person's goals.</p>	<p>People after a first or recurrent stroke Median age (IQR): Intervention: 62 (47 to 66) years Control: 60 (50 to 69) years N = 30</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: People requiring enteral feeding support at baseline Type of stroke: Not stated/unclear</p>	<p>Dysphagia present/return to normal diet at <3 months</p>	<p>Setting: Inpatients in China</p> <p>Funding: This work was supported by the following grants: National Science Foundation of China 81101460; Guangzhou Municipal Science and Technology Program 12S182060084; the Fundamental Research Funds from the Central Universities 12ykpy38; National Science Foundation of China 81071606; and Guangdong Natural Science Foundation 10151008901000157</p>
Lee 2014 ⁶¹	<p>Neuromuscular electrical stimulation (NMES) (n=46) Neuromuscular electrical stimulation was provided at an intensity of 3mA and increased gradually by 1mA. Each session was 30 minutes per day, 5 times a week for a total of 3 weeks.</p> <p>Usual care (n=46) Usual care only.</p> <p>Concomitant therapy: All people received traditional dysphagia</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.1 (10.6) years N = 92</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding</p>	<p>Occurrence of chest infection at ≥3 months Dysphagia present/return to normal diet at ≥3 months Swallowing ability at ≥3 months</p>	<p>Setting: Inpatients at Republic of Korea.</p> <p>Funding: No additional information.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	therapy including thermal-tactile stimulation with any combination of lingual-strengthening exercises, laryngeal adduction-elevation exercises, effortful swallow maneuver, Mendelsohn maneuver, Masako maneuver and Shaker exercises by one speech therapist every day. Both group received 60 minutes of therapy within a day for 15 days.	support: Not stated/unclear Type of stroke: Not stated/unclear		
Lee 2015 ⁶⁰	<p>Lisinopril (n=47) 2.5 mg once daily at bedtime.</p> <p>Placebo (n=46) The control group participants were given identical placebo once daily at bedtime.</p> <p>Concomitant therapy: No additional information</p>	<p>People after a first or recurrent stroke Mean age (SD): 83.9 (6.3) years N = 93</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Mortality at ≥3 months Occurrence of chest infection at ≥3 months Occurrence of aspiration at ≥3 months Swallowing ability at <3 months</p>	<p>Setting: 2 subacute hospitals, affiliated geriatric outpatient clinics, and speech therapy clinics in Hong Kong</p> <p>Funding: Funded by the Health and Health Services Research Grant number 07080201 from the Food and Health Bureau of the Hong Kong SAR government</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Lee 2021 ⁶²	<p>Neuromuscular electrical stimulation (NMES) (n=26) The sequential 4-channel NMES was adjustable for latency, amplitude, and duration of current. The pulse frequency, pulse duration, and interphase interval are 80 Hz, 300 μs, and 100 μs, respectively.</p>	<p>People after a first or recurrent stroke Mean age (SD): 71.2 (9.4) years N = 52</p> <p>Severity of dysphagia: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months Swallowing ability at <3 months</p>	<p>Setting: Rehabilitation unit of 3 teaching hospitals (Seoul National University Bundang Hospital, Daegu Fatima General Hospital, and the Jeju University Hospital) in South Korea.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Placebo/sham therapy (n=26) The sham group had electrodes attached at the same locations but did not undergo the NMES during swallowing.</p> <p>Concomitant therapy: During the interval between the initial and follow-up videofluoroscopic swallowing study, all participants received conventional swallowing therapies.</p>	<p>Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		<p>Funding: Research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health and Welfare, Republic of Korea (grant number: HI18C1169). This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT and Future Planning (NRF-2016R1D1A1B03935 130).</p>
Liang 2021 ⁶⁵	<p>Neuromuscular electrical stimulation (NMES) (n=36) NMES at a frequency of 30–80 Hz, and an intensity of 5–50 mA. The current was adjusted according to the patient’s feedback for 30 min/ time, once /d, five times/week, and this was performed for a total of four weeks.</p> <p>Usual care (n=36) The control group received swallowing function training and conventional medical treatment. The swallowing training is performed for four weeks.</p> <p>Concomitant therapy: All patients received conventional medical</p>	<p>People after a first or recurrent stroke Mean age (SD): 62.9 (5.83) years N = 72</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Occurrence of chest infection at <3 months	<p>Setting: Hainan General Hospital, Hainan Affiliated Hospital of Hainan Medical University in China.</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	treatment, which primarily included nutrition of brain cells, improvement of microcirculation, anti-platelet aggregation, antihypertensive therapy, and nutritional support, when necessary.			
Lim 2009 ⁶⁶	<p>Neuromuscular electrical stimulation (NMES) (n=13) Electrical stimulation was applied at an amplitude of approximately 7 mA. The therapy sessions were for 1 h at a frequency of 5 per week. Five trials were carried out per week.</p> <p>Usual care (n=9) The tactile thermal stimulation procedures were standardized and conducted by a co-operating occupational therapist. Five trials were carried out per week.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 64.9 (10.6) years N = 28</p> <p>Severity of dysphagia: Severe Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>	<p>Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients at Ilsan Paik Hospital in South Korea</p> <p>Funding: No additional information.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Lim 2014 ⁶⁷	<p>Transcranial magnetic stimulation (TMS) (n=20) 1 Hz magnetic stimulation at 100% intensity of the resting motor threshold in the hot spot was applied for 20 minutes each, 5 times a week for 2 weeks.</p> <p>Neuromuscular electrical stimulation (NMES) (n=20) 30 minutes per day, 5 times a week for a total of 2 weeks. The intensity was between 7mA and 9mA.</p>	<p>People after a first or recurrent stroke Mean age (SD): 62.6 (11.8) years N = 60</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months)</p>	<p>Occurrence of aspiration at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in South Korea.</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Usual care only (n=20) Usual care only.</p> <p>Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson manoeuvre and food intake training for 4 weeks.</p>	<p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>		
Lin 2018 ⁶⁸	<p>Transcranial magnetic stimulation (TMS) (n=13) 10 minutes of excitatory 5-Hz rTMS (600 pulses totally) at threshold intensity. Therapy was delivered in 10 daily sessions over a 2-week conditioning period (only weekdays).</p> <p>Placebo/sham therapy (n=15) Same procedure except a placebo coil was used which delivered <5% of the magnetic output with an audible click sound on discharge and induced minimal scalp current sensation.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 70.9 (12.7) years N = 28</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Chronic (>6 months)</p> <p>People requiring enteral feeding support: Mixed (Predominately people requiring nasogastric tubes)</p> <p>Type of stroke: Mixed</p>	<p>Occurrence of aspiration at <3 months</p>	<p>Setting: Inpatients in Taiwan</p> <p>Funding: This work was supported by the Taipei Veterans General Hospital Grant (V103-168C).</p>
Li 2022 ⁶⁴	<p>Transcranial direct current stimulation (n=32) 1mA, 20 minute sessions per day, 6 days per week for 6 days.</p>	<p>People after a first or recurrent stroke Mean age (SD): 59.83 (10.36) years</p>	<p>Dysphagia present/return to normal diet at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Inpatients in China.</p> <p>Funding: No funding.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Usual care (n=32) Usual care only.</p> <p>Concomitant therapy: Conventional medicine and swallowing rehabilitation including respiratory training, direct oral feeding training, ice stimulation, acid stimulation, shaker training and neuromuscular electrical stimulation.</p>	<p>N = 64</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Mean time after stroke (SD): 11.1 (2.5) days</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>		
Liu 2018 ⁷⁰	<p>Acupuncture/electroacupuncture (acupuncture) (n=50) Acupuncture once a day for 30 min, excluding weekends, over 8 weeks of treatment.</p> <p>Standard swallowing training - behavioural exercises (n=50) Rehabilitation swallowing training including swallowing muscle training, pushing exercise, closed glittis training, Mendelsohn maneuver, ice-massage, tongue muscle training, food placement, food form, feeding position, progressive adjustment of food intake, interaction swallowing. The therapy was conducted one-on-one for 30 min once a day, excluding weekends, over 8 weeks of treatment.</p> <p>Concomitant therapy: Subjects in both groups received</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 67.1 (10.7) years</p> <p>N = 100</p> <p>Severity of dysphagia: Severe</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>	<p>Dysphagia present/return to normal diet at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Acupuncture out-patient clinic of Hangzhou Hospital of Traditional Chinese Medicine in China</p> <p>Funding: Supported by Zhejiang province administration of Traditional Chinese Medicine funded Project: Effects of nape acupuncture on dysphagia in pseudobulbar palsy in different stages (Project No: 2014ZA094).</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	rehabilitative swallowing training.			
Liu 2022 ⁶⁹	<p>Transcranial magnetic stimulation (TMS) (n=30) 5Hz applied at an intensity of 80%, for a stimulation time of 2s, an interval of 10s between each stimulation for a duration of 20 minutes, a total of 100 repetitions and 1,000 stimuli. The treatment period was once a day for 5 days a week for 2 weeks.</p> <p>Placebo/sham therapy (n=30) The same therapy, but the coil perpendicular to the surface of the skull instead.</p> <p>Concomitant therapy: All people received traditional dysphagia treatment for 30 minutes each day, including sensory stimulation, tongue retraction exercise and oropharyngeal muscle strengthening exercises.</p>	<p>People after a first or recurrent stroke Mean age (SD): 67.7 (10.9) years N = 60</p> <p>Severity of dysphagia: Moderate Time after stroke: Subacute (7 days – 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Mortality at <3 months Occurrence of chest infections at <3 months Dysphagia present/return to normal diet at <3 months Occurrence of aspiration at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in China.</p> <p>Funding: No funding.</p>
Mao 2022 ⁷⁵	<p>Transcranial direct current stimulation (TDCS) (n=20) 1.6mA, 20 min each time, once a day, 6 days each week, for a total of 8 weeks.</p> <p>Usual care (n=20) (a) Motor and sensory training of the muscles around the mouth and tongue 60 min each time, once a day (b) Breath training, once a day (c) External laryngeal electrical stimulation once a day (d) Balloon dilatation. Eight times a day, 6</p>	<p>People after a first or recurrent stroke Mean age (SD): 60.6 (7.7) years N = 40</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months)</p>	<p>Swallowing ability at ≥3 months Nutrition at ≥3 months</p>	<p>Setting: Rehabilitation ward in Tongren Hospital, Shanghai Jiao Tong University School of Medicine in China.</p> <p>Funding: This study was supported by the Shanghai Tongren Hospital Project (TRYJ201607) “The clinical effect of different rehabilitation strategy based on the evaluation of VFSS.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>days per week, a total of 8 weeks.</p> <p>Concomitant therapy: Patients in both groups were given secondary prevention of stroke.</p>	<p>People requiring enteral feeding support: Not stated/unclear Type of stroke: Posterior circulation stroke (POCS)</p>		
Matos 2022 ⁷⁶	<p>Neuromuscular electrical stimulation (NMES) (n=20) Electrostimulation using the Neurodyn Portable TENS/FES technique. Therapy was provided for 30 minutes each day for 5 days.</p> <p>Placebo/sham therapy (n=20) The same therapy. However, the machine was switched on with the intensity set at 0 during therapy.</p> <p>Concomitant therapy: All people received conventional speech therapy. Training was performed once a day for five consecutive days. Enteral diet was maintained when the person was unable to have a safe oral diet. A mixed diet was possible dependent on the person.</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear years N = 40</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: People requiring enteral feeding support at baseline Type of stroke: Not stated/unclear</p>	<p>Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in Brazil</p> <p>Funding: No funding received.</p>
Meng 2018 ⁷⁷	<p>Neuromuscular electrical stimulation (NMES) (n=20) Combination of two groups. Group 1) NMES where 1 pair of electrodes was placed on the surface of both sides of suprahyoid and another pair on the surface of the upper and lower edge of thyroid cartilage. Group 2) 2 pairs of</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.6 (12.3) years N = 30</p> <p>Severity of dysphagia: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients at China</p> <p>Funding: The work was supported by the National Natural Science Foundation of China (81502246), Science and Technology Bureau of Qingdao (16-5-1-58-jch), Health and Family Planning Commission of Shandong Province</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>electrodes placed on the suprahyoid, including 1 pair which was placed on either sides of the region of geniohyoid muscle movement, another pair was placed on either side of the region of mylohyoideus muscle movement. In both groups NMES was applied at a frequency of 80 Hz and wave amplitude of 0-25 mA. Provided for 30 minutes, 5 days per week and in 10 sessions over 2 weeks (in addition to usual care).</p> <p>Usual care (n=10) Usual care only.</p> <p>Concomitant therapy: All people received conventional therapy with medications, general rehabilitation therapy and traditional dysphagia therapy (a combination of therapeutic exercise, compensatory manoeuvres and diet texture modifications). This was provided for 30 minutes, 5 days a week for 10 sessions over the study.</p>	<p>Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		<p>(2015WS0353, 2016WS0255).</p>
<p>Moon 2017⁸⁰</p>	<p>Behavioural intervention (expiratory muscle strength training) (n=9) The training consisted of taking a deep breath and biting a mouthpiece, during which time the patient was told to blow faster and stronger. Each patient received seven trainings per session, five times a week for four weeks. Breaks of</p>	<p>People after a first or recurrent stroke Mean age (SD): 63 (5.5) years N = 18 Severity of dysphagia: Not stated/unclear Time after stroke:</p>	<p>Occurrence of aspiration at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients, Hospital in South Korea. Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>30 seconds were provided after one session.</p> <p>Usual care (n=9) Traditional swallowing treatment was composed of orofacial exercises, thermal-tactile stimulation, the Mendelson manoeuvre, effortful swallow, and supraglottic manoeuvre. All swallowing treatments were carried out by the responsible therapists.</p> <p>Concomitant therapy: All participants performed traditional swallowing rehabilitation therapy in 30 minute sessions five times a week for four weeks.</p>	<p>Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
Moon 2018 ⁷⁹	<p>Behavioural interventions (Tongue pressure strength and accuracy training) (n=10) The TPSAT group underwent TPSAT for 30 min in the morning and traditional dysphagia therapy for 30 min in the afternoon five times per week for 8 weeks.</p> <p>Usual care (n=9) The control group underwent traditional therapy for 30 min in the morning and 30 min in the afternoon, five times per week for 8 weeks.</p> <p>Concomitant therapy: Treatment was given in addition to standard stroke care, including</p>	<p>People after a first or recurrent stroke Mean age (SD): 62 (4.17), 63.5 (6.05) years N = 19 Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Around 60% of people</p>	Swallowing ability at <3 months	<p>Setting: Inpatients in the Republic of Korea.</p> <p>Funding: This work was supported by the Gachon University research fund of 2016 (GCU-2016-0219).</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	thrombolysis if administered at admission to hospital and rehabilitation. In both groups, standardized physical and occupational therapies were included.	required enteral feeding support. Type of stroke: Mixed		
Nordio 2021 ¹⁸	<p>Behavioural interventions (biofeedback) (n=9) sEMG-Biofeedback applied through the ProComp5 Infiniti System. People were required to perform manoeuvres for swallowing strength, coordination and efficacy. This training lasted for 40 minutes (with additional two five-minute pauses between exercises) with the support of muscle activity's visualisation on the screen through the sEMG-biofeedback and of verbal feedback about correct execution from the speech therapist. Intervention for 1 hour per day for 5 weeks (on week days only, 25 sessions in total).</p> <p>Usual care (n=8) The same random behavioural exercises of the experimental group (40 minutes, excluding pauses), without sEMG-biofeedback application. People only received verbal feedback.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 70.1 (10.8) years N = 17</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in Italy.</p> <p>Funding: No funding was received.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
Park 2012 ⁹⁶	<p>Neuromuscular electrical stimulation (NMES) (n=10) Effortful swallow with infrahyoid sensory electrical stimulation delivered for 4 weeks. A pulse rate of 80 Hz with a duration of 700 microseconds was used. All people received three sets of 20 minutes of exercise per week for 4 weeks.</p> <p>Placebo/sham therapy (n=10) The same procedure except the intensity was adjusted until the person felt the tingling sense in their neck, but not enough to cause muscle contraction.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.3 (15.1) years N = 20</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p>	<p>Setting: Inpatients in the Republic of Korea</p> <p>Funding: This trial was sponsored and funded by Phagenesis, Ltd. (Manchester, UK).</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Park 2013 ⁹⁵	<p>Transcranial magnetic stimulation (TMS) (n=9) 10 minutes of real 5Hz transcranial magnetic stimulation. A session of stimulation consisted of 10 trains of 5 Hz stimulation, each lasting for 10 seconds and then repeated every minute given through a 70 mm figure-of-eight coil positioned over the pharyngeal hot spot of the intact hemisphere. Delivered for 2 weeks.</p> <p>Placebo/sham therapy (n=9) Sham TMS for the same time period. Same protocol except the coil was tilted 90 degrees to produce the same noise but not</p>	<p>People after a first or recurrent stroke Mean age (SD): 71.3 (7.5) years N = 18</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Inpatients in the Republic of Korea.</p> <p>Funding: Research was supported by Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education, Science and Technology (grant number: 2010-0003964).</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	produce motor cortical stimulation. Concomitant therapy: No additional information.	Type of stroke: Not stated/unclear		
Park 2016 ⁹³	Behavioural interventions (Expiratory muscle strength training [EMST]) (n=17) EMST using support from a device. Intervention was performed 5 days per week, with 5 sets of 5 breaths through the device for a total of 25 breaths per day. Placebo/sham therapy (n=16) Placebo group performed training using a sham device with no spring loading within the device. 5 days per week, with 5 sets of 5 breaths through the device for a total of 25 breaths per day. Concomitant therapy: All participants were given 30 minutes of traditional dysphagia therapy per day.	People after a first or recurrent stroke Mean age (SD): 65.0 (11.0) years N = 33 Severity of dysphagia: Severe Time after stroke: Chronic (>6 months) People requiring enteral feeding support: Mixed Type of stroke: Mixed	Occurrence of aspiration at <3 months Swallowing ability at <3 months	Reported as Park 2016A in forest plots. Setting: Rehabilitation centre of the Inje University Busan Paik Hospital in South Korea Funding: This research was carried out without funding. This study was included in the Cochrane review, Bath 2018 ⁶ .
Park 2016 ⁹³	Neuromuscular electrical stimulation (NMES) (n=31) 80 Hz pulse rate and a fixed biphasic pulse duration of 700 microseconds. The stimulation intensity was set to a level to induce a strong muscle contraction. Therapy was provided for 30 minutes per session, 5 sessions per week for 6 weeks.	People after a first or recurrent stroke Mean age (SD): 54.9 (12.1) years N = 61 Severity of dysphagia: Not stated/unclear Time after stroke:	Occurrence of aspiration at <3 months Swallowing ability at <3 months	Reported as Park 2016B in forest plots. Setting: Inpatients in South Korea. Funding: This research was carried out without funding. This study was included in the Cochrane review, Bath 2018 ⁶ .

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Placebo/sham therapy (n=30) Described as placebo NMES in the study, where sensory stimulation only was provided (intensity averaging from 3.0 to 5.0 mA). Otherwise the same procedure.</p> <p>Concomitant therapy: All people received effortful swallowing exercises and conventional dysphagia therapy (additional information not provided).</p>	<p>Chronic (>6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
<p>Park 2017⁹⁷</p> <p>Subsidiary studies: Chang 2015¹³</p>	<p>Behavioural intervention (head lift exercise) (n=20) This consisted of isometric and isokinetic types. All people performed sustained head-raising exercise, followed by 30 consecutive repetitions of head raising, which were enough to observe their toes without raising their shoulders. Conducted 5 days a week for 4 weeks (20 sessions).</p> <p>Usual care (n=17) Usual care only.</p> <p>Concomitant therapy: 30 minutes traditional dysphagia therapy was provided to all. This included oro-facial muscle exercises, thermal tactile stimulation using ice sticks and therapeutic manoeuvres.</p>	<p>People after a first or recurrent stroke Mean age (SD): 60.3 (12.8) years N = 37</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p>	<p>Setting: Inpatients in South Korea.</p> <p>Funding: This work was supported by the 2015 Inje University research grant.</p>
Park 2018 ⁹⁴	<p>Behavioural interventions (chin-tuck against</p>	<p>People after a first or</p>	<p>Occurrence of aspiration at <3 months</p>	<p>Setting: Inpatients in the Republic of Korea.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>resistance exercises) (n=13) Chin tuck against resistance performed using a chin tuck against resistance (CTAR) device in a sitting position on a chair. In isometric CTAR, the person was asked to chin tuck against the device 3 times for 60 seconds with no repetition. In isotonic CTAR, the person performs 30 consecutive repetitions by strongly pressing against the resistance of the device and releasing it again.</p> <p>Usual care (n=12) Usual care only.</p> <p>Concomitant therapy: Conventional dysphagia treatment was available to all such as orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. For 30 minutes/day, five days per week for 4 weeks.</p>	<p>recurrent stroke Mean age (SD): 60.4 (15.3) years N = 25</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Chronic (>6 months) People requiring enteral feeding support: Mixed Type of stroke: Mixed</p>	Swallowing ability at <3 months	Funding: This work was supported by the 2016 Inje University research grant.
Park 2019 ⁹¹	<p>Behavioural interventions (effortful swallowing therapy) (n=15) Effortful swallowing training. People were asked to push their tongue firmly onto their palate, while squeezing the neck muscles, and to swallow as forcefully as possible. This was performed 10 times per session, with 3 sessions per day, 5 days per week for 4 weeks.</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.7 (10.4) years N = 30</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Chronic (>6 months)</p>	Swallowing ability at <3 months	<p>Setting: Inpatients in South Korea.</p> <p>Funding: This work was supported by BB21+ project in 2018.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Usual care (n=15) Instructed to swallow naturally without intentional force from the tongue and neck muscles, according to the same schedule as that of the experimental group.</p> <p>Concomitant therapy: Both groups received the same conventional dysphagia therapy (e.g. compensatory techniques such as the chin tuck and head tilting and rotation; therapeutic techniques such as orofacial muscle exercises, thermal tactile stimulation using ice sticks, expiratory training) from occupational therapists. The therapy was administered for 30 minutes per day, consecutively for 5 days per week for 4 weeks.</p>	<p>People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>		
<p>Perez 1998¹⁰⁰</p> <p>Subsidiary papers: Smithard, 1997¹⁰⁶</p>	<p>Nifedipine (n=8) Slow release nifedipine 30 mg orally, daily treatment for 4 weeks.</p> <p>Placebo/sham therapy (n=9) Placebo - matching tablet; treatment for 4 weeks.</p> <p>Concomitant therapy: No additional information</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 17</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear</p>	<p>Mortality at <3 months Dysphagia present/return to normal diet at <3 months</p>	<p>Setting: Inpatients, Queen Mary's NHS Trust in the United Kingdom.</p> <p>Funding: No additional information</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
		Type of stroke: Not stated/unclear		
Sawan 2020 ¹⁰³	<p>Transcranial direct current stimulation (TDCS) (n=20) A constant current of 2mA intensity was applied for 30 minutes. Stimulation was applied for five consecutive sessions for 2 weeks.</p> <p>Placebo/sham therapy (n=20) Sham therapy applied for the same amount of time. The sham produced the same tingling sensation but had no other active effect through the use of a different machine.</p> <p>Concomitant therapy: Everyone received a selected physiotherapy program.</p>	<p>People after a first or recurrent stroke Mean age (SD): 51.8 (5.4) years N = 40</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Occurrence of aspiration at <3 months	<p>Setting: Inpatients at Egypt.</p> <p>Funding: No specific grant from any funding agency in the public, commercial or not-for-profit sectors.</p>
Shigematsu 2013 ¹⁰⁴	<p>Transcranial direct current stimulation (TDCS) (n=10) Anodal tDCS for 10 days. The anodal electrodes were placed according to the international 10-20 EEG electrode system. The current was 1m A and was provided for 20 minutes a day for 10 days (over 2 weeks).</p> <p>Placebo/sham therapy (n=10) Sham tDCS. Same procedure but the current was put up to 1mA and then reduced over 40 seconds (so people felt an initial sensation but then there was no active treatment afterwards).</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.8 (7.8) years N = 20</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: People requiring enteral feeding</p>	Swallowing ability at <3 months	<p>Setting: Inpatients in Japan.</p> <p>Funding: No financial support for the research.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Concomitant therapy: People who were at risk of aspiration and could not meet the safety conditions required for oral intake were tube fed and underwent oral intake rehabilitation. People who could eat and drink safely with compensatory conditions received both oral intake rehabilitation and indirect therapy.</p>	<p>support at baseline Type of stroke: Mixed</p>		
Song 2004 ¹⁰⁷	<p>Behavioural intervention (nurse-led swallowing exercises) (n=29) Nurse-led swallowing exercises, oral stimulation and oral care.</p> <p>Usual care (n=24) Not explicitly stated.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 53</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months</p>	<p>Setting: China</p> <p>Funding: No additional information.</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Su 2011 ¹⁰⁸	<p>Acupuncture/electroacupuncture (electroacupuncture) (n=30) Needles were inserted and twirled for 1-2 minutes with a frequency of 200 r/min until deqi sensation. A continuous wave was applied with a frequency of 120 times/min. Total time of electroacupuncture was 30 minutes.</p>	<p>People after a first or recurrent stroke Mean age: 67.5 years N = 60</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke:</p>	<p>Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in China</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>People received two treatment courses (15 days for each course, 30 days in total).</p> <p>Usual care (n=30) Includes basic swallowing training and food intake training. People received two treatment courses (15 days for each course, 30 days in total).</p> <p>Concomitant therapy: No additional information.</p>	<p>Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
<p>Suntrup 2015¹¹¹</p> <p>Subsidiary study: Dziewas 2014²³</p>	<p>Pharyngeal electrical stimulation (PES) (n=20) 0.2 ms pulse duration at a frequency of 5 Hz with 280 V. In the treatment condition stimulation was delivered for a total of 10 min at this intensity. The intervention was repeated daily for three consecutive days.</p> <p>Placebo/sham therapy (n=10) The intervention was the same as the study group but in the sham condition the catheter was left connected to the base station for 10 min without current flow between the electrodes.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 64.2 (14.6) years N = 30</p> <p>Severity of dysphagia: Very severe Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: People requiring enteral feeding support at baseline Type of stroke: Mixed</p>	<p>Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months</p>	<p>Setting: Inpatients, neurological intensive care unit (ICU) at the University Hospital Muenster in Turkey.</p> <p>Funding: No additional information.</p>
<p>Suntrup-Krueger 2018¹¹⁰</p>	<p>Transcranial direct current stimulation (TDCS) (n=30) Anodal tDCS was performed at 1mA for 20 minutes, once daily on 4 consecutive days.</p>	<p>People after a first or recurrent stroke Mean age (SD): 68.1 (13.1) years</p>	<p>Occurrence of chest infection at <3 months Length of hospital stay at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in Germany</p> <p>Funding: This work was supported by the German Research</p>

Study	Intervention and comparison	Population	Outcomes	Comments
Subsidiary papers: , 2013 ⁸⁷	<p>Placebo/sham therapy (n=30) Stimulation was only applied for 30 seconds and gradually ramped down with the electrodes left in place for a further 20 minutes.</p> <p>Concomitant therapy: No additional information.</p>	<p>N = 60</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Acute (72 hours - 7 days)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Mixed</p>		Foundation (TE 840/1-1, SU 922/1-1).
Tageldin 2020 ¹¹³	<p>Transcranial magnetic stimulation (TMS) (n=15) People received bilateral 10 sessions repeated five times per week for 2 successive weeks. Each train was 120% of the motor threshold intensity, 3-Hz frequency and 10s duration, with 50s inter-train intervals. The total number of pulses in each session was 300 (3 Hz x 10s x 10 trains) pulses in each side.</p> <p>Placebo/sham therapy (n=15) The same procedure except the coil was angled 90 degrees away by lifting the lateral aspect of the coil which delivers a very small proportion of the dose (<25%).</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 56.5 (9.1) years</p> <p>N = 30</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Acute (72 hours - 7 days)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>	Swallowing ability at <3 months	<p>Setting: Inpatients in Egypt.</p> <p>Funding: No financial support or sponsorship.</p>
Tarihci Cakmak 2022 ¹¹⁴	<p>Neuromuscular electrical stimulation (NMES) (n=19) 45 minutes of NMES, pulse rate of 80Hz,</p>	<p>People after a first or recurrent stroke</p>	<p>Mortality at <3 months and ≥3 months</p> <p>Occurrence of chest infections at</p>	<p>Setting: Outpatient follow up in Turkey.</p> <p>Funding: Funded by Istanbul University</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>biphasic pulse duration of 700 microseconds, stimulation intensity not exceeding 25mA with intensity starting at 2mA and increasing by 0.5mA until the person felt the vibration in their neck.</p> <p>Usual care (n=19) Usual care only.</p> <p>Concomitant therapy: Traditional dysphagia therapy for 45 minutes, 5 days a week for 3 weeks including diet modifications, oral hygiene education, compensatory methods and exercises.</p>	<p>Mean age (SD): 63.3 (9.9) years N = 28</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Chronic (>6 months)</p> <p>People requiring enteral feeding support: Mixed</p> <p>Type of stroke: Mixed</p>	<p><3 months and ≥3 months</p> <p>Occurrence of aspiration at <3 months and ≥3 months</p> <p>Swallowing ability at <3 months and ≥3 months</p>	<p>Scientific Research Projects Coordination Unit.</p>
Umay 2017 ¹¹⁵	<p>Neuromuscular electrical stimulation (Sensory level electrical stimulation [SES]) (n=58) Stimulation for 60 minutes a day, 5 days per week, for 4 weeks up to a total of 20 sessions.</p> <p>Placebo/sham therapy (n=40) Patients in group 2 received sham stimulation, the electrodes were placed at the same positions as in active stimulation; however, the stimulator was turned off. Therefore, the patients received no current stimulation for the treatment period.</p> <p>Concomitant therapy: All patients under the supervision of the same physiotherapist received daily care for</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 61.6 (10.0) years N = 98</p> <p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Mixed</p>	<p>Swallowing ability at <3 months</p>	<p>Setting: This study was conducted at the Physical Medicine and Rehabilitation (PMR) and Otolaryngology Head and Neck Surgery Clinics, Turkey.</p> <p>Funding: No financial support and sponsorship</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	oral hygiene, thermal (cold) and tactile stimulation, swallowing manoeuvres, head and trunk positioning, dietary modification, and oral motor exercises including lips, tongue, and jaw movements. 60 minutes a day, 5 days a week, for 4 weeks; cognitive, respiratory, and sensorimotor functional rehabilitation programs were added to this program.			
Unluer 2019 ¹¹⁶	<p>Transcranial magnetic stimulation (TMS) (n=15) 1 Hz at 90% of the resting motor threshold intensity at the hot spot for 20 min daily for five consecutive days (for a total of 1200 pulses each day).</p> <p>Usual care (n=15) Conventional dysphagia rehabilitation included oropharyngeal muscle strengthening exercises, thermal tactile stimulation, Masako and Mendelson manoeuvres, vocal cord exercises, Shaker exercises, and tongue retraction exercises for 4 weeks. The conventional dysphagia rehabilitation took 30–45 min in the control group.</p> <p>Concomitant therapy: All patients received conventional dysphagia rehabilitation under the control of a trained physical therapist 3 days per week. In</p>	<p>People after a first or recurrent stroke Mean age (SD): 68.6 (12.4) years N = 30</p> <p>Severity of dysphagia: Mixed</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Mixed</p> <p>Type of stroke: Not stated/unclear</p>	<p>Occurrence of aspiration at <3 months</p> <p>Dysphagia present/return to normal diet at <3 months</p> <p>Swallowing ability at <3 months</p>	<p>Setting: Physiotherapy and Rehabilitation and Hacettepe University Faculty of Medicine, Department of Neurology in Turkey.</p> <p>Funding: No additional information</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	addition, a home program was implemented 2 days per week.			
Vasant 2016 ¹¹⁸ Subsidiary papers: Vasant 2014 ¹¹⁷	<p>Pharyngeal electrical stimulation (PES) (n=18) 0.2 ms pulses, maximum 280 V, 5 Hz frequency and an intensity 75% of the maximum tolerated. 3 sessions of PES for 10 minutes on 3 consecutive days.</p> <p>Placebo/sham therapy (n=18) Sham stimulation (catheter in situ with stimulator turned off) for the same period.</p> <p>Concomitant therapy: Both groups continued to receive standard swallowing treatments.</p>	<p>People after a first or recurrent stroke Median age (IQR): Intervention: 71 (56 to 79) years Control: 71 (61 to 78) years N = 36</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Type of stroke: Not stated/unclear</p>	<p>Mortality at ≥3 months Occurrence of aspiration at ≥3 months Dysphagia present/return to normal diet at ≥3 months Length of hospital stay at ≥3 months Swallowing ability at ≥3 months</p>	<p>Setting: Inpatients. Stroke units in 3 Greater Manchester hospitals (Salford Royal, University Hospital of South Manchester, and Trafford General), in the United Kingdom.</p> <p>Funding: National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0107-12076).</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>
Wang 2017 ¹²⁰	<p>Physical stimulation (Rood intervention) (n=48) The patients in the observation group received Rood technology intervention, and the pharyngeal and palatal arches and tongue were rapidly stimulated with ice cotton sticks. For the root, in order to avoid nausea, each part was stimulated back and forth 5 times, 5 min/time, 3 times/d, and the intervention was continued for 14 days.</p> <p>Usual care (n=48)</p>	<p>People after a first or recurrent stroke Mean age (SD): 51.9 (4.9) years N = 96</p> <p>Severity of dysphagia: Mixed Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months Nutrition at <3 months</p>	<p>Setting: Affiliated Hospital of Hangzhou Normal University in China.</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>The patients in the control group received routine oral intervention, regular oral massage, 3 times/d, and continued intervention for 14 days.</p> <p>Concomitant therapy: No additional information</p>			
<p>Wang 2019¹²³</p>	<p>Physical stimulation (thermal tactile stimulation) (n=30) By adding 1 g of Sichuan red pepper powder to 50 mL of mineral water, a capsaicin concentration of 150 mg/L was obtained, based on the Chinese Pharmacopoeia. Nectar viscosity was obtained by adding 3.5 g of thickener Resource ThickenUp (Nestle Nutrition, Barcelona, Spain) to 100 mL of mineral water. Treatment was administered to patients three times per day before each meal for 3 weeks.</p> <p>Placebo/sham therapy (n=30) In the control group, the solution and the nectar bolus were made to be identical to that in the intervention group, except for capsaicin.</p> <p>Concomitant therapy: Both groups received the same conventional dysphagia treatments such as orofacial muscle exercises, thickeners, postures, and therapeutic or</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.0 (12.1) years N = 60</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Mixed (Around 60% of people required enteral feeding support.) Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients. Yancheng City No.1 People's Hospital in China.</p> <p>Funding: This work was funded by Postgraduate Research & Practice Innovation Program of Jiangsu Province; Integrated Care Model for Patients with Dysphagia after Stroke grant number KYCX18_254</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	compensatory manoeuvres.			
Wang 2020 ¹²²	<p>Transcranial direct current stimulation (TDCS) (n=14) The direct current was gradually increased to 1 mA within 5 s and subsequently maintained for 20 min. Each hemisphere was stimulated consecutively for 20 min with an interval of 30 min. All patients received 20 intervention sessions (five times per week for 4 weeks).</p> <p>Placebo/sham therapy (n=14) The treatment protocol for the sham tDCS group was identical to that for the tDCS group, except that the direct current was gradually increased to 1 mA within 5 s and turned off 30 s later in order to produce an initial tingling sensation.</p> <p>Concomitant therapy: Patients in both groups received catheter balloon dilatation and conventional swallowing therapy.</p>	<p>People after a first or recurrent stroke Mean age (SD): 61.7 (10.9) years N = 28</p> <p>Severity of dysphagia: Severe Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: People requiring enteral feeding support at baseline Type of stroke: Not stated/unclear</p>	Swallowing ability at <3 months	<p>Setting: Department of Rehabilitation Medicine, the First Affiliated Hospital of Fujian Medical University in China.</p> <p>Funding: The study was supported by Startup Fund for scientific research, Fujian Medical University (Grant number, 2016QH071), and National Natural Science Foundation of China (81572219).</p>
Wang 2022 ¹²¹	<p>Behavioural intervention (tongue-pressure resistance training) (n=19) Tongue-pressure resistance training by a JMS tongue pressure measurement device according to the standard protocols. The same Speech and Language Pathologist performed training for 20 minutes/day, 5 days a week for 4 weeks.</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 37</p> <p>Severity of dysphagia: Not stated/unclear</p>	Occurrence of chest infection at <3 months	<p>Setting: Inpatients at China.</p> <p>Funding: Funded by the Shanghai Commission of Science and Technology of China (No. 19411968700, 20412420200), General Program of National Natural Science Foundation of China (No. 81972140), the</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Usual care (n=18) Usual care only.</p> <p>Concomitant therapy: Conventional dysphagia rehabilitation training, including oro-facial motor control exercises, oro-facial muscles sensory stimulation, respiratory training and airway protection manipulation. Performed for 30 minutes/day, 5 days a week for 4 weeks</p>	<p>Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Mixed Type of stroke: Not stated/unclear</p>		<p>National Key R&D Program of China (No. 2018YFC2001700) and the Shanghai Municipal Key Clinical Speciality (No. shslczdzk02702).</p>
Warusevitane 2015 ¹²⁴	<p>Metoclopramide (n=30) 10mg metoclopramide (colourless solution 10mL) three times a day via a nasogastric tube. Treatment was continued until nasogastric feeding was no longer necessary or for a maximum of 21 days.</p> <p>Placebo/sham therapy (n=30) Normal saline placebo for the same timing and duration.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): 78.1 (8.9) years N = 60</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: People requiring enteral feeding support at baseline Type of stroke: Mixed</p>	<p>Mortality at <3 months Occurrence of chest infection at <3 months Occurrence of aspiration at <3 months Dysphagia present/return to normal diet at <3 months</p>	<p>Setting: Inpatients in the United Kingdom.</p> <p>Funding: No additional information.</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Xia 2011 ¹²⁷	<p>Neuromuscular electrical stimulation (NMES) (n=40) Two direction square waves, with a wave width being 700 microseconds, frequency 80 Hz and</p>	<p>People after a first or recurrent stroke Mean age (SD): 65.6 (14.5) years N = 80</p>	<p>Swallowing ability at <3 months</p>	<p>Setting: Inpatients in China</p> <p>Funding: The project was supported by a grant from the Health Bureau of Hubei</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>wave amplitude 0-25 mA. Treatment was administered twice a day, lasting 30 minutes each time, 5 days a week for 4 successive weeks.</p> <p>Usual care (n=40) Conventional swallowing training only.</p> <p>Concomitant therapy: Conventional swallowing training including basic training and direct food intake training.</p>	<p>Severity of dysphagia: Not stated/unclear</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>		<p>Province, China (No. JX5B36).</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Xia 2016 ¹²⁸	<p>Acupuncture/electroacupuncture (acupuncture) (n=62) The nape, scalp, and tongue acupuncture were conducted by an acupuncturist using Traditional Chinese Medicine (TCM) theory. The needles remained in place for 30 minutes. Acupuncture was performed after swallowing training for 24 sessions, which comprised of sessions six times a week for a period of four weeks.</p> <p>Usual care (n=62) Functional training was applied to the feeding and swallowing organs (lip, cheek, tongue, soft palate, pharynx, throat, and esophageal sphincter). Each patient had one-on-one treatment for 30 minutes per session. A training intervention consisted of 24 sessions six times a week for four weeks.</p>	<p>People after a first or recurrent stroke</p> <p>Mean age (SD): 65.7 (14.3) years N = 124</p> <p>Severity of dysphagia: Very severe</p> <p>Time after stroke: Subacute (7 days - 6 months)</p> <p>People requiring enteral feeding support: Not stated/unclear</p> <p>Type of stroke: Not stated/unclear</p>	Swallowing ability at <3 months	<p>Setting: Departments of Neurology and Physical Medicine and Rehabilitation, Hubei Xinhua Hospital in Wuhan in China.</p> <p>Funding: This study was supported by a grant from Hubei province health department of China [NO.JX5B36].</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Concomitant therapy: All patients were given general medication, supportive mental health treatment (i.e. psychotherapy and health education), and standard swallowing training.</p>			
Yang 2012 ¹²⁹	<p>Transcranial direct current stimulation (TDCS) (n=9) Anodal transcranial direct current stimulation (1mA for 20 minutes for 10 days).</p> <p>Placebo/sham therapy (n=7) Sham tDCS using the same procedure except the current was increased and then tapered down and turned off after 30s of stimulation.</p> <p>Concomitant therapy: All people received 30 minutes of conventional swallowing training during the sessions. Swallowing training consisted of a structured program including direct therapies such as diet modification, positioning, behavioural manoeuvres (including Mendelsohn manoeuvre, supraglottic and effortful swallowing) and indirect therapies such as physical manoeuvre such as oral motor exercise and thermal tactile stimulation.</p>	<p>People after a first or recurrent stroke Mean age (SD): 70.5 (11.0) years N = 16</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Swallowing ability <3 months and ≥3 months	<p>Setting: Inpatients in South Korea.</p> <p>Funding: This work was supported by grant no (03-2008-004) from the SNUBH Research Fund.</p>
Youssef 2015 ¹³⁰	<p>Pharyngeal electrical stimulation (PES) (n=9)</p>	<p>People after a first or</p>	Occurrence of chest infection at <3 months	Setting: Egypt

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Pharyngeal electrical stimuli (0.2-ms pulses, 280 V) was delivered at a set frequency (5 Hz), intensity (75% of maximal tolerated), and duration (10 minutes) for a period of 10 minutes. The treatment regime in total comprises three stimulation sessions, once a day for three consecutive days.</p> <p>Placebo/sham therapy (n=9) During Sham pharyngeal stimulation, the same method was used. However, on commencement of stimulation, the constant current generator was switched off and the intraluminal pharyngeal catheter was left in situ in the subject for the duration of intervention.</p> <p>Concomitant therapy: All patients continued to receive standard clinical care throughout the study.</p>	<p>recurrent stroke Mean age (SD): 65.5 (10.1) years N = 18</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Swallowing ability at <3 months	Funding: No additional information
Yuan 2003 ¹³¹	<p>Adaptations for oral feeding - Thickened fluids (n=18) Enteral nutrition agent with thickener and swallowing therapy.</p> <p>Behavioural intervention (swallowing therapy) (n=22) Traditional liquid diet and swallowing therapy. Concomitant therapy: No additional information.</p> <p>Usual care (n= 24)</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 64</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding</p>	<p>Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months Nutrition at <3 months</p>	<p>Setting: China</p> <p>Funding: No additional information</p> <p>This study included unpublished material or material that could not be obtained by the NICE developer and was available from the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>Liquid diet only and no swallowing therapy</p> <p>Concomitant therapy: No additional information.</p>	<p>support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
<p>Zhang 2020¹³⁴</p>	<p>Behavioural intervention (bundle of care including exercises) (n=40) Bundle of care delivered by neuropsychologists, chief nurses, supervising nurses and rehabilitation trained nurses. This included psychological protection (counselling), health education, an eating intervention (food intake of 3-5 mL/min in a semi-recumbant position, people who needed to be supine could lie in a lateral position, for people seated their head and neck should be slightly forward and tilt 30 degrees to the healthy side. Gradual transition from soft food to harder foods. Instruction on eating), rehabilitation training (monophonic method used to conduct lip movement training. Ice cotton swabs were used to stimulate the person's cheek and around the pharyngeal arch, and they were asked to do a short swallow).</p> <p>Usual care (n=40) Usual care only.</p> <p>Concomitant therapy: Routine rehabilitation included basic protection, specialist</p>	<p>People after a first or recurrent stroke Mean age (SD): 63.9 (5.5) years N = 80</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months Swallowing ability at <3 months</p>	<p>Setting: Inpatients in China.</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	protection and eating guidance.			
Zhang 2021 ¹³³	<p>Diet modification (n=28) In addition to the conventional swallowing training, this group was given direct training with soft food (viscosity 4750 to 5113 cP), depending on their willingness to eat it. The food was prepared with thickener and water at a temperature of 25 degrees centigrade. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days a week for 6 weeks, for a total of 30 days.</p> <p>Behavioural interventions (n= 27) Intensive swallowing training with tongue-hold swallow. During direct eating/swallowing training, a person was asked to hold their tongue gently between their teeth. The therapist then applied a 5-mL food bolus onto the middle of the tongue using a spoon, and the person swallowed it with their tongue in a straight position when they felt the maximum intensity of current stimulation in the submental muscles with synchronized electrical stimulation using the VitalStim neuromuscular stimulator. The NMES treatment was performed the same as in the control group. Each training session</p>	<p>People after a first or recurrent stroke Mean age (SD): 63.1 (7.0) years N = 83</p> <p>Severity of dysphagia: Mixed (Inclusion criteria states mild-moderate) Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Occurrence of chest infection at <3 months	<p>Setting: People attending the Affiliated Hospital of Guizhou Medical University in China.</p> <p>Funding: No additional information.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days</p> <p>Usual care (n=28) Usual care only.</p> <p>Concomitant therapy: Each person received the following conventional swallowing training. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intelect VitalStim model 5900 was performed.</p>			
Zheng 2014 ¹³⁶	<p>Behavioural intervention (Individualised multi-disciplinary rehabilitation programme) (n=44) Oropharyngeal exercises deriving from speech language pathology and including soft palate, tongue, and facial muscle exercises as well as stomatognathic function exercises were performed. These rehabilitation training exercises were performed 2 times per day, and each exercise was repeatedly practiced for about 30 minutes.</p> <p>Usual care (n=44) The control group patients were treated according to the traditional neurology or</p>	<p>People after a first or recurrent stroke Mean age (SD): 66 (3) years N = 88</p> <p>Severity of dysphagia: Moderate Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Dysphagia present/return to normal diet at <3 months	<p>Setting: Inpatient department of Neurology, Qilu Hospital of Shandong University in China</p> <p>Funding: No additional information</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>

Study	Intervention and comparison	Population	Outcomes	Comments
	<p>internal medicine practices, and were assisted to feed in accordance with their will.</p> <p>Concomitant therapy: Treatment was given in addition to standard stroke care, including thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of antihypertensives (all people), oral antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic stroke) were recommended for secondary prevention as per each site's local practice.</p>			
Zheng 2022 ¹³⁵	<p>Acupuncture/electroacupuncture (n=60) Acupuncture for 30 minutes, once daily five times a week for three weeks per course of treatment with two courses in total.</p> <p>Placebo/sham therapy (n=60) The same procedure but using blunt needles instead.</p> <p>Concomitant therapy: All people received swallowing functioning training and symptomatic treatment for 30 minutes, 5 times a week for 6 weeks.</p>	<p>People after a first or recurrent stroke Mean age (SD): 60.2 (7.1) years N = 120</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days – 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	Dysphagia present/return to normal diet at <3 months	<p>Setting: Outpatients in China.</p> <p>Funding: No funding.</p>

1 **1.1.5.2. Oesophageal dysphagia**

2 **Table 3: Summary of the study reporting an intervention for oesophageal dysphagia**
3 **included in the evidence review**

Study	Intervention and comparison	Population	Outcomes	Comments
Allami 2022 ²	<p>Domperidone (n=76) Domperidone 10mg once a day from the first day of hospitalisation until discharge.</p> <p>Placebo (n=74) Placebo once a day from the first day of hospitalisation until discharge.</p> <p>Concomitant therapy: Standard stroke care available to all.</p>	<p>People after a first or recurrent stroke Mean age: 68 years N = 150</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: People not requiring enteral feeding support at baseline Type of stroke: Mixed (majority anterior circulation)</p>	<p>Mortality at <3 months Occurrence of aspiration at <3 months Dysphagia present/return to normal diet/return to normal diet at <3 months Length of hospital stay at <3 months</p>	<p>Setting: Initially inpatients in the neurology department of Bouali hospital in Iran.</p> <p>Funding: No financial interests.</p>

4

5 **1.1.5.3. Adaptations to support people with dysphagia**

6 **Table 4: Summary of studies reporting adaptations to support people with dysphagia**
7 **included in the evidence review**

Study	Intervention and comparison	Population	Outcomes	Comments
<p>Carnaby 2006¹¹</p> <p>Subsidiary papers: Mann 1997⁷⁴</p>	<p>Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery) (n=102) Standard low-intensity swallowing therapy composed of swallowing compensation strategies, mainly</p>	<p>People after a first or recurrent stroke Mean age (SD): 71.1 (12.6) years N = 306</p> <p>Severity of dysphagia:</p>	<p>Occurrence of chest infection at ≥3 months Dysphagia present/return to normal diet at ≥3 months Discharge to residential service at ≥3 months Length of hospital stay at ≥3 months</p>	<p>Setting: People at a university teaching hospital, the Royal Peth Hospital, which provides medical services for the eastern suburban region of Perth in Western Australia.</p> <p>Funding: This study was supported by an</p>

	<p>environmental modifications (eg, upright positioning for feeding); safe swallowing advice (Eg, reduced rate of eating); appropriate dietary modification, under the direction of the study speech pathologist, three times per week for a month, or for the duration of the hospital stay.</p> <p>Usual care (n=102) Usual care consisted of patient management by the attending physicians as per usual practice. Physicians referred their patients to the existing hospital speech pathology service if they considered it to be appropriate. Treatment, if offered, consisted mainly of supervision for feeding and precautions for safe swallowing (eg, positioning, slowed rate of feeding).</p> <p>A third arm was included in the analysis (n=102) where people received combination therapy and additional swallowing exercises that was not included in the analysis as this included a combination of interventions in the protocol given the context of the trial and so was not considered a valid comparison.</p> <p>Concomitant therapy: No additional information</p>	<p>Not stated/unclear Time after stroke: Acute (72 hours - 7 days) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>		<p>educational grant from the Royal Perth Hospital Medical Research Foundation.</p>
DePippo 1994 ²¹	<p>Modified diet (n=77) Combination of two groups. Group B were</p>	<p>People after a first or</p>	<p>Mortality at <3 months</p>	<p>Setting: Inpatient rehabilitation unit in</p>

	<p>prescribed a diet based on the results of the MBS evaluation. Patients in this group were reevaluated by the dysphagia therapist every other week for the need to change the prescribed diet consistency. Group C received this and were seen daily in a mealtime dysphagia management group where additional instructions and reinforcement of compensatory swallowing techniques were given.</p> <p>Usual care (n=38) One formal dysphagia treatment session, attended by the patient and relevant family members. They were given the option of selecting either a regular diet or one of four graded levels of diets designed for patients with dysphagia, and with all-liquid consistencies or with thickened liquids only. Training in the use of appropriate compensatory swallowing techniques found to improve swallowing during the MBS were given but no reinforcement.</p> <p>Concomitant therapy: No additional information.</p>	<p>recurrent stroke Mean age: 74.5 years N = 115</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Nutrition at <3 months Hydration at <3 months</p>	<p>the United States of America</p> <p>Funding: Supported by US Public Health Service grant No. 1-RO1-DC00885.</p>
<p>Garon 1997³¹</p>	<p>Free water protocol (n=10) Water was placed out of the person's immediate reach in their room. People were instructed to notify a nurse or family member when they wanted water. No water was allowed with</p>	<p>People after a first or recurrent stroke Mean age: 77 years N = 20</p> <p>Severity of dysphagia:</p>	<p>Occurrence of chest infection at <3 months Hydration at <3 months</p>	<p>Setting: Inpatients in the United States of America.</p> <p>Funding: No additional information.</p>

	<p>meals or for an hour following meals, and a pre-rinse was utilised prior to any water intake to reduce the possibility of ingesting oral bacteria or oral food stasis.</p> <p>Usual care (thickened liquids) (n=10) Allowed as much thickened liquids as they desired, with meals and as requested. Intake amounts were recorded in the same manner as the study group.</p> <p>Concomitant therapy: No additional information.</p>	<p>Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
Murray 2016 ⁸¹	<p>Free water protocol (n=9) Adapted from the original Frazier Water Protocol. Water was permitted anytime between meals but not at mealtime, with food, medication or for 30 minutes after a meal. People also had access to the thickened liquid that they were assessed to be safely consuming.</p> <p>Usual care (thickened fluids) (n=7) Thickened liquid only intervention. People were allowed to drink only the mildly, moderately or extremely thickened liquid deemed safe from their VFSS.</p> <p>Concomitant therapy: All people in both arms were required to adhere to a daily oral</p>	<p>People after a first or recurrent stroke Mean age (SD): 78.9 (6.7) years N = 16</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Subacute (7 days - 6 months) People requiring enteral feeding support: Not stated/unclear Type of stroke: Mixed</p>	<p>Occurrence of chest infection at <3 months Hydration at <3 months</p>	<p>Setting: Stroke units from two acute hospitals and three inpatient rehabilitation facilities in an Australian capital city.</p> <p>Funding: This research was supported by the Royal Adelaide Hospital/Institute of Medical and Veterinary Science Clinical Research Grant for Allied Health, Nursing and Pharmacy (January 2009) and a Clinical Research Development Grant awarded to the first author by the National Stroke Foundation, Australia (dated 15th December 2011).</p>

	<p>hygiene routine which involved brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch.</p>			
Yuan 2003 ¹³¹	<p>Behavioural intervention (swallowing therapy) (n=22) Traditional liquid diet and swallowing therapy. Concomitant therapy: No additional information.</p> <p>Usual care (n= 24) Liquid diet only and no swallowing therapy</p> <p>This study includes a third arm (n=18) that was not included in this analysis as it compares the use of thickened enteral fluids that was not a comparison included in the protocol.</p> <p>Concomitant therapy: No additional information.</p>	<p>People after a first or recurrent stroke Mean age (SD): Not stated/unclear N = 64</p> <p>Severity of dysphagia: Not stated/unclear Time after stroke: Not stated/unclear People requiring enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>	<p>Occurrence of chest infection at <3 months Dysphagia present/return to normal diet at <3 months Length of hospital stay at <3 months Nutrition at <3 months</p>	<p>Setting: China</p> <p>Funding: No additional information</p> <p>This study was included in the Cochrane review, Bath 2018⁶.</p>
Zhang 2021 ¹³³	<p>Diet modification (n=28) In addition to the conventional swallowing training, this group was given direct training with soft food (viscosity 4750 to 5113 cP), depending on their willingness to eat it. The food was prepared with thickener and water at a temperature of 25 degrees centigrade. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days a week for 6 weeks, for a total of 30 days.</p>	<p>People after a first or recurrent stroke Mean age (SD): 63.1 (7.0) years N = 83</p> <p>Severity of dysphagia: Mixed (Inclusion criteria states mild-moderate) Time after stroke: Subacute (7 days - 6 months) People requiring</p>	<p>Occurrence of chest infection at <3 months</p>	<p>Setting: People attending the Affiliated Hospital of Guizhou Medical University in China.</p> <p>Funding: No additional information.</p>

<p>Behavioural interventions (n= 27) Intensive swallowing training with tongue-hold swallow. During direct eating/swallowing training, a person was asked to hold their tongue gently between their teeth. The therapist then applied a 5-mL food bolus onto the middle of the tongue using a spoon, and the person swallowed it with their tongue in a straight position when they felt the maximum intensity of current stimulation in the submental muscles with synchronized electrical stimulation using the VitalStim neuromuscular stimulator. The NMES treatment was performed the same as in the control group. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days</p> <p>Usual care (n=28) Usual care only.</p> <p>Concomitant therapy: Each person received the following conventional swallowing training. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intellect VitalStim model 5900 was performed.</p>	<p>enteral feeding support: Not stated/unclear Type of stroke: Not stated/unclear</p>		
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- 1 See Appendix D for full evidence tables.

1 1.1.5.4. Summary matrices

2 Table 5: A matrix summarising the results comparing interventions for oropharyngeal dysphagia to placebo/sham therapy

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Mortality	<3 months	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 60 Low quality	1 outcome (1 study) N = 150 Very low quality	No evidence identified.	1 outcome (1 study) N = 17 Very low quality	1 outcome (1 study) N = 33 Low quality	1 outcome (3 studies) N = 259 Very low quality	No evidence identified.	No evidence identified.	1 outcome (2 studies) N = 50 Very low quality
Mortality	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 71 Low quality	No evidence identified.	No evidence identified.	1 outcome (2 studies) N = 198 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Person/participant generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 162 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of chest infections	<3 months	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 60 High quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 59 Very low quality	No evidence identified.
Occurrence of chest infections	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 71 Low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS		TMS
Occurrence of aspiration	<3 months	No evidence identified.	1 outcome (1 study) N = 26 Very low quality	1 outcome (1 study) N = 60 Moderate quality	1 outcome (1 study) N = 150 Low quality	No evidence identified.	No evidence identified.	2 outcomes (4 studies) N = 149 Very low quality	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 40 Very low quality	1 outcome (2 studies) N = 72 Very low quality	1 outcome (2 studies) N = 46 Moderate quality
Occurrence of aspiration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (2 studies) N = 139 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Dysphagia present/return to normal diet	<3 months	1 outcome (1 study) N = 120 Moderate quality	No evidence identified.	1 outcome (1 study) N = 60 Moderate quality	1 outcome (1 study) N = 150 Very low quality	No evidence identified.	1 outcome (1 study) N = 17 Very low quality	2 outcomes (2 studies) N = 66 Low-very low quality	2 outcomes (3 studies) N = 184 Very low quality	1 outcome (1 study) N = 120 Very low quality	1 outcome (1 study) N = 44 Moderate quality	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Dysphagia present/return to normal diet	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	2 outcomes (2 studies) N = 154 Low-very low quality	No evidence identified.	No evidence identified.	No evidence identified.
Discharge to residential service	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Discharge to residential service	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 162 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 33 Low quality	2 outcomes (4 studies) N = 248	No evidence identified.	1 outcome (1 study) N = 59 Low quality	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
									Low quality			
Length of hospital stay	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	<3 months	No evidence identified.	2 outcomes (2 studies) N = 53 Low quality	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 48 Low quality	No evidence identified.	2 outcomes (5 studies) N = 263 Very low quality	1 outcome (3 studies) N = 241 Low quality	1 outcome (1 study) N = 120 Very low quality	2 outcomes (9 studies) N = 275 Low-very low quality	2 outcomes (6 studies) N = 138 Very low
Swallowing ability	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (2 studies)	No evidence identified.	1 outcome (1 study) N = 16	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioral interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
									N = 197 Low quality		Moderate quality	
Nutrition	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 162 Low quality	No evidence identified.	No evidence identified.	No evidence identified.
Nutrition	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 162 Low quality	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

1 **Table 6: A matrix summarising the results comparing interventions for oropharyngeal dysphagia to usual care**

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Mortality	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (2 studies) N = 71 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Mortality	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 127 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 77 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Carer generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of chest infections	<3 months	1 outcome (1 study) N = 60 Very low quality	1 outcome (6 studies) N = 273 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (4 studies) N = 194 Very low quality	No evidence identified.	1 outcome (2 studies) N = 156 Very low quality	No evidence identified.	No evidence identified.
Occurrence of chest infections	≥3 months	No evidence identified.	1 outcome (1 study) N = 26 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (3 studies) N = 154 Low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of aspiration	<3 months	No evidence identified.	1 outcome (8 studies) N = 211	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (3 studies)	No evidence identified.	1 outcome (1 study)	No evidence identified.	1 outcome (2 studies)

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
			Very low quality			identified.	identified.	studies) N = 107 Very low quality	identified.	N = 96 Very low quality	identified.	studies) N = 68 Very low quality
Occurrence of aspiration	≥3 months	No evidence identified.	1 outcome (1 study) N = 26 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (2 studies) N = 104 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 28 Very low quality
Dysphagia present/return to normal diet	<3 months	1 outcome (5 studies) N = 357 Very low quality	2 outcomes (7 studies) N = 345 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	2 outcomes (5 studies) N = 199 Very low quality	No evidence identified.	2 outcomes (2 studies) N = 156 Moderate-low quality	No evidence identified.	1 outcome (2 studies) N = 91 Very low quality
Dysphagia present/return to normal diet	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 77	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 30

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
								Very low quality				Very low quality
Discharge to residential service	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Discharge to residential service	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	<3 months	No evidence identified.	1 outcome (2 studies) N = 126 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 33 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Re-admission	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	<3 months	2 outcomes (3 studies) N = 281 High-very low quality	2 outcomes (10 studies) N = 319 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	2 outcomes (8 studies) N = 342 Low-very low quality	No evidence identified.	1 outcome (1 study) N = 60 Low quality	No evidence identified.	2 outcomes (3 studies) N = 129 Very low quality
Swallowing ability	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 34 Very low quality	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 40 Very low quality	1 outcome (1 study) N = 28 Very low quality
Nutrition	<3 months	No evidence identified.	1 outcome (1 study) N = 46 Very low quality	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 96 Low quality	No evidence identified.	No evidence identified.				

Outcomes	Timepoint	Acupuncture/electro-acupuncture	Behavioural interventions	Metoclopramide	Domperidone	Lisinopril	Nifedipine	NMES	PES	Physical stimulation	TDCS	TMS
Nutrition	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 77 Very low quality	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 40 Low quality	No evidence identified.
Hydration	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

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Table 7: A matrix summarising the results comparing interventions for oesophageal dysphagia and adaptations to support people with dysphagia to placebo/sham therapy

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
Mortality	<3 months	1 outcome (1 study) N = 150 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
Mortality	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of chest infections	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of chest infections	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of aspiration	<3 months	1 outcome (1 study) N = 150 Moderate quality	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of aspiration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Dysphagia present/return to normal diet	<3 months	1 outcome (1 study) N = 150 Very low quality	No evidence identified.	No evidence identified.	No evidence identified.
Dysphagia present/return to normal diet	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Discharge to residential service	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
Discharge to residential service	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Nutrition	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Nutrition	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

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2**Table 8: A matrix summarising the results comparing interventions for oesophageal dysphagia and adaptations to support people with dysphagia to usual care**

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Thickened fluids	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
Mortality	<3 months	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 115 Very low quality	No evidence identified.	No evidence identified.
Mortality	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 204 Low quality
Person/participant generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Person/participant generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Carer generic health-related quality of life	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of chest infections	<3 months	No evidence identified.	1 outcome (1 study) N = 42 Low quality	1 outcome (2 studies) N = 171) Low quality	1 outcome (2 studies) N = 34 Very low quality	No evidence identified.
Occurrence of chest infections	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 204 Low quality
Occurrence of aspiration	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Occurrence of aspiration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Thickened fluids	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
Dysphagia present/return to normal diet	<3 months	No evidence identified.	1 outcome (1 study) N = 42 Low quality	No evidence identified.	No evidence identified.	No evidence identified.
Dysphagia present/return to normal diet	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 204 Low quality
Discharge to residential service	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Discharge to residential service	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 204 Low quality
Length of hospital stay	<3 months	No evidence identified.	1 outcome (1 study) N = 42 Low quality	No evidence identified.	No evidence identified.	No evidence identified.
Length of hospital stay	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 204 Low quality
Re-admission	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Re-admission	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	<3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Swallowing ability	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Nutrition	<3 months	No evidence identified.	1 outcome (1 study)	1 outcome (1 study)	No evidence identified.	No evidence identified.

Outcomes	Timepoint	Oesophageal dysphagia: Domperidone	Adaptations: Thickened fluids	Adaptations: Modified diet	Adaptations: Free water protocol	Adaptations: combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
			N = 42 Low quality	N = 115 Very low quality		
Nutrition	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.
Hydration	<3 months	No evidence identified.	No evidence identified.	1 outcome (1 study) N = 115 Very low quality	2 outcomes (2 studies) N = 34 Very low quality	No evidence identified.
Hydration	≥3 months	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.	No evidence identified.

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2 **1.1.6. Summary of the effectiveness evidence**

3 **1.1.6.1. Interventions for oropharyngeal dysphagia**

4 **1.1.6.1.1. Acupuncture/electroacupuncture**

5 **Table 9: Clinical evidence summary: acupuncture/electroacupuncture compared to**
6 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with acupuncture/electroacupuncture	
Dysphagia present/return to normal diet (dysphagia present) at <3 months	120 (1 RCT) follow-up: 6 weeks	⊕⊕⊕ ○ Moderate ^a	RR 0.49 (0.34 to 0.70)	750 per 1,000	383 fewer per 1,000 (495 fewer to 225 fewer)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)

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8 **Table 10: Clinical evidence summary: acupuncture/electroacupuncture compared to**
9 **usual care**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with acupuncture/electroacupuncture	
Occurrence of chest infections at <3 months	60 (1 RCT) follow-up: 30 days	⊕○○ ○ Very low ^{a,b}	RR 0.80 (0.37 to 1.74)	333 per 1,000	67 fewer per 1,000 (210 fewer to 247 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	357 (5 RCTs) follow-up: mean 4 weeks	⊕○○ ○ Very low ^{b,c}	RR 0.74 (0.65 to 0.85)	757 per 1,000	197 fewer per 1,000 (265 fewer to 114 fewer)	MID (precision) = RR 0.8-1.25.
Swallowing ability (videofluoroscopic swallowing study, 0-8, higher values)	60 (1 RCT) follow-up: 30 days	⊕○○ ○ Very low ^{b,d}	-	The mean swallowing ability at <3 months	MD 1.87 higher (0.53 higher to 3.21 higher)	MID = 0.67 (0.5 x median baseline SD)

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with acupuncture/electroacupuncture	
are better, change score) at <3 months				was 3.03		
Swallowing ability (Standardised swallowing assessment, dysphagia outcome severity scale, VFSS dysphagia evaluation, water drinking test [different scale ranges], lower values are better, final values) at <3 months	221 (2 RCTs) follow-up: mean 6 weeks	⊕⊕⊕⊕ High ^e	-	-	SMD 1.21 SD lower (1.36 lower to 1.06 lower)	MID = 0.5 SD (SMD)
<p>a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)</p> <p>b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias in measurement of the outcome)</p> <p>d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)</p> <p>e. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis</p> <p>f. While statistical heterogeneity is present, all effect sizes are within the same MID and so this has been deemed to not be important heterogeneity</p>						

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1 **1.1.6.1.1. Behavioural interventions**

2 **Table 11: Clinical evidence summary: behavioural interventions compared to**
3 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with behavioural interventions	
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score) at <3 months	26 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	-	The mean occurrence of aspiration at <3 months was -0.31	MD 1 lower (1.76 lower to 0.24 lower)	MID = 0.35 (0.5 x median baseline SD)
Swallowing ability (videofluoroscopic dysphagia scale, 0-100, lower values are better, change score) at <3 months	26 (1 RCT) follow-up: 4 weeks	⊕⊕○○ Low _a	-	The mean swallowing ability at <3 months was -5.27	MD 10.42 lower (15.9 lower to 4.94 lower)	MID = 4.7 (0.5 x median baseline SD)
Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months	27 (1 RCT) follow-up: 4 weeks	⊕⊕○○ Low _{b,c}	-	The mean swallowing ability at <3 months was 0.6	MD 1.3 higher (0.19 higher to 2.41 higher)	MID = 0.28 (0.5 x median baseline SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)

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Table 12: Clinical evidence summary: behavioural interventions compared to usual care

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with behavioural interventions	
Occurrence of chest infections at <3 months	273 (6 RCTs) follow-up: mean 5 weeks	⊕○○○ Very low _{a,b}	RD -0.11 (-0.20 to -0.01)	209 per 1,000	110 fewer per 1,000 (200 fewer to 10 fewer) _c	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 1.00 (0.8-0.9 = serious, <0.8 = very serious)
Occurrence of chest infections at ≥3 months	26 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{d,e}	RR 0.31 (0.07 to 1.40)	400 per 1,000	276 fewer per 1,000 (372 fewer to 160 more)	MID (precision) = RR 0.8-1.25. MID (clinical importance) : 50 per 1,000.
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final values) at <3 months	211 (8 RCTs) follow-up: mean 5 weeks	⊕○○○ Very low _{e,f}	-	The mean occurrence of aspiration at <3 months was 1.6	MD 0.86 lower (1.15 lower to 0.58 lower)	MID = 0.59 (0.5 x median baseline SD)
Occurrence of aspiration at ≥3 months	26 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{e,g,h}	RR 0.50 (0.17 to 1.43)	500 per 1,000	250 fewer per 1,000 (415 fewer to 215 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	273 (4 RCTs) follow-up: mean 3 weeks	⊕○○○ Very low _{a,e,i}	RR 0.75 (0.57 to 0.97)	742 per 1,000	186 fewer per 1,000 (319 fewer to 22 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal	72 (3 RCTs) follow-up:	⊕○○○ Very low _{e,g,i}	RR 2.14 (0.54 to 8.48)	278 per 1,000	317 more per 1,000 (128 fewer to 2,078 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with behavioural interventions	
diet) at <3 months	mean 6 weeks					
Length of hospital stay (days, lower values are better, final values) at <3 months	126 (2 RCTs) follow-up: mean 3 weeks	⊕○○○ Very low _{a,e,i}	-	The mean length of hospital stay was 22.22 days	MD 1.91 days lower (7.51 lower to 3.7 higher) No clinically important difference	MID = 2.9 (0.5 x median baseline SD)
Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale, Mann Assessment of Swallowing, ASHA-NOMS [different scale ranges], higher values are better, change scores) at <3 months	134 (6 RCTs) follow-up: mean 6 weeks	⊕○○○ Very low _{e,f}	-	-	SMD 0.79 SD higher (0.43 higher to 1.14 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Functional Oral Intake Scale, Dysphagia Severity Rating Scale, Videofluoroscopic Dysphagia Rating Scale, Water swallowing test, dysphagia severity [different scale ranges], higher values are better, final values) at <3 months	185 (4 RCTs) follow-up: mean 4 weeks	⊕○○○ Very low _{e,f}	-	-	SMD 0.72 SD higher (0.42 higher to 1.02 higher)	MID = 0.5 SD (SMD)
Nutrition (units unclear, final values) at <3 months	46 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,e}	-	The mean nutrition at <3 months was 36.6	MD 0.2 higher (5.63 lower to 6.03 higher) No clinically important difference	MID = 5.0 (0.5 x median baseline SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions,

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with behavioural interventions	
bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)						
b. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)						
c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study						
d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)						
e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs						
f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)						
g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)						
h. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)						
i. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis						

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2 **1.1.6.1.2. Drug interventions (metoclopramide, domperidone, lisinopril and**
3 **nifedipine)**

4 **Table 13: Clinical evidence summary: drug intervention (metoclopramide) compared to**
5 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (metoclopramide)	
Mortality at <3 months	60 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _a	RR 0.67 (0.32 to 1.39)	400 per 1,000	132 fewer per 1,000 (272 fewer to 156 more)	MID (precision) = RR 0.8-1.25.
Occurrence of chest infections at <3 months	60 (1 RCT) follow-up: 3 weeks	⊕⊕⊕⊕ High	RR 0.31 (0.17 to 0.57)	867 per 1,000	598 fewer per 1,000 (719 fewer to 373 fewer)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration (number of episodes of aspiration, lower values are better,	60 (1 RCT) follow-up: 3 weeks	⊕⊕⊕○ Moderate _a	-	The mean occurrence of aspiration at <3 months was 0.73	MD 0.7 lower (1.03 lower to 0.37 lower)	MID = 0.27 (0.5 x median baseline SD)

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (metoclopramide)	
final value) at <3 months						
Dysphagia present/return to normal diet (return to normal diet) at <3 months	60 (1 RCT) follow-up: 3 weeks	⊕⊕⊕○ Moderate ^a	RR 1.35 (0.93 to 1.96)	567 per 1,000	198 more per 1,000 (40 fewer to 544 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

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2 **Table 14: Clinical evidence summary: drug intervention (domperidone) compared to**
3 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (domperidone)	
Mortality at <3 months	150 (1 RCT) follow-up: 11 days	⊕○○○ Very low ^{a,b}	RR 0.97 (0.14 to 6.73)	27 per 1,000	1 fewer per 1,000 (23 fewer to 155 more)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration at <3 months	150 (1 RCT) follow-up: 11 days	⊕⊕○○ Low ^c	RR 0.22 (0.11 to 0.42)	541 per 1,000	422 fewer per 1,000 (481 fewer to 314 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	150 (1 RCT) follow-up: 11 days	⊕○○○ Very low ^{a,b}	RR 1.17 (0.37 to 3.66)	68 per 1,000	11 more per 1,000 (43 fewer to 180 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment because of population indirectness (as the proportion of people with oropharyngeal dysphagia was unclear)
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c. Downgraded by 2 increments because of population and outcome indirectness (as the proportion of people with oropharyngeal dysphagia was unclear and as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)

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1 **Table 15: Clinical evidence summary: drug intervention (lisinopril) compared to**
2 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (lisinopril)	
Mortality at ≥3 months	71 (1 RCT) follow-up: 26 weeks	⊕⊕○○ Low _{a,b}	RR 2.19 (1.19 to 4.02)	263 per 1,000	313 more per 1,000 (50 more to 795 more)	MID (precision) = RR 0.8-1.25.
Occurrence of chest infections at ≥3 months	71 (1 RCT) follow-up: 26 weeks	⊕⊕○○ Low _{a,b}	RR 1.22 (0.78 to 1.90)	474 per 1,000	104 more per 1,000 (104 fewer to 426 more)	MID (precision) = RR 0.8-1.25.
Swallowing ability (Royal Brisbane Hospital Outcome Measure for Swallowing, scale range unclear, higher values are better, final value) at <3 month	48 (1 RCT) follow-up: 12 weeks	⊕⊕○○ Low _{a,b}	-	The mean swallowing ability at <3 months was 3.5	MD 0.7 higher (0.16 lower to 1.56 higher)	MID = 0.38 (0.5 x median baseline SD)

a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

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4 **Table 16: Clinical evidence summary: drug intervention (nifedipine) compared to**
5 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (nifedipine)	
Mortality at <3 months	17 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	RR 1.13 (0.08 to 15.19)	111 per 1,000	14 more per 1,000 (102 fewer to 1,577 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with drug intervention (nifedipine)	
Dysphagia present/return to normal diet (dysphagia present) at <3 months	17 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	RR 0.68 (0.23 to 1.97)	556 per 1,000	178 fewer per 1,000 (428 fewer to 539 more)	MID (precision) = RR 0.8-1.25.
<p>a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)</p> <p>b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p>						

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2 **1.1.6.1.3. Neuromuscular electrical stimulation (NMES)**

3 **Table 17: Clinical evidence summary: neuromuscular electrical stimulation (NMES)**
4 **compared to placebo/sham therapy**

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with neuromuscular electrical stimulation (NMES)	
Mortality at <3 months	33 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _a	RR 0.94 (0.22 to 4.00)	188 per 1,000	11 fewer per 1,000 (146 fewer to 563 more)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final value) at <3 months	117 (3 RCTs) follow-up: mean 4 weeks	⊕○○○ Very low _{b,c,d}	-	The mean occurrence of aspiration at <3 months was 1.1	MD 0.66 lower (1.78 lower to 0.45 higher)	MID = 0.87 (0.5 x median baseline SD)
Occurrence of aspiration at <3 months	32 (1 RCT) follow-up: 3 weeks	⊕○○○ Very low _{a,e}	RR 1.32 (0.46 to 3.81)	267 per 1,000	85 more per 1,000 (144 fewer to 749 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia)	33 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _a	RR 0.86 (0.51 to 1.43)	688 per 1,000	96 fewer per 1,000 (337 fewer to 296 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with neuromuscular electrical stimulation (NMES)	
present) at <3 months						
Dysphagia present/return to normal diet (return to normal diet) at <3 months	33 (1 RCT) follow-up: 1 weeks	⊕○○○ Very low _{d,f}	RR 1.42 (0.63 to 3.18)	353 per 1,000	148 more per 1,000 (131 fewer to 769 more)	MID (precision) = RR 0.8-1.25.
Length of hospital stay (days, lower values are better, final value) at <3 months	33 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _d	-	The mean length of hospital stay was 12.12 days	MD 0.04 days higher (3.25 lower to 3.33 higher)	MID = 2.1 (0.5 x median control group SD)
Swallowing ability (Functional Oral Intake Scale, Videofluoroscopic Dysphagia Scale, Mann Assessment of Swallowing Ability [different scale ranges], higher values are better, change scores) at <3 months	230 (4 RCTs) follow-up: mean 4 weeks	⊕○○○ Very low _{a,c}	-	-	SMD 0.69 SD higher (0.16 lower to 1.54 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months	33 (1 RCT) follow-up: 1 weeks	⊕○○○ Very low _{d,g}	-	The mean swallowing ability at <3 months was 3.18	MD 0.26 higher (1.16 lower to 1.68 higher)	MID = 0.92 (0.5 x median baseline SD)

- a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- b. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)
- c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
- d. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- e. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with neuromuscular electrical stimulation (NMES)	
f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)						
g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)						

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Table 18: Clinical evidence summary: neuromuscular electrical stimulation (NMES) compared to usual care

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with neuromuscular electrical stimulation (NMES)	
Mortality at <3 months	71 (2 RCTs) follow-up: mean 3 weeks	⊕○○○ ○ Very low _{a,b,c}	RD 0.05 (-0.06 to 0.17)	29 per 1,000	50 more per 1,000 (60 fewer to 170 more) _d	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 0.29 (0.8-0.9 = serious, <0.8 = very serious)
Mortality at ≥3 months	127 (2 RCTs) follow-up: 36 weeks	⊕○○○ ○ Very low _{a,b,c}	RD 0.02 (-0.05 to 0.09)	21 per 1,000	20 more per 1,000 (50 fewer to 90 more) _d	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 0.25 (0.8-0.9 = serious, <0.8 = very serious)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with neuromuscular electrical stimulation (NMES)	
Person/participant generic health-related quality of life (EQ-VAS, 0-100, higher values are better, final value) at ≥3 months	77 (1 RCT) follow-up: 1 years	⊕○○○ ○ Very low _{a,e}	-	The mean person/participant generic health-related quality of life at ≥3 months was 61.48	MD 10.38 higher (0.69 lower to 21.45 higher)	MID = 9.8 (0.5 x median baseline SD)
Occurrence of chest infections at <3 months	194 (4 RCTs) follow-up: mean 5 weeks	⊕○○○ ○ Very low _{b,f}	RD - 0.05 (-0.13 to 0.04)	66 per 1,000	50 fewer per 1,000 (130 fewer to 40 more) _d	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 0.96 (0.8-0.9 = serious, <0.8 = very serious)
Occurrence of chest infections at ≥3 months	154 (3 RCTs) follow-up: mean 27 weeks	⊕○○○ ○ Very low _{g,h}	RD - 0.12 (-0.33 to 0.09)	172 per 1,000	120 fewer per 1,000 (330 fewer to 90 more) _c	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 0.96 (0.8-0.9 =

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with neuromuscular electrical stimulation (NMES)	
						serious, <0.8 = very serious)
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months	74 (2 RCTs) follow-up: mean 4 weeks	⊕○○○ ○ Very low _{e,g,h}	-		MD 0.55 lower (1.76 lower to 0.67 higher)	MID = 1.2 (0.5 x median baseline SD)
Occurrence of aspiration at <3 months	33 (1 RCT) follow-up: 3 weeks	⊕○○○ ○ Very low _{e,i,j}	RR 1.13 (0.43 to 2.98)	313 per 1,000	41 more per 1,000 (178 fewer to 619 more)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months	77 (1 RCT) follow-up: 1 years	⊕○○○ ○ Very low _{a,e}	-	The mean occurrence of aspiration at ≥3 months was 3.5	MD 0.67 lower (1.46 lower to 0.12 higher)	MID = 0.86 (0.5 x median baseline SD)
Occurrence of aspiration at ≥3 months	27 (1 RCT) follow-up: 3 months	⊕○○○ ○ Very low _{e,f,j}	RR 0.71 (0.29 to 1.73)	500 per 1,000	145 fewer per 1,000 (355 fewer to 365 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	142 (4 RCTs) follow-up: mean 3 weeks	⊕⊕○○○ Low _{e,k}	RR 0.66 (0.52 to 0.85)	778 per 1,000	264 fewer per 1,000 (373 fewer to 117 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal diet) at <3 months	57 (1 RCT) follow-up: 12 weeks	⊕○○○ ○ Very low _{e,l}	RR 1.26 (0.69 to 2.31)	385 per 1,000	100 more per 1,000 (119 fewer to 504 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with neuromuscular electrical stimulation (NMES)	
Dysphagia present/return to normal diet (dysphagia present) at ≥3 months	77 (1 RCT) follow-up: 1 years	⊕○○○ ○ Very low _{a,e}	RR 0.79 (0.61 to 1.02)	846 per 1,000	178 fewer per 1,000 (330 fewer to 17 more)	MID (precision) = RR 0.8-1.25.
Length of hospital stay (days, lower values are better, final values) at <3 months	33 (1 RCT) follow-up: 3 weeks	⊕○○○ ○ Very low _{e,i}	-	The mean length of hospital stay was 13 days	MD 0.84 days lower (5.2 lower to 3.52 higher)	MID = 2.4 (0.5 x median baseline SD)
Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months	130 (3 RCTs) follow-up: mean 6 weeks	⊕⊕○○ Low _r	-	-	SMD 0.91 SD higher (0.55 higher to 1.28 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome and Severity Scale, Standardised swallowing assessment, Dysphagia severity [different scale ranges], higher values are better, final values) at <3 months	212 (5 RCTs) follow-up: mean 3 weeks	⊕○○○ ○ Very low _{e,h,m}	-	-	SMD 1.07 SD higher (0.05 lower to 2.19 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at ≥3 months	34 (1 RCT) follow-up: 15 weeks	⊕○○○ ○ Very low _{a,e}	-	The mean swallowing ability at ≥3 months was 6	MD 0.2 higher (0.74 lower to 1.14 higher)	MID = 0.9 (0.5 x median baseline SD)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with neuromuscular electrical stimulation (NMES)	
Nutrition (Mini Nutritional Assessment-short form, 0-14, higher values are better, final value) at ≥3 months	77 (1 RCT) follow-up: 1 years	⊕○○○ ○ Very low ^{a,e}	-	The mean nutrition at ≥3 months was 11.58	MD 0.21 higher (1 lower to 1.42 higher)	MID = 1.4 (0.5 x median baseline SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

b. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)

c. Downgraded by 1 to 2 increments for imprecision due to zero events and small sample size

d. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)

g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, and bias due to missing outcome data)

h. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

i. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to deviations from the intended interventions)

j. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)

k. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process, bias due to deviations from the intended intervention, bias due to missing outcome data and bias in measurement of the outcome)

l. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)

m. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias in measurement of the outcome)

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1 **1.1.6.1.4. Pharyngeal electrical stimulation (PES)**

2 **Table 19: Clinical evidence summary: pharyngeal electrical stimulation (PES)**
3 **compared to placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with pharyngeal electrical stimulation (PES)	
Mortality at <3 months	259 (3 RCTs) follow-up: mean 2 weeks	⊕○○○ Very low _{a,b}	RR 2.13 (0.42 to 10.75)	8 per 1,000	9 more per 1,000 (5 fewer to 81 more)	MID (precision) = RR 0.8-1.25.
Mortality at ≥3 months	198 (2 RCTs) follow-up: mean 3 months	⊕○○○ Very low _{b,c}	RR 0.87 (0.38 to 2.00)	108 per 1,000	14 fewer per 1,000 (67 fewer to 108 more)	MID (precision) = RR 0.8-1.25.
Person/participant generic health-related quality of life (EQ-5D, -0.11-1, higher values are better, change score) at ≥3 months	162 (1 RCT) follow-up: 12 weeks	⊕○○○ Very low _{b,c}	-	The mean person/participant generic health-related quality of life at ≥3 months was -0.04	MD 0.12 higher (0 to 0.24 higher)	MID = 0.03 (EQ-5D established value)
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final values) at <3 months	172 (3 RCTs) follow-up: mean 2 weeks	⊕⊕○○ Low _a	-	The mean occurrence of aspiration at <3 months was 2.86	MD 0.2 lower (0.72 lower to 0.31 higher)	MID = 0.75 (0.5 x median baseline SD)
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at ≥3 months	139 (2 RCTs) follow-up: mean 3 months	⊕○○○ Very low _{b,c,d}	-	The mean occurrence of aspiration at ≥3 months was 3.65	MD 0.36 lower (2.18 lower to 1.46 higher)	MID = 1 (0.5 x median baseline SD)
Dysphagia present/return to normal diet (dysphagia present) at <3 months	154 (2 RCTs) follow-up: mean 2 weeks	⊕○○○ Very low _{a,b,d}	RR 0.76 (0.30 to 1.94)	765 per 1,000	184 fewer per 1,000 (535 fewer to 719 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet	30 (1 RCT)	⊕○○○ Very low _{b,e}	RR 1.50 (0.65	400 per 1,000	200 more per 1,000 (140 fewer	MID (precision)

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with pharyngeal electrical stimulation (PES)	
(return to normal diet) at <3 months	follow-up: 3 days		to 3.47)		to 988 more)	= RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at ≥3 months	126 (1 RCT) follow-up: 12 weeks	⊕○○○ Very low _{b,c}	RR 0.87 (0.64 to 1.20)	589 per 1,000	77 fewer per 1,000 (212 fewer to 118 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal diet) at ≥3 months	28 (1 RCT) follow-up: 3 months	⊕⊕○○ Low _b	RR 2.00 (0.78 to 5.14)	286 per 1,000	286 more per 1,000 (63 fewer to 1,183 more)	MID (precision) = RR 0.8-1.25.
Discharge to residential service at ≥3 months	162 (1 RCT) follow-up: 12 weeks	⊕○○○ Very low _{b,c}	RR 0.96 (0.74 to 1.25)	587 per 1,000	23 fewer per 1,000 (153 fewer to 147 more)	MID (precision) = RR 0.8-1.25.
Length of hospital stay (hours, lower values are better, final values) at <3 months	30 (1 RCT) follow-up: 12 weeks	⊕⊕○○ Low _b	-	The mean length of hospital stay was 1017 hours	MD 11 hours higher (343.25 lower to 365.25 higher)	MID = 247 (0.5 x median control group SD)
Length of hospital stay (days, lower values are better, final values) at <3 months	218 (3 RCTs) follow-up: mean 9 weeks	⊕⊕○○ Low _a	-	The mean length of hospital stay was 50.0 days	MD 3.09 days lower (9.39 lower to 3.2 higher)	MID = 13.1 (0.5 x median control group SD)
Swallowing ability (Functional Oral Intake Scale, Dysphagia Severity Rating Scale [different scale ranges], higher values are better, final values) at <3 months	241 (3 RCTs) follow-up: mean 1 weeks	⊕⊕○○ Low _a	-	-	SMD 0.05 SD lower (0.3 lower to 0.21 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Dysphagia Severity Rating	197 (2 RCTs) follow-up:	⊕⊕○○ Low _c	-	The mean swallowing	MD 0.3 higher (1.08 lower to	MID = 1.9 (0.5 x median

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with pharyngeal electrical stimulation (PES)	
Scale, 0-12, lower values are better, final values) at ≥3 months	mean 3 months			ability at ≥3 months was 4.2	1.68 higher)	baseline SD)
Nutrition (albumin, g/L, higher values are better, final value) at <3 months	162 (1 RCT) follow-up: 2 weeks	⊕⊕○○ Low _c	-	The mean nutrition at <3 months was 36.6	MD 0.4 higher (1.22 lower to 2.02 higher)	MID = 2.9 (0.5 x median baseline SD)
Nutrition (albumin, g/L, higher values are better, final value) at ≥3 months	162 (1 RCT) follow-up: 12 weeks	⊕⊕○○ Low _c	-	The mean nutrition at ≥3 months was 41.1	MD 0.6 higher (1.07 lower to 2.27 higher)	MID = 2.9 (0.5 x median baseline SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias due to deviations from the intended interventions and bias due to missing outcome data)

d. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

e. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias in selection of reported result)

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2 **1.1.6.1.5. Physical stimulation**

3 **Table 20: Clinical evidence summary: physical stimulation compared to placebo/sham therapy**

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Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with physical stimulation	
Dysphagia present/return to normal diet (return to normal diet) at <3 months	120 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	RR 1.00 (0.06 to 15.62)	17 per 1,000	0 fewer per 1,000 (16 fewer to 244 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with physical stimulation	
Swallowing ability (standardised swallowing assessment, scale range unclear, lower values are better, change score) at <3 months	120 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	-	The mean swallowing ability at <3 months was -5.02	MD 1.43 lower (2.32 lower to 0.54 lower)	MID = 1.21 (0.5 x median baseline SD)
<p>a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)</p> <p>b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p>						

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2 **Table 21: Clinical evidence summary: physical stimulation compared to usual care**

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with physical stimulation	
Occurrence of chest infections at <3 months	156 (2 RCTs) follow-up: mean 3 weeks	⊕○○○ Very low _{a,b}	RR 0.31 (0.11 to 0.90)	167 per 1,000	115 fewer per 1,000 (148 fewer to 17 fewer)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration at <3 months	96 (1 RCT) follow-up: 2 weeks	⊕○○○ Very low _{a,b,c}	RR 0.35 (0.15 to 0.82)	354 per 1,000	230 fewer per 1,000 (301 fewer to 64 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	96 (1 RCTs) follow-up: 3 weeks	⊕⊕○○ Low _a	RR 0.51 (0.35 to 0.75)	771 per 1,000	378 fewer per 1,000 (501 fewer to 193 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal diet) at <3 months	60 (1 RCT) follow-up: 3 weeks	⊕⊕⊕○ Moderate _d	RR 3.00 (1.71 to 5.25)	300 per 1,000	600 more per 1,000 (213 more to 1,275 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with physical stimulation	
Swallowing ability (Eat-10, 0-40, lower values are better, change score) at <3 months	60 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _{b,d}	-	The mean swallowing ability at <3 months was -9.4	MD 2.37 lower (3.7 lower to 1.04 lower)	MID = 1.38 (0.5 x median control group SD)
Nutrition (albumin, units unclear, higher values are better, final value) at <3 months	96 (1 RCT) follow-up: 2 weeks	⊕⊕○○ Low _a	-	The mean nutrition at <3 months was 30.37	MD 5.7 higher (4.41 higher to 6.99 higher)	MID = 1.3 (0.5 x median baseline SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)
d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)

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2 **1.1.6.1.6. Transcranial direct current stimulation (TDCS)**

3 **Table 22: Clinical evidence summary: transcranial direct current stimulation (TDCS)**
4 **compared to placebo/sham therapy**

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with transcranial direct current stimulation (TDCS)	
Mortality at <3 months	42 (1 RCT) follow-up: 1 months	⊕⊕○○ Low _a	RR 1.11 (0.11 to 11.26)	67 per 1,000	7 more per 1,000 (59 fewer to 684 more)	MID (precision) = RR 0.8-1.25.
Occurrence of chest infection at <3 months	59 (1 RCT) follow-up: 3 weeks	⊕○○○ Very low _{a,b}	RR 0.71 (0.40 to 1.26)	533 per 1,000	155 fewer per 1,000 (320 fewer to 139 more)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration (penetration aspiration)	72 (2 RCTs) follow-up:	⊕○○○ Very low _{a,c}	-	The mean occurrence of aspiration at	MD 0.39 lower (1.65 lower)	MID = 0.7 (0.5 x median

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with transcranial direct current stimulation (TDCS)	
scale, 1-8, lower values are better, change score) at <3 months	mean 3 weeks			<3 months was -0.75	to 0.88 higher)	baseline SD)
Occurrence of aspiration at <3 months	40 (1 RCT) follow-up: 2 weeks	⊕○○○ Very low _{d,e}	RR 0.35 (0.18 to 0.71)	850 per 1,000	553 fewer per 1,000 (697 fewer to 247 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (dysphagia present) at <3 months	44 (1 RCT) follow-up: 1 months	⊕⊕⊕○ Moderate _a	RR 0.40 (0.19 to 0.84)	682 per 1,000	409 fewer per 1,000 (552 fewer to 109 fewer)	MID (precision) = RR 0.8-1.25.
Length of hospital stay (days, lower values are better, final value) at <3 months	59 (1 RCT) follow-up: 3 weeks	⊕⊕○○ Low _{a,b}	-	The mean length of hospital stay was 13.4 days	MD 2.8 days higher (0.28 lower to 5.88 higher)	MID = 2.6 (0.5 x median baseline SD)
Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months	167 (5 RCTs) follow-up: mean 3 weeks	⊕⊕○○ Low _{a,f}	-	-	SMD 0.51 SD higher (0.19 higher to 0.82 higher)	MID = 0.5 SD (SMD)
Swallowing ability (Functional Oral Intake Scale, Dysphagia	108 (4 RCTs) follow-up: mean 5 weeks	⊕○○○ Very low _{a,c,f}	-	-	SMD 0.34 SD higher (0.66 lower to 1.35 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with transcranial direct current stimulation (TDCS)	
Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, final values) at <3 months						
Swallowing ability (Functional dysphagia scale, 0-100, lower values are better, change score) at ≥3 months	16 (1 RCT) follow-up: 3 months	⊕⊕⊕○ Moderate ^b	-	The mean swallowing ability at ≥3 months was 6.3	MD 22.83 lower (32.35 lower to 13.31 lower)	MID = 3.4 (0.5 x median control group SD)
<p>a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>b. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)</p> <p>c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis</p> <p>d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)</p> <p>e. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specifies it should be reported in a continuous form)</p> <p>f. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process and bias in measurement of the outcome)</p>						

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Table 23: Clinical evidence summary: transcranial direct current stimulation (TDCS) compared to usual care

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with transcranial direct current stimulation (TDCS)	
Dysphagia present/return to normal diet (dysphagia present) at <3 months	64 (1 RCT) follow-up: 6 days	⊕○○○ Very low _{a,b}	RR 1.07 (0.91 to 1.26)	875 per 1,000	61 more per 1,000 (79 fewer to 228 more)	MID (precision) = RR 0.8-1.25.
Swallowing ability (functional oral intake scale, 1-7, higher values are better, final value) at <3 months	64 (1 RCT) follow-up: 6 days	⊕○○○ Very low _{a,b}	-	The mean swallowing ability at <3 months was 3.6	MD 0.9 higher (0.09 higher to 1.71 higher)	MID = 0.6 (0.5 x median baseline SD)
Swallowing ability (functional dysphagia scale, 0-100, lower values are better, final value) at ≥3 months	40 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{b,c}	-	The mean swallowing ability at ≥3 months was 56.8	MD 10.6 lower (20.86 lower to 0.34 lower)	MID = 6.9 (0.5 x median control group SD)
Nutrition (albumin, units unclear, higher values are better, final value) at ≥3 months	40 (1 RCT) follow-up: 3 months	⊕⊕○○ Low _c	-	The mean nutrition at ≥3 months was 44.8	MD 8.1 higher (6.73 higher to 9.47 higher)	MID = 0.45 (0.5 x median control group SD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data and bias in selection of the reported result)

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

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1 **1.1.6.1.7. Transcranial magnetic stimulation (TMS)**

2 **Table 24: Clinical evidence summary: transcranial magnetic stimulation (TMS)**
3 **compared to placebo/sham therapy**

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with transcranial magnetic stimulation (TMS)	
Mortality at <3 months	99 (3 RCTs) follow-up: mean 2 weeks	⊕○○○ Very low _{a,c}	RD -0.06 (-0.15 to 0.03)	60 per 1,000	60 fewer per 1,000 (150 fewer to 30 more) ^b	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies. OIS determined power for the sample size = 0.70 (0.8-0.9 = serious, <0.8 = very serious)
Occurrence of chest infections at <3 months	49 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{d,e}	RD 0.00 (-0.08 to 0.08)	0 per 1,000	0 fewer per 1,000 (80 fewer to 80 more) ^b	Sample size used to determine precision: 75-150 = serious imprecision, <75 = very serious imprecision
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at <3 months	95 (3 RCTs) follow-up: mean 3 weeks	⊕○○○ Very low _{c,d}	-	The mean occurrence of aspiration at <3 months was 4.0	MD 0.97 lower (1.67 lower to 0.28 lower)	MID = 1.1 (0.5 x median baseline SD)
Dysphagia present/return to normal diet (removal of feeding tube) at <3 months	49 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{c,d}	RR 1.24 (0.65 to 2.37)	385 per 1,000	92 more per 1,000 (135 fewer to 527 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with transcranial magnetic stimulation (TMS)	
Swallowing ability (dysphagia outcome and severity scale, dysphagia grade, videofluoroscopic dysphagia scale, swallowing activity and participation profile scores [different scale ranges], lower values are better, final values) at <3 months	134 (5 RCTs) follow-up: mean 4 weeks	⊕○○○ Very low _{c,f,g}	-	-	SMD 0.76 SD lower (1.98 lower to 0.45 higher)	MID = 0.5 SD (SMD)
Swallowing ability (standardised swallowing assessment, swallowing activity and participation scale [different scale ranges], lower values are better, final values) at ≥3 months	53 (2 RCTs) follow-up: mean 8 months	⊕○○○ Very low _{c,g,h}	-	-	SMD 1.35 SD lower (4.3 lower to 1.61 higher)	MID = 0.5 SD (SMD)

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

b. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)

e. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

f. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)

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Table 25: Clinical evidence summary: transcranial magnetic stimulation (TMS) compared to usual care

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with transcranial magnetic stimulation (TMS)	
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months	68 (2 RCTs) follow-up: mean 5 weeks	⊕○○○ Very low _{a,b}	-	The mean occurrence of aspiration at <3 months was 2.62	MD 0.65 lower (1.35 lower to 0.05 higher)	MID = 0.7 (0.5 x median baseline SD)
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months	28 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{b,c}	-	The mean occurrence of aspiration at ≥3 months was 3.62	MD 0.02 lower (2.29 lower to 2.25 higher)	MID = 0.7 (0.5 x median baseline SD)
Dysphagia present/return to normal diet (dysphagia present) at <3 months	61 (1 RCT) follow-up: 2 weeks	⊕○○○ Very low _{b,d}	RR 0.50 (0.29 to 0.85)	690 per 1,000	345 fewer per 1,000 (490 fewer to 103 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal diet) at <3 months	30 (1 RCT) follow-up: 1 months	⊕○○○ Very low _{b,c}	RR 1.00 (0.56 to 1.79)	600 per 1,000	0 fewer per 1,000 (264 fewer to 474 more)	MID (precision) = RR 0.8-1.25.
Dysphagia present/return to normal diet (return to normal diet) at ≥3 months	30 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{b,c}	RR 1.11 (0.64 to 1.92)	600 per 1,000	66 more per 1,000 (216 fewer to 552 more)	MID (precision) = RR 0.8-1.25.
Swallowing ability (water swallow test, swallowing ability and function evaluation [different scale ranges], higher values are better, final	89 (2 RCTs) follow-up: mean 4 weeks	⊕○○○ Very low _{b,e,f}	-	-	SMD 0.37 SD higher (0.26 lower to 1 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with transcranial magnetic stimulation (TMS)	
values) at <3 months						
Swallowing ability (functional dysphagia scale, 0-100, lower values are better, change score) at <3 months	40 (1 RCT) follow-up: 4 weeks	⊕○○○ Very low _{a,b}	-	The mean swallowing ability at <3 months was -12.6	MD 4.6 lower (10.47 lower to 1.27 higher)	MID = 6.4 (0.5 x median baseline SD)
Swallowing ability (swallowing ability and functional evaluation, scale range unclear, higher values are better, final value) at ≥3 months	28 (1 RCT) follow-up: 3 months	⊕○○○ Very low _{b,c}	-	The mean swallowing ability at >3 months was 7.1	MD 0.39 higher (1.03 lower to 1.81 higher)	MID = 1.1 (0.5 x median baseline SD)
<p>a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)</p> <p>b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>c. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)</p> <p>d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)</p> <p>e. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data and bias in measurement of the outcome)</p> <p>f. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis</p>						

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1 **1.1.6.2. Interventions for oesophageal dysphagia**

2 **Table 26: Clinical evidence summary: drug interventions (domperidone) compared to**
3 **placebo/sham therapy**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with placebo/sham therapy	Risk difference with domperidone	
Mortality at <3 months	150 (1 RCT) follow-up: 11 days	⊕○○○ Very low _{a,b}	RR 0.97 (0.14 to 6.73)	27 per 1,000	1 fewer per 1,000 (23 fewer to 155 more)	MID (precision) = RR 0.8-1.25.
Occurrence of aspiration at <3 months	150 (1 RCT) follow-up: 11 days	⊕⊕⊕○ Moderate _a	RR 0.22 (0.11 to 0.42)	541 per 1,000	422 fewer per 1,000 (481 fewer to 314 fewer)	MID (precision) = RR 0.8-1.25.
Dysphagia present/Return to normal diet (presence of nasogastric tube) at <3 months	150 (1 RCT) follow-up: 11 days	⊕○○○ Very low _{b,c}	RR 1.17 (0.37 to 3.66)	68 per 1,000	11 more per 1,000 (43 fewer to 180 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment because of population indirectness (as it was unclear the proportion of people who had oesophageal dysphagia)
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c. Downgraded by 2 increments because of population indirectness (as it was unclear the proportion of people who had oesophageal dysphagia) and outcome indirectness (due to the measure being a surrogate measure for the protocol outcome)

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5 **1.1.6.3. Adaptations to support people with dysphagia**

6

7 **Table 27: Clinical evidence summary: modified diet compared to usual care**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - modified diet	
Mortality at <3 months	115 (1 RCT) follow-up: 8 weeks	⊕○○○ Very low _{a,b}	RD 0.00 (-0.04 to 0.04)	0 per 1,000	0 fewer per 1,000 (40 fewer to 40 more) _c	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - modified diet	
Occurrence of chest infections at <3 months	171 (2 RCTs) follow-up: mean 7 weeks	⊕⊕○○ Low _d	RR 2.67 (1.26 to 5.69)	106 per 1,000	177 more per 1,000 (28 more to 497 more)	MID (precision) = RR 0.8-1.25.
Nutrition (calorie-nitrogen deficit) at <3 months	115 (1 RCT) follow-up: 8 weeks	⊕○○○ Very low _{a,e}	RR 1.23 (0.25 to 6.07)	53 per 1,000	12 more per 1,000 (39 fewer to 267 more)	MID (precision) = RR 0.8-1.25.
Hydration (dehydration) at <3 months	115 (1 RCT) follow-up: 8 weeks	⊕○○○ Very low _{a,e}	RR 0.16 (0.02 to 1.53)	79 per 1,000	66 fewer per 1,000 (77 fewer to 42 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

b. Downgraded by 1 to 2 increments for imprecision due to zero events and small sample size

c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

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2 **Table 28: Clinical evidence summary: free water protocol compared to usual care**

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - free water protocol	
Occurrence of chest infection at <3 months	34 (2 RCTs) follow-up: mean 26 days	⊕○○○ Very low _{a,b}	RD 0.00 (-0.16 to 0.16)	0 per 1,000	0 fewer per 1,000 (160 fewer to 160 more) _c	MID (precision) = RR 0.8-1.25.
Hydration (dehydration) at <3 months	20 (1 RCT) follow-up: 30 days	⊕○○○ Very low _{b,d,e}	RD 0.00 (-0.17 to 0.17)	0 per 1,000	0 fewer per 1,000 (170 fewer to 170 more) _c	MID (precision) = RR 0.8-1.25.

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - free water protocol	
Hydration (fluid intake, mL, higher values are better, final value) at <3 months	14 (1 RCT) follow-up: 21 days	⊕○○○ Very low _{b,f}	-	The mean hydration at <3 months was 1103 mL	MD 0 mL (247.5 lower to 247.5 higher)	MID = 123.5mL (0.5 x control group SD)
<p>a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process and bias due to deviations from the intended interventions)</p> <p>b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study</p> <p>d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)</p> <p>e. Downgraded by 1 or 2 increments because of outcome indirectness (as protocol outcome that is stated to be a continuous outcome is reported in the study as a dichotomous outcome)</p> <p>f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)</p>						

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2 **Table 29: Clinical evidence summary: combinations (modified diet, positioning**
3 **modifying bolus volume/mode of delivery) compared to usual care**

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - combinations (modified diet, positioning, modifying bolus volume/mode of delivery)	
Mortality at ≥3 months	204 (1 RCT) follow-up: 6 months	⊕⊕○○ Low _a	RR 0.87 (0.51 to 1.48)	225 per 1,000	29 fewer per 1,000 (110 fewer to 108 more)	MID (precision) = RR 0.8-1.25.
Occurrence of chest infections at ≥3 months	204 (1 RCT)	⊕⊕○○ Low _{a,b}	RR 0.54	471 per 1,000	216 fewer per 1,000	MID (precision) = RR 0.8-1.25.

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with usual care	Risk difference with Adaptations for oral feeding - combinations (modified diet, positioning, modifying bolus volume/mod e of delivery)	
	follow-up: 6 months		(0.37 to 0.80)		(296 fewer to 94 fewer)	
Dysphagia present/return to normal diet (return to normal diet) at ≥3 months	204 (1 RCT) follow-up: 6 months	⊕⊕○○ Low _{a,b}	RR 1.14 (0.91 to 1.43)	559 per 1,000	78 more per 1,000 (50 fewer to 240 more)	MID (precision) = RR 0.8-1.25.
Discharge to residential service at ≥3 months	204 (1 RCT) follow-up: 6 months	⊕⊕○○ Low _{a,b}	RR 0.65 (0.38 to 1.13)	255 per 1,000	89 fewer per 1,000 (158 fewer to 33 more)	MID (precision) = RR 0.8-1.25.
Length of hospital stay at ≥3 months	204 (1 RCT) follow-up: 6 months	⊕⊕○○ Low _{a,b}	-	The mean length of hospital stay was 21.4 days	MD 2.2 days lower (5.73 lower to 1.33 higher)	MID = 6.2 (0.5 x median control group SD)
<p>a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>b. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)</p>						

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See Appendix F for full GRADE tables.

1 **1.1.7. Economic evidence**

2 **1.1.7.1. Included studies**

3 Two health economic studies with relevant comparisons were included in this review. The
4 first study compared combination therapy (modified diet, positioning, modifying bolus
5 volume/mode of delivery) compared to usual care.⁴⁸ This study was also included in the
6 previous guideline (GC162).⁸² The second study³⁴ compared thickened fluids to routine
7 clinical practice.

8
9 These studies are summarised in the health economic evidence profiles below (Table 30 and
10 Table 31) and the health economic evidence table in Appendix H.

11
12 No health economic studies were included any other forms of behaviour interventions or
13 adaptations for oral feeding and no economic evidence was found for acupuncture/
14 electroacupuncture, electrotherapy and drug interventions.

15 **1.1.7.2. Excluded studies**

16 No relevant health economic studies were excluded due to assessment of limited
17 applicability or methodological limitations.

18 See also the health economic study selection flow chart in Appendix G.

1 **1.1.8. Summary of included economic evidence**2 **Table 30: Health economic evidence profile: Adaptations to oral feeding - combination therapy (modified diet, positioning, modifying**
3 **bolus volume/mode of delivery) versus usual care**

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Marsh 2010 ⁴⁸ (UK)	Partially applicable ^(a)	Potentially serious limitations ^(b)	<ul style="list-style-type: none"> Decision tree model based on treatment effect from an RCT included in the clinical review (Carnaby et al. 2006¹¹). Cost-consequence analysis (health outcomes included reduction in chest infections) Population: Patients with stroke within the previous 7 days with a clinical diagnosis of swallowing difficulty and no history of swallowing treatment or surgery of the head or neck. Comparators: <ol style="list-style-type: none"> Usual care: 4.8 sessions equivalent to 1.28 hours for one month. Intervention delivered by an NHS hospital day nurse (non-specialised staff). Standard 'low intensity' swallowing therapy: 7.8 sessions equivalent to 3.22 hours. Intervention delivered by a Band 7 hospital SLT. <p>Time horizon: 1 year</p>	2 vs 1: Saves £220 ^(c)	<p>From clinical review (2 - 1); ^(d) Occurrence of chest infection ≥ 3 months (RR): 0.54 (95% CI: 0.37, 0.80)</p> <p>Return to normal diet ≥ 3 months (RR): 1.14 (95% CI: 0.91, 1.43)</p> <p>Discharge to residential service ≥ 3 months (RR): ^(e) 0.65 (95% CI: 0.38, 1.13)</p> <p>Length of hospital stay ≥ 3 months (MD): -2.2 (95% CI: -5.73, 1.33)</p>	Results suggest that low intensity swallowing therapy dominates usual care (lower costs and improved clinical outcomes), with an infection risk ratio of 0.54, which resulted in cost-savings of £381 per patient for the treatment of chest infections and total cost-savings of £220 per patient.	<p>Threshold analysis: standard low intensity swallowing therapy is cost saving, as long as probability of developing a chest infection with standard therapy is below 38%.</p> <p>The cost of chest infection requiring hospital admission was varied between £1,800 and £5,100. Standard low intensity swallowing therapy is cost saving, as long as the cost of chest infection requiring hospital admission is above £2,000.</p>

4 Abbreviations: EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); MD= mean difference; QALY= quality-adjusted life
5 years; RCT= randomised controlled trial; RR= risk ratio; SLT= Speech and language therapist.

6 (a) QALYs not reported as EQ5D not collected. 2009 UK resource use and costs may not reflect current UK NHS context.

- 1 (b) Primary clinical data inputs based on a single RCT. The probability of a chest infection requiring either hospital or community care was based on descriptive data not specific to
 2 dysphagia patients. Costs of treating a chest infection in a hospital or community setting were taken from Guest et al 1997 and updated to 2009 prices. Probabilistic sensitivity
 3 analysis not performed.
 4 (c) 2009 UK pounds. Cost components incorporated: Costs of staff time for the initial strategy, future costs of treating chest infections in hospital and community. Standard low
 5 intensity swallowing therapy is more costly initially when compared to usual care (£219 versus £58) but it is associated with lower rates of chest infections and lower cost of
 6 treating chest infections (£651 versus £871).
 7 (d) Between-group differences in clinical outcomes taken from figures 117-120 in the guideline clinical review.
 8 (e) Lower values are better. Study aim was to reduce the rate of institutionalisation following stroke (discharge to residential service).

9 **Table 31: Adaptations for oral feeding - food consistency modification versus routine clinical practice**

Study	Applicability	Limitations	Other comments	Incremental cost	Incr effects	Cost effectiveness	Uncertainty
Pelczarska 2020 ³⁴ (Poland)	Partially applicable ^(a)	Potentially serious limitations ^(b)	<ul style="list-style-type: none"> • Probabilistic (dynamic) decision analytic model • Cost-utility analysis (QALYs) • Population: Adults who have had a stroke with the aspiration level 10–14 on GUSS scale (patients who tolerate semisolid intake but not fluids). • Comparators: <ol style="list-style-type: none"> 1. Routine clinical practice^(d) 2. Xanthan gum-based consistency modification therapy (Nutilis Clear®) plus routine clinical practice for an average of approximately 5 weeks. Time horizon: 1 year	2 – 1: £163 ^(c)	2 – 1: 0.02 QALYs	2 – 1: £8,076 per QALY gained.	Results were robust to changes in costs, transition probabilities utility values and (lifetime) time horizon. The only scenario that produced an ICER >£20,000 per QALY gained was when the model assumed that the effectiveness of Nutilis Clear® stems only from the patients' years of life gained as opposed to there being a quality-of-life benefit (ICER of £29,795).

10 Abbreviations: EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); GUSS= Gugging Swallowing Screen; ICER=
 11 incremental cost-effectiveness ratio; QALY= quality-adjusted life years; RCT= randomised controlled trial

12 (a) Polish context and may not reflect current UK NHS context. Utilities for a few health states were based on non-stroke population with dysphagia. Population tariff for EQ-5D not
 13 reported.

14 (b) Lack references for unit costs and resource use estimates creates uncertainty for the results presented for UK context. Study only assesses one type of oral feeding
 15 intervention. Clinical effectiveness (reduced aspiration) data not based on stroke-specific population. Study was funded by manufacturer of intervention. Cost of Nutilis Clear® is
 16 lower in the UK.

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- (c) *Polish zloty (PLN) converted to UK pounds. Converted using 2019 purchasing power parities.⁹⁰ Year of costs/resource use estimates not reported so assumed to be 2019 based on year of study write-up. Cost components included direct costs of dysphagia treatment (including Nutilis Clear® costs), aspiration pneumonia treatment, and monitoring.*
- (d) *Including the use of behavioural compensations and manoeuvres (posture, sensory enhancement) as well as rehabilitation exercises aiming to alter swallowing physiology through strength and skill exercises.*

1

2 1.1.9. Economic model

3 This area was not prioritised for new cost-effectiveness analysis.

4 1.1.10. Unit costs

5 Relevant unit costs are provided below to aid consideration of cost effectiveness.

6 The tables below include unit costs relevant to the interventions being considered in this
7 review. Table 32 presents staff costs related to people who may deliver oral feeding
8 interventions. Studies included in the clinical review reported varied resource use (see Table
9 1 for details). This was expected given the inclusion of several distinct interventions and
10 combinations of treatments provided. The majority of clinical studies took place in an
11 inpatient setting apart from 5 studies which assessed outpatients and one study (Feng
12 2012²⁹) which considered inpatients and outpatients. The committee highlighted that physical
13 stimulation, behavioural interventions and adaptive oral-feeding interventions primarily
14 require staff time and are considered to be the most reflective of current practice, with a few
15 exceptions outlined in the sections 1.1.10.5 below.

16 **Table 32: Unit costs of health care professionals who may be involved in delivering**
17 **oral feeding interventions**

Resource	Cost per working hour ^(a)		Source
	Hospital	Community	
Band 5 Speech and language therapist (SLT)	£40	£42	PSSRU 2021 ⁴⁷
Band 6 SLT specialist	£53	£55	
Band 7 SLT (advanced)	£64	£67	
Nurse (Band 6/7)	£58/£69	£54/£64	
Specialty Registrar (48-hour work week, hospital only)	£52		

18 (a) Note: Costs per working hour include salary, salary oncosts, overheads (management and other non-care
19 staff costs including administration and estates staff), capital overheads and qualification costs

20 1.1.10.1. Electrotherapies (NMES, PES, tDCS, TMS, FES)

21 The cost of electrotherapies relates primarily to the staff time to administer it and will depend
22 on how long sessions are and how often they are given, and duration of treatment. There are
23 also equipment costs.

24 Neuromuscular Electrical Stimulation (NMES) was the most frequently evaluated of out the
25 electrotherapy interventions, which varied between studies in terms of frequency and
26 duration. Sessions ranged from 20-60 minutes and were typically delivered 5 days per week
27 for 2-6 weeks. Previous economic evaluations of electrotherapy in other clinical areas
28 (NMES, FES) have not included the costs of equipment used by rehabilitation therapists in
29 the analysis as the per-use costs were expected to be small (MacPherson 2017⁷² Woods
30 2017¹²⁶). While one study⁶⁶ assessing NMES mentioned the use a dual channel TENS
31 machine, which costs £31.10,⁸⁸ a few other studies reported using the VitalStim®. As this is a
32 more costly device a breakdown of the costs is provided below. Note, the cost does not
33 include training costs for health care professionals as these could not be identified. An
34 alternative device is Ampcare ESP, however costs for this device were not provided as none
35 of the clinical evidence used this device and UK costs could not be identified.

1 **Table 33: Breakdown of cost of VitalStim NMES intervention**

Resource	Unit cost	Resource use	Total cost	Source
Band 6/7 Speech and language therapist (SLT)	Band 6: £53 Band 7: £64	5-20hrs ^(a)	Band 6: £265-£1,060 Band 7: £320-£1,280	Cost per working hour ^(b) (PSSRU 2021) ⁴⁷
VitalStim® Electrodes	£17.50	20-40 units ^(a)	£350-£700	£210 pack 12. ¹⁵ 2 electrodes per session.
VitalStim® Plus Electrotherapy System	£0.39	10-20 sessions ^(a)	£3.94-£7.88	Annuitised cost per session. £2,394 per machine. ¹⁵ (c)
Total cost lower range (5 hours, 10 sessions) with band 6/7 SLT			Band 6: £618.94 Band 7: £673.94	Lim 2014{, #4201} and Meng 2018{, #4217}
Total cost upper range (20 hours, 20 sessions) with band 6/7 SLT			Band 6: £1,767.88 Band 7: £1,987.88	Xia 2011{, #4279}

- 2 a) Seven RCTs reported used of VitalStim in clinical review (Carnaby 2020,{, #4122} Jing 2016,{, #4552} Liang
3 2021,{, #4547} Lim 2014,{, #4201} Meng 2018,{, #4217} Tarihci Cakmak 2022,{, #5177} Xia 2011{, #4279}).
4 Frequency of sessions and session duration ranged from 30min, 5 days per week for 2 weeks (total 5hrs, 10
5 sessions) (Lim 2015 and Mend 2018) to 1hr, 5 days per week for 4 weeks (total 20hrs, 20 sessions) (Xia
6 2011).
7 b) Note: Costs per working hour include salary, salary oncosts, overheads (management and other non-care
8 staff costs including administration and estates staff), capital overheads and qualification costs
9 c) Cost per session calculated by dividing upfront cost by estimated sessions per year and annuitised device
10 lifetime. Device lifetime 5 years. Annuitisation factor of 3.5% applied to the device lifetime. Estimated use per
11 year 1,300 sessions (5 per day, 5 days per week, 52 weeks a year).

12 A 2010 NHS Purchasing and Supply Agency report on Functional electrical stimulation (FES)
13 for dropped foot of central neurological origin included an initial assessment appointment
14 costing £140 and on a clinic model in which the costs of the FES device are incorporated in
15 the ongoing clinical charges.¹¹² Each ongoing clinical appointment was estimated at £300.
16 FES can also be delivered at home; however, availability varies across current practice.

17
18 All included studies that assessed pharyngeal electrical stimulation (PES) reported 3 days of
19 10-minute sessions. The Phagenyx® Neurostimulation system was referenced as the
20 specific device used in these studies, however, pricing information is currently unavailable.¹⁰⁹
21 Committee discussion has suggested that PES is a high-cost intervention, with the cost for
22 the base unit estimated to be approximately £10,000, with another £1,000 required per
23 multisession use of the Phagenyx® catheter.

24 There was more variation for studies that assessed transcranial direct current stimulation
25 (tDCS), as sessions typically lasted 20 minutes but ranged from 10-30 minutes and were
26 provided 3-6 times per week for 2-8 weeks. The price of a tDCS device varies from £7,000 to
27 £13,000 (incl. tax) (2018 prices based on €8,000 to €14,000 reported in Sauvaget, 2018¹⁰²),
28 which covers the cap, electrodes, ear clips, cables, and an EEG add-on feature.

29
30 Study participants who received transcranial magnetic stimulation (TMS) were typically given
31 daily sessions lasting 10-20 minutes for 5 days per week, with the total intervention lasting 2
32 weeks. TMS would incur additional resource use as it is not currently used in UK clinical
33 practice. This would include device costs, which have been previously reported to be £431²⁷
34 (€503, converted using 2015 purchasing power parities⁹⁰).
35

1.1.10.2. Acupuncture and electroacupuncture

The cost of acupuncture relates primarily to the staff time to administer it and will depend on how long sessions are and how often they are given, and duration of treatment. In the clinical review, the frequency and duration for delivering acupuncture and electroacupuncture varied across studies. Acupuncture sessions typically lasted 30 minutes and were given 6 days per week for 4-8 weeks.

Equipment costs for acupuncture relate to the needles used. A previous economic model developed for the Chronic Pain NICE guideline (NG193)⁸³ used a cost per needle of £0.06. A large acupuncture individual patient meta-analysis in chronic pain reported the number of needles across studies, and the most frequent range was between 10 and 14.¹¹⁹

Two studies included in the clinical review (Su 2011¹⁰⁸ and Han 2004³⁵) provided acupuncture with electroacupuncture. Example electroacupuncture equipment costs (shown in Table 34) **Error! Reference source not found.** were taken from the analysis conducted as part of the osteoarthritis guideline update⁸⁴. These devices were the ES-160 (included as it was used in two of the four clinical studies in the osteoarthritis review of electroacupuncture) and AS-super 4, which is a popular alternative in clinical practice. The analysis assumed that both devices have a lifespan of 5 years. Other costs associated with electrotherapy include batteries, needles, disinfectant swabs, and surgeons' gloves.

Table 34: Example equipment costs for electroacupuncture^(a)

Device details	Device cost	Cost of crocodile clips	Cost of lead cables
ES-160	£395 ³⁹	£24 ^{42 (b)}	£41.10 ^{38 (b)}
AS-super 4	£240 ³⁷	£23 ^{36 (c)}	NA

(a) Taken from online sources, excluding VAT.

(b) Cost of 10 units based on the assumption that 10 needles are utilised per session.

(c) Clips and cables sold together. Costs were converted using 2020/21 purchasing power parities.⁹⁰

1.1.10.3. Drug interventions

Table 35 describes the cost of drugs reported in the clinical studies. Note that metoclopramide is the most expensive, but this seemed to be indicated for a very specific population (people with acute stroke requiring enteral feeding support).¹²⁴

Table 35: Unit costs of drugs interventions (metoclopramide, domperidone, lisinopril and nifedipine)

Drug	Size	Cost/pack ^(a)	Cost per day
Metoclopramide hydrochloride 1 mg per 1 ml ^(b)	150	£15.50	£3.10
Domperidone (as Domperidone maleate) 10 mg tablets ^(c)	30	£0.73	£0.03
Lisinopril 2.5mg tablets ^(d)	28	£0.73	£0.03
Nifedipine 30mg modified-release tablets ^(e)	28	£6.85	£0.24

(a) Costs are based on the NHS Drug Tariff price from the BNF¹⁰ accessed 28/09/22

(b) Reported in Warusevitane 2015.¹²⁴ Participants received 10mg metoclopramide (colourless solution 10mL) 3 times a day via a nasogastric tube. Treatment was continued until nasogastric feeding was no longer necessary or for a maximum of 21 days. BNF drug cost is based on Metoclopramide 5mg/5ml oral solution sugar free (Rosemont Pharmaceuticals Ltd).

(c) Reported in Allami 2022.² Participants received domperidone 10mg once a day from the first day of hospitalisation until discharge. BNF drug cost is based on Domperidone 10mg tablets (A A H Pharmaceuticals Ltd)

(d) Reported in Lee 2015.⁶⁰ Participants received lisinopril 2.5 mg once daily at bedtime. A low dose regime was chosen as it was less likely to cause hypotension, electrolyte disturbances, and impair renal function. BNF drug cost is based on Lisinopril 2.5mg tablets (A A H Pharmaceuticals Ltd)

1 (e) Reported in Perez 1998.¹⁰⁰ Participants received slow release nifedipine 30 mg orally, to be taken daily for 4
2 weeks. BNF drug cost is based on Nidef 30mg modified-release tablets (Morningside Healthcare Ltd).
3

4 **1.1.10.4. Adaptations for oral feeding (diet modification, mode of delivery/bolus** 5 **volume, carbonation, positioning, free water protocol and swallow** 6 **strategies)**

7 Table 36 describes costs associated with diet modification interventions. One study
8 assessing a thermal tactile intervention (Wang 2019¹²³) also reported the use of food
9 thickener as part of the intervention. Adaptation interventions reported in the clinical review
10 are not expected to incur additional resource as they reflect current practice.

11 **Table 36: Unit costs of diet modifications**

Feed thickeners	Size	Cost/pack	Cost per day
Nutillis® Clear powder ^(a)	175g	£8.46	£1.84
Resource® ThickenUp® powder ^(b)	227g	£4.99	£0.24

12 (a) Reported in Pelczarska 2020³⁴ as part of economic evidence review. Model cohort participants was 37.96
13 based on weighted average of the share of each available product consistency (Garcia 2005³⁰, and the
14 average daily demand for fluids in post-stroke patients (National Stroke Foundation 2010.⁸⁶ BNF cost based
15 on Nutillis® Clear (Nutricia Ltd).

16 (b) Reported in Wang 2019¹²³ capsaicin concentration of 6g/150 mL (Not available in BNF). Nectar viscosity
17 was obtained by adding 3.5 g of thickener Resource ThickenUp to 100 mL of mineral water. Treatment was
18 administered to patients three times per day before each meal for 3 weeks. BNF cost based on Resource
19 ThickenUp powder (Nestle Health Science).

20 **1.1.10.5. Behavioural interventions**

21 The committee noted that behavioural interventions are currently provided in clinical practice.
22 Additional resource use for some of these interventions was identified, as one study that
23 assessed biofeedback (Nordio 2021¹⁸ utilised the ProComp5 Infiniti System, which retails for
24 £2,104 (\$3,150⁸). Expiratory muscle strength training (EMST) devices were significantly less
25 costly, as Moon 2017⁸⁰ reported the use of the EMST 150, which costs £37 ((\$54.99) Aspire
26 Products LLC., USA).⁴ Costs were converted using 2020/21 purchasing power parities.⁹⁰

27 **1.1.10.6. Physical stimulation (such as flavours, thermal or tactile)**

28 Three clinical studies were included that assessed physical stimulation interventions (Feng
29 2012,²⁹ Wang 2017¹²⁰ and Wang 2019¹²³), which outlined resource use requirements that
30 were either low-cost or equivalent to current practice. Many studies reported the use of
31 thermal or tactile stimulation as part of usual care or concomitant therapy.

32 **1.1.11. Economic considerations: trade-off between net clinical effects and** 33 **costs**

34 **1.1.12. Evidence statements**

35 **Effectiveness/Qualitative**

36 **Economic**

37 One cost-consequence analysis found that in post-stroke adults with swallowing difficulties,
38 low-intensity swallowing therapy dominates usual care (lower costs and improved clinical
39 outcomes), with an infection risk ratio of 0.54, which resulted in cost-savings of £381 for the
40 treatment of chest infections and total cost-savings of £220 per patient. This study was
41 assessed as partially applicable with potentially serious limitations.
42

1 One cost-utility analysis found that in post-stroke adults with swallowing difficulties, Xanthan
2 gum-based consistency modification therapy plus routine clinical practice was cost-effective
3 compared to routine clinical practice alone (ICER of £8,076 per QALY gain). This study was
4 assessed as partially applicable with potentially serious limitations.

5

6 **1.1.13. The committee's discussion and interpretation of the evidence**

7 **1.1.13.1. The outcomes that matter most**

8 The committee included the following outcomes: mortality, person/participant generic health-
9 related quality of life, carer generic health-related quality of life, occurrence of chest
10 infections, occurrence of aspiration, dysphagia present/return to normal diet, discharge to
11 residential service, length of hospital stay, readmission, swallowing ability, nutrition and
12 hydration. All outcomes were considered equally important for decision making and therefore
13 have all been rated as critical.

14 Mortality was considered of key importance due to the direct impact that swallowing
15 problems could have on the outcome. Person/participant health-related quality of life
16 outcomes were considered particularly important as holistic measures of the impact on the
17 person's quality of living. Occurrence of chest infections, aspiration, dysphagia presence,
18 swallowing ability, nutrition and hydration were thought as important for understanding the
19 effect of the intervention on swallowing and the direct consequences of this. Discharge to
20 residential service, length of hospital stay and readmission were thought of as important
21 outcomes to measure the consequences for the person's future following the intervention.

22 The committee chose to investigate these outcomes at less than 3 months and greater than
23 or equal to 3 months, as they considered that there could be a difference in the short term
24 and the long-term effects of the intervention that would likely be delineated by a 3-month time
25 period, rather than a 6-month time period used in the majority of reviews in this guideline.

26 The evidence for this question varied with some outcomes not being reported for any
27 comparison, while others were reported more extensively. No comparison reported carer
28 generic health-related quality of life or readmission. Reporting of person/participant generic
29 health-related quality of life, discharge to residential service, nutrition and hydration was
30 generally limited. The most widely reported outcomes were dysphagia present/return to
31 normal diet, swallowing ability and occurrence of aspiration.

32 **1.1.13.2. The quality of the evidence**

33 One systematic review and in total 82 randomised controlled trials were reviewed. These
34 reported a range of different comparisons:

35 The following interventions were compared:

- 36 • Interventions for people with OPD after stroke
 - 37 ○ Acupuncture/electroacupuncture compared to placebo and usual care
 - 38 ○ Behavioural interventions compared to placebo/sham therapy and usual care
 - 39 ○ Drug interventions (including metoclopramide, domperidone, lisinopril and nifedipine)
40 compared to placebo (The study comparing domperidone to placebo included a mixed
41 population of people with oropharyngeal and oesophageal dysphagia)
 - 42 ○ Neuromuscular electrical stimulation (NMES) compared to placebo/sham therapy and
43 usual care
 - 44 ○ Pharyngeal electrical stimulation (PES) compared to placebo/sham therapy
 - 45 ○ Physical stimulation compared to placebo/sham therapy and usual care

- 1 ○ Transcranial direct current stimulation (TDCS) compared to placebo/sham therapy and
2 usual care
- 3 ○ Transcranial magnetic stimulation (TMS) compared to placebo/sham therapy and usual
4 care
- 5 ● Interventions for people with oesophageal dysphagia after stroke
- 6 ○ Drug interventions (domperidone) compared to placebo/sham therapy (This study
7 includes a mixed population of people with oropharyngeal and oesophageal dysphagia)
- 8 ● Adaptations to support people with dysphagia after stroke
- 9 ○ Diet modification compared to usual care
- 10 ○ Free water protocol compared to usual care
- 11 ○ Combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
12 compared to usual care

13 There was limited evidence investigating the use of drug interventions, pharyngeal electrical
14 stimulation (PES) and physical stimulation compared to other interventions. There were no
15 studies comparing interventions to no treatment. There were no studies comparing
16 acupuncture/electroacupuncture and adaptations to placebo/sham therapy and drug
17 interventions and pharyngeal electrical stimulation to usual care.

18 Outcomes were generally of low or very low quality, with the majority being of very low
19 quality. This was mainly due to risk of bias and imprecision. Risk of bias was a problem in a
20 lot of studies and was mainly due to risk of bias arising from the randomisation process and
21 bias due to missing outcome data, though all reasons for downgrading outcomes for risk of
22 bias were present at least once during the analysis.

23 A moderate number of outcomes were downgraded due to imprecision. This was probably
24 due to the included studies being, in general, small and that there were few that could be
25 meta-analysed to improve the precision in the outcome. Where more studies were available,
26 more precision was seen.

27 Where meta-analysis was conducted, a minority of outcomes were downgraded for
28 inconsistency due to heterogeneity that could not be resolved by the agreed sensitivity and
29 subgroup analyses. Sensitivity and subgroup analyses often did not resolve the
30 heterogeneity either due to there being homogeneity in the subgroups present or there being
31 an insufficient number of studies included in the results to allow for valid subgroups to be
32 formed. The majority of studies did not clearly report the severity of dysphagia in a form that
33 could easily be used in a subgroup analysis. Most included people in the acute and subacute
34 periods after stroke, with very few included people in the chronic period. The majority did not
35 report whether people received support from enteral feeding but, when reported, the
36 populations often involved a mixture of people who did and did not receive such support
37 (except in the case of drug interventions with metoclopramide –see the benefits and harms
38 section). The type of stroke was not commonly reported, but when it appeared, it was often
39 posterior circulation stroke. However, this did not resolve the heterogeneity when
40 investigated.

41 A small number of outcomes were downgraded for indirectness. This was due to either
42 population indirectness, where the proportion of people with oropharyngeal dysphagia was
43 unclear, or outcome indirectness, where the outcome was reported in a dichotomous form
44 when the protocol specified that the outcome would be accepted in a continuous form.

45 These factors introduced additional uncertainty in the results. The effect on risk of bias did
46 not appear to influence the direction of the effect in the trials. The committee took all these
47 factors into account when interpreting the evidence.

1 **1.1.13.2.1. Acupuncture/electroacupuncture**

2 Acupuncture/electroacupuncture was compared to placebo/sham therapy and usual care.

- 3 • When compared to placebo/sham therapy, 1 outcome of moderate quality was reported.
4 This was downgraded due to risk of bias, with the majority of the evidence being
5 downgraded due to high risk of bias (due to bias arising from the randomisation process).
- 6 • When compared to usual care, 4 outcomes of high to very low quality that were reported,
7 with the majority being of very low quality. They were downgraded due to risk of bias
8 (arising from the randomisation process, deviations from the intended interventions,
9 missing outcome data, measurement of the outcome and selection of the reported result),
10 inconsistency that could not be resolved by sensitivity or subgroup analyses and
11 imprecision.

12
13 **1.1.13.2.2. Behavioural interventions**

14 Behavioural interventions were compared to placebo/sham therapy and usual care:

- 15 • When compared to placebo/sham therapy, 3 outcomes ranging from low to very low
16 quality, with the majority being of low quality were reported. They were downgraded for
17 risk of bias (arising from the randomisation process and missing outcome data) and
18 imprecision.
- 19 • When compared to usual care, 10 outcomes of very low quality were reported. They were
20 downgraded due to risk of bias (arising from the randomisation process, deviations from
21 the intended interventions, missing outcome data, measurement of the outcome and
22 selection of the reported result), inconsistency with heterogeneity that could not be
23 resolved by sensitivity or subgroup analyses, outcome indirectness (due to reporting an
24 outcome specified to be a continuous outcome in the protocol as a dichotomous outcome)
25 and imprecision.

26
27 **1.1.13.2.3. Drug interventions for OPD**

28 The following drug interventions for OPD were compared to placebo: metoclopramide,
29 domperidone, lisinopril and nifedipine.

- 30 • When metoclopramide was compared to placebo, 4 outcomes ranging from high to low
31 quality, with the majority being of moderate quality were reported. They were downgraded
32 for imprecision.
- 33 • When domperidone was compared to placebo, 3 outcomes of low to very low quality were
34 reported, with the majority being of very low quality. They were commonly downgraded for
35 population and/or outcome indirectness (due to including a mixed population of people
36 with oropharyngeal and oesophageal dysphagia, and reporting an outcome specified to be
37 continuous in the protocol in a dichotomous form, respectively) and imprecision.
- 38 • When lisinopril was compared to placebo, 3 outcomes of low quality were reported. These
39 were downgraded for risk of bias (due to missing outcome data) and imprecision.
- 40 • When nifedipine was compared to placebo, 2 outcomes of very low quality were reported.
41 These were downgraded for risk of bias (due to bias arising from the randomisation
42 process) and imprecision.

43

44

1 **1.1.13.2.4. Neuromuscular electrical stimulation (NMES)**

2 Neuromuscular electrical stimulation (NMES) was compared to placebo/sham therapy and
3 usual care:

- 4 • When compared to placebo/sham therapy, 8 outcomes of low to very low quality were
5 reported, with the majority being of very low quality. They were commonly downgraded for
6 risk of bias (due to bias arising from the randomisation process, deviations from the
7 intended interventions and missing outcome data), inconsistency with heterogeneity that
8 could not be resolved by sensitivity or subgroup analyses, outcome indirectness (due to
9 an outcome specified to be a continuous outcome in the protocol being reported as a
10 dichotomous outcome) and imprecision.
- 11 • When compared to usual care, 17 outcomes ranging from low to very low quality, with the
12 majority being of very low quality were reported. They were downgraded for risk of bias
13 (due to bias arising from the randomisation process, deviations from the intended
14 interventions, missing outcome data and the measurement of the outcome), inconsistency
15 with heterogeneity that could not be resolved by sensitivity or subgroup analyses,
16 outcome indirectness (due to an outcome stated in the protocol to be required in a
17 continuous form being reported in a dichotomous form) and imprecision.

18 **1.1.13.2.5. Pharyngeal electrical stimulation (PES)**

19 Pharyngeal electrical stimulation (PES) was compared to placebo/sham therapy. This
20 comparison included 16 outcomes of low quality, with the majority being of low quality were
21 reported. They were commonly downgraded for risk of bias (due to bias arising from the
22 randomisation process, deviations from the intended interventions and missing outcome
23 data), inconsistency with heterogeneity that could not be resolved by sensitivity or subgroup
24 analyses and imprecision.

25 **1.1.13.2.6. Physical stimulation**

26 Physical stimulation was compared to placebo/sham therapy and usual care:

- 27 • When compared to placebo/sham therapy, 2 outcomes of very low quality were reported.
28 These were downgraded for risk of bias (due to bias arising from the randomisation
29 process and measurement of the outcome) and imprecision.
- 30 • When compared to usual care, 6 outcomes of moderate to very low quality, with the
31 majority being of very low quality were reported. They were commonly downgraded for
32 risk of bias (due to bias arising from the randomisation process, deviations from the
33 intended interventions, missing outcome data, the measurement of the outcome and the
34 selection of the reported result), inconsistency with heterogeneity that could not be
35 resolved with sensitivity or subgroup analyses, outcome indirectness (due to an outcome
36 stated in the protocol to be required in a continuous form being reported in a dichotomous
37 form) and imprecision.

38 **1.1.13.2.7. Transcranial direct current stimulation (TDCS)**

39 Transcranial direct current stimulation (TDCS) was compared to placebo/sham therapy and
40 usual care:

- 41 • When compared to placebo/sham therapy, 9 outcomes ranging from moderate to very low
42 quality, with the majority being of very low quality were reported. They were commonly
43 downgraded for risk of bias (due to bias arising from the randomisation process and in
44 measurement of the outcome), inconsistency with heterogeneity that could not be
45 resolved by sensitivity or subgroup analyses, outcome indirectness (due to an outcome
46 stated in the protocol to be required in a continuous form being reported in a dichotomous
47 form) and imprecision.
- 48 • When compared to usual care, 2 outcomes of low and very low quality were reported.
49 They were downgraded for imprecision and risk of bias (due to bias arising from the

1 randomisation process and deviations from the intended interventions) and imprecision,
2 respectively.

3 **1.1.13.2.8. Transcranial magnetic stimulation (TMS)**

4 Transcranial magnetic stimulation (TMS) was compared to placebo/sham therapy and usual
5 care:

- 6 • When compared to placebo/sham therapy, 4 outcomes of moderate-very low quality, with
7 the majority being of very low quality were reported. They were commonly downgraded for
8 risk of bias (due to bias arising from the randomisation process, deviations from the
9 intended interventions, missing outcome data and bias in measurement of the outcome
10 and the selection of the reported result), inconsistency with heterogeneity that could not
11 be resolved by sensitivity or subgroup analyses and imprecision.
- 12 • When compared to usual care, 8 outcomes of very low quality were reported. They were
13 commonly downgraded for risk of bias (due to bias arising from the randomisation
14 process, missing outcome data and in the measurement of the outcome), inconsistency
15 with heterogeneity that could not be resolved by sensitivity or subgroup analyses and
16 imprecision.

17 **1.1.13.2.9. Drug interventions for oesophageal dysphagia**

18 When domperidone was compared to placebo, 3 outcomes of low to very low quality were
19 reported, with the majority being of very low quality. They were commonly downgraded for
20 population and/or outcome indirectness (due to the inclusion of a mixed population of people
21 with oropharyngeal and oesophageal dysphagia, and reporting an outcome specified to be
22 continuous in the protocol in a dichotomous form respectively) and imprecision. (Note: This
23 study is also included for drug interventions for oropharyngeal dysphagia. The committee
24 considered this mixed population during their interpretation of the evidence.

25 **1.1.13.2.10. Adaptations to support people with dysphagia**

26 The following adaptations were compared to usual care: modified diet, free water protocol
27 and combinations of these approaches (modified diet, positioning, modifying bolus
28 volume/mode of delivery).

- 29 • When modified diet was compared to usual care, 4 outcomes of low to very low quality,
30 with the majority being of very low quality were reported. These were commonly
31 downgraded for risk of bias (due to bias arising from the randomisation process,
32 deviations from the intended interventions and missing outcome data) and imprecision.
- 33 • When the free water protocol was compared to usual care, 3 outcomes of very low quality
34 were reported. These were commonly downgraded for risk of bias (due to bias arising
35 from the randomisation process and deviations from the intended interventions).
- 36 • When combinations (modified diet, positioning, modifying bolus volume/mode of delivery)
37 was compared to usual care, 5 outcomes of low quality were reported. Outcomes were
38 downgraded for either imprecision or imprecision and risk of bias (due to missing outcome
39 data).

40

41 **1.1.13.3. Benefits and harms**

42 **1.1.13.3.1. Key uncertainties**

43 The committee acknowledged that the majority of the studies included in the analysis were
44 small trials and that the outcomes were often of very low quality due to risk of bias and
45 imprecision. In general, the committee noted that larger, high-quality trials, with adequate
46 blinding procedures, randomisation and allocation concealment and minimised attrition, while

1 also considering outcomes relevant to clinical and economic analysis, were required to make
2 further decisions about recommending treatments.

3 **1.1.13.3.2. Acupuncture/electroacupuncture**

4 When compared to placebo/sham therapy, acupuncture/electroacupuncture was shown to
5 have a clinically important benefit in reducing the presence of dysphagia at less than 3
6 months. When compared to usual care, acupuncture/electroacupuncture was shown to have
7 clinically important benefits in reducing the occurrence of chest infections, occurrence of
8 aspiration, dysphagia presence and improving swallowing ability at less than 3 months. The
9 committee acknowledged the limited amount of evidence comparing acupuncture to
10 placebo/sham therapy and the low to very low quality of the evidence.

11 The committee discussed the potential benefits of acupuncture that were identified in the
12 evidence and noted that without evidence comparing acupuncture to placebo/sham therapy it
13 was difficult to determine if there was a treatment-specific effect from the acupuncture itself.
14 Therefore, they agreed that further research was required. They noted that acupuncture and
15 electroacupuncture is not currently provided by speech and language therapists in NHS
16 stroke services and so further research into the effects of the treatment, including health
17 economic evaluation in an NHS setting, would be useful for future evaluation of the
18 treatment.

19 **1.1.13.3.3. Behavioural interventions**

20 When compared to placebo/sham therapy, behavioural interventions were shown to have a
21 clinically important benefit in swallowing ability at less than 3 months. When compared to
22 usual care, behavioural interventions were shown to have a clinically important benefit in
23 reducing the occurrence of chest infections and aspiration at less than 3 months and greater
24 than or equal to 3 months, reducing dysphagia presence at less than 3 months, and
25 improving return to normal diet and swallowing function at less than 3 months. There was no
26 clinically important difference seen in length of hospital stay at less than 3 months (although
27 the committee noted the difference was still 1.91 days, which may still be a significant
28 reduction for some people) and nutrition at less than 3 months.

29 The committee noted the heterogeneity in interventions provided in this category. This
30 included: effortful swallowing, tongue-to-palate resistance training, modified chin tuck against
31 resistance, tongue pressure strength and accuracy training, tongue hold swallow, cervical
32 isometric exercises, expiratory muscle strength training, biofeedback as an adjunct to
33 exercises, kinesio taping and balloon dilatation. The committee noted that therapies such as
34 tongue-to-palate resistance training, modified chin tuck against resistance, tongue pressure
35 and accuracy training, tongue hold swallow and cervical isometric exercises were more likely
36 to be provided by speech and language therapists in the NHS. Meanwhile, the other
37 therapies (in particular balloon dilatation) were less likely to be provided, if at all.

38 Therapies were provided for a range of 20 minutes to 1 hour per day (on average 30
39 minutes) for 5 days per week for on average 2 to 4 weeks during the acute-subacute periods
40 after stroke. The committee noted that the 5 days of therapy is at a higher intensity than that
41 recommended when this guideline was first published in 2013 (where therapy for 3 days a
42 week was recommended). The committee agreed that the new synthesis of the evidence for
43 behavioural interventions highlighted the need for a higher intensity of swallowing therapy as
44 standard care for people with OPD. They agreed that therapy should be offered for at least 5
45 days a week in order to ensure that people are provided with the best chance of achieving
46 good recovery of swallowing function. Lay members on the committee noted that the intense
47 therapy they received for swallowing initially was very valuable to them and that the results
48 they saw were rapid and impactful.

49 Evaluating the evidence, the committee agreed that behavioural interventions were an
50 important treatment for managing of swallowing problems after stroke and so recommended

1 that they should be offered at least 5 days a week according to the individual need of the
2 person after stroke.

3 **1.1.13.3.4. Drug interventions for oropharyngeal dysphagia**

4 Only 1 study was available to compare each drug intervention to placebo. The 1 study
5 comparing results for domperidone to placebo reported a mixed population of people with
6 oropharyngeal and oesophageal dysphagia, so the committee considered the results for both
7 people with either condition. When metoclopramide was compared to placebo, clinically
8 important benefits were seen in reducing mortality, occurrence of chest infections,
9 occurrence of aspiration and in helping people to return to normal diet. When domperidone
10 was compared to placebo, a clinically important benefit was seen in reducing the occurrence
11 of aspiration, but no clinically important difference was seen in reducing mortality and
12 dysphagia presence at less than 3 months. When lisinopril was compared to placebo, a
13 clinically important benefit was seen in improving swallowing ability at less than 3 months.
14 However, clinically important harms were seen in mortality and occurrence of chest infections
15 at greater than or equal to 3 months. When nifedipine was compared to placebo, a clinically
16 important benefit was seen in improving the presence of dysphagia at less than 3 months but
17 a clinically important harm in mortality at less than 3 months (however, the harm in mortality
18 was noted to occur due to the small sample size with unequal distribution of participants
19 between study arms while the number of deaths in each study arm was equal).

20 While the committee acknowledged the positive evidence for metoclopramide and
21 domperidone, they agreed that further research is required before the treatment can be
22 recommended widely for use by people with swallowing problems after stroke. They
23 acknowledged that a large research study is currently being conducted to investigate the use
24 of metoclopramide for people with swallowing problems after stroke (MAPS-2 trial). They
25 also acknowledged the presence of MHRA warnings on the safety of the use of
26 metoclopramide (due to the risk of neurological adverse events) and domperidone (due to
27 the risk of cardiovascular adverse events). Taking these factors into account they did not
28 make a research recommendation. The committee did not recommend lisinopril and
29 nifedipine as they are not routinely used as treatments for swallowing problems. The
30 committee also agreed not to recommend further research into these treatments due to an
31 absence of convincing, positive evidence for their use.

32

33 **1.1.13.3.5. Neuromuscular electrical stimulation (NMES)**

34 When compared to placebo/sham therapy, clinically important benefits were seen in reducing
35 mortality and dysphagia presence and helping return to normal diet at less than 3 months.
36 Unclear effects were seen with swallowing ability at less than 3 months with 1 outcome
37 showing clinically important benefits while another showing no clinically important difference.
38 No clinically important difference was seen in length of hospital stay. An unclear effect was
39 seen with occurrence of aspiration at less than 3 months with 1 outcome showing no
40 clinically important difference while another showed a clinically important harm.

41 When compared to usual care, clinically important benefits were seen in person/participant
42 generic health-related quality of life at greater than or equal to 3 months, reducing
43 occurrence of chest infections, at less than 3 months and greater than or equal to 3 months,
44 reducing dysphagia presence at less than 3 months and greater than or equal to 3 months,
45 helping return to normal diet at less than 3 months and improving swallowing ability at less
46 than 3 months. An unclear effect was seen in occurrence of aspiration at less than and
47 greater than or equal to 3 months with 1 outcome indicating a clinically important benefit
48 while another indicated no clinically important difference. No clinically important difference
49 was seen in length of hospital stay at less than 3 months, swallowing ability at greater than
50 and equal to 3 months and nutrition at greater than or equal to 3 months. A clinically
51 important harm was seen in mortality at less than 3 months and greater than or equal to 3
52 months.

1 The committee discussed the clinically important harm seen in mortality. They were uncertain
2 about this because the major mortality risk with dysphagia is the development of aspiration
3 pneumonia, but NMES was associated with a reduction in chest infections. The committee
4 were therefore uncertain about what could be causing mortality and whether it was related to
5 the intervention itself or was due to chance. The committee noted that the sample size for the
6 outcomes was low (65 and 89 respectively) and were of very low quality with very serious
7 imprecision, so the results may be due to chance. Due to this there was uncertainty in the
8 results.

9 Based on this, the committee did not make a recommendation on the use of neuromuscular
10 electrical stimulation at this time, agreeing that further research was required and so made a
11 research recommendation.

12 **1.1.13.3.6. Pharyngeal electrical stimulation (PES)**

13 When compared to placebo/sham therapy, clinically important benefits were seen in reducing
14 mortality at greater than or equal to 3 months, improving person/participant generic health-
15 related quality of life at greater than or equal to 3 months, reducing dysphagia presence and
16 improving return to normal diet at less than 3 months and greater than or equal to 3 months.
17 No clinically important difference was seen in reducing mortality at less than 3 months,
18 occurrence of aspiration at less than 3 months and greater than or equal to 3 months,
19 discharge to residential service at greater than or equal to 3 months, length of hospital stay
20 (though the committee noted this included a reduction of 3.09 days in hospital stay which is
21 likely a clinically important reduction for some people), swallowing ability and nutrition at less
22 than 3 months and greater than or equal to 3 months. There was no evidence comparing
23 pharyngeal electrical stimulation to usual care.

24 The committee acknowledged the positive results of this trial and agreed that further
25 evidence was required before a recommendation could be made. They noted that a larger
26 trial was currently being undertaken in this area (PhEAST) which will provide further
27 evidence.

28 **1.1.13.3.7. Physical stimulation**

29 When physical stimulation was compared to placebo/sham therapy, clinically important
30 benefits were seen in swallowing ability at less than 3 months with no difference in return to
31 normal diet at less than 3 months. When compared to usual care, clinically important benefits
32 were seen in reducing the occurrence of chest infections and occurrence of aspiration at less
33 than 3 months, presence of dysphagia at less than 3 months, helping return to normal diet,
34 swallowing ability and nutrition at less than 3 months.

35 The committee acknowledge the positive results of the trial and that physical stimulation is a
36 part of normal practice in the NHS alongside behavioural interventions. This may include the
37 use of different sensory stimulations, such as thermal stimulation (either heat or cold) or
38 tactile stimulus to help induce swallowing. With the evidence available, the committee agreed
39 that this was still relevant to current practice and therefore agreed that this should be
40 included in the interventions offered to people who had swallowing problems after stroke.

41 **1.1.13.3.8. Transcranial direct current stimulation (TDCS)**

42 When compared to placebo/sham therapy, clinically important benefits were seen in reducing
43 occurrence of chest infection at less than 3 months, reducing dysphagia presence at less
44 than 3 months and improving swallowing ability at greater than or equal to 3 months. Unclear
45 effects were seen in occurrence of aspiration at less than 3 months and swallowing ability at
46 less than 3 months with a clinically important benefit in 1 outcome and a no clinically
47 important difference in 1 outcome for each. No clinically important difference was seen in
48 mortality at less than 3 months. A clinically important harm was seen in length of hospital

1 stay at less than 3 months. When compared to usual care, clinically important benefits were
2 seen in improving swallowing ability and nutrition at greater than or equal to 3 months.

3 The committee acknowledged the mixed results from the trials, but the potential for benefits.
4 They also noted that transcranial direct current stimulation is not widely available in the NHS
5 at this time. The committee agreed that a recommendation for further research was
6 appropriate at this time and that more evidence was required before recommending the
7 treatment for use.

8 **1.1.13.3.9. Transcranial magnetic stimulation (TMS)**

9 When compared to placebo/sham therapy, clinically important benefits were seen in reducing
10 mortality, occurrence of aspiration and improving swallowing ability at less than 3 months.
11 When compared to usual care, a clinically important benefit was seen in reducing dysphagia
12 presence at less than 3 months. No clinically important difference was found in occurrence of
13 aspiration, return to normal diet and swallowing ability at less than 3 months and greater than
14 or equal to 3 months.

15 The committee acknowledge the mixed results from the trials, but the potential for benefits.
16 They also noted that transcranial magnetic stimulation is not widely available in the NHS at
17 this time. With the evidence available, that consists of studies with small sample sizes and
18 overall very low quality evidence, the committee agreed that a recommendation for further
19 research was appropriate at this time and that more evidence was required before
20 recommending the treatment for use.

21 **1.1.13.3.10. Drug interventions for oesophageal dysphagia**

22 One study reported the use of domperidone compared to placebo. This study reported a
23 mixed population of people with oropharyngeal and oesophageal dysphagia, so the
24 committee considered the results for people with either condition. When domperidone was
25 compared to placebo, a clinically important benefit was seen in reducing the occurrence of
26 aspiration, but no clinically important difference was seen in reducing mortality and
27 dysphagia presence at less than 3 months. While the committee acknowledged the positive
28 evidence for domperidone, they agreed that further research is required before the treatment
29 can be recommended widely for use by people with swallowing problems after stroke.

30 **1.1.13.4.11. Adaptations to support people with dysphagia**

31 When modified diets were compared to usual care, there was a clinically important benefit in
32 reducing dehydration at less than 3 months. No clinically important difference was seen in
33 reducing mortality and in improving nutrition at less than 3 months. A clinically important
34 harm was seen in the occurrence of chest infections at less than 3 months.

35 When the free water protocol was compared to usual care, there was no clinically important
36 difference seen in the occurrence of chest infections and hydration at less than 3 months.
37 When a combination of modifying diet, positioning, modifying bolus volume and mode of
38 delivery was compared to usual care, clinically important benefits were seen in reducing
39 mortality, occurrence of chest infections, helping return to normal diet and reducing
40 discharge to residential service at greater than or equal to 3 months. There was no clinically
41 important difference in length of hospital stay (however, the committee noted that the
42 reduction of 2.2 days would still be significant for some people).

43 Given the results when the different adaptations were combined, the committee agreed that
44 the combination of approaches to support people who are eating and drinking are important
45 to helping to support safe swallowing. The committee discussed the challenges of using
46 thickened fluids and how the taste and texture of fluid thickener may make people less likely
47 to drink and reduce a person's quality of life. This evidence was not identified in this review
48 but was reflected by the experiences of people on the committee. The committee discussed
49 this against the results of the free water protocol. They agreed that the results showed that

1 the free water protocol, when used correctly with people for whom it is appropriate, was not
2 inferior to usual care.

3 The committee acknowledged that those who were recommended the free water protocol
4 were at risk of aspiration when drinking thin liquids. They agreed that the results showed the
5 free water protocol did not increase the occurrence of chest infections in those for whom it
6 was appropriate and therefore could be recommended by Speech and Language Therapists
7 for those drinking thickened fluids.

8 The committee agreed that the free water protocol would only be appropriate for people with
9 adequate cognitive abilities, those independent for mouthcare and mobile as these factors
10 reduce the risk of aspiration pneumonia and represent the population studied in the
11 evidence.

12 **1.1.13.4. Cost effectiveness and resource use**

13 Two studies were included as part of the economic evidence - one of which assessed
14 adaptations to oral feeding, while the other focused on a combination of swallowing
15 strategies and dietary modifications. No economic evidence was identified for other forms of
16 adaptation or behavioural interventions, as was the case for acupuncture and
17 electroacupuncture, electrotherapies and drug interventions.

18 The first included study was a UK cost-consequence analysis that compared usual care (0.3
19 hours of weekly therapy by a day ward nurse) to standard low-intensity swallowing therapy
20 (0.80 hours per week delivered by a Band 7 hospital speech and language therapist (SLT)).
21 Both groups received treatment for one month, however the SLT group received swallowing
22 therapy composed of swallowing strategies such as upright positioning, advice and
23 appropriate diet modification. The clinical benefit from the low-intensity speech and language
24 therapy was taken from a study included in the clinical review, whose results indicated a
25 reduction in chest infections. Costs for staff time and the treatment of chest infections in
26 either hospital or a community setting were applied to both groups, with an infection risk ratio
27 of 0.54, which resulted in cost-savings of £381 per patient for the treatment of chest
28 infections and total cost-savings of £220 per patient. The study conducted various threshold
29 analyses, which found that the low intensity swallowing therapy remained cost-saving as long
30 as the probability of developing a chest infection when receiving the SLT therapy is below
31 38%. The authors then varied the cost of treating a chest infection that required a hospital
32 admission from £1,800 and £5,100 and found that the swallowing therapy remained cost-
33 saving as long as the cost of treating chest infections in hospital is above £2,000.

34 The analysis was assessed as partially applicable for this review as it did not collect EQ-5D
35 scores from participants and therefore QALYs could not be estimated. As well as this, costs
36 and resource use estimates were based on 2009 values, which may not reflect the current
37 UK NHS context. Potentially serious limitations were also identified as the primary clinical
38 data was based on a single RCT. The data used to estimate the probability of a someone
39 with a chest infection requiring medical care was not specific to dysphagia patients either. In
40 addition, the cost of treating a chest infection was based on 1997 values which were then
41 updated to 2009 prices, further reducing the relevance to current UK practice. Lastly,
42 probabilistic sensitivity analysis was not performed which limits the certainty towards the
43 robustness of the results.

44
45 The second study included as economic evidence was a Polish cost-utility analysis that
46 compared routine clinical practice (involving behavioural compensations and manoeuvres
47 plus rehabilitation exercises) to Xanthan gum-based consistency modification therapy (Nutilis
48 Clear®) plus routine clinical practice for an average of approximately 5 weeks. Clinical data
49 from the literature was used to assign transition probabilities for both trial arms, as there was
50 evidence to suggest a reduced risk of aspiration pneumonia from Nutilis clear, stemming

1 from the prevention of aspiration. An increased risk of death for patients with aspiration
2 pneumonia was also applied (RR=2.99; 95%CI: 2.44 to 3.66). Utility weights were then
3 assigned to aspiration and aspiration pneumonia health states. The results found that the
4 modification therapy was cost-effective compared to usual care (cost per QALY gain was
5 £8,076). The study did not assess the probability of Nutilis clear being cost-effective at a
6 £20,000 threshold, however the results of the sensitivity analyses were robust to changes in
7 costs, the time horizon and the risk of developing either aspiration or pneumonia. The
8 analysis was found to be partially applicable for this review, as the polish setting may not
9 reflect a UK NHS context, EQ-5D population tariff was not reported and the utility inputs for a
10 few health states was based on dysphagia populations that were not stroke-specific.
11 Potentially serious limitations were noted as the references for unit costs and resource use
12 estimates were not reported, which makes it the study conclusions difficult to apply to a UK
13 context - for instance, the treatment and monitoring cost for pneumonia could be a lot higher
14 than was reported and the cost of Nutilis Clear® is lower in the UK at £64 compared to £224
15 reported in the analysis. Furthermore, the clinical effectiveness data that reported the
16 reduced risk of aspiration also not based on stroke-specific population. The study was also
17 funded by manufacturer of the intervention.

18 In addition to published economic studies, relevant unit costs were presented to the
19 committee to aid consideration of cost effectiveness of the different oral feeding
20 interventions. These costs demonstrated that behavioural and adaptations to oral feeding, as
21 well physical stimulation, and drug interventions incurred lower costs compared to other
22 interventions in the review. The committee agreed behavioural therapy and adaptations to
23 oral feeding interventions would not have a significant resource impact as a lot of these
24 interventions reflect current practice and do not require expensive equipment for staff to
25 deliver them. The typical staff cost was estimated to be approximately £500-£600, based on
26 studies reporting interventions that were delivered for 30 minutes, 5 days per week for 4
27 weeks. Equipment costs were also low as behavioural interventions included items such as
28 curved spoons (£6-£20), while diet modification strategies included food thickeners which
29 cost £5 for 3-week daily consumption (Resource® ThickenUp® powder). Physical stimulation
30 (such as flavours, thermal or tactile) required little staff time as interventions were delivered
31 for either 4-5 seconds or for 5 minutes for three weeks, with equipment costs involving
32 thermal stimulation costing £2-£6 for 100 capsaicin capsules or 100g Sichuan red pepper
33 powder. Expiratory muscle strength training and Biofeedback are not as frequently used in
34 current practice and require additional costs – for instance, the ProComp5 infinity system was
35 used as part of a biofeedback intervention, which costs over £2,100. This base unit would be
36 used for multiple patients but require single use electrodes. Expiratory muscle strength
37 training (EMST) devices were less costly, such as the EMST 150 used in Moon 2017, which
38 costs approximately £37.

39 The clinical evidence showed that when behavioural interventions and physical stimulation
40 were compared placebo/sham (respectively), clinically important benefit in swallowing ability
41 was reported. When compared to usual care, clinically important benefits for behavioural
42 interventions and physical stimulation were also seen for reducing the occurrence of chest
43 infections and aspiration, reducing dysphagia presence and improving return to normal diet
44 and swallowing function. The committee acknowledged that benefits shown are due to
45 interventions that were delivered for 5 days per week, which is at a higher intensity than the
46 previous 2013 guideline recommendations (where therapy for 3 days a week was
47 recommended). Despite concerns of the resource impact from the change in practice across
48 some stroke units, the committee agreed that therapy should be offered for at least 5 days a
49 week in order to ensure that people are provided with the best chance of achieving good
50 recovery of swallowing function. As such, the committee made an 'offer' recommendation for
51 behavioural interventions (with the exception of expiratory muscle strength training and
52 Biofeedback due to their lack of use in current practice and additional costs) and physical
53 stimulation to be provided for at least 5 days per week.

1 Clinical evidence for adaptations to support people with dysphagia showed that when a
2 combination of modifying diet, positioning, modifying bolus volume and mode of delivery was
3 compared to usual care, clinically important benefits were seen in reducing mortality,
4 occurrence of chest infections, helping return to normal diet and reducing discharge to
5 residential service at ≥ 3 months. As these interventions are provided in current practice and
6 would not incur a significant resource impact, the committee decided on an 'offer'
7 recommendation for combining different adaptations.

8 The clinical evidence showed that when a free water protocol was compared to usual care,
9 there was no clinically important difference seen in the occurrence of chest infections and
10 hydration. The committee agreed that the free water protocol would only be appropriate for
11 people with adequate cognitive abilities, those independent for mouthcare and mobile as
12 these factors reduce the risk of aspiration pneumonia and represent the population studied in
13 the evidence. As such, a 'consider' recommendation was made.

14 Drug costs were typically £0.03-£0.24 per day and were given for 2-4 weeks, with the
15 exception of metoclopramide (£3.10 per day), however but this seemed to be indicated for a
16 very specific population that is people with acute stroke requiring enteral feeding support. No
17 clinical evidence was identified for drug interventions compared to usual care or for drug
18 interventions for oesophageal dysphagia (other than domperidone to placebo) to any
19 comparison. Only 1 study was available to compare each drug intervention to placebo.
20 Clinically important benefits were seen for all drugs, however, clinically important harms seen
21 in lisinopril (for mortality and occurrence of chest infections) and in nifedipine (for mortality).
22 Given the absence of convincing, positive evidence for lisinopril and nifedipine, the
23 committee did not recommend further research into the use of these treatments. However,
24 the committee acknowledged the positive evidence for metoclopramide and domperidone,
25 they agreed that further research is required before the treatment can be recommended
26 widely for use by people with swallowing problems after stroke. Therefore, a research
27 recommendation was made to assess both drugs for the improvement in swallowing for
28 people with oesophageal dysphagia after stroke.

29 Neuromuscular electrical stimulation (NMES), Transcranial magnetic stimulation (TMS) and
30 both acupuncture and electroacupuncture were considered to incur a higher resource impact
31 than the aforementioned interventions as they were not as frequently used in current practice
32 and either involved higher levels of staff time or had similar staff time requirements to the
33 lower cost interventions but had additional equipment costs. For NMES, some devices were
34 reported as standard TENS units which are only around £30, but a few studies did report
35 using the VitalStim electrotherapy system, which retails for over £2,300 and requires
36 electrodes which cost around £35 per use which need to be changed between each patient.
37 Based on the number of sessions reported in the clinical evidence, the device lifetime and
38 cost per electrode, it is estimated the cost per course is from £619 (assuming 5 hours over
39 10 sessions with a Band 6 SLT) to £1,988 (assuming 20hours over 20 sessions with Band 7
40 SLT). Given the uncertainty in the clinical results reported section **Error! Reference source**
41 **not found.** and the potentially high cost, the committee agreed that further research was
42 required, therefore a research recommendation was made.

43 Transcranial magnetic stimulation was considered to be more costly as some studies
44 reported that the intervention was delivered by a neurologist, as well previous studies
45 reporting devices to cost over £400. However, specific costs for the devices reported in the
46 review were difficult to find and the devices that retailed online were advertised for
47 depression and anxiety for home-use which may not be as applicable for this intervention.
48 Considering the mixed results from the trials, but the potential for benefits (see section 0), the
49 committee agreed that further evidence was required before a recommendation could be
50 made, especially considering that this intervention is not frequently used in current practice.
51 Therefore, a research recommendation was made.

1 Acupuncture and electroacupuncture had higher staff time requirements compared to other
2 studies included in the review, as sessions were given for 30 minutes, 6 days per week for 4-
3 8 weeks. For electroacupuncture specifically, the purchase of devices and other accessories
4 is also required, with devices ranging from £200-400. The committee discussed the clinical
5 evidence and noted that benefits were seen for acupuncture/electroacupuncture when
6 compared to usual care (see section **Error! Reference source not found.**). However, the
7 committee acknowledged the absence of evidence comparing acupuncture to placebo/sham
8 therapy, which created uncertainty towards a treatment-specific effect from the acupuncture
9 itself. There is also uncertainty towards the cost-effectiveness of acupuncture and
10 electroacupuncture as no economic evidence was available, and a recommendation would
11 incur resource impact as these interventions are not currently provided for in current practice
12 to support oral feeding. A recommendation would therefore require stroke units to either hire
13 an acupuncturist or incur training costs for rehabilitation therapists. Due to the uncertainty
14 surrounding the clinical and cost-effectiveness, a research recommendation was made.

15 Transcranial direct current stimulation (tDCS) and Pharyngeal electrical stimulation (PES)
16 were considered to be the most expensive as they are not frequently used in NHS practice,
17 as well as some studies reporting that interventions were neurologist-delivered and
18 contained high equipment costs, with both devices having estimates of around £10,000.
19 Training costs may also apply for staff to deliver these interventions. Considering the mixed
20 results from the trials, but the potential for benefits (see section 0) the committee agreed that
21 further evidence was required before a recommendation could be made, especially
22 considering that this intervention is not frequently used in current practice. Therefore, a
23 research recommendation was made.

24 For pharyngeal electrical stimulation, no evidence with a comparison to usual care was
25 available. When compared to placebo/sham therapy, clinically important benefits were seen
26 in reducing mortality, improving health-related quality of life, reducing dysphagia presence
27 and improving return to normal diet. No clinically important difference was seen in reducing
28 mortality, occurrence of aspiration, discharge to residential service and swallowing ability and
29 nutrition. Despite the positive results of the trial, committee agreed that further evidence was
30 required and as such as research recommendation was made.

31 **1.1.13.5. Other factors the committee took into account**

32 Nutrition and hydration outcomes were not widely reported in the studies included in this
33 review. Albumin was reported in a number of studies and included in the Cochrane review
34 and so was included in the report. The nutrition experts on the committee noted that albumin
35 alone is not a helpful measurement of the nutrition status of a person in the acute period after
36 a stroke and has limited use in the chronic phase as it often gives inadequate information,
37 may lead to people being misdiagnosed as having problems with their nutrition status and
38 miss people who are in need of extra support. The committee recommended that outcomes
39 listed in the protocol for this review (including: the Malnutrition university screening tool, Mini
40 Nutritional Assessment, Geriatric Nutritional Risk Index and others) would be more
41 appropriate tools to use. The committee recommended that further research should consider
42 including outcomes investigating nutrition and hydration using the measures considered in
43 the protocol for this review.

44 Race and ethnicity were not widely reported in the studies included in this review. Research
45 for different interventions was conducted in different countries (for example: all the studies
46 investigating pharyngeal electrical stimulation were investigated in European countries, all of
47 the studies investigating acupuncture were investigated in China). People may have a
48 preference to different treatments than others based on their experiences, cultural and family
49 background. Healthcare professionals should take this into account when working with the
50 person who has had a stroke and others involved in their care when coming to a decision
51 about the best way to support the individual. Further research is required that involves stroke

1 survivors from diverse backgrounds to ensure that best care can be provided in an NHS
2 healthcare setting that reflects the needs of the diverse people that it serves.

3 **1.1.14. Recommendations supported by this evidence review**

4 This evidence review supports recommendations 1.11.2 to 1.11.7 and the recommendations
5 for research on swallowing – neurostimulation, swallowing – neuromuscular electrical
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7

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1 Appendices

2 Appendix A Review protocols

3 A.1 Review protocol for the clinical and cost- 4 effectiveness of interventions and adaptations to 5 support oral feeding

ID	Field	Content
0.	PROSPERO registration number	CRD42021276234
1.	Review title	In people after stroke, what is the clinical and cost-effectiveness of interventions to support oral feeding compared with alternative interventions or usual care to reduce difficulties with oral feeding?
2.	Review question	4.1 In people after stroke, what is the clinical and cost-effectiveness of interventions to support oral feeding compared with alternative interventions or usual care to reduce/improve difficulties with oral feeding?
3.	Objective	<p>To determine the clinical and cost-effectiveness of interventions to support oral feeding compared to alternative interventions or usual care for people after a stroke who require extra support with oral feeding.</p> <p>The review contains two groups of interventions:</p> <ul style="list-style-type: none"> • Interventions to improve swallowing to support oral feeding • Adaptations to support oral feeding <p>This review will incorporate the results of a Cochrane review (currently in development, estimated publication date: September 2021) discussing the interventions to improve swallowing.</p>
4.	Searches	<p>The following databases (from inception) will be searched:</p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • Epistemonikas • AMED • CINAHL

		<p>Searches will be restricted by:</p> <ul style="list-style-type: none"> • English language studies • Human studies <p>Other searches:</p> <ul style="list-style-type: none"> • Inclusion lists of systematic reviews <p>The searches may be re-run 6 weeks before the final committee meeting and further studies retrieved for inclusion if relevant.</p> <p>The full search strategies will be published in the final review.</p> <p>Medline search strategy to be quality assured using the PRESS evidence-based checklist (see methods chapter for full details).</p>
5.	Condition or domain being studied	Adults and young people (16 or older) after a stroke
6.	Population	<p>Inclusion:</p> <ul style="list-style-type: none"> • Adults (age ≥ 16 years) who have had a first or recurrent stroke (including people after subarachnoid haemorrhage) <p>Exclusion:</p> <ul style="list-style-type: none"> • Children (age < 16 years) • People who had a transient ischaemic attack • People with mechanical dysphagia • People with other pre-existing neurological conditions causing dysphagia
7.	Intervention	<p>Interventions for oropharyngeal dysphagia (this section will incorporate the results from an in development Cochrane review, likely publication date: September 2021):</p> <ul style="list-style-type: none"> • Acupuncture/electroacupuncture • Behavioural interventions e.g. CTAR, Massako exercises, biofeedback, strength & skill training, effortful swallows, EMST • Drug intervention <ul style="list-style-type: none"> ○ Metoclopramide ○ Glyceride trinitrate patches • Neuromuscular electrical stimulation (NMES) • Pharyngeal electrical stimulation (PES)

		<ul style="list-style-type: none"> • Physical stimulation (such as flavours, thermal or tactile) • Transcranial direct current stimulation (tDCS) • Transcranial magnetic stimulation (TMS) <p>Interventions specifically for oesophageal dysphagia:</p> <ul style="list-style-type: none"> • Drug intervention <ul style="list-style-type: none"> ○ Erythromycin ○ Metoclopramide ○ Domperidone ○ Prucalopride <p>Adaptations for oral feeding:</p> <ul style="list-style-type: none"> • Thickened fluids • Modifying bolus volume/mode of delivery • Modified diet • Swallow strategies (such as chin tuck, head turn, supraglottic swallow, bolus hold etc.) • Carbonation • Positioning • Free water protocol • Combinations of the above <p>Where studies include a mixture of the above categories studies will be included if at least 80% satisfy the criteria for one category. If <10% of participants are in a different category (for example: 9% receive tongue exercises, 91% receive carbonated water), this study will be included in the majority category without downgrading for indirectness. If 10-20% are in a different category, this study will be included in the majority category and downgraded for intervention indirectness.</p>
8.	Comparator	<ul style="list-style-type: none"> • Placebo/sham therapy • Usual care • No treatment <p>These groups will be analysed separately.</p>
9.	Types of study to be included	<ul style="list-style-type: none"> • Systematic reviews of RCTs • Parallel RCTs • Cluster randomised trials • Cluster randomised crossover trials (unit of randomisation = stroke unit) • Crossover studies (for people after chronic stroke only) • Non-randomised studies (if insufficient RCT evidence is available) <ul style="list-style-type: none"> ○ Prospective cohort studies ○ Retrospective cohort studies

		Published NMAs and IPDs will be considered for inclusion.
10.	Other exclusion criteria	<ul style="list-style-type: none"> • Non-English language studies • Non comparative cohort studies • Before and after studies • Crossover RCTs (for people after acute/subacute stroke) • Conference abstracts will be excluded as it is expected there will be sufficient full text published studies available.
11.	Context	People with swallowing difficulties after a stroke
12.	Primary outcomes (critical outcomes)	<p>All outcomes are considered equally important for decision making and therefore have all been rated as critical:</p> <p>At time period...</p> <ul style="list-style-type: none"> • <3 months • ≥3 months <ul style="list-style-type: none"> • Mortality (dichotomous outcomes) • Person/participant generic health-related quality of life (continuous outcomes will be prioritised [validated measures]) <ul style="list-style-type: none"> ○ EQ-5D ○ SF-6D ○ SF-36 ○ SF-12 ○ Other measures (AQOL, HUI, 15D, QWB) • Carer generic health-related quality of life (continuous outcomes will be prioritised [validated measures]) <ul style="list-style-type: none"> ○ EQ-5D ○ SF-6D ○ SF-36 ○ SF-12 ○ Other utility measures (AQOL, HUI, 15D, QWB) • Occurrence of chest infections (dichotomous outcomes) • Occurrence of aspiration (continuous outcomes will be prioritised) <ul style="list-style-type: none"> ○ Penetration Aspiration Scale • Dysphagia present/Return to normal diet (dichotomous outcomes) • Discharge to residential service (dichotomous outcomes) • Length of hospital stay (continuous outcome will be prioritised) • Re-admission (dichotomous outcomes)

		<ul style="list-style-type: none"> • Swallowing ability (continuous outcomes will be prioritised) • Nutrition (continuous outcomes will be prioritised) <ul style="list-style-type: none"> ○ Malnutrition universal screening tool (MUST) ○ Mini Nutritional Assessment (MNA) ○ Geriatric Nutritional Risk Index (GNRI) ○ Modified Mini Nutritional Assessment-short form (MMNA-sf-BMI or MNA-SF-CC) ○ Short nutritional assessment questionnaire (SNAQ) ○ Nutritional Risk Screening tool 2002 (NRS-2002) ○ Mini Nutritional Assessment-short form (MNA-sf) ○ Malnutrition Screening Tool (MST) ○ Nutritional Risk Index (NRI) ○ Modified Nutrition Risk in the Critically Ill score (mNUTRIC)* • Hydration (continuous outcomes will be prioritised) <ul style="list-style-type: none"> ○ Fluid balance charts ○ Fluid charts ○ Biochemical measures (for example: sodium, urea, creatinine, eGFR) ○ Urine analysis ○ Urine osmolality ○ Blood pressure ○ Reliance on a Carer to Drink Assessment Tool ○ Urine colour (continuous outcome prioritised) ○ Sensation of thirst ○ Subjective global assessment including skin turgor, dry mucous membranes, tongue dryness etc. <p>If not mentioned above, other validated scores will be considered and discussed with the committee to deliberate on their inclusion.</p>
14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated.</p> <p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.</p>

		<p>A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4).</p> <p>10% of all evidence reviews are quality assured by a senior research fellow. This includes checking:</p> <ul style="list-style-type: none"> • papers were included /excluded appropriately • a sample of the data extractions • correct methods are used to synthesise data • a sample of the risk of bias assessments <p>Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.</p> <p>Study investigators may be contacted for missing data where time and resources allow.</p>
15.	Risk of bias (quality) assessment	<p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual.</p> <ul style="list-style-type: none"> • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) • Non randomised study, including cohort studies: Cochrane ROBINS-I
16.	Strategy for data synthesis	<ul style="list-style-type: none"> • Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). Fixed-effects (Mantel-Haenszel) techniques will be used to calculate risk ratios for the binary outcomes where possible. Continuous outcomes will be analysed using an inverse variance method for pooling weighted mean differences. <p>Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. An I^2 value greater than 50% will be considered indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented pooled using random-effects.</p> <ul style="list-style-type: none"> • GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias is tested for when there are more than 5 studies for an outcome.

		<p>The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/</p> <ul style="list-style-type: none"> • Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. • WinBUGS will be used for network meta-analysis, if possible given the data identified. 	
17.	Analysis of sub-groups	<p>Subgroups that will be investigated if heterogeneity is present:</p> <p>Severity of dysphagia (as stated by category):</p> <ul style="list-style-type: none"> • Mild • Moderate • Severe • Very severe <p>Time after stroke at the start of the trial</p> <ul style="list-style-type: none"> • Hyperacute <72 hours • Acute 72 hours – <7 days • Subacute 7 days – 6 months • Chronic >6 months <p>People requiring enteral feeding support at baseline</p> <ul style="list-style-type: none"> • People requiring enteral feeding support at baseline • People not requiring enteral feeding support at baseline • Mixed <p>Type of stroke (using the Bamford scale):</p> <ul style="list-style-type: none"> • Total anterior circulation stroke (TACS) • Partial anterior circulation stroke (PACS) • Lacunar stroke (LACS) • Posterior circulation stroke (POCS) 	
18.	Type and method of review	<input checked="" type="checkbox"/>	Intervention
		<input type="checkbox"/>	Diagnostic
		<input type="checkbox"/>	Prognostic
		<input type="checkbox"/>	Qualitative
		<input type="checkbox"/>	Epidemiologic
		<input type="checkbox"/>	Service Delivery
		<input type="checkbox"/>	Other (please specify)

19.	Language	English	
20.	Country	England	
21.	Anticipated or actual start date	24/02/2021	
22.	Anticipated completion date	14/12/2022	
23.	Stage of review at time of this submission	Review stage	Started
		Preliminary searches	<input type="checkbox"/>
		Piloting of the study selection process	<input type="checkbox"/>
		Formal screening of search results against eligibility criteria	<input type="checkbox"/>
		Data extraction	<input type="checkbox"/>
		Risk of bias (quality) assessment	<input type="checkbox"/>
		Data analysis	<input type="checkbox"/>
24.	Named contact	<p>5a. Named contact National Guideline Centre</p> <p>5b Named contact e-mail StrokeRehabUpdate@nice.nhs.uk</p> <p>5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and National Guideline Centre</p>	
25.	Review team members	<p>From the National Guideline Centre:</p> <p>Bernard Higgins (Guideline lead)</p> <p>George Wood (Senior systematic reviewer)</p> <p>Madelaine Zucker (Systematic reviewer)</p> <p>Kate Lovibond (Health economics lead)</p> <p>Claire Sloan (Health economist)</p> <p>Joseph Runicles (Information specialist)</p> <p>Nancy Pursey (Senior project manager)</p>	
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.	
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with	

		NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.	
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10175	
29.	Other registration details	N/A	
30.	Reference/URL for published protocol	N/A	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: <ul style="list-style-type: none"> • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE. 	
32.	Keywords	Adults; Enteral feeding; Intervention; Oral feeding; Rehabilitation; Stroke; Swallowing	
33.	Details of existing review of same topic by same authors	N/A	
34.	Current review status	<input type="checkbox"/>	Ongoing
		<input type="checkbox"/>	Completed but not published
		<input checked="" type="checkbox"/>	Completed and published
		<input type="checkbox"/>	Completed, published and being updated
		<input type="checkbox"/>	Discontinued
35..	Additional information	N/A	
36.	Details of final publication	www.nice.org.uk	

1 **A.2 Health economic review protocol**

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	<ul style="list-style-type: none"> • Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	<p>A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.</p> <p>Databases searched:</p> <ul style="list-style-type: none"> • Centre for Reviews and Dissemination NHS Economic Evaluations Database (NHS EED) – all years (closed to new records April 2015) • Centre for Reviews and Dissemination Health Technology Assessment database – all years (closed to new records March 2018) • International HTA database (INAHTA) – all years • Medline and Embase – from 2014 (due to NHS EED closure)
Review strategy	<p>Studies not meeting any of the search criteria above will be excluded. Studies published before 2006 (including those included in the previous guideline), abstract-only studies and studies from non-OECD countries or the USA will also be excluded.</p> <p>Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).⁸⁵</p> <p>Studies published in 2006 or later that were included in the previous guideline will be reassessed for inclusion and may be included or selectively excluded based on their relevance to the questions covered in this update and whether more applicable evidence is also identified.</p> <p>Inclusion and exclusion criteria</p> <ul style="list-style-type: none"> • If a study is rated as both ‘Directly applicable’ and with ‘Minor limitations’ then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either ‘Not applicable’ or with ‘Very serious limitations’ then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as ‘Partially applicable’, with ‘Potentially serious limitations’ or both then there is discretion over whether it should be included. <p>Where there is discretion</p> <p>The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS</p>

setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2006 or later (including any such studies included in the previous guideline) but that depend on unit costs and resource data entirely or predominantly from before 2006 will be rated as ‘Not applicable’.
- Studies published before 2006 (including any such studies included in the previous guideline) will be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

1 Appendix B Literature search strategies

2 B.1 Clinical search literature search strategy

3 Searches were constructed using a PICO framework where population (P) terms were
4 combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are
5 rarely used in search strategies as these concepts may not be indexed or described in the
6 title or abstract and are therefore difficult to retrieve. Search filters were applied to the search
7 where appropriate.

8 **Table 37: Database parameters, filters and limits applied**

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 08 January 2023	Randomised controlled trials Systematic review studies Observational studies

Database	Dates searched	Search filter used
		Exclusions (animal studies, letters, comments, editorials, case studies/reports) English language
Embase (OVID)	1974 – 08 January 2023	Randomised controlled trials Systematic review studies Observational studies Exclusions (animal studies, letters, comments, editorials, case studies/reports, conference abstracts) English language
The Cochrane Library (Wiley)	Cochrane Reviews to 2023 Issue 1 of 12 CENTRAL to 2023 Issue 1 of 12	Exclusions (clinical trials, conference abstracts)
Epistemonikos (The Epistemonikos Foundation)	Inception – 08 January 2023	Exclusions (Cochrane reviews) English language
AMED, Allied and Complementary Medicine (OVID)	Inception – 08 January 2023	Exclusions (animal studies, letters, comments, case reports) English language
Current Nursing and Allied Health Literature - CINAHL (EBSCO)	Inception – 08 January 2023	Randomised controlled trials Human Exclusions (Medline records, animal studies) English Language

1

2 **Medline (Ovid) search terms**

1.	exp Stroke/
2.	Stroke Rehabilitation/
3.	exp Cerebral Hemorrhage/
4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack*".ti,ab.
7.	or/1-6
8.	letter/
9.	editorial/
10.	news/

11.	exp historical article/
12.	Anecdotes as Topic/
13.	comment/
14.	case report/
15.	(letter or comment*).ti.
16.	or/8-15
17.	randomized controlled trial/ or random*.ti,ab.
18.	16 not 17
19.	animals/ not humans/
20.	exp Animals, Laboratory/
21.	exp Animal Experimentation/
22.	exp Models, Animal/
23.	exp Rodentia/
24.	(rat or rats or mouse or mice or rodent*).ti.
25.	or/18-24
26.	7 not 25
27.	limit 26 to English language
28.	Deglutition/
29.	exp Deglutition Disorders/
30.	((swallow* or deglutit* or dysphag*) adj5 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)).ti,ab,kf.
31.	Pharynx/ or pharyngeal muscles/
32.	((pharynx* or oropharynx*) adj3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)).ti,ab,kf.
33.	erythromycin/
34.	metoclopramide/
35.	domperidone/
36.	(Erythromycin* or metoclopramide* or domperidone* or prucalopride*).ti,ab,kf.
37.	((viscos* or viscous or thick* or thin* or ultrathick*) adj3 (fluid* or liquid* or drink* or beverage*)).ti,ab,kf.
38.	(nectar-thick or honey-thick or spoon-thick).ti,ab,kf.
39.	(Bolus adj3 (volume* or viscosit* or viscous or consistenc* or paste* or liquid* or size* or hold or holding or held or thick* or thin* or ultrathick*)).ti,ab,kf.
40.	Deglutition Disorders/dh, rh, th
41.	((diet* or feed* or meal* or food*) adj3 (puree* or mash* or soft* or blend* or pulveri?ed or modifi* or strateg* or adjustment*)).ti,ab,kf.
42.	(dysphagia adj3 (management or strateg* or therap*)).ti,ab,kf.
43.	(Chin tuck or chin down or Mendelsohn maneuver).ti,ab,kf.
44.	exp carbonated beverage/
45.	((carbonat* or fizzy or sparkling) adj2 (drink* or liquid* or water* or beverage* or fluid*)).ti,ab,kf.
46.	(soda water* or seltzer water*).ti,ab,kf.
47.	((body or head or neck or throat or upright or chin or supraglottic or position* or posture* or movement* or strateg* or technique*) adj3 swallow*).ti,ab,kf.
48.	free water protocol*.ti,ab,kf.
49.	or/28-48

50.	27 and 49
51.	randomized controlled trial.pt.
52.	controlled clinical trial.pt.
53.	randomi#ed.ti,ab.
54.	placebo.ab.
55.	randomly.ti,ab.
56.	Clinical Trials as topic.sh.
57.	trial.ti.
58.	Or/51-57
59.	Meta-Analysis/
60.	exp Meta-Analysis as Topic/
61.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
62.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
63.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
64.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
65.	(search* adj4 literature).ab.
66.	(medline or pubmed or cochrane or embase or psychlit or psychlit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
67.	cochrane.jw.
68.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
69.	Or/59-68
70.	Epidemiologic studies/
71.	Observational study/
72.	exp Cohort studies/
73.	(cohort adj (study or studies or analys* or data)).ti,ab.
74.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
75.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
76.	Controlled Before-After Studies/
77.	Historically Controlled Study/
78.	Interrupted Time Series Analysis/
79.	(before adj2 after adj2 (study or studies or data)).ti,ab.
80.	exp case control studies/
81.	case control*.ti,ab.
82.	Cross-sectional studies/
83.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
84.	Or/70-83
85.	50 and (58 or 69 or 84)

1 Embase (Ovid) search terms

1.	exp Cerebrovascular accident/
2.	exp Brain infarction/
3.	Stroke Rehabilitation/

4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack".ti,ab.
7.	Intracerebral hemorrhage/
8.	or/1-7
9.	letter.pt. or letter/
10.	note.pt.
11.	editorial.pt.
12.	case report/ or case study/
13.	(letter or comment*).ti.
14.	(conference abstract or conference paper).pt.
15.	or/9-14
16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16
18.	animal/ not human/
19.	nonhuman/
20.	exp Animal Experiment/
21.	exp Experimental Animal/
22.	animal model/
23.	exp Rodent/
24.	(rat or rats or mouse or mice or rodent*).ti.
25.	or/17-24
26.	8 not 25
27.	limit 26 to English language
28.	dysphagia/
29.	swallowing/
30.	((swallow* or deglutit* or dysphag*) adj5 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)).ti,ab,kf.
31.	exp pharynx/
32.	((pharyn* or oropharyn*) adj3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)).ti,ab,kf.
33.	*erythromycin/
34.	*metoclopramide/
35.	*domperidone/
36.	*prucalopride/
37.	(Erythromycin* or metoclopramide* or domperidone* or prucalopride*).ti,ab,kf.
38.	((viscos* or viscous or thick* or thin* or ultrathick*) adj3 (fluid* or liquid* or drink* or beverage*)).ti,ab,kf.
39.	(nectar-thick or honey-thick or spoon-thick).ti,ab,kf.
40.	(Bolus adj3 (volume* or viscosit* or viscous or consistenc* or paste* or liquid* or size* or hold or holding or held or thick* or thin* or ultrathick*)).ti,ab,kf.
41.	Deglutition Disorders/dh, rh, th
42.	((diet* or feed* or meal* or food*) adj3 (puree* or mash* or soft* or blend* or pulveri?ed or modifi* or strateg* or adjustment*)).ti,ab,kf.
43.	(dysphagia adj3 (management or strateg* or therap*)).ti,ab,kf.

44.	(Chin tuck or chin down or Mendelsohn maneuver).ti,ab,kf.
45.	exp carbonated beverage/
46.	((carbonat* or fizzy or sparkling) adj2 (drink* or liquid* or water* or beverage* or fluid*)).ti,ab,kf.
47.	(soda water* or seltzer water*).ti,ab,kf.
48.	((body or head or neck or throat or upright or chin or supraglottic or position* or posture* or movement* or strateg* or technique*) adj3 swallow*).ti,ab,kf.
49.	free water protocol*.ti,ab,kf.
50.	Or/28-49
51.	27 and 50
52.	random*.ti,ab.
53.	factorial*.ti,ab.
54.	(crossover* or cross over*).ti,ab.
55.	((doubl* or singl*) adj blind*).ti,ab.
56.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
57.	crossover procedure/
58.	single blind procedure/
59.	randomized controlled trial/
60.	double blind procedure/
61.	Or/52-60
62.	systematic review/
63.	meta-analysis/
64.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
65.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
66.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
67.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
68.	(search* adj4 literature).ab.
69.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
70.	cochrane.jw.
71.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
72.	Or/62-71
73.	Clinical study/
74.	Observational study/
75.	family study/
76.	longitudinal study/
77.	retrospective study/
78.	prospective study/
79.	cohort analysis/
80.	follow-up/
81.	cohort*.ti,ab.
82.	80 and 81
83.	(cohort adj (study or studies or analys* or data)).ti,ab.

84.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
85.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
86.	(before adj2 after adj2 (study or studies or data)).ti,ab.
87.	exp case control study/
88.	case control*.ti,ab.
89.	cross-sectional study/
90.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
91.	Or/73-79,82-90
92.	51 and (61 or 72 or 91)

1 Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Stroke] explode all trees
#2.	MeSH descriptor: [Stroke Rehabilitation] explode all trees
#3.	MeSH descriptor: [Cerebral Hemorrhage] explode all trees
#4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident"):ti,ab
#5.	((cerebro* or brain or brainstem or cerebral*) near/3 (infarct* or accident*)):ti,ab
#6.	brain attack*:ti,ab
#7.	(or #1-#6)
#8.	conference:pt or (clinicaltrials or trialsearch):so
#9.	#7 not #8
#10.	MeSH descriptor: [Deglutition] this term only
#11.	MeSH descriptor: [Deglutition Disorders] explode all trees
#12.	((swallow* or deglutit* or dysphag*) near/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)):ti,ab
#13.	MeSH descriptor: [Pharynx] this term only
#14.	MeSH descriptor: [Pharyngeal Muscles] this term only
#15.	((pharyn* or oropharyn*) near/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)):ti,ab
#16.	MeSH descriptor: [erythromycin] this term only
#17.	MeSH descriptor: [metoclopramide] this term only
#18.	MeSH descriptor: [domperidone] this term only
#19.	(Erythromycin* or metoclopramide* or domperidone* or prucalopride*):ti,ab
#20.	((viscos* or viscous or thick* or thin* or ultrathick*) near/3 (fluid* or liquid* or drink* or beverage*)):ti,a
#21.	(nectar-thick or honey-thick or spoon-thick):ti,ab
#22.	(Bolus near/3 (volume* or viscosit* or viscous or consistenc* or paste* or liquid* or size* or hold or holding or held or thick* or thin* or ultrathick*)):ti,ab
#23.	((diet* or feed* or meal* or food*) near/3 (puree* or mash* or soft* or blend* or pulveri?ed or modifi* or strateg* or adjustment*)):ti,ab
#24.	(dysphagia near/3 (management or strateg* or therap*)):ti,ab
#25.	(Chin tuck or chin down or Mendelsohn maneuver):ti,ab
#26.	MeSH descriptor: [carbonated beverage] this term only
#27.	((carbonat* or fizzy or sparkling) near/2 (drink* or liquid* or water* or beverage* or fluid*)):ti,ab
#28.	(soda water* or seltzer water*):ti,ab

#29.	((body or head or neck or throat or upright or chin or supraglottic or position* or posture* or movement* or strateg* or technique*) near/3 swallow*):ti,ab
#30.	free water protocol*:ti,ab
#31.	(or #10-#30)
#32.	#9 and #31

1 CINAHL search terms

S1.	((MH "Cerebrovascular Disorders") OR (MH "Basal Ganglia Cerebrovascular Disease+") OR (MH "Carotid Artery Diseases+") OR (MH "Cerebral Ischemia+") OR (MH "Cerebral Vasospasm") OR (MH "Intracranial Arterial Diseases+") OR ((MH "Intracranial Embolism and Thrombosis")) OR (MH "Intracranial Hemorrhage+") OR (MH "Stroke") OR (MH "Vertebral Artery Dissections") OR (MH "Stroke Patients") OR (MH "Stroke Units")) OR (TI (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral))
S2.	((MH "Deglutition") OR (MH "Gagging")) OR (MH "Deglutition Disorders") OR (TI (swallow* or deglutit* or dysphag*) N3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)) OR AB (swallow* or deglutit* or dysphag*) N3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)) OR (TI ((swallow* or deglutit* or dysphag*) adj5 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*))
S3.	(randomized controlled trials OR MH double-blind studies OR MH single-blind studies OR MH random assignment OR MH pretest-posttest design OR MH cluster sample OR TI (randomised OR randomized) OR AB (random*) OR TI (trial) OR (MH (sample size) AND AB (assigned OR allocated OR control)) OR MH (placebos) OR PT (randomized controlled trial) OR AB (control W5 group) OR MH (crossover design) OR MH (comparative studies) OR AB (cluster W3 RCT)) NOT ((MH animals+ OR MH animal studies OR TI animal model*)
S4.	S1 AND S2 AND S3

2 AMED search terms

1.	exp Stroke/
2.	exp Cerebral Hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)):ti,ab.
5.	"brain attack*".ti,ab.
6.	or/1-5
7.	case report/
8.	(letter or comment*).ti.
9.	or/7-8
10.	randomized controlled trials/ or random*.ti,ab.
11.	9 not 10
12.	animals/ not humans/
13.	(rat or rats or mouse or mice or rodent*).ti.
14.	or/11-13
15.	6 not 14
16.	(Erythromycin* or metoclopramide* or domperidone* or prucalopride*).ti,ab.
17.	((viscos* or thick* or thin* or ultrathick*) adj3 (fluid* or liquid* or drink* or beverage*)):ti,ab.
18.	(nectar-thick or honey-thick or spoon-thick).ti,ab.

Database	Dates searched	Search filters and limits applied
	Quality of Life 1974 – 08 January 2023	Exclusions (animal studies, letters, comments, editorials, case studies/reports, conference abstracts) English language
NHS Economic Evaluation Database (NHS EED) (Centre for Research and Dissemination - CRD)	Inception –31 st March 2015	
Health Technology Assessment Database (HTA) (Centre for Research and Dissemination – CRD)	Inception – 31 st March 2018	
The International Network of Agencies for Health Technology Assessment (INAHTA)	Inception - 08 January 2023	English language
PsycINFO (OVID)	1 January 2014 – 08 January 2023	Health economics studies Exclusions (animal studies, letters, case reports) Human English language
Current Nursing and Allied Health Literature - CINAHL (EBSCO)	1 January 2014 – 08 January 2023	Health economics studies Exclusions (Medline records, animal studies, letters, editorials, comments, theses) Human English language

1 Medline (Ovid) search terms

1.	exp Stroke/
2.	exp Cerebral Hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	or/1-5
7.	letter/
8.	editorial/
9.	news/
10.	exp historical article/

11.	Anecdotes as Topic/
12.	comment/
13.	case report/
14.	(letter or comment*).ti.
15.	or/7-14
16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16
18.	animals/ not humans/
19.	exp Animals, Laboratory/
20.	exp Animal Experimentation/
21.	exp Models, Animal/
22.	exp Rodentia/
23.	(rat or rats or mouse or mice or rodent*).ti.
24.	or/17-23
25.	6 not 24
26.	Economics/
27.	Value of life/
28.	exp "Costs and Cost Analysis"/
29.	exp Economics, Hospital/
30.	exp Economics, Medical/
31.	Economics, Nursing/
32.	Economics, Pharmaceutical/
33.	exp "Fees and Charges"/
34.	exp Budgets/
35.	budget*.ti,ab.
36.	cost*.ti.
37.	(economic* or pharmaco?economic*).ti.
38.	(price* or pricing*).ti,ab.
39.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*).ab.
40.	(financ* or fee or fees).ti,ab.
41.	(value adj2 (money or monetary)).ti,ab.
42.	or/26-41
43.	quality-adjusted life years/
44.	sickness impact profile/
45.	(quality adj2 (wellbeing or well being)).ti,ab.
46.	sickness impact profile.ti,ab.
47.	disability adjusted life.ti,ab.
48.	(qal* or qtime* or qwb* or daly*).ti,ab.
49.	(euroqol* or eq5d* or eq 5*).ti,ab.

50.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
51.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
52.	(hui or hui1 or hui2 or hui3).ti,ab.
53.	(health* year* equivalent* or hye or hyes).ti,ab.
54.	discrete choice*.ti,ab.
55.	rosser.ti,ab.
56.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
57.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
58.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
59.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
60.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
61.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
62.	or/43-61
63.	25 and 42
64.	25 and 62
65.	limit 63 to English language
66.	limit 64 to English language

1 Embase (Ovid) search terms

1.	exp Cerebrovascular accident/
2.	exp Brain infarction/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*).ti,ab.
5.	"brain attack".ti,ab.
6.	Intracerebral hemorrhage/
7.	or/1-6
8.	letter.pt. or letter/
9.	note.pt.
10.	editorial.pt.
11.	case report/ or case study/
12.	(letter or comment*).ti.
13.	or/8-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animal/ not human/
17.	nonhuman/
18.	exp Animal Experiment/
19.	exp Experimental Animal/
20.	animal model/
21.	exp Rodent/
22.	(rat or rats or mouse or mice).ti.

23.	or/15-22
24.	7 not 23
25.	health economics/
26.	exp economic evaluation/
27.	exp health care cost/
28.	exp fee/
29.	budget/
30.	funding/
31.	budget*.ti,ab.
32.	cost*.ti.
33.	(economic* or pharmaco?economic*).ti.
34.	(price* or pricing*).ti,ab.
35.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
36.	(financ* or fee or fees).ti,ab.
37.	(value adj2 (money or monetary)).ti,ab.
38.	or/25-37
39.	quality adjusted life year/
40.	"quality of life index"/
41.	short form 12/ or short form 20/ or short form 36/ or short form 8/
42.	sickness impact profile/
43.	(quality adj2 (wellbeing or well being)).ti,ab.
44.	sickness impact profile.ti,ab.
45.	disability adjusted life.ti,ab.
46.	(qal* or qtime* or qwb* or daly*).ti,ab.
47.	(euroqol* or eq5d* or eq 5*).ti,ab.
48.	(qol* or hqol* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
49.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
50.	(hui or hui1 or hui2 or hui3).ti,ab.
51.	(health* year* equivalent* or hye or hyes).ti,ab.
52.	discrete choice*.ti,ab.
53.	rosser.ti,ab.
54.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
55.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
56.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
57.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
58.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
59.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
60.	or/39-59
61.	limit 24 to English language
62.	38 and 61
63.	60 and 61

1 **NHS EED and HTA (CRD) search terms**

#1.	MeSH DESCRIPTOR Stroke EXPLODE ALL TREES
#2.	MeSH DESCRIPTOR Cerebral Hemorrhage EXPLODE ALL TREES
#3.	(stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident")
#4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*))
#5.	("brain attack*")
#6.	#1 OR #2 OR #3 OR #4 OR #5

2 **INAHTA search terms**

1.	(brain attack*) OR (((cerebro* or brain or brainstem or cerebral*) and (infarct* or accident*)) OR ((stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident")) OR ("Cerebral Hemorrhage"[mhe]) OR ("Stroke"[mhe])
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3 **CINAHL search terms**

1.	MH "Economics+"
2.	MH "Financial Management+"
3.	MH "Financial Support+"
4.	MH "Financing, Organized+"
5.	MH "Business+"
6.	S2 OR S3 or S4 OR S5
7.	S1 not S6
8.	MH "Health Resource Allocation"
9.	MH "Health Resource Utilization"
10.	S8 OR S9
11.	S7 OR S10
12.	(cost or costs or economic* or pharmacoeconomic* or price* or pricing*) OR AB (cost or costs or economic* or pharmacoeconomic* or price* or pricing*)
13.	S11 OR S12
14.	PT editorial
15.	PT letter
16.	PT commentary
17.	S14 or S15 or S16
18.	S13 NOT S17
19.	MH "Animal Studies"
20.	(ZT "doctoral dissertation") or (ZT "masters thesis")
21.	S18 NOT (S19 OR S20)
22.	PY 2014-
23.	S21 AND S22
24.	MW Stroke or MH Cerebral Hemorrhage
25.	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
26.	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
27.	"brain attack*"
28.	S24 OR S25 OR S26 OR S27
29.	S23 AND S28

1 **PsycINFO search terms**

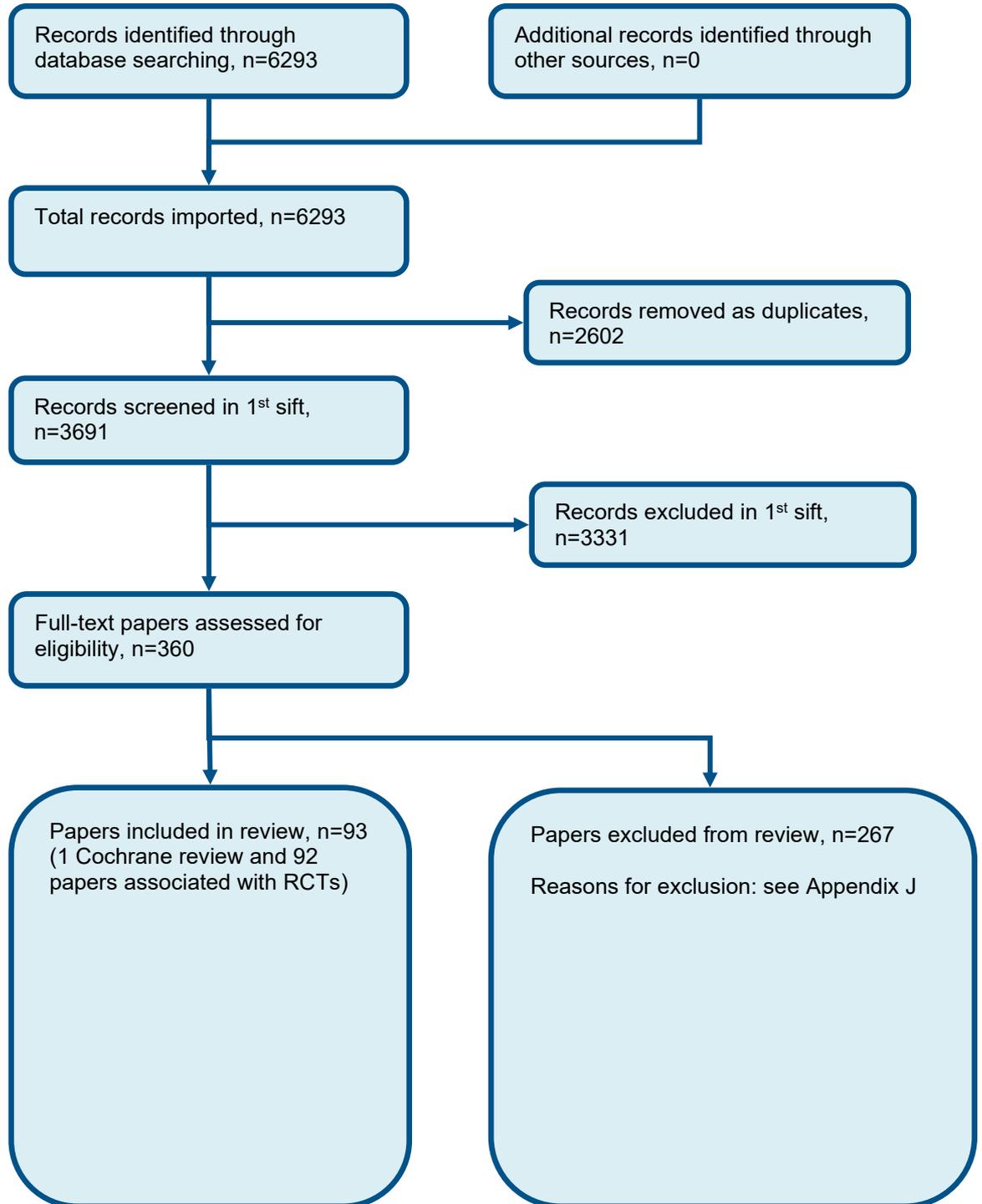
1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack".ti,ab.
6.	Cerebrovascular accidents/
7.	exp Brain damage/
8.	(brain adj2 injur*).ti.
9.	or/1-8
10.	Letter/
11.	Case report/
12.	exp Rodents/
13.	or/10-12
14.	9 not 13
15.	limit 14 to (human and english language)
16.	First posting.ps.
17.	15 and 16
18.	15 or 17
19.	"costs and cost analysis"/
20.	"Cost Containment"/
21.	(economic adj2 evaluation\$).ti,ab.
22.	(economic adj2 analy\$).ti,ab.
23.	(economic adj2 (study or studies)).ti,ab.
24.	(cost adj2 evaluation\$).ti,ab.
25.	(cost adj2 analy\$).ti,ab.
26.	(cost adj2 (study or studies)).ti,ab.
27.	(cost adj2 effective\$).ti,ab.
28.	(cost adj2 benefit\$).ti,ab.
29.	(cost adj2 utili\$).ti,ab.
30.	(cost adj2 minimi\$).ti,ab.
31.	(cost adj2 consequence\$).ti,ab.
32.	(cost adj2 comparison\$).ti,ab.
33.	(cost adj2 identificat\$).ti,ab.
34.	(pharmacoeconomic\$ or pharmaco-economic\$).ti,ab.
35.	or/19-34
36.	(0003-4819 or 0003-9926 or 0959-8146 or 0098-7484 or 0140-6736 or 0028-4793 or 1469-493X).is.
37.	35 not 36
38.	18 and 37

2

3

1 **Appendix C Effectiveness evidence study selection**

2 **Figure 1: Flow chart of clinical study selection for the review of interventions and**
3 **adaptations to support oral feeding**



4
5
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1 **Appendix D Effectiveness evidence**

2 **1.1.16. , 2013**

Bibliographic Reference NCT01970384 Transcranial direct current stimulation for dysphagia therapy in acute stroke patients; 2013

3

4 **1.1.16.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	Suntrup-Krueger, Sonja, Ringmaier, Corinna, Muhle, Paul et al. (2018) Randomized trial of transcranial direct current stimulation for poststroke dysphagia. <i>Annals of neurology</i> 83(2): 328-340

5

6

7 **1.1.17. Ahn, 2017**

Bibliographic Reference Ahn, Young Hyun; Sohn, Hyun-Joo; Park, Jin-Sung; Ahn, Tae Gyu; Shin, Yong Beom; Park, Minsu; Ko, Sung-Hwa; Shin, Yong-II; Effect of bihemispheric anodal transcranial direct current stimulation for dysphagia in chronic stroke patients: A randomized clinical trial.; *Journal of rehabilitation medicine*; 2017; vol. 49 (no. 1); 30-35

8

1 1.1.17.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients or outpatient follow up.
Study dates	No additional information.
Sources of funding	Supported by Mid-career Researcher Program through the National Research Foundation of Korea funded by the Ministry of Science, ICT & Future Planning (NRF-2014R1A2A2A01002501).
Inclusion criteria	Age 18-80 years; first-ever stroke, confirmed with brain imaging and clinical observation by a doctor; at least 6 months since stroke onset; dysphagia due to stroke, with a Dysphagia Outcome and Severity Scale (DOSS) score at enrollment of no more than 5 (mild-to-severe dysphagia); unilateral cortical or subcortical hemispheric lesion confirmed with brain imaging analysis; inpatients or outpatients who could receive therapy for dysphagia 5 times per week; no history of abnormal response to brain or electrical stimulation; people who were informed of the purpose of the current study and submitted a written informed consent.
Exclusion criteria	Pre-existing and active major neurological disease; pre-existing and active major psychiatric disease, such as major depression, schizophrenia, bipolar disease or dementia; brain lesion in areas other than the cortical and subcortical regions; presence of a potential transcranial direct current stimulation risk factor (intracerebral metal due to previous brain surgery, hypersensitivity to pain, history of seizure, etc.).

Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Transcranial direct current stimulation (tDCS) N=13</p> <p>Transcranial direct current stimulator delivered using a battery-driven constant-current direct current stimulator through 2 pairs of saline-soaked electrodes (25cm² rectangular surface electrodes; current density, 0.04 mA/cm² at 1mA). Four electrodes were used for bihemispheric transcranial direct current stimulation. They received a total of 10 sessions of 20 minute and 1mA stimulation (5 times per week for 2 weeks).</p> <p>Concomitant therapy: All people simultaneously had dysphagia therapy, consisting of direct and indirect methods. The direct methods included compensatory methods, such as diet modification, appropriate positioning and behavioural manoeuvres, including Mendelsohn manoeuvre, and supraglottic and effortful swallowing. The indirect approach included oromotor exercise and thermal tactile stimulation. The dysphagia therapy was carried out with the same protocol in both hospitals and performed by 2 occupational therapists.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	<p>Mixed</p> <p>Mild to severe</p>
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	<p>Mixed</p> <p>Mixture of cortical and subcortical</p>

Population subgroups	No additional information.
Comparator	<p>Placebo/sham N=13</p> <p>Sham transcranial direct current stimulation. The same protocol was applied, except that the 1mA current was delivered for only 30s through 2 anodal electrodes, producing an initial tingling sensation but no significant changes in cortical excitability.</p> <p>Concomitant therapy: All people simultaneously had dysphagia therapy, consisting of direct and indirect methods. The direct methods included compensatory methods, such as diet modification, appropriate positioning and behavioural manoeuvres, including Mendelsohn manoeuvre, and supraglottic and effortful swallowing. The indirect approach included oromotor exercise and thermal tactile stimulation. The dysphagia therapy was carried out with the same protocol in both hospitals and performed by 2 occupational therapists.</p>
Number of participants	26
Duration of follow-up	2 weeks
Indirectness	No additional information.
Additional comments	No additional information. All people appear to have completed the intervention and were analysed.

1

2 **1.1.17.2. Study arms**3 **1.1.17.2.1. Transcranial direct current stimulation (tDCS) (N = 13)**

4 Transcranial direct current stimulator delivered using a battery-driven constant-current direct current stimulator through 2 pairs of
5 saline-soaked electrodes (25cm² rectangular surface electrodes; current density, 0.04 mA/cm² at 1mA). Four electrodes were used
6 for bihemispheric transcranial direct current stimulation. They received a total of 10 sessions of 20 minute and 1mA stimulation (5
7 times per week for 2 weeks). Concomitant therapy: All people simultaneously had dysphagia therapy, consisting of direct and indirect
8 methods. The direct methods included compensatory methods, such as diet modification, appropriate positioning and behavioural

1 manoeuvres, including Mendelsohn manoeuvre, and supraglottic and effortful swallowing. The indirect approach included oromotor
 2 exercise and thermal tactile stimulation. The dysphagia therapy was carried out with the same protocol in both hospitals and
 3 performed by 2 occupational therapists.

4

5 **1.1.17.2.2. Placebo/sham therapy (N = 13)**

6 Sham transcranial direct current stimulation. The same protocol was applied, except that the 1mA current was delivered for only 30s
 7 through 2 anodal electrodes, producing an initial tingling sensation but no significant changes in cortical excitability. Concomitant
 8 therapy: All people simultaneously had dysphagia therapy, consisting of direct and indirect methods. The direct methods included
 9 compensatory methods, such as diet modification, appropriate positioning and behavioural manoeuvres, including Mendelsohn
 10 manoeuvre, and supraglottic and effortful swallowing. The indirect approach included oromotor exercise and thermal tactile
 11 stimulation. The dysphagia therapy was carried out with the same protocol in both hospitals and performed by 2 occupational
 12 therapists.

13

14 **1.1.17.3. Characteristics**

15 **1.1.17.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 13)	Placebo/sham therapy (N = 13)
% Female	n = 4 ; % = 31	n = 7 ; % = 54
Sample size		
Mean age (SD) (years)	61.62 (10.28)	66.38 (10.67)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial direct current stimulation (tDCS) (N = 13)	Placebo/sham therapy (N = 13)
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	12.27 (4.92)	11.62 (4.56)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Cortical	n = 6 ; % = 46	n = 10 ; % = 77
Sample size		
Subcortical	n = 7 ; % = 54	n = 3 ; % = 23
Sample size		

1 **1.1.17.4. Outcomes**2 **1.1.17.4.1. Study timepoints**

- 3 • Baseline
- 4 • 2 week (<3 months)

5

6 **1.1.17.4.2. Continuous outcome**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 13	Transcranial direct current stimulation (tDCS), 2 week, N = 13	Placebo/sham therapy, Baseline, N = 13	Placebo/sham therapy, 2 week, N = 13
Swallowing ability (Dysphagia Outcome Severity Scale) Scale range: 0-7. Change scores. Mean (SD)	3.46 (1.27)	0.62 (0.77)	3.08 (1.26)	0.38 (0.65)

7 Swallowing ability (Dysphagia Outcome Severity Scale) - Polarity - Higher values are better

8

9

10 **1.1.17.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**11 **1.1.17.4.4. Continuous outcome-Swallowing ability (Dysphagia Outcome Severity Scale)-Mean SD-Transcranial direct current stimulation (tDCS)-Placebo/sham-t2**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.18. Allami, 2022**

Bibliographic Reference Allami, Abbas; Kianimajd, Somaieh; Mavandadi, Shirin; Paybast, Sepideh; Evaluation of domperidone efficacy to prevent aspiration pneumonia in patients with acute ischemic stroke: a randomized clinical trial.; Acta neurologica Belgica; 2022

3

4 **1.1.18.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	IRCT20201001048896N1
Study type	Randomised controlled trial (RCT)
Study location	Iran
Study setting	Initially inpatients in the neurology department of Bouali hospital, Iran.
Study dates	2019 to 2021.

Sources of funding	No financial interests.
Inclusion criteria	People with acute ischaemic stroke and age over 18 years.
Exclusion criteria	People with recombinant tissue plasminogen activator therapy; hypersensitivity to the prescribed medication; pregnancy; evidence of pulmonary infection before recruitment; a history of chronic neurodegenerative diseases that affects swallowing; oesophageal disorders; people who were discharged in less than 3 days.
Recruitment / selection of participants	People were recruited from the neurology department of Bouali hospital, Qazvin, Iran.
Intervention(s)	Domperidone N=76 Domperidone 10mg once a day from the first day of hospitalisation until discharge. Concomitant therapy: Standard stroke care available to all.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	People not requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed Majority anterior circulation

Population subgroups	No additional information.
Comparator	Placebo N=74 Placebo once a day from the first day of hospitalisation until discharge. Concomitant therapy: Standard stroke care available to all.
Number of participants	150
Duration of follow-up	Until discharge (4-11 days)
Indirectness	Population indirectness - type of dysphagia unclear, so may include people with oropharyngeal or oesophageal dysphagia.
Additional comments	Intention to treat (no withdrawals)

1

2 **1.1.18.2. Study arms**

3 **1.1.18.2.1. Domperidone (N = 76)**

4 Domperidone 10mg once a day from the first day of hospitalisation until discharge. Concomitant therapy: Standard stroke care
5 available to all.

6

7 **1.1.18.2.2. Placebo (N = 74)**

8 Placebo once a day from the first day of hospitalisation until discharge. Concomitant therapy: Standard stroke care available to all.

9

1 **1.1.18.3. Characteristics**2 **1.1.18.3.1. Arm-level characteristics**

Characteristic	Domperidone (N = 76)	Placebo (N = 74)
% Female	n = 28 ; % = 36.8	n = 32 ; % = 43.2
Sample size		
Mean age (SD) (years)	66 (NR)	69 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Diabetes mellitus	n = 23 ; % = 30.3	n = 34 ; % = 46
Sample size		
Hypertension	n = 51 ; % = 67.1	n = 57 ; % = 77
Sample size		
Renal failure	n = 1 ; % = 1.3	n = 5 ; % = 6.8
Sample size		
Myocardial infarction	n = 24 ; % = 31.6	n = 28 ; % = 37.8
Sample size		

Characteristic	Domperidone (N = 76)	Placebo (N = 74)
Cerebrovascular accident	n = 22 ; % = 28.9	n = 14 ; % = 18.9
Sample size		
Chronic obstructive pulmonary disease	n = 1 ; % = 1.3	n = 1 ; % = 1.4
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Anterior circulation	n = 63 ; % = 82.9	n = 54 ; % = 73
Sample size		
Posterior circulation	n = 13 ; % = 17.1	n = 20 ; % = 27
Sample size		

1 **1.1.18.4. Outcomes**

2 **1.1.18.4.1. Study timepoints**

- 3 • Baseline
4 • 11 day (4-11 days (until discharge))

5

6 **1.1.18.4.2. Dichotomous outcomes**

Outcome	Domperidone, Baseline, N = 76	Domperidone, 11 day, N = 76	Placebo, Baseline, N = 74	Placebo, 11 day, N = 74
Occurrence of aspiration Aspiration pneumonia	n = NA ; % = NA	n = 9 ; % = 11.8	n = NA ; % = NA	n = 40 ; % = 54.1
No of events				
Dysphagia present/return to normal diet (presence of nasogastric tube)	n = NA ; % = NA	n = 6 ; % = 7.9	n = NA ; % = NA	n = 5 ; % = 6.8
No of events				
Mortality	n = NA ; % = NA	n = 2 ; % = 2.6	n = NA ; % = NA	n = 2 ; % = 2.7
No of events				

7 Occurrence of aspiration - Polarity - Lower values are better

8 Dysphagia present/return to normal diet (presence of nasogastric tube) - Polarity - Lower values are better

9 Mortality - Polarity - Lower values are better

1 **1.1.18.4.3. Continuous outcomes**

Outcome	Domperidone, Baseline, N = 76	Domperidone, 11 day, N = 76	Placebo, Baseline, N = 74	Placebo, 11 day, N = 74
Length of hospital stay (days)	NA to NA	4 to 7	NA to NA	7 to 11
Range				
Length of hospital stay (days)	NA (NA)	5 (NR)	NA (NA)	9 (NR)
Mean (SD)				

2 Length of hospital stay - Polarity - Lower values are better

3

4

5 **1.1.18.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.18.4.5. Dichotomous outcomes - Occurrence of aspiration - No of events - Domperidone - Placebo - t11**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable (Population indirectness as unclear the proportion of people who had oesophageal dysphagia)

7

1 **1.1.18.4.6. Dichotomous outcomes-Dysphagia present/return to normal diet (presence of nasogastric tube)-No Of Events-**
 2 **Domperidone-Placebo-t11**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable <i>(Population indirectness as unclear the proportion of people who had oesophageal dysphagia)</i>

3
 4 **1.1.18.4.7. Dichotomous outcomes-Mortality-No Of Events-Domperidone-Placebo-t11**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable <i>(Population indirectness as unclear the proportion of people who had oesophageal dysphagia)</i>

5
 6 **1.1.19. Arreola, 2021**

Bibliographic Reference Arreola, Viridiana; Ortega, Omar; Alvarez-Berdugo, Daniel; Rofes, Laia; Tomsen, Noemi; Cabib, Christopher; Muriana, Desiree; Palomera, Elisabet; Clave, Pere; Effect of Transcutaneous Electrical Stimulation in Chronic Poststroke Patients with Oropharyngeal Dysphagia: 1-Year Results of a Randomized Controlled Trial.; Neurorehabilitation and neural repair; 2021; vol. 35 (no. 9); 778-789

1 1.1.19.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT02379182.
Study type	Randomised controlled trial (RCT)
Study location	Spain.
Study setting	Outpatient follow up.
Study dates	October 01, 2014 to June 16, 2016.
Sources of funding	This study was supported by a research grant from DJO Global. Financial support was also received by grants from Fondo de Investigaciones Sanitarias Instituto de Salud Carlos III (14/00453, 18/00241); Proyectos de Investigacion Clinica Independiente, Instituto de Salud Carlos III; and Programa de Estabilizacion de Investigadores y de Intensificacion de la Actividad Investigadora en el Sistema Nacional de Salud (INT15/00026, INT16/00111).
Inclusion criteria	Age at least 18 years old; clinical indications of oropharyngeal dysphagia; capacity to comply with the protocol; confirmed stroke diagnosis; no oropharyngeal dysphagia history before stroke; a score of 0-1 on NIHSS question 1a.
Exclusion criteria	No additional information.
Recruitment / selection of participants	No additional information.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=60

	<p>Pooled results of two groups (following the approach used in the Cochrane review to classify both motor and sensory electrical stimulation as NMES). Group 1 (n = 30) received transcutaneous electrical stimulation at motor level. 100% intensity at the motor threshold. Electrodes placed in a suprahyoid configuration to target the muscular mouth floor complex formed by the anterior belly of the digastric, the mylohyoid and the geniohyoid muscles. The initial current intensity was readjusted every 10 minutes if necessary. They did not perform any active exercise or manoeuvre during the sessions. At 6 months follow-up, and after a positive V-VST test with signs of impaired safety of swallow, those people with a Penetration Aspiration Scale Score of at least 2 during VFS3 received a second cycle of treatment using the same protocol. Sessions included two 1 hour sessions per day for the first week and one 1 hour session per day for the second week (15 sessions over 2 weeks). Group 2 (n = 30) received transcutaneous electrical stimulation at the sensory level. This occurred for the same period of time but treatment intensity was set to 75% of the motor threshold and the electrode placement was in the thyrohyoid pattern aiming to stimulate either the cutaneous sensory afferents of C2-C3 spinal nerves. Every 10 minutes, the person was asked if the initial intensity sensory perception was maintained, and in the case of reduction due to a common physiological habituation phenomena, it was readjusted to a sensory perception similar to the previous one.</p> <p>Concomitant therapy: Standard compensatory clinical care including adaptation of fluids with thickening agents, texture-modified diet, oral hygiene recommendations, postural changes if necessary (chin down and head rotation to the affected side) and nutritional advice.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	No additional information.
Comparator	Usual care N=29 Usual care only. Concomitant therapy: Standard compensatory clinical care including adaptation of fluids with thickening agents, texture-modified diet, oral hygiene recommendations, postural changes if necessary (chin down and head rotation to the affected side) and nutritional advice.
Number of participants	89
Duration of follow-up	1 year
Indirectness	No additional information.
Additional comments	Method of analysis unclear (appears to be completers only).

1

2 **1.1.19.2. Study arms**3 **1.1.19.2.1. Neuromuscular electrical stimulation (NMES) (N = 60)**

4 Pooled results of two groups (following the approach used in the Cochrane review to classify both motor and sensory electrical
5 stimulation as NMES). Group 1 (n = 30) received transcutaneous electrical stimulation at motor level. 100% intensity at the motor
6 threshold. Electrodes placed in a suprahyoid configuration to target the muscular mouth floor complex formed by the anterior belly of
7 the digastric, the mylohyoid and the geniohyoid muscles. The initial current intensity was readjusted every 10 minutes if necessary.
8 They did not perform any active exercise or manoeuvre during the sessions. At 6 months follow-up, and after a positive V-VST test
9 with signs of impaired safety of swallow, those people with a Penetration Aspiration Scale Score of at least 2 during VFS3 received a
10 second cycle of treatment using the same protocol. Sessions included two 1 hour sessions per day for the first week and one 1 hour
11 session per day for the second week (15 sessions over 2 weeks). Group 2 (n = 30) received transcutaneous electrical stimulation at

1 the sensory level. This occurred for the same period of time but treatment intensity was set to 75% of the motor threshold and the
 2 electrode placement was in the thyrohyoid pattern aiming to stimulate either the cutaneous sensory afferents of C2-C3 spinal nerves.
 3 Every 10 minutes, the person was asked if the initial intensity sensory perception was maintained, and in the case of reduction due to
 4 a common physiological habituation phenomena, it was readjusted to a sensory perception similar to the previous one. Concomitant
 5 therapy: Standard compensatory clinical care including adaptation of fluids with thickening agents, texture-modified diet, oral hygiene
 6 recommendations, postural changes if necessary (chin down and head rotation to the affected side) and nutritional advice.

7
 8 **1.1.19.2.2. Usual care (N = 29)**

9 Usual care only. Concomitant therapy: Standard compensatory clinical care including adaptation of fluids with thickening agents,
 10 texture-modified diet, oral hygiene recommendations, postural changes if necessary (chin down and head rotation to the affected side)
 11 and nutritional advice.

12
 13 **1.1.19.3. Characteristics**

14 **1.1.19.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 60)	Usual care (N = 29)
% Female	n = 21 ; % = 36	n = 10 ; % = 35
Sample size		
Mean age (SD) (years)	74.44 (11.56)	73.52 (11.56)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NA ; % = NA	n = NA ; % = NA
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 60)	Usual care (N = 29)
Hypertension	n = 48 ; % = 80	n = 22 ; % = 75.86
Sample size		
Dyslipidaemia	n = 33 ; % = 55	n = 20 ; % = 68.97
Sample size		
Diabetes mellitus	n = 30 ; % = 50	n = 12 ; % = 41
Sample size		
Atrial fibrillation	n = 19 ; % = 31.67	n = 7 ; % = 24.14
Sample size		
Previous stroke	n = 11 ; % = 18.33	n = 8 ; % = 27.59
Sample size		
Coronary artery disease	n = 13 ; % = 21.67	n = 5 ; % = 17.24
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	480.44 (929.87)	630.4 (1247.76)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 60)	Usual care (N = 29)
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
PACI	n = 27 ; % = 45	n = 8 ; % = 27.59
Sample size		
TACI	n = 8 ; % = 13.33	n = 3 ; % = 10.34
Sample size		
LACI	n = 15 ; % = 25	n = 11 ; % = 37.93
Sample size		
POSI	n = 8 ; % = 13.33	n = 2 ; % = 6.9
Sample size		
Undertermined	n = 2 ; % = 3.33	n = 5 ; % = 17.24
Sample size		

1

2 **1.1.19.4. Outcomes**3 **1.1.19.4.1. Study timepoints**

- 4 • Baseline
- 5 • 1 year (≥3 months)

6

1 **1.1.19.4.2. Dichotomous outcomes (1)**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 60	Neuromuscular electrical stimulation (NMES), 1 year, N = 60	Usual care, Baseline, N = 29	Usual care, 1 year, N = 29
Mortality From study flow diagram. Motor group: 3 died. Sensory group: 1 died. Control group: 1 died. No of events	n = NA ; % = NA	n = 4 ; % = 7	n = NA ; % = NA	n = 1 ; % = 3
Occurrence of chest infection Taken from supplementary material. Sensory group: 1 bronchitis. Control: 4 respiratory infection, 2 bronchitis (assuming that these were separate people). No of events	n = NA ; % = NA	n = 1 ; % = 2	n = NA ; % = NA	n = 6 ; % = 21

2 Mortality - Polarity - Lower values are better

3 Occurrence of chest infection - Polarity - Lower values are better

4 **1.1.19.4.3. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 60	Neuromuscular electrical stimulation (NMES), 1 year, N = 51	Usual care, Baseline, N = 29	Usual care, 1 year, N = 26
Person/participant generic health-related quality of life (EQ-VAS) Scale range: 0-100. Final values. Motor group = 71.43 (11.63). Sensory group = 72.31 (16.01). Mean (SD)	61.66 (22.92)	71.86 (13.96)	68.7 (16.09)	61.48 (27.03)

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 60	Neuromuscular electrical stimulation (NMES), 1 year, N = 51	Usual care, Baseline, N = 29	Usual care, 1 year, N = 26
Occurrence of aspiration (Maximum Penetration Aspiration Score) Scale range: 1-8. Final values. Motor = 2.62 (1.98). Sensory = 3.04 (1.57). Mean (SD)	4.64 (1.87)	2.83 (1.8)	4.55 (1.55)	3.5 (1.61)
Nutrition (Mini Nutritional Assessment-short form) Scale range: 0-14. Final values. Motor = 11.96 (2.071). Sensory = 11.63 (1.91). Mean (SD)	10.75 (2.41)	11.79 (2)	10.08 (2.99)	11.58 (2.8)

- 1 Person/participant generic health-related quality of life (EQ-VAS) - Polarity - Higher values are better
- 2 Occurrence of aspiration (Maximum Penetration Aspiration Score) - Polarity - Lower values are better
- 3 Nutrition (Mini Nutritional Assessment-short form) - Polarity - Higher values are better

4 **1.1.19.4.4. Dichotomous outcomes (2)**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 60	Neuromuscular electrical stimulation (NMES), 1 year, N = 51	Usual care, Baseline, N = 29	Usual care, 1 year, N = 26
Dysphagia present/Return to normal diet (prevalence of people with unsafe swallows) Motor = 61.5% (16). Sensory = 72.0% (18). Control = 84.6% (22). No of events	n = 60 ; % = 100	n = 34 ; % = 67	n = 29 ; % = 100	n = 22 ; % = 85

- 5 Dysphagia present/Return to normal diet (prevalence of people with unsafe swallows) - Polarity - Lower values are better

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1.1.19.4.5. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

1.1.19.4.6. Dichotomous outcomes(1)-Mortality-NoOfEvents-Neuromuscular electrical stimulation (NMES)-Usual care-t1

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1.1.19.4.7. Dichotomous outcomes(1)-Occurrence of chest infection-NoOfEvents-Neuromuscular electrical stimulation (NMES)-Usual care-t1

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1.1.19.4.8. Continuous outcomes-Person/participant generic health-related quality of life(EQ-VAS)-MeanSD-Neuromuscular electrical stimulation (NMES)-Usual care-t1

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.19.4.9.** *Continuous outcomes-Swallowing ability (Maximum Penetration Aspiration Score)-Mean SD-Neuromuscular electrical*
 2 *stimulation (NMES)-Usual care-t1*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.19.4.10.** *Continuous outcomes-Nutrition (Mini Nutritional Assessment-short form)-Mean SD-Neuromuscular electrical*
 5 *stimulation (NMES)-Usual care-t1*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.19.4.11.** *Dichotomous outcomes(2)-Dysphagia present/Return to normal diet (prevalence of people with unsafe swallows)-*
 8 *No of Events-Neuromuscular electrical stimulation (NMES)-Usual care-t1*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.20. Bath, 2016**

Bibliographic Reference Bath, Philip M; Scutt, Polly; Love, Jo; Clave, Pere; Cohen, David; Dziewas, Rainer; Iversen, Helle K; Ledl, Christian; Ragab, Suzanne; Soda, Hassan; Warusevitane, Anushka; Woisard, Virginie; Hamdy, Shaheen; Swallowing Treatment Using Pharyngeal Electrical Stimulation (STEPS) Trial, Investigators; Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial.; Stroke; 2016; vol. 47 (no. 6); 1562-70

2

3 **1.1.20.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323 Love, J. and Bath, P. M. W. (2012) A multi-centre, double blind, randomised controlled clinical investigation to validate the EPS1 device as a treatment for stroke-induced dysphagia: a study of Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS Study).
Trial name / registration number	ISRCTN25681641.
Study type	Randomised controlled trial (RCT)
Study location	United Kingdom, Spain, Germany, Denmark, France.
Study setting	Inpatients.
Study dates	April 2012 to September 2014.
Sources of funding	This trial was sponsored and funded by Phagenesis, Ltd. (Manchester, UK).

Inclusion criteria	Admitted to hospital with a clinical stroke syndrome because of ischaemic or haemorrhagic stroke; aged at least 18 years; had clinical dysphagia identified using bedside testing (as assessed by a nurse or speech and language therapist using a local clinical assessment and confirmed by failure on the Toronto Bedside Swallowing Screening Test); were alert or rousable (score of 0-1 on question 1a of the NIHSS); had a Penetration Aspiration Score of at least 3); could be treated within 42 days of stroke onset.
Exclusion criteria	History of dysphagia; dysphagia from a condition other than stroke; advanced dementia; implanted pacemaker or cardiac defibrillator in situ; unstable cardiopulmonary status or a condition that compromised cardiac or respiratory status; distorted oropharyngeal anatomy; additional diagnosis of a progressive neurological disorder; receiving continuous oxygen treatment; pregnant or nursing mother.
Recruitment / selection of participants	International, multicenter trial. People recruited on admission to hospital.
Intervention(s)	<p>Pharyngeal electrical stimulation (PES) N=87</p> <p>Pharyngeal electrical stimulation. Treatment was started once dysphagia was confirmed by videofluoroscopic swallowing assessment and given daily for 3 days. An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference between the threshold and tolerance levels.</p> <p>Concomitant therapy: Treatment was given in addition to standard stroke care, including thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of antihypertensives (all people), oral antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic stroke) were recommended for secondary prevention as per each site's local practice.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Mixed Around 60% of people required enteral feeding support.
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=75 The same procedure but when the levels were established, had the stimulation turned off. Concomitant therapy: Treatment was given in addition to standard stroke care, including thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of antihypertensives (all people), oral antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic stroke) were recommended for secondary prevention as per each site's local practice.
Number of participants	162
Duration of follow-up	2 weeks, 12 weeks.
Indirectness	No additional information.
Additional comments	Per protocol analysis.

1 **1.1.20.2. Study arms**

2 **1.1.20.2.1. Pharyngeal electrical stimulation (PES) (N = 87)**

3 Pharyngeal electrical stimulation. Treatment was started once dysphagia was confirmed by videofluoroscopic swallowing assessment
4 and given daily for 3 days. An electric current of 5Hz was increased incrementally from 1mA to detect threshold and then tolerated
5 intensity levels in all people. This was then continued for 10 minutes at a treatment current of threshold plus 75% of the difference
6 between the threshold and tolerance levels. Concomitant therapy: Treatment was given in addition to standard stroke care, including
7 thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of antihypertensives (all people), oral
8 antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic stroke) were recommended for
9 secondary prevention as per each site's local practice.

10

11 **1.1.20.2.2. Placebo/sham therapy (N = 75)**

12 The same procedure but when the levels were established, had the stimulation turned off. Concomitant therapy: Treatment was given
13 in addition to standard stroke care, including thrombolysis if administered at admission to hospital and rehabilitation. Systematic use of
14 antihypertensives (all people), oral antithrombotic and lipid-lowering agents, and carotid endarterectomy (people with ischaemic
15 stroke) were recommended for secondary prevention as per each site's local practice.

16

17 **1.1.20.3. Characteristics**

18 **1.1.20.3.1. Arm-level characteristics**

Characteristic	Pharyngeal electrical stimulation (PES) (N = 87)	Placebo/sham therapy (N = 75)
% Female	n = 39 ; % = 45	n = 29 ; % = 39
Sample size		
Mean age (SD) (years)	74 (9.9)	74.9 (12.6)
Mean (SD)		

Characteristic	Pharyngeal electrical stimulation (PES) (N = 87)	Placebo/sham therapy (N = 75)
Ethnicity	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Asian	n = 9 ; % = 10.3	n = 6 ; % = 8
Sample size		
Black	n = 0 ; % = 0	n = 4 ; % = 5.3
Sample size		
White	n = 74 ; % = 85.1	n = 65 ; % = 86.7
Sample size		
Other	n = 4 ; % = 4.6	n = 0 ; % = 0
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	12.6 (9.5)	14.4 (10)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NA ; % = NA	n = NA ; % = NA
Sample size		

Characteristic	Pharyngeal electrical stimulation (PES) (N = 87)	Placebo/sham therapy (N = 75)
Nasogastric	n = 52 ; % = 59.8	n = 38 ; % = 50.7
Sample size		
PEG	n = 3 ; % = 3.4	n = 1 ; % = 1.3
Sample size		
Other	n = 4 ; % = 4.6	n = 9 ; % = 12
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Total anterior circulation	n = 21 ; % = 24.4	n = 20 ; % = 28.2
Sample size		
Partial anterior circulation	n = 44 ; % = 51.2	n = 25 ; % = 35.2
Sample size		
Lacunar	n = 21 ; % = 24.4	n = 25 ; % = 35.2
Sample size		
Posterior circulation	n = 0 ; % = 0	n = 1 ; % = 1.4
Sample size		

1 **1.1.20.4. Outcomes**

2 **1.1.20.4.1. Study timepoints**

- 3 • Baseline
 4 • 2 week (<3 months)
 5 • 12 week (≥3 months)

6
 7 **1.1.20.4.2. Dichotomous outcomes (1)**

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 87	Pharyngeal electrical stimulation (PES), 2 week, N = 87	Pharyngeal electrical stimulation (PES), 12 week, N = 87	Placebo/sham therapy, Baseline, N = 75	Placebo/sham therapy, 2 week, N = 75	Placebo/sham therapy, 12 week, N = 75
Mortality (Death) No of events	n = NA ; % = NA	n = 1 ; % = 1.3	n = 9 ; % = 11.5	n = NA ; % = NA	n = 1 ; % = 1.6	n = 9 ; % = 14.3
Occurrence of chest infections No of events	n = NA ; % = NA	n = NR ; % = NR	n = 21 ; % = 24	n = NA ; % = NA	n = NR ; % = NR	n = 11 ; % = 15
Discharged to residential service (Institution) No of events	n = NA ; % = NA	n = NA ; % = NA	n = 49 ; % = 62.8	n = NA ; % = NA	n = NA ; % = NA	n = 44 ; % = 69.8

- 8 Mortality (Death) - Polarity - Lower values are better
 9 Occurrence of chest infections - Polarity - Lower values are better
 10 Discharged to residential service (Institution) - Polarity - Lower values are better

1 **1.1.20.4.3. Dichotomous outcomes (2)**

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 87	Pharyngeal electrical stimulation (PES), 2 week, N = 70	Pharyngeal electrical stimulation (PES), 12 week, N = 70	Placebo/sham therapy, Baseline, N = 75	Placebo/sham therapy, 2 week, N = 56	Placebo/sham therapy, 12 week, N = 56
Dysphagia present/Return to normal diet (Any Penetration Aspiration Score >3) Used as a surrogate measure for dysphagia present. Downgrade for indirectness. No of events	n = NA ; % = NA	n = 60 ; % = 85.7	n = 36 ; % = 51.4	n = NA ; % = NA	n = 45 ; % = 80.4	n = 33 ; % = 58.9

2 Dysphagia present/Return to normal diet (Any Penetration Aspiration Score >3) - Polarity - Lower values are better

3 **1.1.20.4.4. Continuous outcomes (1)**

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 87	Pharyngeal electrical stimulation (PES), 2 week, N = 87	Pharyngeal electrical stimulation (PES), 12 week, N = 87	Placebo/sham therapy, Baseline, N = 75	Placebo/sham therapy, 2 week, N = 75	Placebo/sham therapy, 12 week, N = 75
Person/participant generic health-related quality of life (EQ-5D) Scale range: -0.11-1. Change scores. Reports the number of participants in total is 113, but not the number for each group. Baseline values used	NR (NR)	NR (NR)	0.08 (0.41)	NR (NR)	NR (NR)	-0.04 (0.39)

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 87	Pharyngeal electrical stimulation (PES), 2 week, N = 87	Pharyngeal electrical stimulation (PES), 12 week, N = 87	Placebo/sham therapy, Baseline, N = 75	Placebo/sham therapy, 2 week, N = 75	Placebo/sham therapy, 12 week, N = 75
but will be downgraded for risk of bias.						
Mean (SD)						
Length of hospital stay (discharge days) (days)	NA (NA)	NA (NA)	27.7 (22.7)	NA (NA)	NA (NA)	28.7 (23)
Mean (SD)						
Swallowing ability (Dysphagia Severity Rating Scale) Scale range: 0-12. Final values. States that there are 133 people and 124 people at each time point but not the distribution between groups. Baseline values used but will be downgraded for risk of bias.	7.6 (3.8)	5.2 (4.1)	4.4 (5.2)	8 (3.9)	4.9 (3.9)	3.9 (5.1)
Mean (SD)						
Nutrition (albumin) (g/L) Reported the total number of participants at 2 weeks as 105 and 12 weeks as 62 with no information about the number in each group. Put down as baseline values but will be	36 (5.7)	37 (5.7)	41.7 (4.6)	36.4 (5.8)	36.6 (4.8)	41.1 (6)

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 87	Pharyngeal electrical stimulation (PES), 2 week, N = 87	Pharyngeal electrical stimulation (PES), 12 week, N = 87	Placebo/sham therapy, Baseline, N = 75	Placebo/sham therapy, 2 week, N = 75	Placebo/sham therapy, 12 week, N = 75
downgraded for risk of bias. Final values.						
Mean (SD)						

- 1 Person/participant generic health-related quality of life (EQ-5D) - Polarity - Higher values are better
- 2 Length of hospital stay (discharge days) - Polarity - Lower values are better
- 3 Swallowing ability (Dysphagia Severity Rating Scale) - Polarity - Lower values are better
- 4 Nutrition (albumin) - Polarity - Higher values are better

5 **1.1.20.4.5. Continuous outcomes (2)**

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 70	Pharyngeal electrical stimulation (PES), 2 week, N = 70	Pharyngeal electrical stimulation (PES), 12 week, N = 70	Placebo/sham therapy, Baseline, N = 56	Placebo/sham therapy, 2 week, N = 56	Placebo/sham therapy, 12 week, N = 56
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change score at 2 weeks, final value at 12 weeks.	4.8 (2.1)	-1.2 (1.8)	3.3 (2.2)	4.7 (1.9)	-1.2 (1.8)	3 (2.1)
Mean (SD)						

- 6 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

1

2

3 **1.1.20.4.6. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**4 **1.1.20.4.7. Dichotomous outcomes(1)-Mortality(Death)-NoOfEvents-Pharyngeal electrical stimulation (PES)-Placebo/sham**
5 **therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.20.4.8. Dichotomous outcomes(1)-Mortality(Death)-NoOfEvents-Pharyngeal electrical stimulation (PES)-Placebo/sham**
8 **therapy-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

10 **1.1.20.4.9. Dichotomous outcomes(1)-Occurrence of chest infections-NoOfEvents-Pharyngeal electrical stimulation (PES)-**
11 **Placebo/sham therapy-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.20.4.10.** *Dichotomous outcomes(1)-Discharged to residential service(Institution)-No Of Events-Pharyngeal electrical*
 3 *stimulation (PES)-Placebo/sham therapy-t12*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.20.4.11.** *Dichotomous outcomes(2)-Dysphagia present/Return to normal diet(Any Penetration Aspiration Score >3)-No Of Events-*
 6 *Pharyngeal electrical stimulation (PES)-Placebo/sham therapy-t2*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.20.4.12.** *Dichotomous outcomes(2)-Dysphagia present/Return to normal diet(Any Penetration Aspiration Score >3)-No Of Events-*
 9 *Pharyngeal electrical stimulation (PES)-Placebo/sham therapy-t12*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.20.4.13.** *Continuous outcomes(1)-Person/participant generic health-related quality of life(EQ-5D)-Mean SD-Pharyngeal electrical*
 2 *stimulation (PES)-Placebo/sham therapy-t12*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.20.4.14.** *Continuous outcomes(1)-Length of hospital stay(discharged days)-Mean SD-Pharyngeal electrical stimulation (PES)-*
 5 *Placebo/sham therapy-t12*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.20.4.15.** *Continuous outcomes(1)-Swallowing ability(Dysphagia Severity Rating Scale)-Mean SD-Pharyngeal electrical*
 8 *stimulation (PES)-Placebo/sham therapy-t2*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.20.4.16.** ***Continuous outcomes(1)-Swallowing ability(Dysphagia Severity Rating Scale)-Mean SD-Pharyngeal electrical***
 2 ***stimulation (PES)-Placebo/sham therapy-t12***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.20.4.17.** ***Continuous outcomes(1)-Nutrition(albumin)-Mean SD-Pharyngeal electrical stimulation (PES)-Placebo/sham***
 5 ***therapy-t2***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.20.4.18.** ***Continuous outcomes(1)-Nutrition(albumin)-Mean SD-Pharyngeal electrical stimulation (PES)-Placebo/sham***
 8 ***therapy-t12***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.20.4.19. Continuous outcomes(2)-Occurrence of aspiration(Penetration Aspiration Scale)-Mean SD-Pharyngeal electrical**
 2 **stimulation (PES)-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3
 4 **1.1.20.4.20. Continuous outcomes(2)-Occurrence of aspiration(Penetration Aspiration Scale)-Mean SD-Pharyngeal electrical**
 5 **stimulation (PES)-Placebo/sham therapy-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6
 7 **1.1.21. Carnaby, 2020**

Bibliographic Reference Carnaby, Giselle D; LaGorio, Lisa; Silliman, Scott; Crary, Michael; Exercise-based swallowing intervention (McNeill Dysphagia Therapy) with adjunctive NMES to treat dysphagia post-stroke: A double-blind placebo-controlled trial.; Journal of oral rehabilitation; 2020; vol. 47 (no. 4); 501-510

8
 9 **1.1.21.1. Study details**

Secondary publication of another included	No additional information.
--	----------------------------

study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT01279824.
Study type	Randomised controlled trial (RCT)
Study location	United States of America.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	Supported by a grant from NIH/ NCMRR: NIH-R21HD054752.
Inclusion criteria	Stroke confirmed by the attending neurologist according to the WHO definition; demonstrated dysphagia on admission to rehabilitation defined by a score <178 on the Mann Assessment of Swallowing Ability; no previous history of swallowing disability; surgery of the head or neck.
Exclusion criteria	No additional information.
Recruitment / selection of participants	People presenting to the sub-acute rehabilitation hospital over a two-year period.
Intervention(s)	<p>Neuromuscular electrical stimulation (NMES) N=18</p> <p>Neuromuscular electrical stimulation applied daily for one-hour over a consecutive 3-week period (anticipated total of 15 hours or until discharge if earlier than 3 weeks). Applied using a VitalStim device.</p> <p>Concomitant therapy: A standardized behavioural swallowing intervention was provided to everyone. This included treatment strategies and maneuvers that are commonly used.</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=18</p> <p>Sham NMES. The device delivered 3 minutes of active stimulation at onset, followed by 20% incremental declinations over a further 3 minutes. After the ramp down period, the electrodes remained no stimulating, until the unit was switched off for >5 minutes. At all times the unit displayed the highest stimulation setting and help for >60 seconds within the first 3 minutes of activation. People were instructed that not everyone would feel the sensation. Treatment was applied for 1 hour daily over a 3 week period.</p> <p>Concomitant therapy: A standardized behavioural swallowing intervention was provided to everyone. This included treatment strategies and maneuvers that are commonly used.</p>

	Usual care N=17 Behavioural swallowing intervention only. Concomitant therapy: A standardized behavioural swallowing intervention was provided to everyone. This included treatment strategies and maneuvers that are commonly used.
Number of participants	53
Duration of follow-up	3 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis appears to be completers only.

1

2 **1.1.21.2. Study arms**

3 **1.1.21.2.1. Neuromuscular electrical stimulation (NMES) (N = 18)**

4 Neuromuscular electrical stimulation applied daily for one-hour over a consecutive 3-week period (anticipated total of 15 hours or until
5 discharge if earlier than 3 weeks). Applied using a VitalStim device. Concomitant therapy: A standardized behavioural swallowing
6 intervention was provided to everyone. This included treatment strategies and maneuvers that are commonly used.

7

8 **1.1.21.2.2. Placebo/sham therapy (N = 18)**

9 Sham NMES. The device delivered 3 minutes of active stimulation at onset, followed by 20% incremental declinations over a further 3
10 minutes. After the ramp down period, the electrodes remained no stimulating, until the unit was switched off for >5 minutes. At all times
11 the unit displayed the highest stimulation setting and help for >60 seconds within the first 3 minutes of activation. People were
12 instructed that not everyone would feel the sensation. Treatment was applied for 1 hour daily over a 3 week period. Concomitant

1 therapy: A standardized behavioural swallowing intervention was provided to everyone. This included treatment strategies and
2 maneuvers that are commonly used.

3

4 **1.1.21.2.3. Usual care (N = 17)**

5 Behavioural swallowing intervention only. Concomitant therapy: A standardized behavioural swallowing intervention was provided to
6 everyone. This included treatment strategies and maneuvers that are commonly used.

7

8 **1.1.21.3. Characteristics**

9 **1.1.21.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 18)	Placebo/sham therapy (N = 18)	Usual care (N = 17)
% Female	n = 8 ; % = 44	n = 10 ; % = 56	n = 10 ; % = 59
Sample size			
Mean age (SD) (years)	62.7 (12.2)	70.6 (11.8)	64.3 (14.7)
Mean (SD)			
Ethnicity	n = NA ; % = NA	n = NA ; % = NA	n = NA ; % = NA
Sample size			
Caucasian	n = 15 ; % = 83	n = 16 ; % = 89	n = 16 ; % = 94
Sample size			
African American	n = 3 ; % = 17	n = 2 ; % = 11	n = 1 ; % = 6
Sample size			

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 18)	Placebo/sham therapy (N = 18)	Usual care (N = 17)
Comorbidities	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Time after stroke (days)	7.83 (3.9)	8.47 (7.17)	6.7 (5.1)
Mean (SD)			
People requiring enteral feeding support at baseline	n = 6 ; % = 33	n = 5 ; % = 28	n = 1 ; % = 6
Sample size			
Type of stroke	n = NA ; % = NA	n = NA ; % = NA	n = NA ; % = NA
Sample size			
TACI	n = 3 ; % = 17	n = 2 ; % = 11	n = 1 ; % = 6
Sample size			
PACI	n = 9 ; % = 50	n = 6 ; % = 33	n = 7 ; % = 41
Sample size			
LACI	n = 1 ; % = 6	n = 7 ; % = 39	n = 1 ; % = 6
Sample size			
POCI	n = 6 ; % = 33	n = 1 ; % = 6	n = 3 ; % = 18

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 18)	Placebo/sham therapy (N = 18)	Usual care (N = 17)
Sample size			

1

2 **1.1.21.4. Outcomes**

3 **1.1.21.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 week (<3 months)

6

7 **1.1.21.4.2. Dichotomous outcomes (1)**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 18	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Placebo/sham therapy, Baseline, N = 18	Placebo/sham therapy, 3 week, N = 16	Usual care, Baseline, N = 17	Usual care, 3 week, N = 16
Mortality	n = NA ; % = NA	n = 3 ; % = 18	n = NA ; % = NA	n = 3 ; % = 19	n = NA ; % = NA	n = 1 ; % = 6
No of events						
Dysphagia present/return to normal diet (Dysphagia present)	n = NA ; % = NA	n = 10 ; % = 59	n = NA ; % = NA	n = 11 ; % = 69	n = NA ; % = NA	n = 13 ; % = 81
No of events						

8 Mortality - Polarity - Lower values are better

9 Dysphagia present/return to normal diet (Dysphagia present) - Polarity - Lower values are better

1 **1.1.21.4.3. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 18	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Placebo/sham therapy, Baseline, N = 18	Placebo/sham therapy, 3 week, N = 16	Usual care, Baseline, N = 17	Usual care, 3 week, N = 16
Length of hospital stay (days admitted) (days)	NA (NA)	12.16 (5.4)	NA (NA)	12.12 (4.2)	NA (NA)	13 (7.2)
Mean (SD)						
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Change scores.	3.72 (1.44)	1.2 (0.97)	3.25 (1.61)	2.1 (1.4)	4.35 (1.8)	0.53 (0.83)
Mean (SD)						

2 Length of hospital stay (days admitted) - Polarity - Lower values are better

3 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

4 **1.1.21.4.4. Dichotomous outcomes (2)**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 18	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Placebo/sham therapy, Baseline, N = 18	Placebo/sham therapy, 3 week, N = 15	Usual care, Baseline, N = 18	Usual care, 3 week, N = 16
Occurrence of aspiration (aspiration on videofluoroscopy evaluation) Dichotomous outcome for an outcome where it is preferred to	n = NA ; % = NA	n = 6 ; % = 35	n = NA ; % = NA	n = 4 ; % = 27	n = NA ; % = NA	n = 5 ; % = 31

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 18	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Placebo/sham therapy, Baseline, N = 18	Placebo/sham therapy, 3 week, N = 15	Usual care, Baseline, N = 18	Usual care, 3 week, N = 16
be reported in a continuous form. Downgrade for indirectness.						
No of events						

1 Occurrence of aspiration (aspiration on videofluoroscopy evaluation) - Polarity - Lower values are better

2

3

4 **1.1.21.4.5. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.21.4.6. Dichotomous outcomes(1)-Mortality-NMESvs.sham-NoOfEvents-Neuromuscular electrical stimulation (NMES)-**
 6 **Placebo/sham therapy-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.21.4.7. Dichotomous outcomes(1)-Mortality-NMESvs.usualcare-NoOfEvents-Neuromuscular electrical stimulation (NMES)-**
 9 **Placebo/sham therapy-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.21.4.8.** *Dichotomous outcomes (1)-Dysphagia present/return to normal diet (Dysphagia present)-NMES vs. sham-No Of Events-*
 3 *Neuromuscular electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.21.4.9.** *Dichotomous outcomes (1)-Dysphagia present/return to normal diet (Dysphagia present)-NMES vs. usual care-*
 6 *No Of Events-Neuromuscular electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.21.4.10.** *Continuous outcomes- Length of hospital stay (days admitted)-NMES vs. sham-Mean SD-Neuromuscular electrical*
 9 *stimulation (NMES)-Placebo/sham therapy-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.21.4.11. Continuous outcomes-Length of hospital stay(days admitted)-NMES vs.usual care-Mean SD-Neuromuscular electrical**
 3 **stimulation (NMES)-Placebo/sham therapy-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.21.4.12. Continuous outcomes-Swallowing ability(Functional Oral Intake Scale)-NMES vs.sham-Mean SD-Neuromuscular**
 6 **electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.21.4.13. Continuous outcomes-Swallowing ability(Functional Oral Intake Scale)-NMES vs.usual care-Mean SD-Neuromuscular**
 9 **electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.21.4.14.** *Dichotomous outcomes (2)-Occurrence of aspiration (aspiration on videofluoroscopy evaluation)-NMES vs. sham-*
 2 *No Of Events-Neuromuscular electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable <i>(Outcome indirectness - outcome specified to be continuous in the protocol but reported in a dichotomous form)</i>

3
 4 **1.1.21.4.15.** *Dichotomous outcomes (2)-Occurrence of aspiration (aspiration on videofluoroscopy evaluation)-NMES vs. usual care-*
 5 *No Of Events-Neuromuscular electrical stimulation (NMES)-Placebo/sham therapy-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Partially applicable <i>(Outcome indirectness - outcome specified to be continuous in the protocol but reported in a dichotomous form)</i>

6
 7 **1.1.22. Carnaby, 2006**

Bibliographic Reference Carnaby, Giselle; Hankey, Graeme J; Pizzi, Julia; Behavioural intervention for dysphagia in acute stroke: a randomised controlled trial.; The Lancet. Neurology; 2006; vol. 5 (no. 1); 31-7

8

1 1.1.22.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323 MANN, G, BAXTER, K, HANKEY, G et al. (1997) Treatment for swallowing disorders following acute stroke: a randomised controlled trial. STROKE-SOCIETY-OF-AUSTRALASIA-ANNUAL-SCIENTIFIC-MEETING
Trial name / registration number	Clinicaltrials.gov = NCT00257764
Study type	Randomised controlled trial (RCT)
Study location	Australia
Study setting	People at a university teaching hospital, the Royal Peth Hospital, which provides medical services for the eastern suburban region of Perth, Western Australia.
Study dates	No additional information.
Sources of funding	This study was supported by an educational grant from the Royal Perth Hospital Medical Research Foundation.
Inclusion criteria	A clinical diagnosis of stroke confirmed by the attending clinician, according to the WHO definition of stroke; onset of stroke within the previous 7 days; the study speech pathologist made a clinical diagnosis of swallowing difficulty (dysphagia), as measured by a score of less than 85 on the Paramatta Hospital's assessment of dysphagia; the person had no history of swallowing treatment or surgery of the head or neck; if the person gave written informed consent to participate in the trial and be followed up for the next 6 months.
Exclusion criteria	No additional information.

Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery) N=102</p> <p>Standard low-intensity swallowing therapy composed of swallowing compensation strategies, mainly environmental modifications (eg, upright positioning for feeding); safe swallowing advice (Eg, reduced rate of eating); appropriate dietary modification, under the direction of the study speech pathologist, three times per week for a month, or for the duration of the hospital stay. The choice of specific swallowing compensation strategies was directed by the findings of the clinical swallowing examination and videofluoroscopy (at baseline and at follow up, if necessary).</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.

Comparator	<p>Combination therapy (as above, with additional swallowing exercises) N=102</p> <p>Standard high-intensity swallowing therapy consisted of direct swallowing exercises (eg, effortful swallowing, supraglottic swallow technique) and appropriate dietary modification, under the direction of the speech pathologist, every working day for a month or daily for the duration of the hospital stay (if less than a month). The choice of specific swallowing exercises was established by the findings of the clinical examination and videofluoroscopy (at baseline and at follow up, if necessary).</p> <p>Concomitant therapy: No additional information</p> <p>Usual care N=102</p> <p>Usual care consisted of patient management by the attending physicians as per usual practice. Physicians referred their patients to the existing hospital speech pathology service if they considered it to be appropriate. Treatment, if offered, consisted mainly of supervision for feeding and precautions for safe swallowing (eg, positioning, slowed rate of feeding). Videofluoroscopic assessment of swallowing function was only undertaken if prescribed by the attending physician.</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	306
Duration of follow-up	1 month, 6 months
Indirectness	No additional information.
Additional comments	Intention to treat - all who were randomised were included in the analysis, including the four people who were subsequently deemed to have not had a stroke.

1 **1.1.22.2. Study arms**

2 **1.1.22.2.1. *Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery) (N = 102)***

3 Standard low-intensity swallowing therapy composed of swallowing compensation strategies, mainly environmental modifications (eg,
4 upright positioning for feeding); safe swallowing advice (Eg, reduced rate of eating); appropriate dietary modification, under the
5 direction of the study speech pathologist, three times per week for a month, or for the duration of the hospital stay. The choice of
6 specific swallowing compensation strategies was directed by the findings of the clinical swallowing examination and videofluoroscopy
7 (at baseline and at follow up, if necessary). Concomitant therapy: No additional information.

8

9 **1.1.22.2.2. *Combination therapy (as above, with additional swallowing exercises) (N = 102)***

10 Standard high-intensity swallowing therapy consisted of direct swallowing exercises (eg, effortful swallowing, supraglottic swallow
11 technique) and appropriate dietary modification, under the direction of the speech pathologist, every working day for a month or daily
12 for the duration of the hospital stay (if less than a month). The choice of specific swallowing exercises was established by the findings
13 of the clinical examination and videofluoroscopy (at baseline and at follow up, if necessary). Concomitant therapy: No additional
14 information

15

16 **1.1.22.2.3. *Usual care (N = 102)***

17 Usual care consisted of patient management by the attending physicians as per usual practice. Physicians referred their patients to
18 the existing hospital speech pathology service if they considered it to be appropriate. Treatment, if offered, consisted mainly of
19 supervision for feeding and precautions for safe swallowing (eg, positioning, slowed rate of feeding). Videofluoroscopic assessment of
20 swallowing function was only undertaken if prescribed by the attending physician. Concomitant therapy: No additional information.

21

1 **1.1.22.3. Characteristics**2 **1.1.22.3.1. Arm-level characteristics**

Characteristic	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery) (N = 102)	Combination therapy (as above, with additional swallowing exercises) (N = 102)	Usual care (N = 102)
% Female	n = 43 ; % = 42.2	n = 42 ; % = 41.2	n = 43 ; % = 42.2
Sample size			
Mean age (SD) (years)	72 (12.4)	69.8 (12.5)	71.4 (12.7)
Mean (SD)			
Ethnicity	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Comorbidities	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Time after stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
All by criteria less than or equal to 7 days			
Sample size			
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			

Characteristic	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery) (N = 102)	Combination therapy (as above, with additional swallowing exercises) (N = 102)	Usual care (N = 102)
Type of stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Total anterior circulation syndrome	n = 30 ; % = 29	n = 36 ; % = 35	n = 42 ; % = 41
Sample size			
Partial anterior circulation syndrome	n = 35 ; % = 34	n = 34 ; % = 33	n = 30 ; % = 29
Sample size			
Lacunar syndrome	n = 25 ; % = 25	n = 23 ; % = 23	n = 19 ; % = 19
Sample size			
Posterior circulation syndrome	n = 10 ; % = 10	n = 8 ; % = 8	n = 10 ; % = 10
Sample size			
Unknown/non-stroke	n = 2 ; % = 2	n = 1 ; % = 1	n = 1 ; % = 1
Sample size			

1

2 **1.1.22.4. Outcomes**3 **1.1.22.4.1. Study timepoints**

- 4
- Baseline

- 6 month (≥3 months)

1.1.22.4.2. *Dichotomous outcomes*

Outcome	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery), Baseline, N = 102	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery), 6 month, N = 102	Combination therapy (as above, with additional swallowing exercises), Baseline, N = 102	Combination therapy (as above, with additional swallowing exercises), 6 month, N = 102	Usual care, Baseline, N = 102	Usual care, 6 month, N = 102
Mortality (Death) No of events	n = NA ; % = NA	n = 20 ; % = 19.4	n = NA ; % = NA	n = 17 ; % = 16.5	n = NA ; % = NA	n = 23 ; % = 22.3
Occurrence of chest infection (chest infection) No of events	n = NA ; % = NA	n = 26 ; % = 25.2	n = NA ; % = NA	n = 28 ; % = 27.2	n = NA ; % = NA	n = 48 ; % = 46.6
Discharge to residential service (institutionalisation) No of events	n = NA ; % = NA	n = 17 ; % = 16.5	n = NA ; % = NA	n = 19 ; % = 18.4	n = NA ; % = NA	n = 26 ; % = 25.2
Dysphagia present/return to normal diet (return to normal diet) No of events	n = NA ; % = NA	n = 65 ; % = 63.1	n = NA ; % = NA	n = 71 ; % = 68.9	n = NA ; % = NA	n = 57 ; % = 55.3

- 4 Mortality (Death) - Polarity - Lower values are better
- 5 Occurrence of chest infection (chest infection) - Polarity - Lower values are better

- 1 Discharge to residential service (institutionalisation) - Polarity - Lower values are better
- 2 Dysphagia present/return to normal diet (return to normal diet) - Polarity - Higher values are better

3 **1.1.22.4.3. Continuous outcome**

Outcome	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery), Baseline, N = 102	Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery), 6 month, N = 102	Combination therapy (as above, with additional swallowing exercises), Baseline, N = 102	Combination therapy (as above, with additional swallowing exercises), 6 month, N = 102	Usual care, Baseline, N = 102	Usual care, 6 month, N = 102
Length of hospital stay (days)	NA (NA)	19.2 (13.3)	NA (NA)	19.1 (10.5)	NA (NA)	21.4 (12.4)
Mean (SD)						

- 4 Length of hospital stay - Polarity - Lower values are better

5
6

7 **1.1.22.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

8 **1.1.22.4.5. Dichotomous outcomes-Mortality(Death)-NoOfEvents-Combination therapy (modified diet, positioning, modifying bolus volume/mode of delivery)-Combination therapy (as above, with additional swallowing exercises)-Usual care-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

11

1 **1.1.22.4.6.** ***Dichotomous outcomes-Occurrence of chest infection (chest infection)-No Of Events-Combination therapy (modified***
 2 ***diet, positioning, modifying bolus volume/mode of delivery)-Combination therapy (as above, with additional***
 3 ***swallowing exercises)-Usual care-t6***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4
 5 **1.1.22.4.7.** ***Dichotomous outcomes-Discharge to residential service (institutionalisation)-No Of Events-Combination therapy***
 6 ***(modified diet, positioning, modifying bolus volume/mode of delivery)-Combination therapy (as above, with***
 7 ***additional swallowing exercises)-Usual care-t6***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

8
 9 **1.1.22.4.8.** ***Dichotomous outcomes-Dysphagia present/return to normal diet (return to normal diet)-No Of Events-Combination***
 10 ***therapy (modified diet, positioning, modifying bolus volume/mode of delivery)-Combination therapy (as above, with***
 11 ***additional swallowing exercises)-Usual care-t6***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

12

1 **1.1.22.4.9.** *Continuous outcome- Length of hospital stay- Mean SD- Combination therapy (modified diet, positioning, modifying*
 2 *bolus volume/mode of delivery)- Combination therapy (as above, with additional swallowing exercises)- Usual care-*
 3 *t6*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.23. Chang, 2015**

Bibliographic Reference Chang, M. Y.; KCT0001901 Effect of shaker exercise on motion of hyolaryngeal complex and aspiration in stroke patients with oropharyngeal dysphagia; 2015

6

7 **1.1.23.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	Park, J S, Hwang, N K, Oh, D H et al. (2017) Effect of head lift exercise on kinematic motion of the hyolaryngeal complex and aspiration in patients with dysphagic stroke. Journal of oral rehabilitation 44(5): 385-391

8

9

1 **1.1.24. Cheng, 2017**

Bibliographic Reference Cheng, Ivy K Y; Chan, Karen M K; Wong, Chun-Sing; Li, Leonard S W; Chiu, Karen M Y; Cheung, Raymond T F; Yiu, Edwin M L; Neuronavigated high-frequency repetitive transcranial magnetic stimulation for chronic post-stroke dysphagia: A randomized controlled study.; Journal of rehabilitation medicine; 2017; vol. 49 (no. 6); 475-481

2

3 **1.1.24.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Hong Kong, China.
Study setting	Outpatient follow up.
Study dates	September 2013 to September 2015.
Sources of funding	Funded by the Early Career Scheme, University Grants Council, Hong Kong.
Inclusion criteria	Presence of post-stroke dysphagia for at least 12 months; adequate cognitive ability to follow simple instructions; aged below 80 years; able to sit upright for at least 30 minutes.

Exclusion criteria	Previous history and/or family history of epilepsy; history of head injury or neurological disease other than stroke; neurosurgery; oral and maxillofacial surgery; dysphagia prior to stroke; presence of magnetic implants inside the body; medically unstable; on medications that lower the neural threshold.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=14</p> <p>Repetitive transcranial magnetic stimulation. 30 100-pulse trains of 5Hz rTMS, with inter-train interval of 15s per day for 10 days over 2 weeks. Biphasic rTMS pulses were delivered through a 70-mm Double Air Film coil attached to a Magstim Rapid. Applied at 90% RMT over the tongue area of the motor cortex of the affected hemisphere, as identified and retrieved from the previous session using the neuronavigation system. For people with bilateral lesions, the left hemisphere was stimulation due to left hemispheric dominance for swallowing.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear

Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=7 Sham rTMS via a 70-mm Double Air Film sham coil which had an identical appearance and noise as the real coil, but does not deliver active stimulation of deep nerves. The stimulation schedule was identical to the intervention group. Concomitant therapy: No additional information.
Number of participants	21
Duration of follow-up	2 months, 12 months
Indirectness	No additional information.
Additional comments	No additional information. Appears to be analysis of completers only.

1

2 **1.1.24.2. Study arms**3 **1.1.24.2.1. Transcranial magnetic stimulation (TMS) (N = 14)**

4 Repetitive transcranial magnetic stimulation. 30 100-pulse trains of 5Hz rTMS, with inter-train interval of 15s per day for 10 days over 2
5 weeks. Biphasic rTMS pulses were delivered through a 70-mm Double Air Film coil attached to a Magstim Rapid. Applied at 90% RMT
6 over the tongue area of the motor cortex of the affected hemisphere, as identified and retrieved from the previous session using the
7 neuronavigation system. For people with bilateral lesions, the left hemisphere was stimulation due to left hemispheric dominance for
8 swallowing. Concomitant therapy: No additional information.

9

1 **1.1.24.2.2. Placebo/sham therapy (N = 7)**

2 Sham rTMS via a 70-mm Double Air Film sham coil which had an identical appearance and noise as the real coil, but does not deliver
3 active stimulation of deep nerves. The stimulation schedule was identical to the intervention group. Concomitant therapy: No additional
4 information.

5

6 **1.1.24.3. Characteristics**7 **1.1.24.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 14)	Placebo/sham therapy (N = 7)
% Female	n = 4 ; % = 36.3	n = 0 ; % = 0
Sample size		
Mean age (SD) (years)	65.1 (8.3)	63.3 (7.8)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	42.4 (19.9)	39.8 (25.4)
Mean (SD)		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 14)	Placebo/sham therapy (N = 7)
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1 Baseline characteristics reported for 11 people in the active arm, 4 in the sham arm.

2

3 **1.1.24.4. Outcomes**

4 **1.1.24.4.1. Study timepoints**

- 5 • Baseline
- 6 • 2 month (<3 months)
- 7 • 12 month (≥3 months)

8

9 **1.1.24.4.2. Continuous outcome**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 11	Transcranial magnetic stimulation (TMS), 2 month, N = 11	Transcranial magnetic stimulation (TMS), 12 month, N = 11	Placebo/sham therapy, Baseline, N = 4	Placebo/sham therapy, 2 month, N = 4	Placebo/sham therapy, 12 month, N = 4
Swallowing ability (Swallowing Activity and Participation Profile scores)	111.1 (61.9)	83.1 (52.4)	74.1 (47.3)	57.8 (24.2)	51 (32.6)	65.3 (39.6)

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 11	Transcranial magnetic stimulation (TMS), 2 month, N = 11	Transcranial magnetic stimulation (TMS), 12 month, N = 11	Placebo/sham therapy, Baseline, N = 4	Placebo/sham therapy, 2 month, N = 4	Placebo/sham therapy, 12 month, N = 4
Scale range: Unclear. Final values.						
Mean (SD)						

1 Swallowing ability (Swallowing Activity and Participation Profile scores) - Polarity - Lower values are better

2

3

4 **1.1.24.4.3.** *Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT*

5 **1.1.24.4.4.** *Continuous outcome-Swallowing ability (Swallowing Activity and Participation Profile scores) - Mean SD - Transcranial*
6 *magnetic stimulation (TMS) - Placebo/sham therapy - t2*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.25. Choi, 2017**

Bibliographic Reference Choi, Jong-Bae; Shim, Sun-Hwa; Yang, Jong-Eun; Kim, Hyun-Dong; Lee, Doo-Ho; Park, Ji-Su; Effects of Shaker exercise in stroke survivors with oropharyngeal dysphagia.; NeuroRehabilitation; 2017; vol. 41 (no. 4); 753-757

9

1 1.1.25.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	This research was carried out without funding.
Inclusion criteria	Dysphagia after stroke confirmed by a videofluoroscopic swallowing study; no significant cognitive deficit (Mini-Mental State Examination score >20); above fair grade obtained on muscle testing of the neck; symmetric posture of the neck; ability to swallow voluntarily.
Exclusion criteria	Neck pain or neck surgery; poor general condition precluding further participation in the experiment; severe communication problem; unstable medical condition; presence of a tracheostomy tube.
Recruitment / selection of participants	People were recruited from rehabilitation centers at 2 local hospitals in the Republic of Korea.
Intervention(s)	Behavioural intervention (Shaker exercise) N=16

	<p>Shaker exercises in addition to conventional dysphagia therapy. Shaker exercises included isometric and isokinetic movements. First, people sustained 3 head lifts held for 60 s without movement in the supine position; a 60 s rest was allowed between lifts. Then, people performed 30 repetitive head lifts while holding in the same supine position. People lifted their head high enough to observe their toes without raising their shoulders. Shaker exercises were carried out in hospital wards under supervision of caregivers.</p> <p>Concomitant therapy: Conventional dysphagia therapy was provided to all which comprised orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist carried out this therapy with participants for 30 minutes a day, 5 days a week for 4 weeks.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=15 Conventional dysphagia therapy only.

	Concomitant therapy: Conventional dysphagia therapy was provided to all which comprised orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist carried out this therapy with participants for 30 minutes a day, 5 days a week for 4 weeks.
Number of participants	31
Duration of follow-up	4 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	No information about method of analysis. Appears to be completers only.

1

2 **1.1.25.2. Study arms**3 **1.1.25.2.1. Behavioural intervention (Shaker exercise) (N = 16)**

4 Shaker exercises in addition to conventional dysphagia therapy. Shaker exercises included isometric and isokinetic movements. First,
5 people sustained 3 head lifts held for 60 s without movement in the supine position; a 60 s rest was allowed between lifts. Then,
6 people performed 30 repetitive head lifts while holding in the same supine position. People lifted their head high enough to observe
7 their toes without raising their shoulders. Shaker exercises were carried out in hospital wards under supervision of caregivers.

8 Concomitant therapy: Conventional dysphagia therapy was provided to all which comprised orofacial muscle exercises, thermal tactile
9 stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist carried out this therapy with
10 participants for 30 minutes a day, 5 days a week for 4 weeks.

11

12 **1.1.25.2.2. Usual care (N = 15)**

13 Conventional dysphagia therapy only. Concomitant therapy: Conventional dysphagia therapy was provided to all which comprised
14 orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational
15 therapist carried out this therapy with participants for 30 minutes a day, 5 days a week for 4 weeks.

1

2 **1.1.25.3. Characteristics**3 **1.1.25.3.1. Arm-level characteristics**

Characteristic	Behavioural intervention (Shaker exercise) (N = 16)	Usual care (N = 15)
% Female	n = 6 ; % = 38	n = 6 ; % = 40
Sample size		
Mean age (SD) (years)	60.81 (10.85)	60.4 (10.5)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	3.44 (1.15)	4.13 (0.99)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.25.4. Outcomes**

3 **1.1.25.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week (<3 months)

6

7 **1.1.25.4.2. Continuous outcomes**

Outcome	Behavioural intervention (Shaker exercise), Baseline, N = 16	Behavioural intervention (Shaker exercise), 4 week, N = 16	Usual care, Baseline, N = 15	Usual care, 4 week, N = 15
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values. Mean (SD)	4.63 (0.8)	3.19 (0.54)	4.87 (0.91)	4.27 (0.88)
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Final values. Mean (SD)	3.13 (0.95)	4.75 (1.06)	3.2 (0.67)	3.73 (1.22)

8 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better
 9 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

10

11

1 **1.1.25.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.25.4.4. Continuousoutcomes-Occurrenceofaspiration(PenetrationAspirationScale)-MeanSD-Behavioural intervention**
 3 **(Shaker exercise)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.25.4.5. Continuousoutcomes-Swallowingability(FunctionalOralIntakeScale)-MeanSD-Behavioural intervention (Shaker**
 6 **exercise)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.26. Cola, 2021**

Bibliographic Reference Cola, Paula Cristina; Onofri, Suely Mayumi Motonaga; Rubira, Claudio Jose; Pedroni, Cristiane Rodrigues; Clave, Pere; da Silva, Roberta Goncalves; Electrical, taste, and temperature stimulation in patients with chronic dysphagia after stroke: a randomized controlled pilot trial.; Acta neurologica Belgica; 2021; vol. 121 (no. 5); 1157-1164

9

10 **1.1.26.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Brazil.
Study setting	Inpatients.
Study dates	Over 4 years.
Sources of funding	
Inclusion criteria	Oropharyngeal dysphagia persisting for at least 3 months after stroke; preserved oral comprehension of simple verbal commands; clinical stability; no pacemaker; no use of tracheostomy; able to sit upright; available for daily care for three consecutive weeks.
Exclusion criteria	People with concomitant neurodegenerative disease or tumours; those who underwent previous swallowing rehabilitation.
Recruitment / selection of participants	People who underwent swallowing assessment at the Dysphagia Lab of the Rehabilitation Center.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=6 Traditional therapy combined with neuromuscular electrical stimulation. A two-channel FES electrical stimulation device was used. Two circular self-adhesive surface electrodes, 3 cm diameter, positioned over the anterior neck below the chin in the level suprahyoid and the skin was prepared with a 70% isopropyl alcohol pad. A biphasic symmetrical rectangular pulse waveform was applied with a stimulation frequency of 80 Hz and a phase duration of 250 microseconds. The stimulator provided a maximum intensity of 30 mA. The intensity was increased in accordance with patient tolerance to maximise motor unit recruitment without discomfort. Care was provided (with concomitant therapy) for 40 minute sessions, 5 days per

	<p>week over 3 weeks. Concomitant therapy: Everyone received a traditional therapy using tactile thermal stimulus program, using sour taste and cold temperature in the oral cavity region. Voluntary swallowing maneuvers were also used, including the Mendelsohn maneuver and effortful swallowing maneuver. Hearing, tactile and visual support were offered to the person. The therapeutic programs were treated in 40 minute sessions, 5 days per week over a three-week period.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Mixed
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Usual care N=2</p> <p>Usual care only.</p> <p>Concomitant therapy: Everyone received a traditional therapy using tactile thermal stimulus program, using sour taste and cold temperature in the oral cavity region. Voluntary swallowing maneuvers were also used, including the Mendelsohn maneuver and effortful swallowing maneuver. Hearing, tactile and visual support were offered to the person. The therapeutic programs were treated in 40 minute sessions, 5 days per week over a three-week period.</p>

Number of participants	8
Duration of follow-up	3 weeks.
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis unclear. Likely intention to treat (no dropouts).

1

2 **1.1.26.2. Study arms**3 **1.1.26.2.1. Neuromuscular electrical stimulation (NMES) (N = 6)**

4 Traditional therapy combined with neuromuscular electrical stimulation. A two-channel FES electrical stimulation device was used.
5 Two circular self-adhesive surface electrodes, 3 cm diameter, positioned over the anterior neck below the chin in the level suprahyoid
6 and the skin was prepared with a 70% isopropyl alcohol pad. A biphasic symmetrical rectangular pulse waveform was applied with a
7 stimulation frequency of 80 Hz and a phase duration of 250 microseconds. The stimulator provided a maximum intensity of 30 mA.
8 The intensity was increased in accordance with patient tolerance to maximise motor unit recruitment without discomfort. Care was
9 provided (with concomitant therapy) for 40 minute sessions, 5 days per week over 3 weeks. Concomitant therapy: Everyone received
10 a traditional therapy using tactile thermal stimulus program, using sour taste and cold temperature in the oral cavity region. Voluntary
11 swallowing maneuvers were also used, including the Mendelsohn maneuver and effortful swallowing maneuver. Hearing, tactile and
12 visual support were offered to the person. The therapeutic programs were treated in 40 minute sessions, 5 days per week over a
13 three-week period.

14

15 **1.1.26.2.2. Usual care (N = 2)**

16 Usual care only. Concomitant therapy: Everyone received a traditional therapy using tactile thermal stimulus program, using sour taste
17 and cold temperature in the oral cavity region. Voluntary swallowing maneuvers were also used, including the Mendelsohn maneuver
18 and effortful swallowing maneuver. Hearing, tactile and visual support were offered to the person. The therapeutic programs were
19 treated in 40 minute sessions, 5 days per week over a three-week period.

20

1 **1.1.26.3. Characteristics**2 **1.1.26.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 6)	Usual care (N = 2)
% Female	n = 3 ; % = 50	n = 0 ; % = 0
Sample size		
Mean age (SD) (years)	62.6 (NR)	70 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	4 to 54	NR to NR
Range		
Time after stroke (Months)	13.6 (NR)	5 (NR)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 4 ; % = 67	n = 2 ; % = 100
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 6)	Usual care (N = 2)
Type of stroke	n = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.26.4. Outcomes**3 **1.1.26.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 week (<3 months)

6

7 **1.1.26.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 6	Neuromuscular electrical stimulation (NMES), 3 week, N = 6	Usual care, Baseline, N = 2	Usual care, 3 week, N = 2
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Final values. Mean (SD)	2.67 (1.63)	4 (2)	1.5 (0.71)	4 (1.41)

8 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

9

10

1 **1.1.26.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.26.4.4. Continuous outcomes-Occurrence of aspiration (Functional Oral Intake Scale)-Mean SD-Neuromuscular electrical**
 3 **stimulation (NMES)-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.27. DePippo, 1994**

Bibliographic Reference DePippo, K L; Holas, M A; Reding, M J; Mandel, F S; Lesser, M L; Dysphagia therapy following stroke: a controlled trial.; Neurology; 1994; vol. 44 (no. 9); 1655-60

6

7 **1.1.27.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.

Study type	Randomised controlled trial (RCT)
Study location	United States of America
Study setting	Inpatient rehabilitation unit
Study dates	Over 24 months (estimated 1992-1994)
Sources of funding	Supported by US Public Health Service grant No. 1-RO1-DC00885.
Inclusion criteria	Stroke defined by clinical history and neurologic examination with compatible CT or MRI; ages 20 to 90 years inclusive; no known history of significant oral or pharyngeal anomaly; laboratory values below end point criteria; failure on the Burke Dysphagia Screening Test; MBS evidence of dysphagia.
Exclusion criteria	No additional information.
Recruitment / selection of participants	People admitted to an inpatient rehabilitation unit over 24 months and meeting the criteria for inclusion.
Intervention(s)	<p>Modified diet N=77</p> <p>Combination of group B and group C. Group B received the diagnostic results and training in the use of compensatory swallowing techniques in a formal dysphagia treatment session, as did the patients in group A. Group B patients did not, however, choose their own diet. A dysphagia therapist prescribed a diet based on the results of the MBS evaluation. Patients in this group were reevaluated by the dysphagia therapist every other week for the need to change the prescribed diet consistency. In questionable cases, a repeat MBS was performed. Group B represented people managed by a therapist-prescribed diet and compensatory swallowing technique recommendations. Group C received the same formal dysphagia treatment session. The dysphagia therapist prescribed and controlled the consistency of the diet. However, people were seen daily in a mealtime dysphagia management group where additional instructions and reinforcement of compensatory swallowing techniques were given. Group C therefore represented the most active therapist intervention group, in which the dysphagia therapist prescribed and controlled the diet and provided daily reinforcement of the recommended compensatory swallowing techniques.</p> <p>Concomitant therapy: No additional information.</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Usual care N=38</p> <p>One formal dysphagia treatment session, attended by the patient and relevant family members, to discuss the results of the MBS evaluation. The dysphagia therapist recommended an appropriate diet consistency based upon the results of the MBS. The patient and/or family members were then asked to choose a diet consistency they felt was most appropriate for them. They were given the option of selecting either a regular diet or one of four graded levels of diets designed for patients with dysphagia, and with all-liquid consistencies or with thickened liquids only. The patient or family also had the freedom to change the diet throughout the course of the rehabilitation stay. During the initial session recommendations and training in the use of appropriate compensatory swallowing techniques found to improve swallowing during the MBS were given, but there was no daily reinforcement of the techniques by a dysphagia therapist. If the patient or family member requested additional rehearsal of techniques during the rehabilitation stay, it was provided. Group A therefore represented patients managed by diet and compensatory swallowing technique recommendations alone.</p> <p>Concomitant therapy: No additional information.</p>

Number of participants	115
Duration of follow-up	Duration of inpatient stay (on average 2 months).
Indirectness	No additional information.
Additional comments	Intention to treat principle

1

2 **1.1.27.2. Study arms**3 **1.1.27.2.1. Modified diet (N = 77)**

4 Combination of group B and group C. Group B received the diagnostic results and training in the use of compensatory swallowing
5 techniques in a formal dysphagia treatment session, as did the patients in group A. Group B patients did not, however, choose their
6 own diet. A dysphagia therapist prescribed a diet based on the results of the MBS evaluation. Patients in this group were reevaluated
7 by the dysphagia therapist every other week for the need to change the prescribed diet consistency. In questionable cases, a repeat
8 MBS was performed. Group B represented people managed by a therapist-prescribed diet and compensatory swallowing technique
9 recommendations. Group C received the same formal dysphagia treatment session. The dysphagia therapist prescribed and
10 controlled the consistency of the diet. However, people were seen daily in a mealtime dysphagia management group where additional
11 instructions and reinforcement of compensatory swallowing techniques were given. Group C therefore represented the most active
12 therapist intervention group, in which the dysphagia therapist prescribed and controlled the diet and provided daily reinforcement of
13 the recommended compensatory swallowing techniques. Concomitant therapy: No additional information.

14

15 **1.1.27.2.2. Usual care (N = 38)**

16 One formal dysphagia treatment session, attended by the patient and relevant family members, to discuss the results of the MBS
17 evaluation. The dysphagia therapist recommended an appropriate diet consistency based upon the results of the MBS. The patient
18 and/or family members were then asked to choose a diet consistency they felt was most appropriate for them. They were given the
19 option of selecting either a regular diet or one of four graded levels of diets designed for patients with dysphagia, and with all-liquid
20 consistencies or with thickened liquids only. The patient or family also had the freedom to change the diet throughout the course of the
21 rehabilitation stay. During the initial session recommendations and training in the use of appropriate compensatory swallowing

1 techniques found to improve swallowing during the MBS were given, but there was no daily reinforcement of the techniques by a
 2 dysphagia therapist. If the patient or family member requested additional rehearsal of techniques during the rehabilitation stay, it was
 3 provided. Group A therefore represented patients managed by diet and compensatory swallowing technique recommendations alone.
 4 Concomitant therapy: No additional information.

5

6 1.1.27.3. Characteristics

7 1.1.27.3.1. *Arm-level characteristics*

Characteristic	Modified diet (N = 77)	Usual care (N = 38)
% Female	n = 31 ; % = 40.3	n = 16 ; % = 42.1
Sample size		
Mean age (SD) (years)	64 to 80	66 to 80
Range		
Mean age (SD) (years)	73.8 (NR)	76 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Modified diet (N = 77)	Usual care (N = 38)
Time after stroke (Weeks)	4.7 (3.4 to 6.6)	4.6 (3.6 to 6.1)
Median (IQR)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.27.4. Outcomes**3 **1.1.27.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 month (Average. Time before discharge. <3 months.)

6

7 **1.1.27.4.2. Dichotomous outcomes**

Outcome	Modified diet, Baseline, N = 77	Modified diet, 2 month, N = 77	Usual care, Baseline, N = 38	Usual care, 2 month, N = 38
Mortality	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
No of events				
Occurrence of chest infections (pneumonia)	n = NA ; % = NA	n = 7 ; % = 9	n = NA ; % = NA	n = 1 ; % = 2.6
No of events				

Outcome	Modified diet, Baseline, N = 77	Modified diet, 2 month, N = 77	Usual care, Baseline, N = 38	Usual care, 2 month, N = 38
Nutrition (calorie-nitrogen deficit) Dichotomous outcome for an outcome specified to be a continuous outcome in the protocol so downgraded for indirectness No of events	n = NA ; % = NA	n = 5 ; % = 6.5	n = NA ; % = NA	n = 2 ; % = 5.3
Hydration (dehydration) Dichotomous outcome for an outcome specified to be a continuous outcome in the protocol so downgraded for indirectness No of events	n = NA ; % = NA	n = 1 ; % = 1.3	n = NA ; % = NA	n = 3 ; % = 7.9

- 1 Mortality - Polarity - Lower values are better
 2 Occurrence of chest infections (pneumonia) - Polarity - Lower values are better
 3 Nutrition (calorie-nitrogen deficit) - Polarity - Lower values are better
 4 Hydration (dehydration) - Polarity - Lower values are better

5

6

7 **1.1.27.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**8 **1.1.27.4.4. Dichotomous outcomes-Mortality-NoOfEvents-Modified diet-Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.27.4.5. Dichotomous outcomes-Occurrence of chest infections (pneumonia)-No Of Events-Modified diet-Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

2

3 **1.1.27.4.6. Dichotomous outcomes-Nutrition (calorie-nitrogen deficit)-No Of Events-Modified diet-Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable <i>(Outcome indirectness as continuous outcome in the protocol stated as a dichotomous outcome in the study)</i>

4

5 **1.1.27.4.7. Dichotomous outcomes-Hydration (dehydration)-No Of Events-Modified diet-Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable <i>(Outcome indirectness as continuous outcome in the protocol stated as a dichotomous outcome in the study)</i>

6

1 **1.1.28. Du, 2016**

Bibliographic Reference Du, Juan; Yang, Fang; Liu, Ling; Hu, Jingze; Cai, Biyang; Liu, Wenhua; Xu, Gelin; Liu, Xinfeng; Repetitive transcranial magnetic stimulation for rehabilitation of poststroke dysphagia: A randomized, double-blind clinical trial.; Clinical neurophysiology : official journal of the International Federation of Clinical Neurophysiology; 2016; vol. 127 (no. 3); 1907-13

2

3 **1.1.28.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	ChiCTR-TRC-12003100.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	April 2013 to January 2014.
Sources of funding	Partly supported by grants from the National Natural Science Foundation of China (Nos. 81201078 and 81100870) and Jiangsu Province Foundation of China (BK20141373).
Inclusion criteria	Dysphagia secondary to first-ever monohemispheric ischaemic stroke, single infarction as confirmed by a CT or MRI scan; time from onset of symptoms was <2 months.

Exclusion criteria	Other concomitant neurological diseases; fever; infection; prior administration of tranquilizer; severe aphasia or cognitive impairment; inability to complete the follow-up; other contraindications for transcranial magnetic stimulation.
Recruitment / selection of participants	People admitted to the Department of Neurology, Jinling Hospital, Jiangsu Province, China.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=28</p> <p>Combination of two groups. Group 1) 3Hz rTMS (n = 15). Group 2) 1Hz rTMS (n = 13). Each person received rTMS daily for 5 consecutive days. In group 1 they received 3Hz rTMS for 10 seconds, with an inter-train interval of 10 seconds and 40 trains with a total of 1200 pulses at 90% rMT on the affected hemisphere. In group 2 they received 1Hz rTMS for 30 seconds, with an inter-train interval of 2 seconds, and 40 trains with a total of 1200 pulses at 100% rMT on the unaffected hemisphere. The coil was oriented at an angle of approximately 45 degrees over the "hot spot" of the hemisphere in the 3Hz and 1Hz rTMS groups.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=12 The same stimulation parameters as the 1Hz rTMS group, except the coil was rotated 90 degrees away from the scalp (producing the same noise and local stimulation, but no effect beyond this). Concomitant therapy: No additional information.
Number of participants	40
Duration of follow-up	3 months
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1

2 **1.1.28.2. Study arms**3 **1.1.28.2.1. *Transcranial magnetic stimulation (TMS) (N = 28)***

4 Combination of two groups. Group 1) 3Hz rTMS (n = 15). Group 2) 1Hz rTMS (n = 13). Each person received rTMS daily for 5
5 consecutive days. In group 1 they received 3Hz rTMS for 10 seconds, with an inter-train interval of 10 seconds and 40 trains with a
6 total of 1200 pulses at 90% rMT on the affected hemisphere. In group 2 they received 1Hz rTMS for 30 seconds, with an inter-train
7 interval of 2 seconds, and 40 trains with a total of 1200 pulses at 100% rMT on the unaffected hemisphere. The coil was oriented at an
8 angle of approximately 45 degrees over the "hot spot" of the hemisphere in the 3Hz and 1Hz rTMS groups. Concomitant therapy: No
9 additional information.

10

1 **1.1.28.2.2. Placebo/sham therapy (N = 12)**

2 The same stimulation parameters as the 1Hz rTMS group, except the coil was rotated 90 degrees away from the scalp (producing the
3 same noise and local stimulation, but no effect beyond this). Concomitant therapy: No additional information.

4

5 **1.1.28.3. Characteristics**6 **1.1.28.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 28)	Placebo/sham therapy (N = 12)
% Female	n = 8 ; % = 29	n = 6 ; % = 50
Sample size		
Mean age (SD) (years)	58.07 (2.64)	58.83 (3.35)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days) Values for rTMS groups are recorded here. 3Hz group = 8 (4-15) days. 1Hz group = 6 (5-28.5) days.	NA (NA to NA)	9 (7 to 26.25)
Median (IQR)		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 28)	Placebo/sham therapy (N = 12)
People requiring enteral feeding support at baseline	n = 7 ; % = 25	n = 5 ; % = 42
Nasogastric feeding		
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Cortical	n = 1 ; % = 4	n = 2 ; % = 17
Sample size		
Subcortical	n = 19 ; % = 68	n = 5 ; % = 42
Sample size		
Massive	n = 8 ; % = 29	n = 5 ; % = 42
Sample size		

1

2 **1.1.28.4. Outcomes**3 **1.1.28.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 month (≥ 3 months)

6

1 **1.1.28.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 28	Transcranial magnetic stimulation (TMS), 3 month, N = 26	Placebo/sham therapy, Baseline, N = 12	Placebo/sham therapy, 3 month, N = 12
Swallowing ability (Standardised swallowing assessment) Scale range: Unclear. Final values. Taken from the Cochrane review (values reported on a graph in the report). Reported 3Hz rTMS = 18.91 (0.91). Reported 1Hz rTMS = 18.53 (0.74). Mean (SD)	24.36 (2.3)	18.72 (0.85)	25.58 (1.73)	22.73 (2.15)

2 Swallowing ability (Standardised swallowing assessment) - Polarity - Lower values are better

3

4

5 **1.1.28.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.28.4.4. Continuous outcomes-Swallowing ability(Standardised swallowing assessment)-MeanSD-Transcranial magnetic stimulation (TMS)-Placebo/sham therapy-t3**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.29. Dziewas, 2014**

Bibliographic Reference Dziewas, R.; DRKS00005509 A single-centre, double blind, randomised controlled clinical trial to evaluate the effect of electrical pharyngeal stimulation as a treatment for stroke related dysphagia in tracheotomized stroke patients; 2014

2

3 **1.1.29.1. Study details**

Secondary publication of another included study- see primary study for details	Suntrup, Sonja, Marian, Thomas, Schroder, Jens Burchard et al. (2015) Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial. Intensive care medicine 41(9): 1629-37
Other publications associated with this study included in review	No additional information. This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

4

5

6 **1.1.30. Dziewas, 2017**

Bibliographic Reference Dziewas, Rainer; Mistry, Satish; Hamdy, Shaheen; Minnerup, Jens; Van Der Tweel, Ingeborg; Schabitz, Wolf; Bath, Philip M; PHAST-TRAC, Investigators; Design and implementation of Pharyngeal electrical Stimulation for early de-cannulation in TRACheotomized (PHAST-TRAC) stroke patients with neurogenic dysphagia: a prospective randomized single-blinded interventional study.; International journal of stroke : official journal of the International Stroke Society; 2017; vol. 12 (no. 4); 430-437

7

1 **1.1.30.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	Dziewas, Rainer, Mistry, Satish, Hamdy, Shaheen et al. (2017) Design and implementation of Pharyngeal electrical Stimulation for early de-cannulation in TRACheotomized (PHAST-TRAC) stroke patients with neurogenic dysphagia: a prospective randomized single-blinded interventional study. International journal of stroke : official journal of the International Stroke Society 12(4): 430-437

2

3

4 **1.1.31. Dziewas, 2018**

Bibliographic Reference	Dziewas, Rainer; Stellato, Rebecca; van der Tweel, Ingeborg; Walther, Ernst; Werner, Cornelius J; Braun, Tobias; Citerio, Giuseppe; Jandl, Mitja; Friedrichs, Michael; Notzel, Katja; Vosko, Milan R; Mistry, Satish; Hamdy, Shaheen; McGowan, Susan; Warnecke, Tobias; Zwitter, Paul; Bath, Philip M; PHAST-TRAC, investigators; Pharyngeal electrical stimulation for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (PHAST-TRAC): a prospective, single-blinded, randomised trial.; The Lancet. Neurology; 2018; vol. 17 (no. 10); 849-859
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6 **1.1.31.1. Study details**

Secondary publication of another included study- see primary study for details	Dziewas, Rainer, Mistry, Satish, Hamdy, Shaheen et al. (2017) Design and implementation of Pharyngeal electrical Stimulation for early de-cannulation in TRACheotomized (PHAST-TRAC) stroke patients with neurogenic dysphagia: a prospective randomized single-blinded interventional study. International journal of stroke : official journal of the International Stroke Society 12(4): 430-437
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Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	ISRCTN18137204.
Study type	Randomised controlled trial (RCT)
Study location	Germany, Austria and Italy.
Study setting	Inpatient at 7 acute care hospitals and 2 rehabilitation facilities.
Study dates	29th May 2015 to 5th July 2017.
Sources of funding	Sponsored by Phagenesis Ltd., Manchester, UK.
Inclusion criteria	Over 18 years of age; had presented with a supratentorial stroke (haemorrhagic or ischaemic); were mechanically ventilated for at least 48 hours post-stroke; were successfully weaned from mechanical ventilation but remained trachetomised; had been free of sedation for at least 3 days at the time of first decannulation screening; scored at least 1 point on the Richmond Agitation and Sedation Scale; could not be decannulated due to severe dysphagia.
Exclusion criteria	Infratentorial stroke; pre-existing dysphagia; pre-existing disease that typically causes dysphagia (for example Parkinson's disease, motor neuron disorders); participation in any other study potentially influencing the outcome of PES; presence of a cardiac pacemaker or an implantable defibrillator, nasal deformity or previous oesophageal surgery or any other circumstance where placement of a standard nasogastric tube would be deemed unsafe; need for high levels of oxygen supply (>2 L/min); required emergency treatment; had less than 3 months life expectancy.
Recruitment / selection of participants	No additional information.
Intervention(s)	Pharyngeal electrical stimulation N=35 Pharyngeal electrical stimulation given on three consecutive days for 10 minutes. The current intensity was individually adjusted and optimised at every session by the healthcare worker interacting with the base stations touchscreen in response to the person's response. The treatment optimisation procedure involved increasing the current intensity incrementally from 1 mA to detect the perceptual threshold and then maximum tolerated threshold intensity levels three

	<p>times each respectively. Thereafter, the optimal treatment intensity was automatically calculated by the base station using the average values of the three trials.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=34</p> <p>Sham therapy using the same procedure but no current was applied.</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	69

Duration of follow-up	2 days, 30 days or Hospital Discharge (whichever is first), 90 days. (The study gives all people open label treatment after 72 hours - therefore, only data before 72 hours will be used).
Indirectness	No additional information.
Additional comments	Intention-to-treat analysis.

1

2 **1.1.31.2. Study arms**

3 **1.1.31.2.1. Pharyngeal electrical stimulation (N = 35)**

4 Pharyngeal electrical stimulation given on three consecutive days for 10 minutes. The current intensity was individually adjusted and
 5 optimised at every session by the healthcare worker interacting with the base stations touchscreen in response to the person's
 6 response. The treatment optimisation procedure involved increasing the current intensity incrementally from 1 mA to detect the
 7 perceptual threshold and then maximum tolerated threshold intensity levels three times each respectively. Thereafter, the optimal
 8 treatment intensity was automatically calculated by the base station using the average values of the three trials. Concomitant therapy:
 9 No additional information.

10

11 **1.1.31.2.2. Placebo/sham therapy (N = 34)**

12 Sham therapy using the same procedure but no current was applied. Concomitant therapy: No additional information.

13

14 **1.1.31.3. Characteristics**

15 **1.1.31.3.1. Arm-level characteristics**

Characteristic	Pharyngeal electrical stimulation (N = 35)	Placebo/sham therapy (N = 34)
% Female	n = 11 ; % = 31	n = 14 ; % = 41
Sample size		

Characteristic	Pharyngeal electrical stimulation (N = 35)	Placebo/sham therapy (N = 34)
Mean age (SD) (years)	61.7 (13)	66.8 (10.3)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Hypertension	n = 23 ; % = 66	n = 26 ; % = 77
Sample size		
Hyperlipidaemia	n = 1 ; % = 3	n = 3 ; % = 9
Sample size		
Diabetes	n = 3 ; % = 9	n = 5 ; % = 15
Sample size		
Atrial fibrillation	n = 3 ; % = 9	n = 2 ; % = 6
Sample size		
Previous stroke/TIA	n = 7 ; % = 20	n = 3 ; % = 9
Sample size		
Severity of dysphagia	n = NA ; % = NA	n = NA ; % = NA
Sample size		

Characteristic	Pharyngeal electrical stimulation (N = 35)	Placebo/sham therapy (N = 34)
FOIS 1	n = 35 ; % = 100	n = 34 ; % = 100
Sample size		
Time after stroke	28 (20 to 49)	28 (18 to 40)
Median (IQR)		
People requiring enteral feeding support at baseline	n = 5 ; % = NR	n = 4 ; % = 18
Requiring PEG		
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.31.4. Outcomes**3 **1.1.31.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 day (<3 months)

6

7 **1.1.31.4.2. Continuous outcomes (1)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 35	Pharyngeal electrical stimulation, 2 day, N = 31	Placebo/sham therapy, Baseline, N = 34	Placebo/sham therapy, 2 day, N = 30
Swallowing ability (Functional Oral Intake Scale)	1 (0)	1.7 (1.2)	1 (0)	1.9 (1.4)

Outcome	Pharyngeal electrical stimulation, Baseline, N = 35	Pharyngeal electrical stimulation, 2 day, N = 31	Placebo/sham therapy, Baseline, N = 34	Placebo/sham therapy, 2 day, N = 30
Scale range: 1-8. Final values.				
Mean (SD)				

1 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

2 **1.1.31.4.3. Dichotomous outcomes**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 35	Pharyngeal electrical stimulation, 2 day, N = 35	Placebo/sham therapy, Baseline, N = 34	Placebo/sham therapy, 2 day, N = 34
Mortality 1 death in the intervention arm	n = NA ; % = NA	n = 1 ; % = 2.9	n = NA ; % = NA	n = 0 ; % = 0
No of events				

3 Mortality - Polarity - Lower values are better

4

5

6 **1.1.31.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.31.4.5. Continuous outcomes(1)-Occurrence of aspiration(Functional Oral Intake Scale)-Mean SD-Pharyngeal electrical stimulation-Placebo/sham therapy-t2**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.31.4.6. Dichotomous outcomes-Mortality-NoOfEvents-Pharyngeal electrical stimulation-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.32. Eom, 2017**

Bibliographic Reference Eom, Mi-Ja; Chang, Moon-Young; Oh, Dong-Hwan; Kim, Hyun-Dong; Han, Na-Mi; Park, Ji-Su; Effects of resistance expiratory muscle strength training in elderly patients with dysphagic stroke.; NeuroRehabilitation; 2017; vol. 41 (no. 4); 747-752

5

6 **1.1.32.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.

Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea
Study setting	NR
Study dates	No additional information
Sources of funding	This research was carried out without funding.
Inclusion criteria	The inclusion criteria for participation were as follows: (1) having dysphagia caused by a stroke, confirmed by a videofluoroscopic swallowing study (VFSS), (2) age > 65, (3) onset duration of < 3 months, (4) a score of ≥ 24 on the Mini-Mental State Examination.
Exclusion criteria	Exclusion criteria were the following: (1) presence of severe orofacial pain including trigeminal neuropathy, (2) significant malocclusion or facial asymmetry, (3) unstable breathing and pulse, (4) tracheostomy, (5) communication disorder like severe aphasia and apraxia (6) inadequate lip closure.
Recruitment / selection of participants	NR
Intervention(s)	Participants in the experimental group used a portal Expiratory Muscle Trainer (EMST150. Aspire Products, LLC) and threshold value was set at the 70% range of MEP. For training, patients were asked to open their mouth after inhalation and locate the EMST mouthpiece between the lips before closing mouth. Then, they were instructed to blow strongly and rapidly until the pressure release valve within the EMST device opens. The pressure release valve was set to open if expiratory pressure exceeded targeted pressure set for the device. Evaluators confirmed whether it was successful by listening to the sound of air rushing. Intervention was performed 5 days per week/4weeks, in five sets of 5 breaths through the device for a total of 25 breaths per day. During training, less than a 1 minute break was provided after each session, considering muscle fatigue and dizziness.
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	NR
Comparator	The placebo group was trained by using a sham EMST device with no loading device. Its exterior is the same as that of an EMST device for the experiment group, but it is a nonfunctional device with little effect of physiologic load on targeted muscles.
Number of participants	26
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.32.2. Study arms**3 **1.1.32.2.1. *Behavioural interventions (resistance expiratory muscle strength training) (N = 13)***

4

5 **1.1.32.2.2. *Placebo (N = 13)***

6

1 **1.1.32.3. Characteristics**2 **1.1.32.3.1. Study-level characteristics**

Characteristic	Study (N = 26)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

3

4 **1.1.32.3.2. Arm-level characteristics**

Characteristic	Behavioural interventions (resistance expiratory muscle strength training) (N = 13)	Placebo (N = 13)
% Female	61.5	53.8
Nominal		
Mean age (SD)	69.2 (4.1)	70.2 (3.6)
Mean (SD)		
Severity of dysphagia PAS	5.08 (0.76)	4.92 (0.64)

Characteristic	Behavioural interventions (resistance expiratory muscle strength training) (N = 13)	Placebo (N = 13)
Mean (SD)		
Type of stroke	NR	NR
Nominal		
Middle cerebral artery	9	9
Nominal		
Basal ganglia	0	1
Nominal		
Midbrain	1	0
Nominal		
Frontal lobe	1	1
Nominal		
Internal capsule	1	1
Nominal		
Pons	1	1
Nominal		

1

2 **1.1.32.4. Outcomes**3 **1.1.32.4.1. Study timepoints**

4 • Baseline

- 4 week

1.1.32.4.2. Continuous outcomes

Outcome	Behavioural interventions (resistance expiratory muscle strength training), Baseline, N = 13	Behavioural interventions (resistance expiratory muscle strength training), 4 week, N = 13	Placebo, Baseline, N = 13	Placebo, 4 week, N = 13
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change scores. Mean (SD)	5.08 (0.76)	-1.31 (1.25)	4.92 (0.64)	-0.31 (0.63)
Swallowing ability (Videofluoroscopic Dysphagia Scale - total score) Scale range: 0-100. Change scores. Mean (SD)	57.96 (9.39)	-15.69 (7.97)	55.04 (9.38)	-5.27 (6.16)

- 4 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better
- 5 Swallowing ability (Videofluoroscopic Dysphagia Scale - total score) - Polarity - Lower values are better

6
7

1 **1.1.32.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.32.4.4. Continuous outcomes - Occurrence of aspiration - Mean SD - Resistance expiratory muscle strength training - Placebo - t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.33. Farpour, 2022**

Bibliographic Reference Farpour, S.; Asadi-Shekaari, M.; Borhani Haghghi, A.; Farpour, H.R.; Improving Swallowing Function and Ability in Post Stroke Dysphagia: A Randomized Clinical Trial; Dysphagia; 2022

5

6 **1.1.33.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	Iranian Registry of Clinical Trials: IRCT20200520047521N1.
Study type	Randomised controlled trial (RCT)

Study location	Iran.
Study setting	Inpatients.
Study dates	February 2021 to November 2021.
Sources of funding	Support from Kerman Neuroscience Research Center, Institute of Neuropharmacology, Kerman University of Medical Sciences, Kerman, Iran (No. 99000137).
Inclusion criteria	Age 18 years or over; presence of ischaemic stroke confirmed with brain imaging; diagnosis of dysphagia according to Northwestern Dysphagia Patient Check Sheet Screening.
Exclusion criteria	Haemorrhagic or lacunar stroke; previous history of dysphagia; presence of neurological disorders other than stroke or neurodegenerative disorders; auditory and/or visual condition interfering with speech therapist or assessor or technician's instruction; history of seizures; those with cardiac pacemaker or metallic implants; previous history of skull surgery or current need of skull surgery; presence of a tracheal cannula; an unstable medical condition which can interfere with the study process (such as haemodynamic instability, decreased level of consciousness, etc.); inability to stay alert during treatment.
Recruitment / selection of participants	People after stroke (at least 24 hours) admitted to the neurology wards and stroke units of Shiraz University of Medical Sciences hospitals.
Intervention(s)	<p>Transcranial Direct Current Stimulation (TDCS) N=24</p> <p>Transcranial direct current stimulation applied for 20 minutes for five days (one session in a day). Intensity was 2mA. The current density of the anodal pad was 0.125mA/cm². The anode was placed on the intact supra marginal gyrus.</p> <p>Concomitant therapy: During stimulation, all people received behavioural therapy according to their condition. The techniques consisted of different passive and active rehabilitative techniques and swallow maneuvers. After each session, the people/caregivers received 10 minutes consultation with the speech therapist about the food modification (if applicable), positioning and the behavioural techniques which were used for the person.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=24</p> <p>Sham transcranial direct current stimulation (same procedure but the current was only applied for 30 s at the beginning and end of the period).</p> <p>Concomitant therapy: During stimulation, all people received behavioural therapy according to their condition. The techniques consisted of different passive and active rehabilitative techniques and swallow maneuvers. After each session, the people/caregivers received 10 minutes consultation with the speech therapist about the food modification (if applicable), positioning and the behavioural techniques which were used for the person.</p>
Number of participants	44
Duration of follow-up	1 week, 1 month.
Indirectness	No additional information.
Additional comments	Method of analysis unclear.

1 **1.1.33.2. Study arms**

2 **1.1.33.2.1. Transcranial Direct Current Stimulation (TDCS) (N = 24)**

3 Transcranial direct current stimulation applied for 20 minutes for five days (one session in a day). Intensity was 2mA. The current
 4 density of the anodal pad was 0.125mA/cm². The anode was placed on the intact supra marginal gyrus. Concomitant therapy: During
 5 stimulation, all people received behavioural therapy according to their condition. The techniques consisted of different passive and
 6 active rehabilitative techniques and swallow maneuvers. After each session, the people/caregivers received 10 minutes consultation
 7 with the speech therapist about the food modification (if applicable), positioning and the behavioural techniques which were used for the
 8 person.

9

10 **1.1.33.2.2. Placebo/sham therapy (N = 24)**

11 Sham transcranial direct current stimulation (same procedure but the current was only applied for 30 s at the beginning and end of the
 12 period). Concomitant therapy: During stimulation, all people received behavioural therapy according to their condition. The techniques
 13 consisted of different passive and active rehabilitative techniques and swallow maneuvers. After each session, the people/caregivers
 14 received 10 minutes consultation with the speech therapist about the food modification (if applicable), positioning and the behavioural
 15 techniques which were used for the person.

16

17 **1.1.33.3. Characteristics**

18 **1.1.33.3.1. Arm-level characteristics**

Characteristic	Transcranial Direct Current Stimulation (TDCS) (N = 24)	Placebo/sham therapy (N = 24)
% Female	n = 9 ; % = 41	n = 12 ; % = 55
Sample size		
Mean age (SD)	65.32 (16.34)	70.68 (16.33)
Mean (SD)		

Characteristic	Transcranial Direct Current Stimulation (TDCS) (N = 24)	Placebo/sham therapy (N = 24)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	4.09 (3.97)	4.5 (3.96)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Cortical	n = 22 ; % = 100	<i>empty data</i>
Sample size		
Brainstem	n = 0	n = 2 ; % = 9.1
Sample size		
Multiple regions	n = 0 ; % = 0	n = 1 ; % = 4.5

Characteristic	Transcranial Direct Current Stimulation (TDCS) (N = 24)	Placebo/sham therapy (N = 24)
Sample size		

1 Reports baseline characteristics for 22 people in each group.

2

3 **1.1.33.4. Outcomes**

4 **1.1.33.4.1. Study timepoints**

- 5 • Baseline
- 6 • 1 month (<3 months)

7

8 **1.1.33.4.2. Continuous outcomes**

Outcome	Transcranial Direct Current Stimulation (TDCS), Baseline, N = 22	Transcranial Direct Current Stimulation (TDCS), 1 month, N = 22	Placebo/sham therapy, Baseline, N = 22	Placebo/sham therapy, 1 month, N = 22
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Final values. Mean (SD)	2.64 (1.65)	6.18 (1.33)	2.5 (1.6)	4.4 (1.94)

9 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

1 **1.1.33.4.3. Dichotomous outcomes**

Outcome	Transcranial Direct Current Stimulation (TDCS), Baseline, N = 22	Transcranial Direct Current Stimulation (TDCS), 1 month, N = 22	Placebo/sham therapy, Baseline, N = 22	Placebo/sham therapy, 1 month, N = 22
Dysphagia present/return to normal diet (number of people with FOIS less than 6)	n = NA ; % = NA	n = 6 ; % = 27	n = NA ; % = NA	n = 15 ; % = 68
No of events				

2 Dysphagia present/return to normal diet (number of people with FOIS less than 6) - Polarity - Lower values are better

3

4

5 **1.1.33.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.33.4.5. Continuous outcomes-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Transcranial Direct Current Stimulation (TDCS)-Placebo/sham therapy-t1**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.33.4.6. Dichotomous outcomes-Dysphagia present/return to normal diet (number of people with FOIS less than 6)-No of Events-Transcranial Direct Current Stimulation (TDCS)-Placebo/sham therapy-t1**

10

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.34. Feng, 2012**

Bibliographic Reference Feng, Xue-gong; Hao, Wen-jie; Ding, Zhou; Sui, Qiang; Guo, Huan; Fu, Jian; Clinical study on tongyan spray for post-stroke dysphagia patients: a randomized controlled trial.; Chinese journal of integrative medicine; 2012; vol. 18 (no. 5); 345-9

3

4 **1.1.34.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Outpatient and inpatients.
Study dates	January 2010 to July 2011.

Sources of funding	Supported by the Project of Beijing Traditional Chinese Medicine Scientific Program (No. JJ2007-010).
Inclusion criteria	Dysphagia symptoms appeared within two weeks to six months after stroke; the symptoms were in compliance with the above diagnostic standard; the SSA scale score was >30; people were conscious and able to cooperate with the examination and treatment; 40-90 years old; signed the informed consent form.
Exclusion criteria	People with consciousness disorder; unstable life signs accompanied with serious heart, kidney etc. dysfunctions; lack of compliance with examination and treatment.
Recruitment / selection of participants	Outpatients at the Neurology Department and inpatients at the Neurology and Acupuncture Departments of Beijing Hospital of Traditional Chinese and Western Medicine.
Intervention(s)	<p>Physical stimulation (Tongyan Spray) N=61</p> <p>Tongyan Spray composed of ginger and clematis radix (producing a heat sensation and using flavours). Spray applied to the pharynx on both sides and the middle part once respectively for each time, three times a day. The spray was applied 30 minutes before meals for people who were able to take food.</p> <p>Concomitant therapy: Conventional treatment was given to all and included maintaining water and electrolyte balance, controlling blood pressure and blood sugar matched with acupuncture therapy (exclusive of the head, face or neck acupoints). Nasogastric tube feeding was provided for people with severe dysphagia. Rehabilitation training was given including tongue to stretch forward, retract backward, to roll, to stretch sideways, together with other initiative activities, other muscle movement, breathing control training and periodic food-taking training. Jelly-like food was used for training at first, but gradually transitioned to paste food and then to solid food. People were trained once a day, and ice stimulation in the pharynx was used additionally for people with poor pharyngeal reflex.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear

Subgroup 3: People requiring enteral feeding support at baseline	Mixed According to inclusion criteria
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=61 Same procedure but using a placebo spray. Concomitant therapy: Conventional treatment was given to all and included maintaining water and electrolyte balance, controlling blood pressure and blood sugar matched with acupuncture therapy (exclusive of the head, face or neck acupoints). Nasogastric tube feeding was provided for people with severe dysphagia. Rehabilitation training was given including tongue to stretch forward, retract backward, to roll, to stretch sideways, together with other initiative activities, other muscle movement, breathing control training and periodic food-taking training. Jelly-like food was used for training at first, but gradually transitioned to paste food and then to solid food. People were trained once a day, and ice stimulation in the pharynx was used additionally for people with poor pharyngeal reflex.
Number of participants	122
Duration of follow-up	28 days (4 weeks).
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1 **1.1.34.2. Study arms**

2 **1.1.34.2.1. Physical stimulation (Tongyan Spray) (N = 61)**

3 Tongyan Spray composed of ginger and clematis radix (producing a heat sensation and using flavours). Spray applied to the pharynx
4 on both sides and the middle part once respectively for each time, three times a day. The spray was applied 30 minutes before meals
5 for people who were able to take food. Concomitant therapy: Conventional treatment was given to all and included maintaining water
6 and electrolyte balance, controlling blood pressure and blood sugar matched with acupuncture therapy (exclusive of the head, face or
7 neck acupoints). Nasogastric tube feeding was provided for people with severe dysphagia. Rehabilitation training was given including
8 tongue to stretch forward, retract backward, to roll, to stretch sideways, together with other initiative activities, other muscle movement,
9 breathing control training and periodic food-taking training. Jelly-like food was used for training at first, but gradually transitioned to
10 paste food and then to solid food. People were trained once a day, and ice stimulation in the pharynx was used additionally for people
11 with poor pharyngeal reflex.

12

13 **1.1.34.2.2. Placebo/sham therapy (N = 61)**

14 Same procedure but using a placebo spray. Concomitant therapy: Conventional treatment was given to all and included maintaining
15 water and electrolyte balance, controlling blood pressure and blood sugar matched with acupuncture therapy (exclusive of the head,
16 face or neck acupoints). Nasogastric tube feeding was provided for people with severe dysphagia. Rehabilitation training was given
17 including tongue to stretch forward, retract backward, to roll, to stretch sideways, together with other initiative activities, other muscle
18 movement, breathing control training and periodic food-taking training. Jelly-like food was used for training at first, but gradually
19 transitioned to paste food and then to solid food. People were trained once a day, and ice stimulation in the pharynx was used
20 additionally for people with poor pharyngeal reflex.

21

22 **1.1.34.3. Characteristics**

23 **1.1.34.3.1. Arm-level characteristics**

Characteristic	Physical stimulation (Tongyan Spray) (N = 61)	Placebo/sham therapy (N = 61)
% Female	n = 17 ; % = 28	n = 24 ; % = 40
Sample size		

Characteristic	Physical stimulation (Tongyan Spray) (N = 61)	Placebo/sham therapy (N = 61)
Mean age (SD) (years)	70.57 (10.53)	71.22 (10.29)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Grade 1	n = 22 ; % = 37	n = 16 ; % = 27
Sample size		
Grade 2-3	n = 38 ; % = 63	n = 44 ; % = 73
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1 Only reports baseline characteristics for 60 people in each study arm.

1

2 **1.1.34.4. Outcomes**3 **1.1.34.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week (<3 months)

6

7 **1.1.34.4.2. Continuous outcomes**

Outcome	Physical stimulation (Tongyan Spray), Baseline, N = 60	Physical stimulation (Tongyan Spray), 4 week, N = 60	Placebo/sham therapy, Baseline, N = 60	Placebo/sham therapy, 4 week, N = 60
Swallowing ability (Standardised swallowing assessment) Scale range: unclear. Change scores. Mean (SD)	NR (NR)	-6.45 (2.53)	NR (NR)	-5.02 (2.42)

8 Swallowing ability (Standardised swallowing assessment) - Polarity - Lower values are better

9 **1.1.34.4.3. Dichotomous outcomes**

Outcome	Physical stimulation (Tongyan Spray), Baseline, N = 60	Physical stimulation (Tongyan Spray), 4 week, N = 60	Placebo/sham therapy, Baseline, N = 60	Placebo/sham therapy, 4 week, N = 60
Dysphagia present/Return to normal diet (Number of people cured) No of events	n = NA ; % = NA	n = 1 ; % = 1.7	n = NA ; % = NA	n = 1 ; % = 1.7

1 Dysphagia present/Return to normal diet (Number of people cured) - Polarity - Higher values are better

2

3

4 **1.1.34.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.34.4.5. Continuous outcomes-Swallowing ability (Standardised swallowing assessment)-Mean SD-Physical stimulation**
 6 **(Tongyan Spray)-Placebo/sham therapy-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.34.4.6. Dichotomous outcomes-Dysphagia present/Return to normal diet (Number of people cured)-No Of Events-Physical**
 9 **stimulation (Tongyan Spray)-Placebo/sham therapy-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

10

11 **1.1.35. Garon, 1997**

Bibliographic Reference Garon, B.R.; Engle, M.; Ormiston, C.; A randomized control study to determine the effects of unlimited oral intake of water in patients with identified aspiration; Journal of Neurologic Rehabilitation; 1997; vol. 11 (no. 3); 139-148

12

1 1.1.35.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	United States of America
Study setting	Inpatient setting.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Newly admitted person after a cerebrovascular accident who had aspiration drinking only thin liquids as documented by a videofluoroscopic swallow evaluation.
Exclusion criteria	History of previous cerebrovascular accident; degenerative neurologic dysfunction; pneumonia; multiple medical diagnoses; reflux or oesophageal disorders; people who were unable to comprehend the risks of the study or with poor cognition.
Recruitment / selection of participants	People who were newly admitted.
Intervention(s)	Free water protocol N=10 Water was placed out of the person's immediate reach in their room. People were instructed to notify a nurse or family member when they wanted water. Amounts of intake were recorded on daily flowcharts, with 200 cc cups used for

	<p>measurement. All three nursing shifts, family members and staff therapists were verbally notified and given demonstrations of measurements. Occupational and physical therapists also recorded amounts of water intake given to the patients during therapy or on outings. No water was allowed with meals or for an hour following meals, and a pre-rinse was utilised prior to any water intake to reduce the possibility of ingesting oral bacteria or oral food stasis.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Usual care (thickened liquids) N=10</p> <p>Allowed as much thickened liquids as they desired, with meals and as requested. Intake amounts were recorded in the same manner as the study group.</p>

	Concomitant therapy: No additional information.
Number of participants	20
Duration of follow-up	30 days
Indirectness	No additional information.
Additional comments	No additional information.

1

2 **1.1.35.2. Study arms**3 **1.1.35.2.1. Free water protocol (N = 10)**

4 Water was placed out of the person's immediate reach in their room. People were instructed to notify a nurse or family member when
5 they wanted water. Amounts of intake were recorded on daily flowcharts, with 200 cc cups used for measurement. All three nursing
6 shifts, family members and staff therapists were verbally notified and given demonstrations of measurements. Occupational and
7 physical therapists also recorded amounts of water intake given to the patients during therapy or on outings. No water was allowed
8 with meals or for an hour following meals, and a pre-rinse was utilised prior to any water intake to reduce the possibility of ingesting
9 oral bacteria or oral food stasis. Concomitant therapy: No additional information.

10

11 **1.1.35.2.2. Usual care (thickened liquids) (N = 10)**

12 Allowed as much thickened liquids as they desired, with meals and as requested. Intake amounts were recorded in the same manner
13 as the study group. Concomitant therapy: No additional information.

14

1 **1.1.35.3. Characteristics**2 **1.1.35.3.1. Arm-level characteristics**

Characteristic	Free water protocol (N = 10)	Usual care (thickened liquids) (N = 10)
% Female	n = 2 ; % = 20	n = 4 ; % = 40
Sample size		
Mean age (SD) (years)	57 to 88	44 to 88
Range		
Mean age (SD) (years)	78 (NR)	76 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	4 to 17	7 to 19
Range		
Time after stroke	12 (NR)	14 (NR)
Mean (SD)		

Characteristic	Free water protocol (N = 10)	Usual care (thickened liquids) (N = 10)
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.35.4. Outcomes**3 **1.1.35.4.1. Study timepoints**

- 4 • Baseline
- 5 • 30 day (<3 months)

6

7 **1.1.35.4.2. Dichotomous outcomes**

Outcome	Free water protocol, Baseline, N = 10	Free water protocol, 30 day, N = 10	Usual care (thickened liquids), Baseline, N = 10	Usual care (thickened liquids), 30 day, N = 10
Occurrence of chest infection	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
No of events				
Hydration (dehydration) Outcome specified to be a continue outcome in the protocol reported only in a usable manner as a dichotomous outcome in the report	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
No of events				

1 Occurrence of chest infection - Polarity - Lower values are better
 2 Hydration (dehydration) - Polarity - Lower values are better

3
4

5 **1.1.35.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.35.4.4. Dichotomous outcomes - Occurrence of chest infection - No Of Events - Free water protocol - Usual care (thickened**
 7 **liquids) - t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.35.4.5. Dichotomous outcomes - Hydration (dehydration) - No Of Events - Free water protocol - Usual care (thickened liquids) - t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Partially applicable (Outcome indirectness - protocol outcome that is stated to be a continuous outcome is reported in the study as a dichotomous outcome)

10

1 **1.1.36. Guillen-Sola, 2017**

Bibliographic Reference Guillen-Sola, Anna; Messagi Sartor, Monique; Bofill Soler, Neus; Duarte, Esther; Barrera, M Camelia; Marco, Ester; Respiratory muscle strength training and neuromuscular electrical stimulation in subacute dysphagic stroke patients: a randomized controlled trial.; Clinical rehabilitation; 2017; vol. 31 (no. 6); 761-771

2

3 **1.1.36.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT02473432
Study type	Randomised controlled trial (RCT)
Study location	Spain
Study setting	Tertiary subacute care hospital in Barcelona (Catalonia, Spain)
Study dates	December 2013 and June 2015
Sources of funding	The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Partially supported by grants from: ISCIII (PI10/01560)/FEDER.
Inclusion criteria	Inclusion criteria were subacute ischemic stroke within 1 to 3 weeks of inclusion and dysphagia confirmed by videofluoroscopic study with a score ≥ 3 in the 8-point Penetration Aspiration Scale.

Exclusion criteria	Patients with cognitive impairment (Short Portable Mental Status Questionnaire <3)17 and/or history of previous neurological diseases that might be associated with the presence of dysphagia were excluded.
Recruitment / selection of participants	NR
Intervention(s)	<p>2 treatment groups - Reported separately.</p> <p>Group II received respiratory training sessions, which consisted of 5 sets of 10 respirations followed by 1 minute of unloaded recovery breathing off the device (Orygen Dual Valve®, Forumed SL, Barcelona, Catalonia, Spain), 18 twice a day, 5 days per week for 3 weeks, with the assistance of a therapist. Training loads were set at a pressure equivalent to 30% of maximal inspiratory and expiratory pressures and increased weekly at intervals of 10 cmH₂O.</p> <p>In addition to standard swallow therapy, Group III received sham respiratory muscle training, with the workloads fixed at 10 cmH₂O throughout the 3-week-intervention period, and neuromuscular electrical stimulation using the Intelect VitalStim device (VitalStim®, Chattanooga Group, Hixson, TN, USA). Under supervision by a speech-language therapist, two electrodes were placed on suprahyoid muscles in 40-minute daily sessions (5 days per week for 3 weeks) and 80 Hz of transcutaneous electrical stimulus was applied, according to VitalStim® instructions; patients were instructed to swallow when they felt muscle contraction.</p> <p>Concomitant therapy - All patients followed a multidisciplinary inpatient rehabilitation program consisting of physical, occupational and speech therapy targeting specific impairments in mobility, activities of daily living, swallowing and communication skills (3 hours per day, 5 days a week, during 3 weeks). All three groups received standard swallow therapy, which consisted of an educational intervention aimed to improve self-management of dysphagia and protect the airway, oral exercises to improve lingual praxis, and compensatory techniques based on video-fluoroscopic findings. These swallowing manoeuvres, oral exercises, and compensatory techniques were individualized according to intrinsic patient characteristics.</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	NR
Comparator	The control group received standard swallow therapy, which consisted of an educational intervention aimed to improve self-management of dysphagia and protect the airway, oral exercises to improve lingual praxis, and compensatory techniques based on videofluoroscopic findings. These swallowing manoeuvres, oral exercises, and compensatory techniques were individualized according to intrinsic patient characteristics.
Number of participants	62
Duration of follow-up	3 weeks and 3 months
Indirectness	NR
Additional comments	NR

1 **1.1.36.2. Study arms**

2 **1.1.36.2.1. *Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy) (N = 20)***

3

4 **1.1.36.2.2. *Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy) (N = 21)***

5

6

7 **1.1.36.2.3. *Usual care (Standard swallow therapy) (N = 21)***

8

9 **1.1.36.3. Characteristics**

10 **1.1.36.3.1. Study-level characteristics**

Characteristic	Study (N = 62)
Ethnicity Nominal	NR
Comorbidities Nominal	NR
People requiring enteral feeding support at baseline Nominal	NR

11

1 **1.1.36.3.2.** *Arm-level characteristics*

Characteristic	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy) (N = 20)	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy) (N = 21)	Usual care (Standard swallow therapy) (N = 21)
% Female	23.8	52.4	42.9
Nominal			
Mean age (SD)	67.9 (10.6)	70.3 (8.4)	68.9 (7)
Mean (SD)			
Severity of dysphagia (PAS)	5 (2.7)	5.5 (2.2)	5.4 (2.3)
Mean (SD)			
Time after stroke (days)	20.8 (8.7)	11 (5.5)	9.3 (5.1)
Mean (SD)			
Type of stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
No of events			
TACI	n = 5 ; % = 25	n = 5 ; % = 23.8	n = 6 ; % = 28.6
No of events			
PACI	n = 10 ; % = 50	n = 8 ; % = 38.1	n = 4 ; % = 19.1
No of events			
LACI	n = 2 ; % = 10	n = 4 ; % = 19	n = 4 ; % = 19.1
No of events			

Characteristic	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy) (N = 20)	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy) (N = 21)	Usual care (Standard swallow therapy) (N = 21)
POCI	n = 0 ; % = 0	n = 1 ; % = 4.8	n = 2 ; % = 9.5
No of events			
Missing data	n = 0 ; % = 0	n = 1 ; % = 4.8	n = 3 ; % = 4.8
No of events			

1

2 **1.1.36.4. Outcomes**3 **1.1.36.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 week
- 6 • 3 month

7

1 1.1.36.4.2. *Dichotomous outcomes*

Outcome	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), Baseline, N = 20	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), 3 week, N = 16	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), 3 month, N = 16	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), Baseline, N = 21	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), 3 week, N = 17	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), 3 month, N = 17	Usual care (Standard swallow therapy), Baseline, N = 21	Usual care (Standard swallow therapy), 3 week, N = 10	Usual care (Standard swallow therapy), 3 month, N = 10
Occurrence of chest infections	n = NR ; % = NR	n = 0 ; % = 0	n = 2 ; % = 13	n = NR ; % = NR	n = 0 ; % = 0	n = 3 ; % = 18	n = NR ; % = NR	n = 2 ; % = 20	n = 4 ; % = 40
No of events									
Occurrence of aspiration (number of people with a penetration aspiration scale score above or equal to 5)	n = 10 ; % = 50	n = NR ; % = NR	n = 4 ; % = 25	n = 13 ; % = 62	n = NR ; % = NR	n = 6 ; % = 35	n = 12 ; % = 57	n = NR ; % = NR	n = 5 ; % = 50

Outcome	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), Baseline, N = 20	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), 3 week, N = 16	Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy), 3 month, N = 16	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), Baseline, N = 21	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), 3 week, N = 17	Neuromuscular electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy), 3 month, N = 17	Usual care (Standard swallow therapy), Baseline, N = 21	Usual care (Standard swallow therapy), 3 week, N = 10	Usual care (Standard swallow therapy), 3 month, N = 10
No of events									

1 Occurrence of chest infections - Polarity - Lower values are better
 2 Occurrence of aspiration (number of people with a penetration aspiration scale score above or equal to 5) - Polarity - Lower values are
 3 better

4
5

6 **1.1.36.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.36.4.4. Dichotomous outcomes - Occurrence of chest infections - No of Events - Inspiratory and Expiratory Muscle Training +**
 8 **standard swallow therapy - Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy -**
 9 **Standard swallow therapy -t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.36.4.5.** *Dichotomous outcomes-Occurrence of chest infections-No Of Events- Behavioural interventions (Inspiratory and*
 3 *Expiratory Muscle Training + standard swallow therapy)-Neuromuscular electrical stimulation (Neuromuscular*
 4 *Electrical Stimulation + sham IMES and standard swallow therapy)-Usual care (Standard swallow therapy)-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

5

6 **1.1.36.4.6.** *Dichotomous outcomes-*
 7 *Occurrence of aspiration (number of people with a penetration aspiration scale score above or equal to 5)-No Of Events-*
 8 *Behavioural interventions (Inspiratory and Expiratory Muscle Training + standard swallow therapy)-Neuromuscular*
 9 *electrical stimulation (Neuromuscular Electrical Stimulation + sham IMES and standard swallow therapy)-Usual*
 10 *care (Standard swallow therapy)-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

11

12 **1.1.37. Han, 2004**

Bibliographic Reference Han, J. C.; An observation on the therapeutic effect of acupuncture for bulbar palsy after acute stroke; Henan journal of practical nervous diseases; 2004; vol. 7 (no. 3); 81-82

13

1 1.1.37.1. Study details

Secondary publication of another included study- see primary study for details	NR
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	NR
Study location	China
Study setting	NR
Study dates	NR
Sources of funding	NR
Inclusion criteria	100% with stroke within 30 days of onset. Degrees of dysphagia not stated
Exclusion criteria	Reduced consciousness, poor compliance, infections at acupoints
Recruitment / selection of participants	NR
Intervention(s)	Scalp and neck acupuncture with electroacupuncture with standard Western medical treatment
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Standard Western medical treatment only
Number of participants	66
Duration of follow-up	3 days
Indirectness	NR
Additional comments	NR

1

2 **1.1.37.2. Study arms**3 **1.1.37.2.1. *Scalp and neck acupuncture with electroacupuncture with standard Western medical treatment (N = 34)***

4

5 **1.1.37.2.2. *Standard Western medical treatment only (N = 32)***

6

1 **1.1.37.3. Characteristics**2 **1.1.37.3.1. Study-level characteristics**

Characteristic	Study (N = 66)
% Female	NR
Nominal	
Mean age (SD)	NR
Nominal	
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

1 **1.1.37.4. Outcomes**

2 **1.1.37.4.1. Study timepoints**

- 3 • 3 day
- 4

5 **1.1.37.4.2. Dichotomous outcomes**

Outcome	Scalp and neck acupuncture with electroacupuncture with standard Western medical treatment, 3 day, N = 34	Standard Western medical treatment only, 3 day, N = 32
Dysphagia present	n = 22 ; % = 64.7	n = 25 ; % = 78.1
No of events		

6 Dysphagia present - Polarity - Lower values are better

7

8

9 **1.1.37.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

10 **1.1.37.4.4. Dichotomous outcomes-Dysphagiapresent-NoOfEvents-Scalp and neck acupuncture with electroacupuncture with standard Western medical treatment-Standard Western medical treatment only-t3**

11

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to deviations from intended intervention and selection of reported result)
Overall bias and Directness	Overall Directness	Directly applicable

12

1 **1.1.38. Hongling, 2006**

Bibliographic Reference Hongling, Jiang; Yongchen, Zhang; Treatment of 40 cases of post-apoplectic dysphagia by acupuncture plus rehabilitation exercise; Journal of Acupuncture and Tuina Science; 2006; vol. 4; 336-338

2

3 **1.1.38.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Two out of five symptoms as hemiplegia, coma, slurred speech, unilateral sensory disturbance, wry mouth and tongue; difficulty in swallowing.
Exclusion criteria	Not having above symptoms; those who cannot cooperate to do chemical examination and treatment; those who have severe primary diseases in the liver, kidneys, hematopoietic system and endocrine system.

Recruitment / selection of participants	All people were inpatients in the hospital.
Intervention(s)	<p>Acupuncture N=40</p> <p>Acupuncture applied to acupoints bilaterally including: Fengchi (GB 20), Tianzhu (BL 10), Tongli (HT 5) and Lianquan (CV 23). Fengchi was punctured 25mm with the needle tip towards the submaxilla. Tianzhu was perpendicularly punctured 20-30 mm. When needling sensation arrived, slow-pressing and tight-lifting technique was first performed six times, then nine times for 1 cycle. This was repeated for 3 cycles. The needles were retained for 20 minutes and manipulated once. Lianquan was vertically punctured 25 mm; when needling sensation arrived, the needle was withdrawn beneath the skin and inserted left-side, then it was again withdrawn beneath the skin and inserted to the right-side, finally the needle was withdrawn. Tongli was perpendicularly needled 10 mm with the same techniques as Fengchi. The needle was retained for 30 minutes and manipulated twice. Two courses were given with each course taking 12 days (with 12 treatments) with a 2 day break between courses (26 days in total). They also received the rehabilitation exercises provided to usual care.</p> <p>Concomitant therapy: Regular internal treatments for cerebrovascular diseases were conducted in both groups.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear

Population subgroups	No additional information.
Comparator	Usual care N=32 Basic rehabilitation with Logemann JA exercise and Mendelsohn exercise; tongue exercises; respiratory control training and feeding exercises. Concomitant therapy: Regular internal treatments for cerebrovascular diseases were conducted in both groups.
Number of participants	72
Duration of follow-up	26 days.
Indirectness	No additional information.
Additional comments	No additional information.

1

2 **1.1.38.2. Study arms**3 **1.1.38.2.1. Acupuncture (N = 40)**

4 Acupuncture applied to acupoints bilaterally including: Fengchi (GB 20), Tianzhu (BL 10), Tongli (HT 5) and Lianquan (CV 23).
5 Fengchi was punctured 25mm with the needle tip towards the submaxilla. Tianzhu was perpendicularly punctured 20-30 mm. When
6 needling sensation arrived, slow-pressing and tight-lifting technique was first performed six times, then nine times for 1 cycle. This was
7 repeated for 3 cycles. The needles were retained for 20 minutes and manipulated once. Lianquan was vertically punctured 25 mm;
8 when needling sensation arrived, the needle was withdrawn beneath the skin and inserted left-side, then it was again withdrawn
9 beneath the skin and inserted to the right-side, finally the needle was withdrawn. Tongli was perpendicularly needled 10 mm with the
10 same techniques as Fengchi. The needle was retained for 30 minutes and manipulated twice. Two courses were given with each
11 course taking 12 days (with 12 treatments) with a 2 day break between courses (26 days in total). They also received the rehabilitation

1 exercises provided to usual care. Concomitant therapy: Regular internal treatments for cerebrovascular diseases were conducted in
 2 both groups.

3

4 **1.1.38.2.2. Usual care (N = 32)**

5 Basic rehabilitation with Logemann JA exercise and Mendelsohn exercise; tongue exercises; respiratory control training and feeding
 6 exercises. Concomitant therapy: Regular internal treatments for cerebrovascular diseases were conducted in both groups.

7

8 **1.1.38.3. Characteristics**

9 **1.1.38.3.1. Arm-level characteristics**

Characteristic	Acupuncture (N = 40)	Usual care (N = 32)
% Female	n = 12 ; % = 30	n = 14 ; % = 44
Sample size		
Mean age (SD) (years)	43 to 76	42 to 76
Range		
Mean age (SD) (years)	55.4 (NR)	54.8 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Acupuncture (N = 40)	Usual care (N = 32)
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
1-3 months	n = 19 ; % = 48	n = 21 ; % = 53
Sample size		
3-6 months	n = 15 ; % = 47	n = 17 ; % = 53
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.38.4. Outcomes**3 **1.1.38.4.1. Study timepoints**

- 4 • Baseline
- 5 • 26 day (<3 months)

6

1 **1.1.38.4.2. Dichotomous outcomes**

Outcome	Acupuncture, Baseline, N = 40	Acupuncture, 26 day, N = 40	Usual care, Baseline, N = 32	Usual care, 26 day, N = 32
Dysphagia present/return to normal diet (people who did not achieve a basic cure, score at least 9 on a 0-10 therapeutic assessment scale)	n = NA ; % = NA	n = 27 ; % = 68	n = NA ; % = NA	n = 28 ; % = 88
No of events				

2 Dysphagia present/return to normal diet (people who did not achieve a basic cure, score at least 9 on a 0-10 therapeutic assessment
3 scale) - Polarity - Lower values are better

4

5

6 **1.1.38.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.38.4.4. Dichotomous outcomes-
8 Dysphagia present/return to normal diet (people who did not achieve a basic cure, score at least 9 on a 0-
9 10 therapeutic assessment scale)-No Of Events-Acupuncture-Usual care-t26**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

10

11 **1.1.39. Huang, 2010**

Bibliographic Reference Huang, Y. C.; Dysphagia after different swallowing therapies; 2010

1

2 **1.1.39.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information
Study location	China
Study setting	No additional information
Study dates	No additional information
Sources of funding	No additional information
Inclusion criteria	Participants with post-stroke dysphagia
Exclusion criteria	No additional information
Recruitment / selection of participants	No additional information
Intervention(s)	No additional information
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information
Comparator	No additional information
Number of participants	97
Duration of follow-up	4 weeks
Indirectness	No additional information
Additional comments	No additional information

1

2 **1.1.39.2. Study arms**3 **1.1.39.2.1. *Acupuncture (N = 32)***

4

5 **1.1.39.2.2. *General swallowing therapy (N = 30)***

6

1 **1.1.39.3. Characteristics**2 **1.1.39.3.1. Study-level characteristics**

Characteristic	Study (N =)
% Female	NR
Nominal	
Mean age (SD)	NR
Nominal	
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

1 **1.1.39.4. Outcomes**

2 **1.1.39.4.1. Study timepoints**

- 3 • 4 week (<3 months)
- 4

5 **1.1.39.4.2. dichotomous outcomes**

Outcome	Acupuncture, 4 week, N = 32	General swallowing therapy, 4 week, N = 30
Dysphagia present	n = 1 ; % = 3.1	n = 10 ; % = 33.3
No of events		

6 Dysphagia present - Polarity - Lower values are better

7

8

9 **1.1.39.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

10 **1.1.39.4.4. dichotomous outcomes-Dysphagiapresent-NoOfEvents-Acupuncture-General swallowing therapy-t0**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to no information on all domains - randomisation, deviation from intended intervention, missing outcome data and measurement of the outcome)
Overall bias and Directness	Overall Directness	Directly applicable

11

1 **1.1.40. Jang, 2019**

Bibliographic Reference Jang, Kyung Won; Lee, Sook Joung; Kim, Sang Beom; Lee, Kyeong Woo; Lee, Jong Hwa; Park, Jin Gee; Effects of mechanical inspiration and expiration exercise on velopharyngeal incompetence in subacute stroke patients.; Journal of rehabilitation medicine; 2019; vol. 51 (no. 2); 97-102

2

3 **1.1.40.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea
Study setting	Rehabilitation centre of a university hospital
Study dates	May 2015 to July 2017
Sources of funding	NR
Inclusion criteria	Patients with subacute stroke who had swallowing difficulty were evaluated by a video fluoroscopic swallowing study (VFSS). Among these the patients who showed VPI on VFSS were enrolled in this study
Exclusion criteria	Patients susceptible to barotrauma (atmospheric pressure injury) due to pulmonary diseases, such as emphysema, those with a previous stroke, those with pharyngeal structural abnormalities, those unable to cooperate for MIE exercise due to

	deteriorated cognitive function or mentality, and those with medical conditions that could affect their swallowing ability were excluded from this study.
Recruitment / selection of participants	No additional information
Intervention(s)	<p>Mechanical inspiration and expiration (MIE). The study group was administered MIE exercise once daily using the CNS-100 Cough Assist® (SungdoMC, Seoul, Korea) and conventional swallowing rehabilitation therapy twice a day. The treatment procedures for inspiration were as follows: starting positive pressure was 15–20 cm H₂O, increased to 40 cm H₂O according to the patients' condition. Inspiration lasted 2 s, or longer if required, and was titrated for patient comfort. The treatment procedures for expiration were as follows: starting with the expiration (negative) pressure was similar to the inspiration pressure, and then the negative pressure was increased to 10–20 cm H₂O above the positive pressure. Negative pressure was then held for 3–6 s, simulating the airflows that occur naturally during the cough. The patient was then instructed to coordinate their respiratory rhythms according to those of the cough assist machine.</p> <p>The study group was administered additional MIE exercise therapy as well as conventional swallowing rehabilitation therapy.</p> <p>Conventional dysphagia rehabilitation consisted of oral motor and sensory stimulation, neuromuscular electrical stimulation of the suprahyoid muscle, and oral and lingual exercises to focus on strength and endurance for the efficacy and safety of the swallowing process. Twenty sessions of conventional swallowing rehabilitation therapy were conducted for both the study and the control groups, twice a day, 5 days a week, for 2 weeks, with each session lasting 30 min. Ten sessions of MIE exercise were conducted for the study group once a day, 5 days a week, for 2 weeks, with each session lasting 30 min.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Very severe

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>The control group was administered conventional swallowing rehabilitation therapy only.</p> <p>Conventional dysphagia rehabilitation consisted of oral motor and sensory stimulation, neuromuscular electrical stimulation of the suprahyoid muscle, and oral and lingual exercises to focus on strength and endurance for the efficacy and safety of the swallowing process (11). Twenty sessions of conventional swallowing rehabilitation therapy were conducted for both the study and the control groups, twice a day, 5 days a week, for 2 weeks, with each session lasting 30 min.</p>
Number of participants	41
Duration of follow-up	2 weeks
Indirectness	NR
Additional comments	NR

1 **1.1.40.2. Study arms**

2 **1.1.40.2.1. *Behavioural interventions (mechanical inspiration and expiration exercise and conventional dysphagia therapy) (N***
 3 ***= 21)***

4

5 **1.1.40.2.2. *Usual care (conventional dysphagia therapy) (N = 20)***

6

7 **1.1.40.3. Characteristics**

8 **1.1.40.3.1. *Study-level characteristics***

Characteristic	Study (N = 36)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

9

1.1.40.3.2. Arm-level characteristics		
Characteristic	Behavioural interventions (mechanical inspiration and expiration exercise and conventional dysphagia therapy) (N = 21)	Usual care (conventional dysphagia therapy) (N = 20)
% Female	44	50
Nominal		
Mean age (SD)	67.28 (9.48)	71.15 (8.61)
Mean (SD)		
Severity of dysphagia PAS	7.62 (0.39)	7.81 (0.7)
Mean (SD)		
Time after stroke (days)	20.48 (13.56)	18.34 (12.45)
Mean (SD)		

2

3 **1.1.40.4. Outcomes**4 **1.1.40.4.1. Study timepoints**

- 5 • Baseline
- 6 • 2 week

7

1 **1.1.40.4.2. Continuous outcomes**

Outcome	Behavioural interventions (mechanical inspiration and expiration exercise and conventional dysphagia therapy), Baseline, N = 21	Behavioural interventions (mechanical inspiration and expiration exercise and conventional dysphagia therapy), 2 week, N = 18	Usual care (conventional dysphagia therapy), Baseline, N = 20	Usual care (conventional dysphagia therapy), 2 week, N = 18
Occurrence of aspiration (PAS) Scale range: 1-8. Change scores. Mean (SD)	7.62 (0.39)	-0.86 (1.24)	7.81 (0.7)	-0.76 (0.97)
Swallowing ability (American Speech-Language-Hearing Association-National Outcome Measurement System Swallowing scale [ASHA-NOMS]) Scale range: 1-8. Change scores. Mean (SD)	2.38 (1.25)	1.26 (1.05)	2.73 (1.54)	0.86 (1.21)

2 Occurrence of aspiration (PAS) - Polarity - Lower values are better

3 Swallowing ability (American Speech-Language-Hearing Association-National Outcome Measurement System Swallowing scale
4 [ASHA-NOMS]) - Polarity - Higher values are better

5

6

1 **1.1.40.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.40.4.4. Continuousoutcomes-Occurrenceofaspiration(PAS)-MeanSD-Mechanical inspiration and expiration exercise and**
 3 **conventional dysphagia therapy-Conventional dysphagia therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.40.4.5. Continuousoutcomes-Swallowingability-:AmericanSpeech-Language-HearingAssociation-**
 6 **NationalOutcomeMeasurementSystemSwallowingscale(ASHA-NOMS)-MeanSD-Mechanical inspiration and**
 7 **expiration exercise and conventional dysphagia therapy-Conventional dysphagia therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.41. Jayasekeran, 2010**

Bibliographic Reference Jayasekeran, Vanoo; Singh, Salil; Tyrrell, Pippa; Michou, Emilia; Jefferson, Samantha; Mistry, Satish; Gamble, Ed; Rothwell, John; Thompson, David; Hamdy, Shaheen; Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions.; Gastroenterology; 2010; vol. 138 (no. 5); 1737-46

10

1 1.1.41.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	United Kingdom.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	Supported by the Health Foundation, Medical Research Council, Research into Aging, and the National Institute of Health Research/Research for Patient Benefit. The study was sponsored by the University of Manchester, UK.
Inclusion criteria	People with an index stroke and swallowing disability seen with videofluoroscopy.
Exclusion criteria	No additional information.
Recruitment / selection of participants	No additional information.
Intervention(s)	Pharyngeal electrical stimulation N=17 The pharyngeal catheter was used to deliver electrical stimulation. Electrical stimulation of the pharynx (at 0.2ms pulses, 280V) was delivered at a set frequency (5Hz), intensity (75% of maximal tolerated) and duration (10 minutes). The maximum tolerated PES intensity was predetermined from each participant's first perceived sensation and pain threshold

	<p>(the point when the pharyngeal sensation became uncomfortable), which were calculated from an average of 3 trials. Therapy was delivered once daily for 3 consecutive days. Follow up was at 2 weeks.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Mixed
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed TACS or PACS
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=14</p> <p>Sham stimulation using the same method. However, on commencement of stimulation, the constant current generator was switched off and the intraluminal pharyngeal catheter was left in situ in the subject for the duration of intervention.</p> <p>Concomitant therapy: No additional information.</p>

Number of participants	31
Duration of follow-up	2 weeks post-intervention
Indirectness	No additional information.
Additional comments	Method of analysis not clear. Appears to be completers only.

1

2 **1.1.41.2. Study arms**3 **1.1.41.2.1. Pharyngeal electrical stimulation (N = 17)**

4 The pharyngeal catheter was used to deliver electrical stimulation. Electrical stimulation of the pharynx (at 0.2ms pulses, 280V) was
5 delivered at a set frequency (5Hz), intensity (75% of maximal tolerated) and duration (10 minutes). The maximum tolerated PES
6 intensity was predetermined from each participant's first perceived sensation and pain threshold (the point when the pharyngeal
7 sensation became uncomfortable), which were calculated from an average of 3 trials. Therapy was delivered once daily for 3
8 consecutive days. Follow up was at 2 weeks. Concomitant therapy: No additional information.

9

10 **1.1.41.2.2. Placebo/sham therapy (N = 14)**

11 Sham stimulation using the same method. However, on commencement of stimulation, the constant current generator was switched
12 off and the intraluminal pharyngeal catheter was left in situ in the subject for the duration of intervention. Concomitant therapy: No
13 additional information.

14

1 **1.1.41.3. Characteristics**2 **1.1.41.3.1. Study-level characteristics**

Characteristic	Study (N = 31)
% Female	n = 19 ; % = 61
Sample size	
Mean age (SD)	75 (2)
Mean (SD)	

3

4 **1.1.41.3.2. Arm-level characteristics**

Characteristic	Pharyngeal electrical stimulation (N = 17)	Placebo/sham therapy (N = 14)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
People requiring enteral feeding support at baseline	n = 6 ; % = 35	n = 5 ; % = 36
Sample size		

Characteristic	Pharyngeal electrical stimulation (N = 17)	Placebo/sham therapy (N = 14)
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
TACS	n = 6 ; % = 38	n = 4 ; % = 36
Sample size		
PACS	n = 10 ; % = 63	n = 6 ; % = 55
Sample size		
LACS	n = 0 ; % = 0	n = 1 ; % = 9
Sample size		
POCS	n = 0 ; % = 0	n = 1 ; % = 9
Sample size		

1 Reports 16 people in the active arm and 12 people in the sham arm.

2

3 1.1.41.4. Outcomes

4 1.1.41.4.1. Study timepoints

- 5 • Baseline
- 6 • 2 week (<3 months)

7

1 **1.1.41.4.2. Dichotomous outcomes**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 17	Pharyngeal electrical stimulation, 2 week, N = 16	Placebo/sham therapy, Baseline, N = 14	Placebo/sham therapy, 2 week, N = 12
Mortality	n = NA ; % = NA	n = 2 ; % = 13	n = NA ; % = NA	n = 0 ; % = 0
No of events				
Occurrence of chest infections (LRTI during admission)	n = NA ; % = NA	n = 2 ; % = 13	n = NA ; % = NA	n = 3 ; % = 25
No of events				
Dysphagia present/return to normal diet (prevalence of dysphagic swallows)	n = NA ; % = NA	n = 4 ; % = 27	n = NA ; % = NA	n = 7 ; % = 58
Reported in discussion. Intervention: 27%. Control: 58%.				
No of events				

2 Mortality - Polarity - Lower values are better

3 Occurrence of chest infections (LRTI during admission) - Polarity - Lower values are better

4 Dysphagia present/return to normal diet (prevalence of dysphagic swallows) - Polarity - Lower values are better

5 **1.1.41.4.3. Continuous outcomes**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 17	Pharyngeal electrical stimulation, 2 week, N = 16	Placebo/sham therapy, Baseline, N = 14	Placebo/sham therapy, 2 week, N = 12
Occurrence of aspiration (Penetration Aspiration)	NA (NA)	3.2 (1.5)	NA (NA)	3.8 (1.3)

Outcome	Pharyngeal electrical stimulation, Baseline, N = 17	Pharyngeal electrical stimulation, 2 week, N = 16	Placebo/sham therapy, Baseline, N = 14	Placebo/sham therapy, 2 week, N = 12
Scale) Scale range: 1-8. Final values.				
Mean (SD)				
Length of hospital stay (days)	NA (NA)	43.19 (18.73)	NA (NA)	54.92 (26.14)
Mean (SD)				

1 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

2 Length of hospital stay - Polarity - Lower values are better

3

4

5 **1.1.41.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.41.4.5. Dichotomous outcomes-Mortality-NoOfEvents-Pharyngeal electrical stimulation-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.42. Jiao, 2022**

Bibliographic Reference Jiao, Y.; Li, G.; Dai, Y.; Clinical effect of repetitive transcranial magnetic stimulation on dysphagia due to stroke; Neurological Sciences; 2022; vol. 43 (no. 5); 3139-3144

1

2 1.1.42.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	August 2015 to August 2017.
Sources of funding	This study was supported by Medical Science and Technology Foundation of Guangdong Province (A2018389).
Inclusion criteria	These people with cerebral infarction were evaluated as per the diagnostic criteria of the acute stroke developed by the fourth National Conference on the Cerebrovascular Disease, and acute cerebral infarction was confirmed by Diffusion-weighted imaging; the swallowing disorder was detected by the radiographic barium meal imaging; the level of the water swallowing test is 3 or more; they have stable vital signs, no serious complications such as respiratory infection, and be willing to participate in the early rehabilitation; they are 40-80 years of age and have signed the medical informed consent.
Exclusion criteria	Subjects with age not conforming to the standard; subjects with serious disease combined with conscious disturbance, infection, severe heart, liver, and kidney diseases, epilepsy, mental disorders, or be in critical condition or unable to cooperate with doctors for treatment; subjects with implantable electronic device; subjects refusing the treatment of rTMS; subjects with abnormal functions on blood routine, coagulation, or the heart, liver and kidney.

Recruitment / selection of participants	In-patients with acute cerebral infarction combined with swallowing disorder hospitalised in the department of neurology of Guangdong Second Provincial General Hospital.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=32</p> <p>rTMS (3 Hz) was used daily to treat people in the rTMS group. People were allowed to sit on the treatment chair. The coil center right against their pterion 1.5cm above was stimulated by an 8-shaped coil probe (70mm in diameter). The pterion was located at the extracranial projection area of the lower part of the precentral gyrus and the rear of inferior frontal gyrus. The treatment parameter should be adjusted. The stimulation frequency was 3 Hz, with intensity of 80% motion threshold. The stimulation time should be 3s, with an interval of 20s. The treatment lasts for 20 minutes, once each day. The person can rest for 2 days after 5-day treatment and then move on to the next course. There were two courses of treatment in total (14 day period).</p> <p>Concomitant therapy: All people were routinely treated with anti-platelet aggregation and statins, supported with nutrition, and corrected water and electrolyte disorder. When people's vital signs were stable and showed no progress during 48 hours, they were given swallowing rehabilitation.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear

Population subgroups	No additional information.
Comparator	<p>Usual care N=29</p> <p>People in the control group received the basic treatment of rehabilitation training: 1) suck training: putting the index finger into mouth to imitate the suck action for 20 times, twice for each day; 2) tongue muscle training: practicing tongue push-up to the front, left and right, 20 cycles/time, twice for each day; 3) pharyngeal cold stimulation training: stimulating the velum, the root of tongue and the retropharyngeal by cotton bud with aqua astricta, 20 cycles/time, twice for each day; 4) pronunciation training: pronouncing "a", "yi" and "wu" in turn, 20 cycles/time, twice for each day; 5) facial muscles training: opening mouth, pouching cheek and breathing out in turn, 20 cycles/time, twice for each day; 6) neck muscle training: enhancing the muscle tone of neck by stretching and rotating the neck to induce swallow reaction, 20 cycles/time, twice for each day; 7) food intake training: trying to sit or being in semi-reclining position, with head turning to the contralateral side. People were encouraged to feed on their own, with assistance being given when necessary, 20 cycles/time, twice for each day; 5 days for treatment and 2 days for rest every week. One course of treatment lasts 1 week, and two courses in total.</p> <p>Concomitant therapy: All people were routinely treated with anti-platelet aggregation and statins, supported with nutrition, and corrected water and electrolyte disorder. When people's vital signs were stable and showed no progress during 48 hours, they were given swallowing rehabilitation.</p>
Number of participants	61
Duration of follow-up	2 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis unclear.

1 **1.1.42.2. Study arms**

2 **1.1.42.2.1. *Transcranial magnetic stimulation (TMS) (N = 32)***

3 rTMS (3 Hz) was used daily to treat people in the rTMS group. People were allowed to sit on the treatment chair. The coil center right
4 against their pterion 1.5cm above was stimulated by an 8-shaped coil probe (70mm in diameter). The pterion was located at the
5 extracranial projection area of the lower part of the precentral gyrus and the rear of inferior frontal gyrus. The treatment parameter
6 should be adjusted. The stimulation frequency was 3 Hz, with intensity of 80% motion threshold. The stimulation time should be 3s,
7 with an interval of 20s. The treatment lasts for 20 minutes, once each day. The person can rest for 2 days after 5-day treatment and
8 then move on to the next course. There were two courses of treatment in total (14 day period). Concomitant therapy: All people were
9 routinely treated with anti-platelet aggregation and statins, supported with nutrition, and corrected water and electrolyte disorder. When
10 people's vital signs were stable and showed no progress during 48 hours, they were given swallowing rehabilitation.

11

12 **1.1.42.2.2. *Usual care (N = 29)***

13 People in the control group received the basic treatment of rehabilitation training: 1) suck training: putting the index finger into mouth to
14 imitate the suck action for 20 times, twice for each day; 2) tongue muscle training: practicing tongue push-up to the front, left and right,
15 20 cycles/time, twice for each day; 3) pharyngeal cold stimulation training: stimulating the velum, the root of tongue and the
16 retropharyngeal by cotton bud with aqua astricta, 20 cycles/time, twice for each day; 4) pronunciation training: pronouncing "a", "yi"
17 and "wu" in turn, 20 cycles/time, twice for each day; 5) facial muscles training: opening mouth, pouching cheek and breathing out in
18 turn, 20 cycles/time, twice for each day; 6) neck muscle training: enhancing the muscle tone of neck by stretching and rotating the
19 neck to induce swallow reaction, 20 cycles/time, twice for each day; 7) food intake training: trying to sit or being in semi-reclining
20 position, with head turning to the contralateral side. People were encouraged to feed on their own, with assistance being given when
21 necessary, 20 cycles/time, twice for each day; 5 days for treatment and 2 days for rest every week. One course of treatment lasts 1
22 week, and two courses in total. Concomitant therapy: All people were routinely treated with anti-platelet aggregation and statins,
23 supported with nutrition, and corrected water and electrolyte disorder. When people's vital signs were stable and showed no progress
24 during 48 hours, they were given swallowing rehabilitation.

25

1 **1.1.42.3. Characteristics**2 **1.1.42.3.1. *Arm-level characteristics***

Characteristic	Transcranial magnetic stimulation (TMS) (N = 32)	Usual care (N = 29)
% Female	n = 14 ; % = 44	n = 12 ; % = 41
Sample size		
Mean age (SD) (years)	57.3 (9.1)	60 (10.6)
Mean (SD)		
Ethnicity	n = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	NR (NR)	NR (NR)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

3

1 **1.1.42.4. Outcomes**

2 **1.1.42.4.1. Study timepoints**

- 3 • Baseline
4 • 2 week (<3 months)

5

6 **1.1.42.4.2. Dichotomous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 32	Transcranial magnetic stimulation (TMS), 2 week, N = 32	Usual care, Baseline, N = 29	Usual care, 2 week, N = 29
Dysphagia present/Return to normal diet (number of people who were not cured)	n = NA ; % = NA	n = 11 ; % = 34	n = NA ; % = NA	n = 20 ; % = 69
No of events				

7 Dysphagia present/Return to normal diet (number of people who were not cured) - Polarity - Lower values are better

8 **1.1.42.4.3. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 32	Transcranial magnetic stimulation (TMS), 2 week, N = 32	Usual care, Baseline, N = 29	Usual care, 2 week, N = 29
Swallowing ability (Water Swallow test) Scale range: 1-5. Final values. Calculated from dichotomous reporting of the number of people in each category.	NR (NR)	2.25 (1.11)	NR (NR)	3 (1.2)
Mean (SD)				

9 Swallowing ability (Water Swallow test) - Polarity - Lower values are better

10

11

1 **1.1.42.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.42.4.5. Dichotomous outcomes-Dysphagia present/Return to normal diet (number of people who were not cured)-No Of Events-**
 3 **Transcranial magnetic stimulation (TMS)-Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.42.4.6. Continuous outcomes-Swallowing ability (Water Swallow test)-Mean SD-Transcranial magnetic stimulation (TMS)-**
 6 **Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.43. Jing, 2016**

Bibliographic Reference Jing, Q.; Yang, X.; Reng, Q.; Effect of neuromuscular electrical stimulation in patients with post-stroke dysphagia; Medical Science Technology; 2016; vol. 57; 1-5

9

10 **1.1.43.1. Study details**

Secondary publication of another included	No additional information.
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study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	February 2013 to May 2014.
Sources of funding	None.
Inclusion criteria	People who met the China diagnostic criteria of cerebrovascular diseases; people whose condition had been diagnosed with cerebral infarction and cerebral haemorrhage by computerized tomography or magnetic resonance imaging scans; dysphagia found within 1 to 3 days after the episode of stroke; people with the grade of dysphagia at least 5; people who had never received rehabilitation training; people with stable vital signs; people who had signed informed consent.
Exclusion criteria	No additional information.
Recruitment / selection of participants	People at the Department of Neurology, Qinghai People's Hospital, Xining.
Intervention(s)	<p>Neuromuscular electrical stimulation (NMES) N=30</p> <p>Additional neuromuscular electrical stimulation therapy using a VitalStim device. The people were also asked to swallow during the stimulation; the amount and texture of the food was adjusted gradually according to the situation of the people. The electrical stimulation therapy was performed using 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: 1) for most of the people with pharyngeal and laryngeal movement defects, the 2 channels were vertically distributed on each</p>

	<p>side of the midline, and the lowest electrode was placed just above the superior thyroid notch; for the people with laryngeal movement dysfunctions and heavy food residue, the first channel was placed closely at the surface of hyoid bone and the electrodes were arranged horizontally, whereas, the second channel was placed horizontally along the midline, and the electrodes were placed just below the superior thyroid notch; the first channel was placed vertically below the chin and the second channel was placed along the buccal branch of the facial nerve. The intensity of stimulation was adjusted until the people felt itching. The people in each group were treated continuously for 10 days.</p> <p>Concomitant therapy: Usual care available to all. Routine drug therapies, including hemostasis, reducing intracranial pressure or dilating blood vessels, and using neurocyte activators, as well as swallowing function training, including exercise training to improve mouth and facial muscle function, sensory stimulation and exercise training to improve tongue function, vocal cord training, chew training and therapeutic feeding.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=30

	Usual care only.
	Concomitant therapy: Usual care available to all. Routine drug therapies, including hemostasis, reducing intracranial pressure or dilating blood vessels, and using neurocyte activators, as well as swallowing function training, including exercise training to improve mouth and facial muscle function, sensory stimulation and exercise training to improve tongue function, vocal cord training, chew training and therapeutic feeding.
Number of participants	60
Duration of follow-up	10 days (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information.

1

2 **1.1.43.2. Study arms**3 **1.1.43.2.1. Neuromuscular electrical stimulation (NMES) (N = 30)**

4 Additional neuromuscular electrical stimulation therapy using a VitalStim device. The people were also asked to swallow during the
5 stimulation; the amount and texture of the food was adjusted gradually according to the situation of the people. The electrical
6 stimulation therapy was performed using 2 channels with the following parameters: bi-directional square wave, wave width of 700 ms,
7 and intensity of electrical stimulus of 6 to 21 mV (+/-10%). The surface electrodes were placed on the surface of swallowing muscles.
8 The treatment mode was selected according to the result of dysphagia evaluation: 1) for most of the people with pharyngeal and
9 laryngeal movement defects, the 2 channels were vertically distributed on each side of the midline, and the lowest electrode was
10 placed just above the superior thyroid notch; for the people with laryngeal movement dysfunctions and heavy food residue, the first
11 channel was placed closely at the surface of hyoid bone and the electrodes were arranged horizontally, whereas, the second channel
12 was placed horizontally along the midline, and the electrodes were placed just below the superior thyroid notch; the first channel was
13 placed vertically below the chin and the second channel was placed along the buccal branch of the facial nerve. The intensity of
14 stimulation was adjusted until the people felt itching. The people in each group were treated continuously for 10 days. Concomitant

1 therapy: Usual care available to all. Routine drug therapies, including hemostasis, reducing intracranial pressure or dilating blood
 2 vessels, and using neurocyte activators, as well as swallowing function training, including exercise training to improve mouth and facial
 3 muscle function, sensory stimulation and exercise training to improve tongue function, vocal cord training, chew training and
 4 therapeutic feeding.

5

6 **1.1.43.2.2. Usual care (N = 30)**

7 Usual care only. Concomitant therapy: Usual care available to all. Routine drug therapies, including hemostasis, reducing intracranial
 8 pressure or dilating blood vessels, and using neurocyte activators, as well as swallowing function training, including exercise training
 9 to improve mouth and facial muscle function, sensory stimulation and exercise training to improve tongue function, vocal cord training,
 10 chew training and therapeutic feeding.

11

12 **1.1.43.3. Characteristics**

13 **1.1.43.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 30)	Usual care (N = 30)
% Female	n = 11 ; % = 37	n = 14 ; % = 47
Sample size		
Mean age (SD) (years)	67.9 (11.39)	68.6 (12.5)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 30)	Usual care (N = 30)
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	4.25 (1)	3.51 (1.12)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.43.4. Outcomes**3 **1.1.43.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)

6

7 **1.1.43.4.2. Dichotomous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 30	Neuromuscular electrical stimulation (NMES), 2 week, N = 30	Usual care, Baseline, N = 30	Usual care, 2 week, N = 30
Dysphagia present/return to normal diet (Dysphagia present)	n = NA ; % = NA	n = 13 ; % = 43	n = NA ; % = NA	n = 21 ; % = 70

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 30	Neuromuscular electrical stimulation (NMES), 2 week, N = 30	Usual care, Baseline, N = 30	Usual care, 2 week, N = 30
Taken from the number of people who were not cured at the end of treatment.				
No of events				

1 Dysphagia present/return to normal diet (Dysphagia present) - Polarity - Lower values are better

2 **1.1.43.4.3. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 30	Neuromuscular electrical stimulation (NMES), 2 week, N = 30	Usual care, Baseline, N = 30	Usual care, 2 week, N = 30
Swallowing ability (Dysphagia severity) Scale range: 0-10. Final values.	3.92 (1.04)	8.01 (1.2)	3.83 (1.18)	5.31 (1.1)
Mean (SD)				

3 Swallowing ability (Dysphagia severity) - Polarity - Higher values are better

4

5

6 **1.1.43.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.43.4.5. Dichotomous outcomes-Dysphagiapresent/returntonormaldiet(Dysphagiapresent)-NoOfEvents-Neuromuscular electrical stimulation (NMES)-Usual care-t2**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.43.4.6. Continuous outcomes-Swallowing ability (Dysphagia severity)-Mean SD-Neuromuscular electrical stimulation (NMES)-**
 3 **Usual care-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.44. Kang, 2012**

Bibliographic Reference Kang, J. H.; Park, R. Y.; Lee, S. J.; Kim, J. Y.; Yoon, S. R.; Jung, K. I.; The effect of bedside exercise program on stroke patients with Dysphagia; Ann Rehabil Med; 2012; vol. 36 (no. 4); 512-20

6

7 **1.1.44.1. Study details**

Secondary publication of another included study- see primary study for details	NR
Other publications associated with	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

this study included in review	
Trial name / registration number	NR
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea
Study setting	Department of Rehabilitation Medicine, Gwangju Veterans Hospital
Study dates	2009 and 2010
Sources of funding	NR
Inclusion criteria	The inclusion criteria were patients who had an onset of stroke within 6 months; whose dysphagia was confirmed by VFSS; who was capable of communication and fairly good understanding; and who can follow instructions, which consisted with at least one step.
Exclusion criteria	The exclusion criteria were any patients with a previous history of other diseases, which may have caused dysphagia; who had severe cognitive disorder, such as dementia; who cannot carry out video fluoroscopy due to incapability of sitting posture; or who was not able to follow study instructions.
Recruitment / selection of participants	NR
Intervention(s)	For the experimental group, additional exercise program for dysphagia treatment was conducted under nursing intervention for at least 1 hour a day, by an average during the 2-month study period. The exercise program was composed with oral, pharyngeal, laryngeal and respiration exercises. The needs of an additional exercise to improve the inadequate stage of swallowing, which were confirmed by a video fluoroscopy, were explained to and recognized by the patients and their caregivers to promote further efforts for this exercise. The oral exercise included lips, tongue and jaw exercises, and the oralpharyngeal exercise included tongue movement, including puling and reaching soft palate with the tip and soft palate exercise, such as yawning and straw blowing, as well as the Shaker exercise. With the expectation of preventing aspiration pneumonia, laryngeal exercises were performed, including airway closure, vocal cord adduction and breathing exercises. At last, for the respiration exercise to facilitate swallowing, effortful swallowing and supraglottis swallowing were exercised. For an effective implementation of the bedside exercise, rehabilitation specialists and occupational therapists provided training

	<p>for nurses. Video recording of the swallowing exercise were played in the wards for the patients and their caregivers, and the daily implementation was checked by the nurses.</p> <p>Concomitant therapy - Both the experimental and control groups visited the occupational therapy room for 30 minutes a day, 5 days a week for two months to carry out a tactile-thermal stimulation.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Both the experimental and control groups visited the occupational therapy room for 30 minutes a day, 5 days a week for two months to carry out a tactile-thermal stimulation
Number of participants	50
Duration of follow-up	2 months
Indirectness	NR

Additional comments	NR
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- 1
- 2 **1.1.44.2. Study arms**
- 3 **1.1.44.2.1. *Additional bedside exercise training (N = 25)***
- 4
- 5 **1.1.44.2.2. *Conventional swallow therapy (N = 25)***
- 6
- 7 **1.1.44.3. Characteristics**
- 8 **1.1.44.3.1. *Study-level characteristics***

Characteristic	Study (N = 50)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	

Characteristic	Study (N = 50)
Type of stroke	NR
Nominal	

1

2 **1.1.44.3.2. Arm-level characteristics**

Characteristic	Additional bedside exercise training (N = 25)	Conventional swallow therapy (N = 25)
% Female	36	28
Nominal		
Mean age (SD)	68.3 (6.6)	66.7 (6.01)
Mean (SD)		
People requiring enteral feeding support at baseline	12	11
Nominal		

3

4 **1.1.44.4. Outcomes**5 **1.1.44.4.1. Study timepoints**

- 6 • Baseline
- 7 • 2 month

8

1 **1.1.44.4.2. Dichotomous outcomes**

Outcome	Additional bedside exercise training, Baseline, N = 25	Additional bedside exercise training, 2 month, N = 25	Conventional swallow therapy, Baseline, N = 25	Conventional swallow therapy, 2 month, N = 25
Occurrence of chest infections (aspiration pneumonia)	n = NR ; % = NR	n = 5 ; % = 20	n = NR ; % = NR	n = 6 ; % = 24
No of events				

2 Occurrence of chest infections (aspiration pneumonia) - Polarity - Lower values are better

3 **1.1.44.4.3. Continuous outcomes**

Outcome	Additional bedside exercise training, Baseline, N = 25	Additional bedside exercise training, 2 month, N = 25	Conventional swallow therapy, Baseline, N = 25	Conventional swallow therapy, 2 month, N = 25
Swallow ability (FOIS) 1-7	2.8 (1.4)	4.6 (1)	2.6 (1.5)	3.6 (1.2)
Mean (SD)				

4 Swallow ability (FOIS) - Polarity - Higher values are better

5

6

1 **1.1.44.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.44.4.5. Continuous outcomes-Swallowability(FOIS)-MeanSD-Additional bedside exercise training-Conventional swallow**
 3 **therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High <i>(due to randomisation and deviation from intended intervention)</i>
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.44.4.6. Dichotomous outcomes-Occurrence of chest infections (aspiration pneumonia)-No Of Events-Additional bedside**
 6 **exercise training-Conventional swallow therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High <i>(due to randomisation and deviation from intended intervention)</i>
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.45. Khedr, 2009**

Bibliographic Reference Khedr, E M; Abo-Elfetoh, N; Rothwell, J C; Treatment of post-stroke dysphagia with repetitive transcranial magnetic stimulation.; Acta neurologica Scandinavica; 2009; vol. 119 (no. 3); 155-61

9

10 **1.1.45.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	United Kingdom.
Study setting	
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Acute hemiplegia with dysphagia; single thromboembolic non-haemorrhagic infarction documented by computerized tomography in the distribution of middle cerebral artery.
Exclusion criteria	Head injury or neurological diseases other than stroke; unstable cardiac dysrhythmia; fever; infection; hyperglycaemia; prior administration of tranquilizer; people unable to give informed consent because of severe aphasia, anosognosia and cognitive deficit.
Recruitment / selection of participants	No additional information.
Intervention(s)	Transcranial magnetic stimulation (TMS) N=14 Transcranial magnetic stimulation applied for 10 minutes every day for five consecutive days. A session of stimulation consisted of 10 trains of 3-Hz stimulation, each lasting for 10 s and then repeated every minute given through a figure-of-eight coil (9 cm diameter loop) positioned over oesophageal cortical area of the affected hemisphere. The intensity of

	<p>stimulation was set at 120% of the resting motor threshold for the first dorsal interosseous muscle of the 'unaffected' hemisphere.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=12</p> <p>Sham rTMS applied using the same parameters, but with the coil held so that the edge was in contact with the head while the remainder was rotated 90 degrees away from the scalp in the sagittal plane to reproduce the noise of the stimulation as well as some of its local sensation.</p> <p>Concomitant therapy: No additional information.</p>

Number of participants	26
Duration of follow-up	5 days
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis unclear.

1

2 **1.1.45.2. Study arms**3 **1.1.45.2.1. *Transcranial magnetic stimulation (TMS) (N = 14)***

4 Transcranial magnetic stimulation applied for 10 minutes every day for five consecutive days. A session of stimulation consisted of 10
5 trains of 3-Hz stimulation, each lasting for 10 s and then repeated every minute given through a figure-of-eight coil (9 cm diameter
6 loop) positioned over oesophageal cortical area of the affected hemisphere. The intensity of stimulation was set at 120% of the resting
7 motor threshold for the first dorsal interosseous muscle of the 'unaffected' hemisphere. Concomitant therapy: No additional
8 information.

9

10 **1.1.45.2.2. *Placebo/sham therapy (N = 12)***

11 Sham rTMS applied using the same parameters, but with the coil held so that the edge was in contact with the head while the
12 remainder was rotated 90 degrees away from the scalp in the sagittal plane to reproduce the noise of the stimulation as well as some
13 of its local sensation. Concomitant therapy: No additional information.

14

1 **1.1.45.3. Characteristics**2 **1.1.45.3.1. Study-level characteristics**

Characteristic	Study (N = 26)
% Female	n = 16 ; % = 62
Sample size	

3

4 **1.1.45.3.2. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 14)	Placebo/sham therapy (N = 12)
Mean age (SD)	58.9 (11.7)	56.2 (13.4)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 14)	Placebo/sham therapy (N = 12)
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.45.4. Outcomes**

3 **1.1.45.4.1. Study timepoints**

- 4 • Baseline
- 5 • 5 day (<3 months)

6

7 **1.1.45.4.2. Dichotomous outcome**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 14	Transcranial magnetic stimulation (TMS), 5 day, N = 14	Placebo/sham therapy, Baseline, N = 12	Placebo/sham therapy, 5 day, N = 12
Mortality 1 in the sham group (reported in the body of the text)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 1 ; % = 8
No of events				

8 Mortality - Polarity - Lower values are better

9

10

1 **1.1.45.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.45.4.4. Dichotomous outcome-Mortality-NoOfEvents-Transcranial magnetic stimulation (TMS)-Placebo/sham therapy-t5**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.46. Khedr, 2010**

Bibliographic Reference Khedr, Eman M; Abo-Elfetoh, Noha; Therapeutic role of rTMS on recovery of dysphagia in patients with lateral medullary syndrome and brainstem infarction.; Journal of neurology, neurosurgery, and psychiatry; 2010; vol. 81 (no. 5); 495-9

5

6 **1.1.46.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)

Study location	Egypt.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Acute ischaemic stroke with bulbar manifestation (dysphagia, nasal regurgitation); people must be conscious and have ischaemic cerebrovascular stroke (lateral medullary infarction or other brainstem infarction with pontomedullary dysfunction and documented by MRI) for the first ever and within 1-3 months from the onset with a degree of dysphagia ranging from grade III-IV.
Exclusion criteria	Head injury or neurological diseases other than stroke; unstable cardiac dysrhythmia; fever; infection; hyperglycaemia; epilepsy; prior administration of tranquiliser; people with intracranial metallic devices or with pacemakers or any other device; people unable to give informed consent because of severe anaesthesia or cognitive deficit.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=11</p> <p>Transcranial magnetic stimulation applied for 10 minutes every day for five consecutive days. A session of stimulation consisted of 10 trains of 3 Hz stimulation, each lasting for 10 s, and then repeated every minute given through a figure-of-eight coil with the center of coil positioned over the provisional oesophageal cortical area of both hemispheres (the best site for stimulation about 3 cm anterior and 6 cm lateral to the vertex). The intensity of stimulation was set to 130% of the resting motor threshold for the first dorsal interosseous muscle of the unaffected hemisphere.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Posterior circulation stroke (POCS) Either lateral medullary infarction or other brainstem infarction.
Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=11 Sham therapy was applied using the same parameters but with the coil held so that the edge was in contact with the head, while the remainder was rotated 90 degrees away from the scalp in the saggital plan to reproduce the noise of the stimulation as well as some of its local sensation. Concomitant therapy: No additional information.
Number of participants	22
Duration of follow-up	5 days.
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis unclear.

1 **1.1.46.2. Study arms**

2 **1.1.46.2.1. *Transcranial magnetic stimulation (TMS) (N = 11)***

3 Transcranial magnetic stimulation applied for 10 minutes every day for five consecutive days. A session of stimulation consisted of 10
 4 trains of 3 Hz stimulation, each lasting for 10 s, and then repeated every minute given through a figure-of-eight coil with the center of
 5 coil positioned over the provisional oesophageal cortical area of both hemispheres (the best site for stimulation about 3 cm anterior
 6 and 6 cm lateral to the vertex). The intensity of stimulation was set to 130% of the resting motor threshold for the first dorsal
 7 interosseous muscle of the unaffected hemisphere. Concomitant therapy: No additional information.

8

9 **1.1.46.2.2. *Placebo/sham therapy (N = 11)***

10 Sham therapy was applied using the same parameters but with the coil held so that the edge was in contact with the head, while the
 11 remainder was rotated 90 degrees away from the scalp in the saggital plan to reproduce the noise of the stimulation as well as some
 12 of its local sensation. Concomitant therapy: No additional information.

13

14 **1.1.46.3. Characteristics**

15 **1.1.46.3.1. *Arm-level characteristics***

Characteristic	Transcranial magnetic stimulation (TMS) (N = 11)	Placebo/sham therapy (N = 11)
% Female	n = 3 ; % = 27	n = 3 ; % = 27
Sample size		
Mean age (SD) (years)	56.1 (13.5)	59.4 (14.4)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 11)	Placebo/sham therapy (N = 11)
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	4.7 (3.4)	4.5 (1.1)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.46.4. Outcomes**3 **1.1.46.4.1. Study timepoints**

- 4 • Baseline
- 5 • 5 day (<3 months)

6

1 **1.1.46.4.2. Dichotomous outcome**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 12	Transcranial magnetic stimulation (TMS), 5 day, N = 12	Placebo/sham therapy, Baseline, N = 12	Placebo/sham therapy, 5 day, N = 12
Mortality 2 people in the 'another brainstem infarction' group who died No of events	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 2 ; % = 17

2 Mortality - Polarity - Lower values are better

3 **1.1.46.4.3. Continuous outcome**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 12	Transcranial magnetic stimulation (TMS), 5 day, N = 11	Placebo/sham therapy, Baseline, N = 12	Placebo/sham therapy, 5 day, N = 11
Swallowing ability (dysphagia grade) Scale range: 1-5. Final values. Mean (SD)	3.6 (0.58)	1.4 (0.43)	3.8 (0.4)	3.74 (0.51)

4 Swallowing ability (dysphagia grade) - Polarity - Lower values are better

5

6

1 **1.1.46.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.46.4.5. Dichotomous outcome-Mortality-NoOfEvents-Transcranial magnetic stimulation (TMS)-Placebo/sham therapy-t5**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.46.4.6. Continuous outcome-Swallowing ability(dysphagiagrade)-MeanSD-Transcranial magnetic stimulation (TMS)-**
 5 **Placebo/sham therapy-t5**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.47. Kim, 2017**

Bibliographic Reference Kim, H D; Choi, J B; Yoo, S J; Chang, M Y; Lee, S W; Park, J S; Tongue-to-palate resistance training improves tongue strength and oropharyngeal swallowing function in subacute stroke survivors with dysphagia.; Journal of oral rehabilitation; 2017; vol. 44 (no. 1); 59-64

8

9 **1.1.47.1. Study details**

Secondary publication of another included	No additional information.
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study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	July 2015 to March 2016.
Sources of funding	This research was carried out without funding.
Inclusion criteria	Post-stroke oropharyngeal dysphagia confirmed by videofluoroscopic swallow study; tongue muscle strength <10 kPa; Mini-Mental Status Examination Score >20; able to swallow voluntarily; cortex damage only.
Exclusion criteria	Secondary stroke; trigeminal neuropathy; significant malocclusion; facial asymmetry; parafunctional habits (clenching, bruxing, tongue thrusting); measurement and exercise not possible because tongue muscle strength was 0 kPa.
Recruitment / selection of participants	Stroke survivors with dyphagia recruited from two university hospitals in the Republic of Korea.
Intervention(s)	Behavioural interventions (tongue-to-palate resistance training) N=18 Tongue-to-palate resistance training. The anterior tongue was positioned longitudinally along the hard palate, just posterior to the alveolar ridge. Posterior tongue was positioned with the posterior border of the hard palate. The experimental group performed 30 exercise repetitions for the anterior and posterior regions. The exercises were conducted in a random sequence. The person's lower chin was palpated during the exercise to verify contraction of the tongue muscles. People were allowed to rest for a few seconds when desired, to prevent excessive muscle fatigue. The intervention was conducted five times per week for 4 weeks.

	Concomitant therapy: Both groups received conventional dysphagia therapy including thermal tactile stimulation, facial massage and various manoeuvres.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=17 Conventional therapy only. Concomitant therapy: Both groups received conventional dysphagia therapy including thermal tactile stimulation, facial massage and various manoeuvres.
Number of participants	41

Duration of follow-up	4 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be only completers analysed.

1

2 **1.1.47.2. Study arms**3 **1.1.47.2.1. Behavioural interventions (tongue-to-palate resistance training) (N = 21)**

4 Tongue-to-palate resistance training. The anterior tongue was positioned longitudinally along the hard palate, just posterior to the
5 alveolar ridge. Posterior tongue was positioned with the posterior border of the hard palate. The experimental group performed 30
6 exercise repetitions for the anterior and posterior regions. The exercises were conducted in a random sequence. The person's lower
7 chin was palpated during the exercise to verify contraction of the tongue muscles. People were allowed to rest for a few seconds when
8 desired, to prevent excessive muscle fatigue. The intervention was conducted five times per week for 4 weeks. Concomitant therapy:
9 Both groups received conventional dysphagia therapy including thermal tactile stimulation, facial massage and various manoeuvres.

10

11 **1.1.47.2.2. Usual care (N = 20)**

12 Conventional therapy only. Concomitant therapy: Both groups received conventional dysphagia therapy including thermal tactile
13 stimulation, facial massage and various manoeuvres.

14

15 **1.1.47.3. Characteristics**16 **1.1.47.3.1. Arm-level characteristics**

Characteristic	Behavioural interventions (tongue-to-palate resistance training) (N = 21)	Usual care (N = 20)
% Female	n = 7 ; % = 39	n = 9 ; % = 53

Characteristic	Behavioural interventions (tongue-to-palate resistance training) (N = 21)	Usual care (N = 20)
Sample size		
Mean age (SD) (years)	62.17 (11.01)	59.29 (10.19)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	4.94 (5.52)	5.29 (5.62)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1 Only reports for 18 people in the experimental group and 17 in the control group.

2

1 **1.1.47.4. Outcomes**

2 **1.1.47.4.1. Study timepoints**

- 3 • Baseline
- 4 • 4 week (<3 months)

5

6 **1.1.47.4.2. Continuous outcomes**

Outcome	Behavioural interventions (tongue-to-palate resistance training), Baseline, N = 21	Behavioural interventions (tongue-to-palate resistance training), 4 week, N = 18	Usual care, Baseline, N = 20	Usual care, 4 week, N = 17
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change scores. Mean (SD)	6 (1.02)	-2.44 (0.85)	5.88 (1.16)	-2.06 (1.14)

7 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

8

9

10 **1.1.47.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.47.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale) - Mean SD - Behavioural interventions (tongue-to-palate resistance training) - Usual care - t4**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.48. Kim, 2019**

3 **Bibliographic Reference** Kim, Hwan-Hee; Park, Ji-Su; Efficacy of modified chin tuck against resistance exercise using hand-free device for dysphagia in stroke survivors: A randomised controlled trial.; Journal of oral rehabilitation; 2019; vol. 46 (no. 11); 1042-1046

3

4 **1.1.48.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea
Study setting	Department of Occupational Therapy, Semyung University, Jecheon, Republic of Korea
Study dates	NR

Sources of funding	Semyung University Research Grant of 2018, Grant/Award Number: NA. This paper was supported by the Semyung University Research Grant of 2018.
Inclusion criteria	The inclusion criteria were as follows: (1) diagnosed as having had a stroke within 6 months post-onset; (2) dysphagia was confirmed by a videofluoroscopic swallowing study (VFSS); (3) liquid aspiration or penetration on VFSS; (4) those with a nasogastric (NG) tube; (5) able to communicate properly, those without any cognitive deficit (>22 points in the Mini-Mental Status Examination); and (6) cortex damage only.
Exclusion criteria	The exclusion criteria were (1) secondary stroke; (2) gastrostomy tube; (3) those who had undergone tracheostomy; (4) those with neck or shoulder pain; and (5) those with cervical herniated nucleus, cervical spine orthosis or brainstem stroke (eg lateral medullary infarction).
Recruitment / selection of participants	NR
Intervention(s)	<p>The experimental group performed the mCTAR exercise using a PhagiaFLEX-HF (Alternative Speech and Swallowing Solutions, Inc). The device is made of polypropylene and has a thickness of about 8 mm and a length of about 20 cm. A total of four curved surfaces are formed, and each curved surface is divided into a fixed portion, supporting portion and chin surface. The method of performing the mCTAR exercise was as follows. First, the subject sat in a comfortable chair. Then, the fixed part of the device was secured to the desk surface. Subsequently, the height of the desk was adjusted in order to firmly attach the chin surface under the chin. The exercise was performed in this posture, and it was further divided into isotonic and isometric exercise. The isometric exercise involved holding the chin down for 10 seconds against the resistance (10 seconds, thrice). Isotonic exercise was repeated 30 times in the chin-down position against resistance.</p> <p>Both groups received traditional dysphagia treatment (TDT) by skilled occupational therapists (30 min/d). TDT included oral facial massage, thermal-tactile stimulation and various compensatory trainings. The intervention was delivered 5 days a week, for 6 weeks.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Severe

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Both groups received traditional dysphagia treatment (TDT) by skilled occupational therapists (30 min/d). TDT included oral facial massage, thermal-tactile stimulation and various compensatory trainings. The intervention was delivered 5 days a week, for 6 weeks.
Number of participants	30
Duration of follow-up	6 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.48.2. Study arms**3 **1.1.48.2.1. *Behavioural interventions (Modified chin tuck against resistance with standard care) (N = 12)***

4

1 **1.1.48.2.2.** *Usual care (Standard care oral facial massage, thermal-tactile stimulation) (N = 13)*

2

3 **1.1.48.3.** **Characteristics**

4 **1.1.48.3.1.** *Study-level characteristics*

Characteristic	Study (N = 25)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Time after stroke	NR
Nominal	
Type of stroke	NR
Nominal	

5

6 **1.1.48.3.2.** *Arm-level characteristics*

Characteristic	Behavioural interventions (Modified chin tuck against resistance with standard care) (N = 12)	Usual care (Standard care oral facial massage, thermal-tactile stimulation) (N = 13)
% Female	50	53.8
Nominal		
Mean age (SD)	63.5 (5.5)	65.2 (6.2)

Characteristic	Behavioural interventions (Modified chin tuck against resistance with standard care) (N = 12)	Usual care (Standard care oral facial massage, thermal-tactile stimulation) (N = 13)
Mean (SD)		
Severity of dysphagia PAS	4.6 (0.82)	4.93 (0.88)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 12 ; % = 100	n = 13 ; % = 100
No of events		

1

2 **1.1.48.4. Outcomes**3 **1.1.48.4.1. Study timepoints**

- 4 • Baseline
- 5 • 6 week

6

7 **1.1.48.4.2. Continuous outcomes**

Outcome	Behavioural interventions (Modified chin tuck against resistance with standard care), Baseline, N = 12	Behavioural interventions (Modified chin tuck against resistance with standard care), 6 week, N = 12	Usual care (Standard care oral facial massage, thermal-tactile stimulation), Baseline, N = 13	Usual care (Standard care oral facial massage, thermal-tactile stimulation), 6 week, N = 13
Occurrence of aspiration (penetration-	4.6 (0.82)	-1.53 (0.74)	4.93 (0.88)	-0.53 (0.99)

Outcome	Behavioural interventions (Modified chin tuck against resistance with standard care), Baseline, N = 12	Behavioural interventions (Modified chin tuck against resistance with standard care), 6 week, N = 12	Usual care (Standard care oral facial massage, thermal-tactile stimulation), Baseline, N = 13	Usual care (Standard care oral facial massage, thermal-tactile stimulation), 6 week, N = 13
aspiration scale) Scale range: 1-8. Change scores.				
Mean (SD)				
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Change score.	3.4 (1.05)	1.67 (0.72)	3.19 (0.68)	0.47 (0.91)
Mean (SD)				

1 Occurrence of aspiration (penetration-aspiration scale) - Polarity - Lower values are better

2 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

3 **1.1.48.4.3. Dichotomous outcomes**

Outcome	Behavioural interventions (Modified chin tuck against resistance with standard care), Baseline, N = 12	Behavioural interventions (Modified chin tuck against resistance with standard care), 6 week, N = 12	Usual care (Standard care oral facial massage, thermal-tactile stimulation), Baseline, N = 13	Usual care (Standard care oral facial massage, thermal-tactile stimulation), 6 week, N = 13
Dysphagia present/return to normal diet (removal of nasogastric tube)	n = 12 ; % = 100	n = 3 ; % = 25	n = 13 ; % = 100	n = 2 ; % = 15

Outcome	Behavioural interventions (Modified chin tuck against resistance with standard care), Baseline, N = 12	Behavioural interventions (Modified chin tuck against resistance with standard care), 6 week, N = 12	Usual care (Standard care oral facial massage, thermal-tactile stimulation), Baseline, N = 13	Usual care (Standard care oral facial massage, thermal-tactile stimulation), 6 week, N = 13
No of events				

1 Dysphagia present/return to normal diet (removal of nasogastric tube) - Polarity - Higher values are better

2

3

4 **1.1.48.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.48.4.5. Continuous outcomes-Swallowing ability (FOIS) functional oral intake scale-Mean SD-Modified chin tuck against**
 6 **resistance with standard care-Standard care oral facial massage, thermal-tactile stimulation-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.48.4.6. Continuous outcomes-Occurrence of aspiration-penetration-aspiration scale (PAS)-Mean SD-Modified chin tuck**
 9 **against resistance with standard care-Standard care oral facial massage, thermal-tactile stimulation-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.48.4.7.** ***Dichotomous outcomes-Dysphagia present/return to normal diet (removal of nasogastric tube)-No Of Events-Behavioural***
 2 ***interventions (Modified chin tuck against resistance with standard care)-Usual care (Standard care oral facial***
 3 ***massage, thermal-tactile stimulation)-t6***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High <i>(due to randomisation and missing outcome data)</i>
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.49. Kim, 2011**

Bibliographic Reference Kim, L.; Chun, M. H.; Kim, B. R.; Lee, S. J.; Effect of repetitive transcranial magnetic stimulation on patients with brain injury and Dysphagia; Ann Rehabil Med; 2011; vol. 35 (no. 6); 765-71

6

7 **1.1.49.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.

Study type	Randomised controlled trial (RCT)
Study location	Korea.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Presence of dysphagia after acute brain injury; disease that was localised to a unilateral cerebral hemisphere (as documented by computerised tomography or magnetic resonance imaging).
Exclusion criteria	A prior diagnosis of another neurological disease; an unstable medical condition; severe cognitive impairment; severe aphasia; history of seizure.
Recruitment / selection of participants	People with dysphagia that occurred after an acute brain injury and whose symptom onset occurred after <3 months.
Intervention(s)	<p>Transcranial direct current stimulation (TMS) N=20</p> <p>Two groups: Group 1 = Magnetic stimulation provided using a circular coil (external diameter, 9cm) over the bilateral anterolateral scalp, commencing at the vertex. Performed on each ipsilesional hemisphere hot spot at 100% of each MEP threshold, at 5 Hz, for 10 sec, and repeated every minute for 20 minutes in the high-frequency stimulation group (total, 1000 pulses). Group 2 = For low frequency stimulation, a 1Hz stimulation at 100% MT was delivered for 20 minutes (total 1200 pulses) on the contralesional hemisphere hot spot. Therapy for 20 minutes, five days a week for 2 weeks.</p> <p>Concomitant therapy: All people received swallowing training comprised of oral and facial sensory training, oral and pharyngeal muscle training, compensatory techniques and neuromuscular electrical stimulation on pharyngeal muscles during rTMS.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Number of participants	30
Duration of follow-up	2 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information. Appears to be ITT no drop outs.

1

2 **1.1.49.2. Study arms**3 **1.1.49.2.1. Transcranial direct current stimulation (TMS) (N = 20)**

4 Two groups: Group 1 = Magnetic stimulation provided using a circular coil (external diameter, 9cm) over the bilateral anterolateral
5 scalp, commencing at the vertex. Performed on each ipsilesional hemisphere hot spot at 100% of each MEP threshold, at 5 Hz, for 10
6 sec, and repeated every minute for 20 minutes in the high-frequency stimulation group (total, 1000 pulses). Group 2 = For low
7 frequency stimulation, a 1Hz stimulation at 100% MT was delivered for 20 minutes (total 1200 pulses) on the contralesional
8 hemisphere hot spot. Therapy for 20 minutes, five days a week for 2 weeks. Concomitant therapy: All people received swallowing
9 training comprised of oral and facial sensory training, oral and pharyngeal muscle training, compensatory techniques and
10 neuromuscular electrical stimulation on pharyngeal muscles during rTMS.

1

2 **1.1.49.2.2. Placebo/sham therapy (N = 10)**

3 Sham stimulation applied using the protocol employed for high-frequency stimulation, but the coil was rotated through 90 degrees;
 4 thus, no stimulation was applied but the noise that was characteristic of stimulation was present. Concomitant therapy: All people
 5 received swallowing training comprised of oral and facial sensory training, oral and pharyngeal muscle training, compensatory
 6 techniques and neuromuscular electrical stimulation on pharyngeal muscles during rTMS.

7

8 **1.1.49.3. Characteristics**9 **1.1.49.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (TMS) (N = 20)	Placebo/sham therapy (N = 10)
% Female	n = 9 ; % = 45	n = 4 ; % = 40
Sample size		
Mean age (SD) (years)	68.1 (10.5)	68.2 (12.6)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial direct current stimulation (TMS) (N = 20)	Placebo/sham therapy (N = 10)
Time after stroke (days)	30.3 (22.9)	29 (9.9)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.49.4. Outcomes**3 **1.1.49.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)

6

7 **1.1.49.4.2. Continuous outcomes**

Outcome	Transcranial direct current stimulation (TMS), Baseline, N = 20	Transcranial direct current stimulation (TMS), 2 week, N = 20	Placebo/sham therapy, Baseline, N = 10	Placebo/sham therapy, 2 week, N = 10
Occurrence of aspiration (Penetration Aspiration Scale)	NR (NR)	-1.8 (2.3)	NR (NR)	-0.7 (1.2)

Outcome	Transcranial direct current stimulation (TMS), Baseline, N = 20	Transcranial direct current stimulation (TMS), 2 week, N = 20	Placebo/sham therapy, Baseline, N = 10	Placebo/sham therapy, 2 week, N = 10
Scale range: 1-8. Change scores.				
Mean (SD)				
Swallowing ability (Functional dysphagia scale) Scale range: Unclear. Change scores.	NR (NR)	-7.3 (9.6)	NR (NR)	-4.4 (4.9)
Mean (SD)				

1 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better
 2 Swallowing ability (Functional dysphagia scale) - Polarity - Lower values are better

3

4

5 **1.1.49.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.49.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale) - Mean SD - Transcranial direct current stimulation (TMS) - Placebo/sham therapy - t2**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.49.4.5. Continuous outcomes-Swallowing ability (Functional dysphagia scale)-Mean SD-Transcranial direct current**
 2 **stimulation (TMS)-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.50. Kumar, 2010**

Bibliographic Reference Kumar, S.; Transcranial direct current stimulation (TDCS) for facilitating swallowing improvement after an acute unilateral hemispheric stroke; 2010

5

6 **1.1.50.1. Study details**

Secondary publication of another included study- see primary study for details	Kumar, Sandeep, Wagner, Cynthia W, Frayne, Colleen et al. (2011) Noninvasive brain stimulation may improve stroke-related dysphagia: a pilot study. Stroke 42(4): 1035-40
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

7

8

1 **1.1.51. Kumar, 2022**

Bibliographic Reference Kumar, S; Marchina, S; Langmore, S; Massaro, J; Palmisano, J; Wang, N; Searls, DE; Lioutas, V; Pisegna, J; Wagner, C; et, al.; Fostering eating after stroke (FEASt) trial for improving post-stroke dysphagia with non-invasive brain stimulation; Scientific reports; 2022; vol. 12 (no. 1); 9607

2

3 **1.1.51.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	Kumar, Sandeep, Wagner, Cynthia W, Frayne, Colleen et al. (2011) Noninvasive brain stimulation may improve stroke-related dysphagia: a pilot study. Stroke 42(4): 1035-40
Trial name / registration number	NCT01919112
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Beth Israel Deaconess Medical Center (BIDMC) in Boston, MA
Study dates	September 2013–September 2019
Sources of funding	This trial was funded Grant support from the National Institute on Deafness and Other Communication Disorders of the National Institutes of Health (NIH) under Award Number R01DC012584 (PI: Kumar). GS acknowledges support from NINDS (U01NS102353) and NIMH (R01MH111874). The content of this work is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. The authors do not have any other conflicts of interest to report.

Inclusion criteria	Patients with an acute-subacute unilateral hemispheric infarction, day 2-day 6 since the qualifying stroke, between 21–90 years of age, with moderate to severe dysphagia, defined as a Penetration And Aspiration Scale ²³ (PAS) score \geq 4 on a standardized videofluoroscopic study (VFSS).
Exclusion criteria	The main exclusion criteria were pre-stroke swallowing difficulties, severe stroke (NIHSS score \geq 25), or presence of any other contraindication for tDCS.
Recruitment / selection of participants	All subjects were recruited at Beth Israel Deaconess Medical Center (BIDMC) in Boston, MA. All consecutive acute ischemic stroke (AIS) patients admitted to BIDMC were screened for trial participation.
Intervention(s)	The stimulation session were performed for 20 min twice daily over 5 consecutive days. Anodal tDCS (2 mA) or sham was delivered via a battery-driven, constant current stimulator (NeuroConn-DC Stimulator Plus) using saline soaked electrodes (anode 3×5 cm; reference electrode 5×7 cm). We targeted the healthy swallowing motor cortex using the 10–20 EEG electrode placement system, placing the anode mid-distance between C3/T3 [left] or C4/T4 [right] over the unaffected hemisphere and the reference electrode over the contralateral supraorbital region. We had previously verified the location of the stimulating electrode using a combination of functional brain MRI (fMRI) and anatomical brain MRI scans. The electrode positioning was re-confirmed in a subset of trial participants using anatomical brain MRI scans. The atDCS electric field (V/m) distribution was modeled using a freely available software package called SimNIBS ³⁶ . The MNI ICBM 152 1 mm T1 weighted image was used to perform simulation. The electric field distribution (V/m) is influenced by the shape, location, and current applied through the electrodes. The High-Dose tDCS group received 2 mA atDCS twice daily for a total of 20 min (total charge density 16 C/cm ²); Low-Dose group received 2 mA alternating with sham stimulation daily for a total of 20 min (total charge density 8 C/cm ²). All stimulation sessions were conducted concurrently with standardized effortful swallowing exercises.
Subgroup 1: Severity of dysphagia (as stated by category)	Mixed
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear

Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	The sham group received sham stimulation twice daily. All stimulation sessions were conducted concurrently with standardized effortful swallowing exercises.
Number of participants	42
Duration of follow-up	1 month
Indirectness	NR
Additional comments	NR

1

2 **1.1.51.2. Study arms**

3 **1.1.51.2.1. *Transcranial direct current stimulation (low and high level groups combined) (N = 27)***

4 Low-dose tDCS and High-dose tDCS groups combined

5

6 **1.1.51.2.2. *Placebo/sham therapy (N = 15)***

7

1 **1.1.51.3. Characteristics**2 **1.1.51.3.1. Study-level characteristics**

Characteristic	Study (N = 42)
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

4 **1.1.51.3.2. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (low and high level groups combined) (N = 27)	Placebo/sham therapy (N = 15)
% Female	59.2	60
Nominal		
Mean age (SD)	69.9 (13.1)	73 (14.1)
Mean (SD)		
Ethnicity	NR	NR
Nominal		
White %	93.3	74.1

Characteristic	Transcranial direct current stimulation (low and high level groups combined) (N = 27)	Placebo/sham therapy (N = 15)
Nominal		
Black %	18.5	0
Nominal		
Asian %	14.3	0
Nominal		
Unknown	0	6.7
Nominal		
Severity of dysphagia PAS score	4 (1.2)	4 (1.5)
Mean (SD)		
Time after stroke (hours)	92.5 (34.8)	93.5 (38.8)
Mean (SD)		

1

2 **1.1.51.4. Outcomes**3 **1.1.51.4.1. Study timepoints**

- 4 • Baseline
- 5 • 1 month

6

1 **1.1.51.4.2. Continuous outcomes (1)**

Outcome	Transcranial direct current stimulation (low and high level groups combined), Baseline, N = 27	Transcranial direct current stimulation (low and high level groups combined), 1 month, N = 27	Placebo/sham therapy, Baseline, N = 15	Placebo/sham therapy, 1 month, N = 15
Swallowing ability (penetration-aspiration scale) Scale range: 1-8. Change scores. Mean (SD)	4 (1.2)	-0.6 (1.4)	4 (1.6)	-0.8 (1.6)

2 Swallowing ability (penetration-aspiration scale) - Polarity - Lower values are better

3 **1.1.51.4.3. Dichotomous outcomes**

Outcome	Transcranial direct current stimulation (low and high level groups combined), Baseline, N = 27	Transcranial direct current stimulation (low and high level groups combined), 1 month, N = 27	Placebo/sham therapy, Baseline, N = 15	Placebo/sham therapy, 1 month, N = 15
Mortality No of events	n = 0 ; % = 0	n = 2 ; % = 7.4	n = 0 ; % = 0	n = 1 ; % = 6.7

4 Mortality - Polarity - Lower values are better

1 **1.1.51.4.4. Continuous outcomes (2)**

Outcome	Transcranial direct current stimulation (low and high level groups combined), Baseline, N = 27	Transcranial direct current stimulation (low and high level groups combined), 1 month, N = 24	Placebo/sham therapy, Baseline, N = 15	Placebo/sham therapy, 1 month, N = 14
Swallowing ability (functional oral intake scale (FOIS)) Scale range: 1-7. Change scores. Mean (SD)	3.1 (1.6)	2.7 (1.2)	2.7 (1.3)	2.1 (1.7)

2 Swallowing ability (functional oral intake scale (FOIS)) - Polarity - Higher values are better

3

4

5 **1.1.51.4.5. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.51.4.6. Continuous outcomes-Swallowing ability (penetration-aspirations scale (PAS)) final value-Mean SD- Transcranial direct current stimulation (low and high level groups combined)-Sham therapy-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.51.4.7. Dichotomous outcomes-Mortality-NoOfEvents- Transcranial direct current stimulation (low and high level groups**
 2 **combined)-Sham therapy-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

3
 4 **1.1.51.4.8. Continuous outcomes(2)-Swallowing ability(functional oral intake scale(FOIS))-MeanSD- Transcranial direct current**
 5 **stimulation (low and high level groups combined)-Placebo/sham therapy-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

6
 7 **1.1.52. Kumar, 2011**

Bibliographic Reference Kumar, Sandeep; Wagner, Cynthia W; Frayne, Colleen; Zhu, Lin; Selim, Magdy; Feng, Wuwei; Schlaug, Gottfried; Noninvasive brain stimulation may improve stroke-related dysphagia: a pilot study.; Stroke; 2011; vol. 42 (no. 4); 1035-40

8
 9 **1.1.52.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
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Other publications associated with this study included in review	<p>Kumar S, Marchina S, Langmore S, Massaro J, Palmisano J, Wang N, Searls DE, Lioutas V, Pisegna J, Wagner C, Shinde A, Schlaug G. Fostering eating after stroke (FEAST) trial for improving post-stroke dysphagia with non-invasive brain stimulation. <i>Sci Rep.</i> 2022 Jun 10;12(1):9607. doi: 10.1038/s41598-022-14390-9. PMID: 35689084; PMCID: PMC9187742.</p> <p>Kumar, S. (2010) Transcranial direct current stimulation (TDCS) for facilitating swallowing improvement after an acute unilateral hemispheric stroke.</p> <p>This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. <i>The Cochrane database of systematic reviews</i> 10: cd000323</p>
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Inpatient stroke service
Study dates	No additional information
Sources of funding	Dr Kumar receives partial salary support from the NIH (NINDS 5U01-NS044876-03 [Site PI]) and receives research support from the Charles and Irene Goldman Neurology Research Fund (PI). Dr Selim receives research support from the NIH (NINDS 1R01-NS 057127-01A1 [PI], NINDS 1R01-NS 045754-01A2 [Co-I], and 5R01-HL46690-14 [Co-I]). Dr Schlaug receives research support from the NIH (NIDCD 1R01 DC008796 [PI], NIDCD 3R01DC008796-02S1 [PI], R01 DC009823-01 [PI], and 1R01-NS 057127 [Co-I]). This study received funding support from NIH (RO1 DC008796 and RO1 DC009823 to Dr Schlaug [PI] and CIMIT to Dr Schlaug [PI]).
Inclusion criteria	All participants were recruited from our inpatient stroke service, were between 24 to 168 hours after their first ischemic stroke at time of enrollment, and had dysphagia secondary to a new unilateral hemispheric infarction.
Exclusion criteria	Patients with difficulty following instructions because of obtundation or cognitive impairment, preexisting swallowing problems, or other contraindications to tDCS were excluded.

Recruitment / selection of participants	No additional information
Intervention(s)	<p>Using the international 10- to 20-EEG electrode system for guidance, a saline-soaked anodal electrode was placed over the undamaged hemisphere, mid-distance between C3 and T3 on the left or C4 and T4 on the right, with a reference electrode over the contralateral supraorbital region. This montage was expected to generate maximal current density over the inferior sensorimotor cortex and the neighboring premotor brain regions critical for reorganization of the swallowing motor cortex after a dysphagic stroke. We confirmed the location of the stimulating electrode and its proximity to the targeted regions by co-registering it with high-resolution T1-weighted MRI scans. A DOSS score was obtained immediately before stimulation sessions (DOSS-pre) and after the fifth session (DOSS-post).</p> <p>The tDCS was applied in conjunction with standardized swallowing maneuvers to provide adequate sensory and motor activation of the swallowing cortex. All participants sucked on a lemon-flavored lollipop during these sessions. Patients reporting dryness of mouth were provided with 1 to 2 small ice chips intermittently. Patients were instructed to “swallow hard” every 30 seconds, thereby generating approximately 60 effortful swallows during each session. We used gesticulations to encourage aphasic patients to swallow at regular intervals. Occurrence of a swallow response was assessed by observing the movement of the thyroid cartilage or by palpating its excursion in patients with thicker necks.</p> <p>Anodal tDCS (2 mA for 30 minutes) was applied daily to the non-lesional hemisphere for 5 consecutive days. The tDCS was delivered through a battery-driven constant current stimulator (Phoresor; Iomed, Salt Lake City, UT), with the following electrode dimensions: 3×5 cm for the anode and 5×6 cm for the reference electrode.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Mixed
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>Sham therapy was applied daily to the non lesional hemisphere for 5 consecutive days for 30 mins.</p> <p>The sham was applied in conjunction with standardized swallowing maneuvers to provide adequate sensory and motor activation of the swallowing cortex. All participants sucked on a lemon-flavored lollipop during these sessions. Patients reporting dryness of mouth were provided with 1 to 2 small ice chips intermittently. Patients were instructed to “swallow hard” every 30 seconds, thereby generating approximately 60 effortful swallows during each session. We used gesticulations to encourage aphasic patients to swallow at regular intervals. Occurrence of a swallow response was assessed by observing the movement of the thyroid cartilage or by palpating its excursion in patients with thicker necks.</p>
Number of participants	14
Duration of follow-up	5 days
Indirectness	NR
Additional comments	NR

- 1 **1.1.52.2. Study arms**
- 2 **1.1.52.2.1. *Transcranial direct current stimulation (N = 7)***
- 3
- 4 **1.1.52.2.2. *Placebo/sham therapy (N = 7)***
- 5
- 6 **1.1.52.3. Characteristics**
- 7 **1.1.52.3.1. *Study-level characteristics***

Characteristic	Study (N = 14)
% Female	NR
Nominal	
Mean age (SD)	NR (NR)
Mean (SD)	
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR

Characteristic	Study (N = 14)
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

1

2 **1.1.52.4. Outcomes**3 **1.1.52.4.1. Study timepoints**

- 4 • Baseline
- 5 • 5 day

6

7 **1.1.52.4.2. Continuous outcomes**

Outcome	Transcranial direct current stimulation, Baseline, N = 7	Transcranial direct current stimulation, 5 day, N = 7	Placebo/sham therapy, Baseline, N = 7	Placebo/sham therapy, 5 day, N = 7
Swallowing ability (Dysphagia Outcome and Severity scale) 1-7 change score	NR (NR to NR)	2.6 (1.91 to 3.29)	NR (NR to NR)	1.26 (0.57 to 1.95)
Mean (95% CI)				
Swallowing ability (Dysphagia Outcome and Severity scale)	NR (NR)	2.14 (1.46)	NR (NR)	4.71 (1.58)

Outcome	Transcranial direct current stimulation, Baseline, N = 7	Transcranial direct current stimulation, 5 day, N = 7	Placebo/sham therapy, Baseline, N = 7	Placebo/sham therapy, 5 day, N = 7
Severity scale) 1-7 change score				
Mean (SD)				

1 Swallowing ability (Dysphagia Outcome and Severity scale) - Polarity - Higher values are better

2

3

4 **1.1.52.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.52.4.4. Continuous outcomes-Swallowing ability(Dysphagia Outcome and Severity scale)-Mean and 95% CI-
6 Transcranial direct current stimulation-Sham stimulation-t5**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation procedure)
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.52.4.5. Continuous outcomes-Swallowing ability(Dysphagia Outcome and Severity scale)-Mean SD-Transcranial direct current
9 stimulation-Sham stimulation-t5**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to the randomisation process)
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.53. Lan, 2013**

Bibliographic Reference Lan, Y; Xu, G; Dou, Z; Wan, G; Yu, F; Lin, T; Biomechanical changes in the pharynx and upper esophageal sphincter after modified balloon dilatation in brainstem stroke patients with dysphagia.; Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society; 2013; vol. 25 (no. 12); e821-9

2

3 **1.1.53.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	August 2011 and May 2012.
Sources of funding	This work was supported by the following grants: National Science Foundation of China 81101460; Guangzhou Municipal Science and Technology Program 12S182060084; the Fundamental Research Funds from the Central Universities 12ykpy38; National Science Foundation of China 81071606; and Guangdong Natural Science Foundation 10151008901000157.

Inclusion criteria	People aged 40-70 years; clinical stroke diagnosis consistent with the World Health Organisation definition of stroke, confirmed by brain magnetic resonance imaging; onset of brainstem stroke within 3-12 months of study; videofluoroscopic evidence of pharyngeal dysphagia defined as having one of the following symptoms present - impaired hypopharyngeal excursion, impaired pharyngeal constriction, impaired upper oesophageal sphincter opening, aspiration, post swallow residue; cognitive abilities sufficient to participate in interactive and intense dysphagia therapy, as defined by a Mini-Mental Status Examination score greater than 23; willingness to participate in clinical and physiological evaluations of swallowing performance and to attend 3 consecutive weeks (15 sessions) of therapy.
Exclusion criteria	Severe cardiac, respiratory, haematologic or other disease; previous history of stroke or multiple strokes; previous head and neck surgery, oesophageal surgery or nasopharyngeal cancer; the presence of other pathology in swallowing-related structures.
Recruitment / selection of participants	People with dysphagia after brainstem stroke at the third affiliated hospital of Sun Yat-sen University and the first affiliated hospital of Sun Yat-sen University of Guangzhou, Guangdong, China.
Intervention(s)	<p>Behavioural interventions (balloon dilatation) N=15</p> <p>Modified balloon dilatation therapy and regular therapy. All dilatation treatment sessions followed a standard protocol. Tube feeding was ceased 2 hours before dilatation. Topical anaesthesia with 2% lidocaine spray was applied in the nasal cavity. A No. 14 urethral catheter with balloon was gently inserted through the nasal cavity until the balloon was estimated to be under the lower margin of the upper oesophageal sphincter. People were asked to phonate to ensure that the catheter was not inserted into the trachea during the process. After that, 3 mL of water was injected into the balloon. The catheter was then pulled gently cephalad while the people was instructed to swallow with effort, attempting to prevent the balloon movement, until balloon slipped out from the upper oesophageal sphincter. Dilatation treatment began with 2-3 mL of water injected into the balloon; the volume of water was increased 0.5-1mL incrementally, depending on the tolerance of the person. The procedure was repeated five to eight times per sessions, around 30 minutes for each process time once a day for 5 consecutive days per week. All dilatations were performed without radiographic or endoscopic guidance. Vital signs were monitored during and after each treatment. Nebulization with dexamethasone, chymotrypsin and gentamycin were administered immediately after each treatment to prevent oesophageal mucosal oedema and to reduce mucus secretion.</p> <p>Concomitant therapy: Everyone received 30 minutes of supervised regular therapy, twice a day, 5 days a week. Several techniques for improving swallowing function were implemented by treating therapists. Programs progressed as indicated to meet the person's goals.</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=15 Usual care only. Concomitant therapy: Everyone received 30 minutes of supervised regular therapy, twice a day, 5 days a week. Several techniques for improving swallowing function were implemented by treating therapists. Programs progressed as indicated to meet the person's goals.
Number of participants	30
Duration of follow-up	3 weeks (end of intervention)
Indirectness	No additional information.

Additional comments	No additional information.
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1

2 **1.1.53.2. Study arms**3 **1.1.53.2.1. Behavioural interventions (balloon dilatation) (N = 15)**

4 Modified balloon dilatation therapy and regular therapy. All dilatation treatment sessions followed a standard protocol. Tube feeding
5 was ceased 2 hours before dilatation. Topical anaesthesia with 2% lidocaine spray was applied in the nasal cavity. A No. 14 urethral
6 catheter with balloon was gently inserted through the nasal cavity until the balloon was estimated to be under the lower margin of the
7 upper oesophageal sphincter. People were asked to phonate to ensure that the catheter was not inserted into the trachea during the
8 process. After that, 3 mL of water was injected into the balloon. The catheter was then pulled gently cephalad while the people was
9 instructed to swallow with effort, attempting to prevent the balloon movement, until balloon slipped out from the upper oesophageal
10 sphincter. Dilatation treatment began with 2-3 mL of water injected into the balloon; the volume of water was increased 0.5-1mL
11 incrementally, depending on the tolerance of the person. The procedure was repeated five to eight times per sessions, around 30
12 minutes for each process time once a day for 5 consecutive days per week. All dilatations were performed without radiographic or
13 endoscopic guidance. Vital signs were monitored during and after each treatment. Nebulization with dexamethasone, chymotrypsin
14 and gentamycin were administered immediately after each treatment to prevent oesophageal mucosal oedema and to reduce mucus
15 secretion. Concomitant therapy: Everyone received 30 minutes of supervised regular therapy, twice a day, 5 days a week. Several
16 techniques for improving swallowing function were implemented by treating therapists. Programs progressed as indicated to meet the
17 person's goals.

18

19 **1.1.53.2.2. Usual care (N = 15)**

20 Usual care only. Concomitant therapy: Everyone received 30 minutes of supervised regular therapy, twice a day, 5 days a week.
21 Several techniques for improving swallowing function were implemented by treating therapists. Programs progressed as indicated to
22 meet the person's goals.

23

1 **1.1.53.3. Characteristics**2 **1.1.53.3.1. Arm-level characteristics**

Characteristic	Behavioural interventions (balloon dilatation) (N = 15)	Usual care (N = 15)
% Female	n = 3 ; % = 20	n = 4 ; % = 27
Sample size		
Mean age (SD) (years)	62 (47 to 66)	60 (50 to 69)
Median (IQR)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Months)	4 (3 to 8)	4 (3 to 7)
Median (IQR)		
People requiring enteral feeding support at baseline	n = 15 ; % = 100	n = 15 ; % = 100
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

3

1 **1.1.53.4. Outcomes**

2 **1.1.53.4.1. Study timepoints**

- 3 • Baseline
- 4 • 3 week (<3 months)

5

6 **1.1.53.4.2. Dichotomous outcome**

Outcome	Behavioural interventions (balloon dilatation), Baseline, N = 15	Behavioural interventions (balloon dilatation), 3 week, N = 15	Usual care, Baseline, N = 15	Usual care, 3 week, N = 15
Dysphagia present/return to normal diet (return to normal diet)	n = NA ; % = NA	n = 12 ; % = 80	n = NA ; % = NA	n = 2 ; % = 13
No of events				

7 Dysphagia present/return to normal diet (return to normal diet) - Polarity - Higher values are better

8

9

10 **1.1.53.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.53.4.4. Dichotomous outcome-Dysphagiapresent/returntonormaldiet(returntonormaldiet)-NoOfEvents-Behavioural**
 12 **interventions (balloon dilatation)-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

13

1 **1.1.54. Lee, 2015**

Bibliographic Reference Lee, Jenny S.W.; Chui, Pui Yuk; Ma, Hon Ming; Auyeung, Tung Wai; Kng, Carolyn; Law, Thomas; Ng, Louisa K.Y.; Tam, Kui Fu; Tang, Wing Han; Chan, Becky Y.T.; Tong, Michael C.F.; Wong, Ka Tak; Yuen, Yuen Har; Yuk, Ka Lok; Kwok, Timothy; Does Low Dose Angiotensin Converting Enzyme Inhibitor Prevent Pneumonia in Older People With Neurologic Dysphagia—A Randomized Placebo-Controlled Trial.; Journal of the American Medical Directors Association; 2015; vol. 16 (no. 8); 702-707

2

3 **1.1.54.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	Registered in ClinicalTrials.gov under the trial number of NCT02358642.
Study type	Randomised controlled trial (RCT)
Study location	Hong Kong
Study setting	2 subacute hospitals, affiliated geriatric outpatient clinics, and speech therapy clinics in Hong Kong
Study dates	NR
Sources of funding	Funded by the Health and Health Services Research Grant number 07080201 from the Food and Health Bureau of the Hong Kong SAR government

Inclusion criteria	All had a history of recent hospitalization in the previous 3 months. They had been on tube-feeding for more than 2 weeks because of neurologic dysphagia as recommended by a trained speech therapist. The clinical diagnosis of cerebrovascular diseases was confirmed by computerized axial tomography of the brain.
Exclusion criteria	Exclusion criteria included the following: life expectancy less than 6 months, baseline systolic blood pressure less than 100 mm Hg, known intolerance to ACE inhibitors, current use of ACE inhibitor or angiotensin receptor blockers, symptomatic chronic lung disease or cardiac failure, frequent withdrawal of enteral tube by patients, serum creatinine >150 mmol/L, and serum potassium >5.1 mmol/L
Recruitment / selection of participants	NR
Intervention(s)	The intervention group participants were given lisinopril 2.5 mg once daily at bedtime. A low dose regime was chosen as it was less likely to cause hypotension, electrolyte disturbances, and impair renal function. A similar low dose ACE inhibitor regime had been shown to be effective in preventing silent aspiration.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	The control group participants were given identical placebo once daily at bedtime.

Number of participants	93
Duration of follow-up	12 weeks and 26 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.54.2. Study arms**3 **1.1.54.2.1. *Lisinopril 2.5 mg once daily at bedtime (N = 47)***

4

5 **1.1.54.2.2. *Placebo (N = 46)***

6

7 **1.1.54.3. Characteristics**8 **1.1.54.3.1. *Study-level characteristics***

Characteristic	Study (N = 71)
Ethnicity	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR

Characteristic	Study (N = 71)
Nominal	

1

2 **1.1.54.3.2. Arm-level characteristics**

Characteristic	Lisinopril 2.5 mg once daily at bedtime (N = 47)	Placebo (N = 46)
% Female	75.8	65.8
Nominal		
Mean age (SD)	83.4 (6.8)	84.4 (5.6)
Mean (SD)		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
No of events		
Stroke %	n = 32 ; % = 100	n = 36 ; % = 94.7
No of events		
Diabetes %	n = 5 ; % = 15.2	n = 10 ; % = 26.3
No of events		
Hypertension %	n = 22 ; % = 66.7	n = 32 ; % = 84.2
No of events		
Dementia %	n = 17 ; % = 51.5	n = 20 ; % = 52.6
No of events		

Characteristic	Lisinopril 2.5 mg once daily at bedtime (N = 47)	Placebo (N = 46)
Parkinson's disease %	n = 3 ; % = 9.1	n = 3 ; % = 7.9
No of events		
COPD %	n = 1 ; % = 3	n = 1 ; % = 2.6
No of events		
Heart failure %	n = 0 ; % = 0	n = 1 ; % = 2.6
No of events		
Severity of dysphagia RBHOMS	3.1 (0.8)	2.9 (0.7)
Mean (SD)		
Time after stroke	NR	NR
Nominal		

1

2 **1.1.54.4. Outcomes**3 **1.1.54.4.1. Study timepoints**

- 4 • Baseline
- 5 • 12 week
- 6 • 26 week

7

1 **1.1.54.4.2. Dichotomous outcomes**

Outcome	Lisinopril 2.5 mg once daily at bedtime, Baseline, N = 47	Lisinopril 2.5 mg once daily at bedtime, 12 week, N = 33	Lisinopril 2.5 mg once daily at bedtime, 26 week, N = 33	Placebo, Baseline, N = 46	Placebo, 12 week, N = 38	Placebo, 26 week, N = 38
Mortality	n = NR ; % = NR	n = NR ; % = NR	n = 19 ; % = 57.6	n = NR ; % = NR	n = NR ; % = NR	n = 10 ; % = 26.3
No of events						
Pneumonia	n = NR ; % = NR	n = NR ; % = NR	n = 14 ; % = 42.4	n = NR ; % = NR	n = NR ; % = NR	n = 7 ; % = 18.4
No of events						
urosepsis	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 2 ; % = 5.3
No of events						
Ischemic heart disease	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 2 ; % = 2.6
No of events						
Pulmonary embolism	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 1 ; % = 3
No of events						
Cancer of skin	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 1 ; % = 3
No of events						
Sudden death	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 2 ; % = 6
No of events						
Aspiration after vomiting	n = NR ; % = NR	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = NR ; % = NR	n = 1 ; % = 3
No of events						

Outcome	Lisinopril 2.5 mg once daily at bedtime, Baseline, N = 47	Lisinopril 2.5 mg once daily at bedtime, 12 week, N = 33	Lisinopril 2.5 mg once daily at bedtime, 26 week, N = 33	Placebo, Baseline, N = 46	Placebo, 12 week, N = 38	Placebo, 26 week, N = 38
Occurrence of chest infection (pneumonia and fatal pneumonia)	n = NA ; % = NA	n = NR ; % = NR	n = 19 ; % = 57.6	n = NA ; % = NA	n = NR ; % = NR	n = 18 ; % = 47.4
No of events						

1 Mortality - Polarity - Lower values are better

2 Occurrence of chest infection (pneumonia and fatal pneumonia) - Polarity - Lower values are better

3 **1.1.54.4.3. Continuous outcomes**

Outcome	Lisinopril 2.5 mg once daily at bedtime, Baseline, N = 29	Lisinopril 2.5 mg once daily at bedtime, 12 week, N = 20	Lisinopril 2.5 mg once daily at bedtime, 26 week, N = 20	Placebo, Baseline, N = 35	Placebo, 12 week, N = 28	Placebo, 26 week, N = 28
Swallowing ability (Royal Brisbane Hospital Outcome Measure for Swallowing) Scale range: unclear. Final values.	3.7 (0.8)	4.2 (1.5)	NR (NR)	2.9 (0.7)	3.5 (1.5)	NR (NR)
Mean (SD)						

4 Swallowing ability (Royal Brisbane Hospital Outcome Measure for Swallowing) - Polarity - Higher values are better

5

6

1 **1.1.54.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.54.4.5. Continuousoutcomes-Swallowingability(RoyalBrisbaneHospitalOutcomeMeasureforSwallowing)-MeanSD-**
 3 **Lisinopril 2.5 mg once daily at bedtime-Placebo-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.54.4.6. Dichotomousoutcomes-Mortality-NoOfEvents-Lisinopril 2.5 mg once daily at bedtime-Placebo-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.54.4.7. Dichotomousoutcomes-Mortality-NoOfEvents-Lisinopril 2.5 mg once daily at bedtime-Placebo-t26**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.54.4.8.** *Continuous outcomes-Swallowing ability(Royal Brisbane Hospital Outcome Measure for Swallowing)-Mean SD-*
 2 *Lisinopril 2.5 mg once daily at bedtime-Placebo-t26*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

3
 4 **1.1.54.4.9.** *Dichotomous outcomes-Occurrence of pneumonia(pneumonia and fatal pneumonia)-No Of Events-Lisinopril 2.5 mg*
 5 *once daily at bedtime-Placebo-t26*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

6
 7 **1.1.55. Lee, 2014**

Bibliographic Reference Lee, Kyeong Woo; Kim, Sang Beom; Lee, Jong Hwa; Lee, Sook Joung; Ri, Jae Won; Park, Jin Gee; The effect of early neuromuscular electrical stimulation therapy in acute/subacute ischemic stroke patients with Dysphagia.; Annals of rehabilitation medicine; 2014; vol. 38 (no. 2); 153-9

8
 9 **1.1.55.1. Study details**

Secondary publication of another included	No additional information.
--	----------------------------

study- see primary study for details	
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	March 2011 to June 2012.
Sources of funding	No additional information.
Inclusion criteria	Age between 18 and 80 years; supratentorial ischaemic stroke; primary diagnosis of stroke confirmed by computer tomography or magnetic resonance imaging; FOIS score of 5 or less; Korean Mini-Mental State Examination score of 21 or higher; stable underlying disease process.
Exclusion criteria	Presence of dysphagia before stroke; previous stroke history; unstable cardiopulmonary status, serious psychological disorder or epilepsy; tumour or radiotherapy of the head and neck region; underwent swallowing therapy before participation in the present study; unstable medical conditions that may interfere with VFSS.
Recruitment / selection of participants	People with a diagnosis of dysphagia within 10 days after stroke.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=46 Neuromuscular electrical stimulation was provided at an intensity of 3mA and increased gradually by 1mA. The stimulation intensity was set at 120% of the mean threshold value. A pulse rate of 80 Hz was used with 700 microseconds duration. Each session was 30 minutes per day, 5 times a week for a total of 3 weeks.

	Concomitant therapy: All people received traditional dysphagia therapy including thermal-tactile stimulation with any combination of lingual-strengthening exercises, laryngeal adduction-elevation exercises, effortful swallow maneuver, Mendelsohn maneuver, Masako maneuver and Shaker exercises by one speech therapist every day. Both group received 60 minutes of therapy within a day for 15 days.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=46 Usual care only. Concomitant therapy: All people received traditional dysphagia therapy including thermal-tactile stimulation with any combination of lingual-strengthening exercises, laryngeal adduction-elevation exercises, effortful swallow maneuver, Mendelsohn maneuver, Masako maneuver and Shaker exercises by one speech therapist every day. Both group received 60 minutes of therapy within a day for 15 days.

Number of participants	92
Duration of follow-up	3 weeks, 6 weeks, 12 weeks.
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis appears to be completers only.

1

2 **1.1.55.2. Study arms**3 **1.1.55.2.1. Neuromuscular electrical stimulation (NMES) (N = 46)**

4 Neuromuscular electrical stimulation was provided at an intensity of 3mA and increased gradually by 1mA. The stimulation intensity
5 was set at 120% of the mean threshold value. A pulse rate of 80 Hz was used with 700 microseconds duration. Each session was 30
6 minutes per day, 5 times a week for a total of 3 weeks. Concomitant therapy: All people received traditional dysphagia therapy
7 including thermal-tactile stimulation with any combination of lingual-strengthening exercises, laryngeal adduction-elevation exercises,
8 effortful swallow maneuver, Mendelsohn maneuver, Masako maneuver and Shaker exercises by one speech therapist every day. Both
9 group received 60 minutes of therapy within a day for 15 days.

10

11 **1.1.55.2.2. Usual care (N = 46)**

12 Usual care only. Concomitant therapy: All people received traditional dysphagia therapy including thermal-tactile stimulation with any
13 combination of lingual-strengthening exercises, laryngeal adduction-elevation exercises, effortful swallow maneuver, Mendelsohn
14 maneuver, Masako maneuver and Shaker exercises by one speech therapist every day. Both group received 60 minutes of therapy
15 within a day for 15 days.

16

1 **1.1.55.3. Characteristics**2 **1.1.55.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 46)	Usual care (N = 46)
% Female	n = 9 ; % = 29	n = 6 ; % = 23
Sample size		
Mean age (SD) (years)	63.4 (11.4)	66.7 (9.5)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	5 (1.4)	5.5 (1.1)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 25 ; % = 81	n = 22 ; % = 85
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

3 Reports 31 people in the intervention group, 26 in the control group.

1

2 **1.1.55.4. Outcomes**

3 **1.1.55.4.1. Study timepoints**

- 4 • Baseline
5 • 12 week (<3 months)

6

7 **1.1.55.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 31	Neuromuscular electrical stimulation (NMES), 12 week, N = 31	Usual care, Baseline, N = 26	Usual care, 12 week, N = 26
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Change scores. Mean (SD)	2 (1.3)	3.1 (1.4)	2.2 (1.5)	1.7 (0.9)

8 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

9 **1.1.55.4.3. Dichotomous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 31	Neuromuscular electrical stimulation (NMES), 12 week, N = 31	Usual care, Baseline, N = 26	Usual care, 12 week, N = 26
Dysphagia present/return to normal diet (normal diet) No of events	n = 0 ; % = 0	n = 15 ; % = 48	n = 0 ; % = 0	n = 10 ; % = 38

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 31	Neuromuscular electrical stimulation (NMES), 12 week, N = 31	Usual care, Baseline, N = 26	Usual care, 12 week, N = 26
Occurrence of chest infection (aspiration pneumonia)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
No of events				

1 Dysphagia present/return to normal diet (normal diet) - Polarity - Higher values are better

2 Occurrence of chest infection (aspiration pneumonia) - Polarity - Lower values are better

3

4

5 **1.1.55.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.55.4.5. Continuous outcomes-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Neuromuscular electrical stimulation (NMES)-Usual care-t12**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.55.4.6. Dichotomous outcomes-Dysphagia present/return to normal diet (normal diet)-No of Events-Neuromuscular electrical stimulation (NMES)-Usual care-t12**

10

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.55.4.7. Dichotomous outcomes-Occurrence of pneumonia-No Of Events-Neuromuscular electrical stimulation (NMES)-Usual**
 3 **care-t12**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.56. Lee, 2021**

Bibliographic Reference Lee, So Young; Park, Donghwi; Jang, Joonyoung; Jang, Eun Gyeong; Lee, Jun Chang; Park, Yulhyun; Cho, Seon; Kim, Won-Seok; Park, Jihong; Kim, Bo Ryun; Seo, Kyoung-Ho; Park, Sungwon; Ryu, Ju Seok; Compensatory Effects of Sequential 4-Channel Neuromuscular Electrical Stimulation for the Treatment of Acute, Subacute, and Chronic Dysphagia in a Prospective, Double-Blinded Randomized Clinical Trial.; Neurorehabilitation and neural repair; 2021; vol. 35 (no. 9); 801-811

6

7 **1.1.56.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
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Other publications associated with this study included in review	No additional information.
Trial name / registration number	Registration number, NCT03670485
Study type	Randomised controlled trial (RCT)
Study location	South Korea
Study setting	Rehabilitation unit of 3 teaching hospitals (Seoul National University Bundang Hospital, Daegu Fatima General Hospital, and the Jeju University Hospital)
Study dates	September 12, 2018 to February 21, 2020
Sources of funding	Research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health and Welfare, Republic of Korea (grant number: HI18C1169). This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT and Future Planning (NRF-2016R1D1A1B03935130).
Inclusion criteria	The study's inclusion criteria were as follows: patients who were age ≥ 19 years and had symptoms of dysphagia; underlying diseases affecting cerebral function such as stroke, traumatic brain injury, brain tumor, and encephalitis; dysphagia as confirmed by the videofluoroscopic swallowing study (VFSS); stable vital signs; agreed to participate in the present study; and gave informed consent. If the patient's Mini-Mental Status Examination (MMSE) score was < 15 , cognitive abilities were considered impaired and included in the study only if additional consent from the guardian was obtained. The VFSS criteria included definite presence of aspiration (defined as a penetration–aspiration scale [PAS] score ≥ 6) or presence of penetration ($2 \leq$ PAS score ≤ 5) with residual material at the vallecular pouch or pyriformis sinus to prevent ceiling effects
Exclusion criteria	Patients who had severe cognitive dysfunction who could not perform 1-step follow commands, serious psychiatric disorders, cervical surgery, respiratory difficulties, allergic reactions to electrodes of NMES, and those who were pregnant or breast-feeding were excluded. As this study evaluates the compensatory applications between the 4-channel NMES and sham groups, there were no restrictions with regard to the stage of dysphagia and hospital settings.
Recruitment / selection of participants	A total of 52 participants (26 for the 4-channel NMES group and 26 for the sham group) were initially enrolled. In the sham group, 1 participant dropped out due to a medical condition and 2 participants were additionally excluded because their underlying diseases were not brain lesion.

<p>Intervention(s)</p>	<p>The sequential 4-channel NMES has 4 channels that were adjustable for latency, amplitude, and duration of current . The device uses 4 pairs of electrodes that were round in shape and 22 mm in size, and 2 types of electrodes with different gap sizes were used: .5 cm (type 1 electrode) and 1 cm (type 2 electrode). The type 1 electrode was used for channels 1, 2, and 4; and the type 2 electrode was used for channel 3. The electrode locations were determined using anatomical landmarks and manual palpation. Channel 1 (right) and 2 (left) electrodes were placed superior to the hyoid bone and posterior to the mandible with a 1-cm interval from the midline to target the digastric and mylohyoid muscles. Channel 3 electrodes were placed on the bilateral superior pole of the thyroid cartilage to target the thyrohyoid muscles, and channel 4 electrodes were placed medial to the sternocleidomastoid muscle and inferior to the thyroid cartilage to target the sternohyoid, omohyoid, and sternothyroid muscles. The pulse frequency, pulse duration, and interphase interval are 80 Hz, 300 μs, and 100 μs, respectively. Channels 1 and 2 start their electrical stimulations first, and channels 3 and 4 start their stimulations 150 and 250 ms later, respectively. The stimulations of channels 1, 2, 3, and 4 lasted 1200, 1200, 1050, and 950 ms, respectively. All stimulations ended simultaneously in a single sequence. All participants were evaluated with initial VFSS in a standardized manner.</p> <p>After randomization, all participants underwent a preparation process before the intervention, where the stimulation intensity was gradually increased to the maximum tolerance level and the application of sequential stimulation of the 4-channel NMES were familiarized for 1–2 sessions. The maximal tolerable stimulation intensity levels were recorded for each electrode pair and used during the intervention. For synchronous stimulation of NMES, patients push the start button and begin swallowing when the NMES pulls the suprahyoid muscles.</p> <p>During the interval between the initial and follow-up VFSS, all participants received conventional swallowing therapies.</p>
<p>Subgroup 1: Severity of dysphagia (as stated by category)</p>	<p>Not stated/unclear</p>

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>All participants were evaluated with initial VFSS in a standardized manner.^{4,23} After randomization, all participants underwent a preparation process before the intervention, where the stimulation intensity was gradually increased to the maximum tolerance level and the application of sequential stimulation of the 4-channel NMES were familiarized for 1–2 sessions. For the intervention, the 4-channel NMES group underwent the 4-channel NMES while swallowing 5 mL of thin (IDDSI, level 0) and extremely thick fluids (IDDSI, level 4) twice, whereas the sham group had electrodes attached at the same locations but did not undergo the NMES during swallowing.</p> <p>During the interval between the initial and follow-up VFSS, all participants received conventional swallowing therapies.</p>
Number of participants	52
Duration of follow-up	1 week
Indirectness	Intervention consists of 1 treatment with NMES and follow up after

Additional comments	NR
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1

2 **1.1.56.2. Study arms**

3 **1.1.56.2.1. *Neuromuscular electrical stimulation (NMES) (N = 26)***

4

5 **1.1.56.2.2. *Placebo/sham therapy (N = 26)***

6

7 **1.1.56.3. Characteristics**

8 **1.1.56.3.1. *Study-level characteristics***

Characteristic	Study (N = 49)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

9

1 **1.1.56.3.2. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 26)	Placebo/sham therapy (N = 26)
% Female	30.8	26.1
Nominal		
Mean age (SD)	68.9 (11)	73.4 (6.7)
Mean (SD)		
Severity of dysphagia VDS	37.27 (16.95)	41.49 (17.24)
Mean (SD)		
Time after stroke days	44.9 (59.7)	40.2 (38.4)
Mean (SD)		

2

3 **1.1.56.4. Outcomes**4 **1.1.56.4.1. Study timepoints**

- 5 • Baseline
- 6 • 1 week

7

1 **1.1.56.4.2. continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 26	Neuromuscular electrical stimulation (NMES), 1 week, N = 26	Placebo/sham therapy, Baseline, N = 26	Placebo/sham therapy, 1 week, N = 23
Occurrence of aspiration (PAS) Scale range: 1-8. Change scores. Mean (SD)	4.69 (1.9)	-2.15 (2.22)	4.86 (2.07)	-0.93 (2.28)
Swallowing ability (VDS) Scale range: 0-100. Change scores. Mean (SD)	37.27 (16.95)	-18.08 (15.71)	41.49 (17.24)	-6.29 (10.44)

2 Occurrence of aspiration (PAS) - Polarity - Lower values are better

3 Swallowing ability (VDS) - Polarity - Lower values are better

4

5

6 **1.1.56.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.56.4.4. continuousoutcomes-Occurrenceofaspiration(PAS)-MeanSD-neuromuscular electrical stimulation-Sham**
8 **neuromuscular electrical stimulation-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable (study only reports one intervention session with follow up after)

1

2 **1.1.56.4.5. continuous outcomes-swallowing ability (VDS)-Mean SD-neuromuscular electrical stimulation-Sham neuromuscular**
 3 **electrical stimulation-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable <i>(study only reports one intervention session with follow up after)</i>

4

5 **1.1.57. Li, 2022**

Bibliographic Reference Li, Hao; Zhao, Long; Yuan, Xiaokai; Zhang, Qingjuan; Pang, Yatao; Li, Hongling; Effect of transcranial direct current stimulation combined with respiratory training on dysphagia in post-stroke patients.; Technology and health care : official journal of the European Society for Engineering and Medicine; 2022

6

7 **1.1.57.1. Study details**

Secondary publication of another included study- see primary study for details	NR
Other publications associated with this study included in review	NR

Trial name / registration number	NR
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Hospitalised patient in the Department of Neurology of 60 the Second Hospital of Hebei Medical University
Study dates	NR
Sources of funding	None to report.
Inclusion criteria	Inclusion criteria: (1) Patients met the diagnostic criteria of China's guidelines for the diagnosis and treatment of acute stroke (2) The age of patients from the first onset is between 18 and 75 years old; (3) The course of disease is within 48 hours to 2 weeks after the disease is stable; (4) The total score of dysphagia screening (eating assessment tool, EAT-10) is more than 3 points; (5) The primary screening test of water swallowing is above grade 3; (6) Patients who were awake and able to cooperate with the trial.
Exclusion criteria	Exclusion criteria: (1) Patients with a history of stroke and swallowing dysfunction; (2) Patients with serious liver and kidney disease, unstable myocardial infarction, and aortic aneurysm or chronic obstructive pulmonary disease; (3) Patients who had respiratory muscle training; (4) Patients who need drug treatment for epileptic seizures; (5) Elderly patients with multiple diseases; (6) Patients with tDCS contraindications.
Recruitment / selection of participants	From December 2017 to January 2019, 64 post-stroke patients who were hospitalized in the Department of Neurology of the Second Hospital of Hebei Medical University were enrolled in this study.
Intervention(s)	<p>The IS200 transcranial direct current stimulator (Sichuan Intelligent Electronic Industry Co., Ltd. Chengdu, China) with 5 cm × 7 cm isotonic saline gelatin sponge electrode as stimulator electrode was used in this study. The anode was placed in the primary motor cortex of the contralateral side (15 cm from the center of the top, then 2 cm from the front of the forehead), and the cathode was placed in the contralateral upper orbit. The current intensity was 1.5 mA, 20 minutes, once per day, 6 days/week.</p> <p>Concomitant therapy: The patients in both groups were treated with conventional medicine and swallowing rehabilitation. On this basis, the patients in control group received respiratory training, and those in the treatment group received tDCS</p>

	and respiratory training. Conventional swallowing rehabilitation includes direct oral feeding training, ice stimulation, acid stimulation, oral exercise, shaker training, training method of swallowing on glottis, Mendelsohn maneuver and neuromuscular electrical stimulation. Respiratory training included lip retraction breathing and breathing trainer, 20 min/time, twice a day. Breath by shrinking lips: Ask the patient to make the lips into a “woo” shape. Inhale with the mouth quickly, exhale slowly, inhale quickly, and then make a “woo” and “toot” sound slowly. Place a piece of toilet paper 10 cm in front of the patient’s mouth, and instruct the patient to blow up the toilet paper.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>The patients in control group received respiratory training, and conventional swallowing rehabilitation.</p> <p>Concomitant therapy: The patients in both groups were treated with conventional medicine and swallowing rehabilitation. On this basis, the patients in control group received respiratory training, and those in the treatment group received tDCS and respiratory training. Conventional swallowing rehabilitation includes direct oral feeding training, ice stimulation, acid stimulation, oral exercise, shaker training, training method of swallowing on glottis, Mendelsohn maneuver and neuromuscular electrical stimulation. Respiratory training included lip retraction breathing and breathing trainer, 20 min/time, twice a day. Breath by shrinking lips: Ask the patient to make the lips into a “woo” shape. Inhale with the mouth</p>

	quickly, exhale slowly, inhale quickly, and then make a “woo” and “toot” sound slowly. Place a piece of toilet paper 10 cm in front of the patient’s mouth, and instruct the patient to blow up the toilet paper.
Number of participants	64
Duration of follow-up	6 days
Indirectness	NR
Additional comments	NR

1

2 **1.1.57.2. Study arms**3 **1.1.57.2.1. Transcranial direct current stimulation (tDCS) (N = 32)**

4 The IS200 transcranial direct current stimulator (Sichuan Intelligent Electronic Industry Co., Ltd. Chengdu, China) with 5 cm × 7 cm
5 isotonic saline gelatin sponge electrode as stimulator electrode was used in this study. The anode was placed in the primary motor
6 cortex of the contralateral side (15 cm from the center of the top, then 2 cm from the front of the forehead), and the cathode was
7 placed in the contralateral upper orbit. The current intensity was 1.5 mA, 20 min/time/d, 6 days/week. Concomitant therapy: The
8 patients in both groups were treated with conventional medicine and swallowing rehabilitation. On this basis, the patients in control
9 group received respiratory training, and those in the treatment group received tDCS and respiratory training. Conventional swallowing
10 rehabilitation includes direct oral feeding training, ice stimulation, acid stimulation, oral exercise, shaker training, training method of
11 swallowing on glottis, Mendelsohn maneuver and neuromuscular electrical stimulation. Respiratory training included lip retraction
12 breathing and breathing trainer, 20 min/time, twice a day. Breath by shrinking lips: Ask the patient to make the lips into a “woo” shape.
13 Inhale with the mouth quickly, exhale slowly, inhale quickly, and then make a “woo” and “toot” sound slowly. Place a piece of toilet
14 paper 10 cm in front of the patient’s mouth, and instruct the patient to blow up the toilet paper.

15

16 **1.1.57.2.2. Usual care (N = 32)**

17 The patients in control group received respiratory training, and conventional swallowing rehabilitation. Concomitant therapy: The
18 patients in both groups were treated with conventional medicine and swallowing rehabilitation. On this basis, the patients in control
19 group received respiratory training, and those in the treatment group received tDCS and respiratory training. Conventional swallowing

1 rehabilitation includes direct oral feeding training, ice stimulation, acid stimulation, oral exercise, shaker training, training method of
 2 swallowing on glottis, Mendelsohn maneuver and neuromuscular electrical stimulation. Respiratory training included lip retraction
 3 breathing and breathing trainer, 20 min/time, twice a day. Breath by shrinking lips: Ask the patient to make the lips into a “woo” shape.
 4 Inhale with the mouth quickly, exhale slowly, inhale quickly, and then make a “woo” and “toot” sound slowly. Place a piece of toilet
 5 paper 10 cm in front of the patient’s mouth, and instruct the patient to blow up the toilet paper.

6

7 **1.1.57.3. Characteristics**

8 **1.1.57.3.1. Study-level characteristics**

Characteristic	Study (N = 64)
Ethnicity Nominal	NR
Comorbidities Nominal	NR
Severity of dysphagia Nominal	NR
People requiring enteral feeding support at baseline Nominal	NR
Type of stroke Nominal	NR

9

1 **1.1.57.3.2. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 32)	Usual care (N = 32)
% Female	n = 11 ; % = 34.4	n = 12 ; % = 37.5
Sample size		
Mean age (SD)	60.22 (10.55)	59.44 (10.16)
Mean (SD)		
Time after stroke (days)	11.5 (2.76)	10.75 (2.11)
Mean (SD)		

2

3 **1.1.57.4. Outcomes**4 **1.1.57.4.1. Study timepoints**

- 5 • Baseline
- 6 • 6 day

7

8 **1.1.57.4.2. Dichotomous outcomes**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 32	Transcranial direct current stimulation (tDCS), 6 day, N = 32	Usual care, Baseline, N = 32	Usual care, 6 day, N = 32
Dysphagia present/Return to normal diet (dysphagia present based on water swallow test)	n = 32 ; % = 100	n = 30 ; % = 93.7	n = 32 ; % = 100	n = 28 ; % = 87.5
No of events				

1 Dysphagia present/Return to normal diet (dysphagia present based on water swallow test) - Polarity - Lower values are better

2 **1.1.57.4.3. Continuous outcome**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 32	Transcranial direct current stimulation (tDCS), 6 day, N = 32	Usual care, Baseline, N = 32	Usual care, 6 day, N = 32
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Final values. Calculated from individual patient data reported in the paper (reports the grades before and after). Mean (SD)	2.2 (1.2)	4.5 (1.5)	2.4 (1.3)	3.6 (1.8)

3 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

4

5

6 **1.1.57.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.57.4.5. Dichotomous outcomes-Dysphagiapresent/Returntonormaldiet(dysphagiapresentbasedonwaterswallowtest)-**
 8 **NoOfEvents-Transcranial direct current stimulation (tDCS)-Usual care-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.57.4.6. Continuous outcome-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Transcranial direct current stimulation**
 2 **(tDCS)-Usual care-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.58. Liang, 2021**

Bibliographic Reference Liang, Yu; Lin, Jing; Wang, Hui; Li, Shufen; Chen, Fang; Chen, Lili; Li, Ling; Evaluating the Efficacy of VitalStim Electrical Stimulation Combined with Swallowing Function Training for Treating Dysphagia following an Acute Stroke.; Clinics (Sao Paulo, Brazil); 2021; vol. 76; e3069

5

6 **1.1.58.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information
Trial name / registration number	No additional information
Study location	China

Study setting	Hainan General Hospital, Hainan Affiliated Hospital of Hainan Medical University
Study dates	August 2017 and July 2019
Sources of funding	No additional information
Inclusion criteria	The inclusion criteria were as follows: first onset, in line with the diagnostic criteria for the acute stroke in Diagnostic Essentials of Various Cerebrovascular Diseases (7), clinical symptoms such as eating difficulties and a choking cough caused by drinking water, as confirmed by a head computed tomography or magnetic resonance imaging scan, and swallowing dysfunction of varying degrees identified by two associate chief physicians with rich clinical experience using Kubota drinking water test (KDWT) (8), with the grade of above III; patients aged 18–80 years; and clear mind, stable condition, and voluntary signing of informed consent
Exclusion criteria	The exclusion criteria included: dysphagia because of non-stroke causes; dysarthria and other motor symptoms; combined neck and diseases of pharynx; patients with serious cognitive impairment and consciousness impairment; combined with other cerebral diseases; and poor compliance and cooperation.
Recruitment / selection of participants	No additional information
Intervention(s)	<p>The experimental group was treated with VitalStim electrical stimulation, swallowing function training, and conventional medical treatment. The instrument used was the VitalStim electrical stimulation therapeutic instrument from the Chattanooga Company, which has a wave width of 700 ms, a frequency of 30–80 Hz, and an intensity of 5–50 mA. During treatment, the two electrodes A and B in channel 1 were horizontally arranged above the hyoid bone, and the two electrodes C and D in channel 2 were horizontally arranged above the upper nail notch and located on both sides of the midline, respectively. The power supply was turned on, and the amplitude of the two channels was slowly increased. The current was adjusted according to the patient's feedback for 30 min/ time, once /d, five times/week, and this was performed for a total of four weeks.</p> <p>Concomitant therapy - All patients received conventional medical treatment, which primarily included nutrition of brain cells, improvement of microcirculation, anti-platelet aggregation, antihypertensive therapy, and nutritional support, when necessary.</p>
Subgroup 1: Severity of	Not stated/unclear

dysphagia (as stated by category)	
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information
Comparator	The control group received swallowing function training and conventional medical treatment, which included the following: 1) Cheek muscle training with the following instructions: first, open and close the mouth, take a blow on the chin, then chew on the lower jaw, massage the skin of the affected cheek, and stimulate the cheek with ice cubes. 2) Tongue muscle training with the following instructions: perform tongue rolling, forward extension, backward contraction, and other movements. If the patient cannot perform autonomous tongue movement, the tongue depressor can be used to gently massage and to perform passive movement. The therapist uses his/her index finger to depress the anterior third part of the patient's tongue, performs horizontal finger tremors for 0.5s, and helps the patient close his jaw twice/d. 3) Suction training, which includes putting the index finger of the patient on a rubber sleeve and placing it in the mouth for suction training (15–20 times/time, 5 min/time, two times/d). 4) Swallowing reflex training where first, the anterior base of the pharyngeal column and base of the upper palate are stimulated with popsicles, and then empty swallowing training is conducted. 5) Throat training where the head is extended forward, submental muscles are extended for 3–4s, a certain resistance is increased under the chin, the patient is instructed to perform resistance lowering action, the back of tongue is raised against the hard palate, and consonants (e.g., G, K, and ch) are emitted. 6) Pharyngeal contraction training where the patient is asked to hold their breath after fully inhaling, to swallow saliva slowly, and then to exhale and cough. The swallowing training is performed for four weeks.
Number of participants	72

Duration of follow-up	4 weeks
Indirectness	No additional information
Additional comments	No additional information

1

2 **1.1.58.2. Study arms**

3 **1.1.58.2.1. *VitalStim Electrical Stimulation Combined with Swallowing Function Training (N = 36)***

4

5 **1.1.58.2.2. *Conventional medical treatment and swallowing function training (N = 36)***

6

7 **1.1.58.3. Characteristics**

8 **1.1.58.3.1. *Study-level characteristics***

Characteristic	Study (N = 72)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	

Characteristic	Study (N = 72)
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

1

2 **1.1.58.3.2. Arm-level characteristics**

Characteristic	VitalStim Electrical Stimulation Combined with Swallowing Function Training (N = 36)	Conventional medical treatment and swallowing function training (N = 36)
% Female	38.89	44.44
Nominal		
Mean age (SD)	62.74 (6.14)	63.14 (5.49)
Mean (SD)		
Time after stroke (days)	31.27 (5.85)	31.85 (6.34)
Mean (SD)		

3

4 **1.1.58.4. Outcomes**5 **1.1.58.4.1. Study timepoints**

- 6 • Baseline
- 7 • 4 week

1

2 **1.1.58.4.2. Dichotomous outcomes**

Outcome	VitalStim Electrical Stimulation Combined with Swallowing Function Training, Baseline, N = 36	VitalStim Electrical Stimulation Combined with Swallowing Function Training, 4 week, N = 36	Conventional medical treatment and swallowing function training, Baseline, N = 36	Conventional medical treatment and swallowing function training, 4 week, N = 36
Occurrence of chest infections (aspiration pneumonia)	n = NR ; % = NR	n = 0 ; % = 0	n = NR ; % = NR	n = 4 ; % = 11.1
No of events				

3 Occurrence of chest infections (aspiration pneumonia) - Polarity - Lower values are better

4

5

6 **1.1.58.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.58.4.4. Dichotomous outcomes - Occurrence of chest infections (aspiration pneumonia) - No Of Events - VitalStim Electrical Stimulation Combined with Swallowing Function Training - Conventional medical treatment and swallowing function training - t4**

9

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and no information on missing data)
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.59. Lim, 2009**

Bibliographic Reference Lim, Kil-Byung; Lee, Hong-Jae; Lim, Sung-Shick; Choi, Yoo-Im; Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial.; Journal of rehabilitation medicine; 2009; vol. 41 (no. 3); 174-8

2

3 **1.1.59.1. Study details**

Secondary publication of another included study- see primary study for details	no additional information
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	no additional information
Study location	Korea
Study setting	Ilsan Paik Hospital, Korea
Study dates	February 2005 to July 2006
Sources of funding	No additional information
Inclusion criteria	Participant selection criteria included primary diagnosis of stroke with magnetic resonance imaging (MRI) or computerized tomography (CT) scans, confirmation of swallowing disorder by videofluoroscopy, a score of 21 or greater on the Mini-Mental State Examination (MMSE), and that they were medically stable at the time of the study.
Exclusion criteria	Exclusion criteria included the inability to receive the treatment for 1 h, a neurological disease other than stroke, a combined behavioural disorder that interfered with administration of therapy, current illness or upper gastrointestinal disease, and an inability to give informed consent because of cognitive impairment or receptive aphasia.

Recruitment / selection of participants	Subjects were divided into 2 groups according to the order of enrolment in the study following admission to the rehabilitation department.
Intervention(s)	Electrical stimulation was applied by an occupational therapist, using a modified hand-held battery-powered electrical stimulator (VitalStim® Dual Channel Unit and electrodes, Chattanooga Group, Hixson, TN, USA). The skin of the anterior neck was prepared with 70% isopropyl alcohol cotton. Two sets of electrodes were used. The top set was placed in the submental region between the anterior belly of the digastric muscle and hyoid bone, and the hyoid bone and thyroid cartilage. The bottom set was placed on the skin between the thyroid cartilage and cricoid cartilage and below the cricoid cartilage (Fig. 1). Through this method, we could stimulate the muscles needed for swallowing, such as the digastric muscle, myohyoid muscle, and thyrohyoid muscle. NMES carries possible risks, including laryngospasm, arrhythmia, hypotension, glottic closure, and burns. We explained the possible adverse effects to the patients before treatment, and we closely observed and recorded every treatment session. After familiarizing the participant with the device, we identified the sensory threshold as the lowest current level at which the participant reported a “tingling” sensation on the skin. The amplitude of the electrical current level was approximately 7 mA. The therapy sessions were for 1 h at a frequency of 5 per week. The VitalStim® device cycles automatically from “on” to “off” to “on” again for 1 sec every min. Because the change in stimulation is ramped, this cycling process takes up to 4 sec.
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	NR

Comparator	The TTS procedures were standardized and conducted by a co-operating occupational therapist (12). An occupational therapist used the standard method for TTS. A cold mirror (size 00) was used to stimulate the oral cavity and an ice stick was used to stimulate the side of the face. Rubbing was carried out firmly, but not so as to cause discomfort. The rubbing extended from as low on the faucial pillar as it was possible to reach, and as high as possible, with no effort made to avoid the tongue. Subjects were asked periodically if they could feel the cold and if it was uncomfortable. They were also instructed to report discomfort as soon as it occurred. Five trials were carried out per week. Therapy sessions for electrical stimulation treatment were the same.
Number of participants	28
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.59.2. Study arms**3 **1.1.59.2.1. *neuromuscular electrical stimulation + thermal-tactile stimulation (N = 13)***

4

5 **1.1.59.2.2. *thermal-tactile stimulation (N = 9)***

6

7 **1.1.59.3. Characteristics**8 **1.1.59.3.1. *Study-level characteristics***

Characteristic	Study (N = 28)
Ethnicity	NR

Characteristic	Study (N = 28)
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

1

2 **1.1.59.3.2. Arm-level characteristics**

Characteristic	neuromuscular electrical stimulation + thermal-tactile stimulation (N = 13)	thermal-tactile stimulation (N = 9)
% Female	12.5	16.6
Nominal		
Mean age (SD)	67.8 (8.1)	60.8 (12.3)
Mean (SD)		
Time after stroke	NR	NR
Nominal		
< 6 months onset	13	9
Nominal		

Characteristic	neuromuscular electrical stimulation + thermal-tactile stimulation (N = 13)	thermal-tactile stimulation (N = 9)
< 6 months onset	13	9
Nominal		
Type of stroke	NR	NR
Nominal		
basal ganglia or thalamus	12	8
Nominal		
MCA territories	2	2
Nominal		
Brainstem	2	2
Nominal		

1

2 **1.1.59.4. Outcomes**3 **1.1.59.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week

6

1 **1.1.59.4.2. dichotomous outcomes**

Outcome	neuromuscular electrical stimulation + thermal-tactile stimulation, Baseline, N = 16	neuromuscular electrical stimulation + thermal-tactile stimulation, 4 week, N = 12	thermal-tactile stimulation, Baseline, N = 12	thermal-tactile stimulation, 4 week, N = 7
Dysphagia present	n = NR ; % = NR	n = 6 ; % = 50	n = NR ; % = NR	n = 6 ; % = 86
No of events				

2 Dysphagia present - Polarity - Lower values are better

3
4

5 **1.1.59.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.59.4.4. dichotomous outcomes-Dysphagiapresent-NoOfEvents-neuromuscular electrical stimulation + thermal-tactile stimulation-thermal-tactile stimulation-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation process and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.60. Lim, 2014**

Bibliographic Reference Lim, Kil-Byung; Lee, Hong-Jae; Yoo, Jeehyun; Kwon, Yong-Geol; Effect of Low-Frequency rTMS and NMES on Subacute Unilateral Hemispheric Stroke With Dysphagia.; Annals of rehabilitation medicine; 2014; vol. 38 (no. 5); 592-602

10

1 1.1.60.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	South Korea.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	Primary diagnosis of unilateral cerebral infarction or haemorrhage with computerised tomography or magnetic resonance imaging scan; stroke onset <3 months; people who could maintain their balance during the evaluation and treatment session; people who had cognitive function enough to cooperate in the treatment (>15-point on the Korean version of Mini-Mental State Examination).
Exclusion criteria	People who could not undergo the videofluoroscopic swallowing study or who failed the examination; presence of dysphagia before stroke; history of prior stroke, epilepsy, tumour, radiotherapy in the head and neck, or other neurological diseases; unstable medical condition; contraindication to magnetic or electrical stimulation.
Recruitment / selection of participants	Stroke patients with dysphagia (no additional information).

<p>Intervention(s)</p>	<p>Transcranial magnetic stimulation (TMS) N=20</p> <p>Before performing TMS, they evaluated motor-evoked potential using Magstim 200 and a coil stimulator (from the mylohyoid muscle). The magnetic stimulation was repeated with a change in intensity. The minimum intensity that showed 100 microvolts or more amplitude in three of the five consecutive stimulations was determined as the resting motor threshold. The location yielding the largest response amplitude in the pharyngeal motor cortex of the contralesional hemisphere was determined as a hot spot. For the treatment, 1 Hz magnetic stimulation at 100% intensity of the resting motor threshold in the hot spot was applied for 20 minutes each, 5 times a week for 2 weeks.</p> <p>Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson maneuver and food intake training for 4 weeks.</p> <p>Neuromuscular electrical stimulation (NMES) N=20</p> <p>NMES was applied using a modified hand-held battery-powered electrical stimulator VitalStim for 30 minutes per day, 5 times a week for a total of 2 weeks. Two sets of electrodes were attached between the digastrics muscle and the hyoid bone and beneath the hyoid bone and the thyroid cartilage for channel 1, and between the thyroid cartilage and the cricoids cartilage and vertically under the cricoid cartilage for channel 2. The waveform produced was a rectangular symmetric biphasic wave mode. The pulse width and frequency were determined at 300 microseconds and 80 Hz with, 100 microseconds of interstimulus intervals. The intensity was between 7mA and 9mA, depending on the compliance of the subjects.</p> <p>Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson maneuver and food intake training for 4 weeks.</p>
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Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=20 Usual care only. Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson maneuver and food intake training for 4 weeks.
Number of participants	60
Duration of follow-up	4 weeks (2 weeks after end of non-usual care interventions)
Indirectness	No additional information.

Additional comments	Intention-to-treat and per-protocol analysis.
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1

2 **1.1.60.2. Study arms**3 **1.1.60.2.1. Transcranial magnetic stimulation (TMS) (N = 20)**

4 Before performing TMS, they evaluated motor-evoked potential using Magstim 200 and a coil stimulator (from the mylohyoid muscle).
5 The magnetic stimulation was repeated with a change in intensity. The minimum intensity that showed 100 microvolts or more
6 amplitude in three of the five consecutive stimulations was determined as the resting motor threshold. The location yielding the largest
7 response amplitude in the pharyngeal motor cortex of the contralesional hemisphere was determined as a hot spot. For the treatment,
8 1 Hz magnetic stimulation at 100% intensity of the resting motor threshold in the hot spot was applied for 20 minutes each, 5 times a
9 week for 2 weeks. Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-
10 strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson maneuver and food intake
11 training for 4 weeks.

12

13 **1.1.60.2.2. Neuromuscular electrical stimulation (NMES) (N = 20)**

14 NMES was applied using a modified hand-held battery-powered electrical stimulator VitalStim for 30 minutes per day, 5 times a week
15 for a total of 2 weeks. Two sets of electrodes were attached between the digastrics muscle and the hyoid bone and beneath the hyoid
16 bone and the thyroid cartilage for channel 1, and between the thyroid cartilage and the cricoids cartilage and vertically under the
17 cricoid cartilage for channel 2. The waveform produced was a rectangular symmetric biphasic wave mode. The pulse width and
18 frequency were determined at 300 microseconds and 80 Hz with, 100 microseconds of interstimulus intervals. The intensity was
19 between 7mA and 9mA, depending on the compliance of the subjects. Concomitant therapy: All people received conventional
20 dysphagia treatment including oropharyngeal muscle-strengthening, exercise for range of motion of the neck and tongue, thermal
21 tactile stimulation, Mendelson maneuver and food intake training for 4 weeks.

22

23 **1.1.60.2.3. Usual care (N = 20)**

24 Usual care only. Concomitant therapy: All people received conventional dysphagia treatment including oropharyngeal muscle-
25 strengthening, exercise for range of motion of the neck and tongue, thermal tactile stimulation, Mendelson maneuver and food intake
26 training for 4 weeks.

1

2 **1.1.60.3. Characteristics**3 **1.1.60.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 20)	Neuromuscular electrical stimulation (NMES) (N = 20)	Usual care (N = 20)
% Female	n = 11 ; % = 55	n = 8 ; % = 40	n = 7 ; % = 35
Sample size			
Mean age (SD) (years)	61.8 (10.4)	65.4 (15.5)	60.6 (7.7)
Mean (SD)			
Ethnicity	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Comorbidities	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Time after stroke (days)	32 (13.9)	37.5 (15.7)	34.6 (12.1)
Mean (SD)			
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			

Characteristic	Transcranial magnetic stimulation (TMS) (N = 20)	Neuromuscular electrical stimulation (NMES) (N = 20)	Usual care (N = 20)
Type of stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR

1

2 **1.1.60.4. Outcomes**3 **1.1.60.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week (<3 months)

6

7 **1.1.60.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 20	Transcranial magnetic stimulation (TMS), 4 week, N = 20	Neuromuscular electrical stimulation (NMES), Baseline, N = 20	Neuromuscular electrical stimulation (NMES), 4 week, N = 20	Usual care, Baseline, N = 20	Usual care, 4 week, N = 20
Occurrence of aspiration (Penetration Aspiration Scale liquid) Scale range: 1-8. Change scores. Mean (SD)	5.1 (1.2)	-2.25 (1.3)	5.5 (1.7)	-2.55 (1.47)	5.3 (1.6)	-1.55 (1.07)
Swallowing ability (Functional)	48.9 (14.9)	-17.2 (11.19)	51.3 (17.6)	-20.6 (12.71)	51.2 (10.8)	-12.6 (7.35)

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 20	Transcranial magnetic stimulation (TMS), 4 week, N = 20	Neuromuscular electrical stimulation (NMES), Baseline, N = 20	Neuromuscular electrical stimulation (NMES), 4 week, N = 20	Usual care, Baseline, N = 20	Usual care, 4 week, N = 20
dysphagia scale liquid) Scale range: 0-100. Change scores. Mean (SD)						

1 Occurrence of aspiration (Penetration Aspiration Scale liquid) - Polarity - Lower values are better
 2 Swallowing ability (Functional dysphagia scale liquid) - Polarity - Lower values are better

3
4

5 **1.1.60.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.60.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale liquid) -**
 7 **Transcranial magnetic stimulation compared to usual care - Mean SD - Transcranial magnetic stimulation (TMS) -**
 8 **Neuromuscular electrical stimulation (NMES) - Usual care - t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.60.4.5.** ***Continuous outcomes-Occurrence of aspiration (Penetration Aspiration Scale liquid)-***
 2 ***Neuromuscular electrical stimulation compared to usual care-Mean SD-Transcranial magnetic stimulation (TMS)-***
 3 ***Neuromuscular electrical stimulation (NMES)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4
 5 **1.1.60.4.6.** ***Continuous outcomes-Swallowing ability (Functional dysphagia scale liquid)-***
 6 ***Transcranial magnetic stimulation compared to usual care-Mean SD-Transcranial magnetic stimulation (TMS)-***
 7 ***Neuromuscular electrical stimulation (NMES)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8
 9 **1.1.60.4.7.** ***Continuous outcomes-Swallowing ability (Functional dysphagia scale liquid)-***
 10 ***Neuromuscular electrical stimulation compared to usual care-Mean SD-Transcranial magnetic stimulation (TMS)-***
 11 ***Neuromuscular electrical stimulation (NMES)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.61. Lin, 2018**

Bibliographic Reference Lin, Wang-Sheng; Chou, Chen-Liang; Chang, Miao-Hsiang; Chung, Yuh-Mei; Lin, Fu-Gong; Tsai, Po-Yi; Vagus nerve magnetic modulation facilitates dysphagia recovery in patients with stroke involving the brainstem - A proof of concept study.; Brain stimulation; 2018; vol. 11 (no. 2); 264-270

2

3 **1.1.61.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT02893033.
Study type	Randomised controlled trial (RCT)
Study location	Taiwan.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	This work was supported by the Taipei Veterans General Hospital Grant (V103-168C).
Inclusion criteria	A diagnosis of stroke-related dysphagia resulting from a first ever brainstem infarction or haemorrhage, which was confirmed through magnetic resonance imaging and presented clinically with bulbar signs, including a flaccid tone of the palate and tongue, bulbar muscle weakness and fasciculations, and a decreased gag reflex; at least 3 months since the first stroke and a stable medical and cognitive condition.

Exclusion criteria	Unstable cardiac dysrhythmia; fever; infection; hyperglycaemia; epilepsy; prior administration of tranquilizers; intracranial magnetic devices, pacemakers or other devices.
Recruitment / selection of participants	Consecutive people with ischaemic or haemorrhagic stroke with chronic bulbar manifestation.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=13</p> <p>rTMS with the center of the coil placed at the left mastoid to stimulate the vagus nerve proximal to the exit from the skull through the jugular foramen. 10 minutes of excitatory 5-Hz rTMS (600 pulses totally) at threshold intensity. A stimulus intensity of 42% of the maximum output was applied if the threshold intensity could not be determined, according to an average value from the experiments. Therapy was delivered in 10 daily sessions over a 2-week conditioning period (only weekdays).</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	<p>Mixed</p> <p>Predominately nasogastric</p>
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	No additional information.
Comparator	Placebo/sham therapy N=15 Sham therapy. Same procedure except a placebo coil was used which delivered <5% of the magnetic output with an audible click sound on discharge and induced minimal scalp current sensation. Concomitant therapy: No additional information.
Number of participants	28 (fully analysed, but 2 dropped out so likely 30).
Duration of follow-up	2 weeks (end of scheduled follow-up).
Indirectness	No additional information.
Additional comments	No additional information. Appears to be completers only.

1

2 **1.1.61.2. Study arms**

3 **1.1.61.2.1. *Transcranial magnetic stimulation (TMS) (N = 15)***

4 rTMS with the center of the coil placed at the left mastoid to stimulate the vagus nerve proximal to the exit from the skull through the
5 jugular foramen. 10 minutes of excitatory 5-Hz rTMS (600 pulses totally) at threshold intensity. A stimulus intensity of 42% of the
6 maximum output was applied if the threshold intensity could not be determined, according to an average value from the experiments.
7 Therapy was delivered in 10 daily sessions over a 2-week conditioning period (only weekdays). Concomitant therapy: No additional
8 information.

9

1 **1.1.61.2.2. Placebo/sham therapy (N = 15)**

2 Sham therapy. Same procedure except a placebo coil was used which delivered <5% of the magnetic output with an audible click
3 sound on discharge and induced minimal scalp current sensation. Concomitant therapy: No additional information.

4

5 **1.1.61.3. Characteristics**6 **1.1.61.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Placebo/sham therapy (N = 15)
% Female	n = 1 ; % = 8	n = 6 ; % = 40
Sample size		
Mean age (SD) (years)	68.5 (12.8)	72.9 (12.2)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Hypertension	n = 12 ; % = 90.9	n = 14 ; % = 93.3
Sample size		
Diabetes mellitus	n = 4 ; % = 27.3	n = 6 ; % = 40
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Placebo/sham therapy (N = 15)
Sample size		
Time after stroke (Months)	25.2 (42.2)	21.6 (19.5)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 11 ; % = 85	n = 11 ; % = 73
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Midbrain	n = 0 ; % = 0	n = 0 ; % = 0
Sample size		
Pons	n = 6 ; % = 46	n = 9 ; % = 60
Sample size		
Medulla	n = 1 ; % = 8	n = 1 ; % = 7
Sample size		
Cerebellum	n = 1 ; % = 8	n = 0 ; % = 0
Sample size		
Multiple	n = 5 ; % = 39	n = 5 ; % = 33
Sample size		

1 Only reports for 13 people in the intervention group.

2

1 **1.1.61.4. Outcomes**

2 **1.1.61.4.1. Study timepoints**

- 3 • Baseline
- 4 • 2 week (<3 months)

5

6 **1.1.61.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 13	Transcranial magnetic stimulation (TMS), 2 week, N = 13	Placebo/sham therapy, Baseline, N = 15	Placebo/sham therapy, 2 week, N = 15
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values. Mean (SD)	4.7 (2.1)	3.5 (2.3)	4.8 (2.4)	4.8 (2.2)

7 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

8

9

10 **1.1.61.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.61.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale) - Mean SD - Transcranial magnetic stimulation (TMS) - Placebo/sham therapy - t2**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.62. Liu, 2022**

Bibliographic Reference	Liu, Huiyu; Peng, Yang; Liu, Zicai; Wen, Xin; Li, Fang; Zhong, Lida; Rao, Jinzhu; Li, Li; Wang, Minghong; Wang, Pu; Hemodynamic signal changes and swallowing improvement of repetitive transcranial magnetic stimulation on stroke patients with dysphagia: A randomized controlled study.; Frontiers in neurology; 2022; vol. 13; 918974
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3

4 **1.1.62.1. Study details**

Secondary publication of another included study- see primary study for details	NR
Other publications associated with this study included in review	NR
Trial name / registration number	NR
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Department of Rehabilitation Medicine
Study dates	NR

Sources of funding	The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.
Inclusion criteria	(1) stroke patients were diagnosed according to the updated definition for the 21st century (33) and were confirmed to be subcortical stroke by computed tomography (CT) or magnetic resonance imaging (MRI); (2) patients with dysphagia confirmed by fiberoptic endoscopic evaluation of swallowing (FEES); (3) patients with stable vital signs, whose disease duration is between 1 and 12 months and their ages range from 18 to 85 years; and (4) patients without taking the medicine which affects swallowing function.
Exclusion criteria	(1) had a history of any other neurogenic diseases, such as epilepsy, tumor, and so on; (2) patients suffering from severe cognitive impairment or aphasia who could not continue to cooperate with treatment; (3) had intracranial metal implants, pacemakers, skull defects, history of seizures, or other contraindications to rTMS treatment; (4) and had a history of sedation, antidepressants, or other drugs that may alter the excitability of the cortex.
Recruitment / selection of participants	The participants were 60 stroke patients with dysphagia, who were recruited from the Department of Rehabilitation Medicine, Yuebei People's Hospital from July 2020 to January 2021.
Intervention(s)	<p>In the rTMS group, a 5-Hz rTMS protocol was applied to the affected mylohyoid cortical region of the affected hemisphere at an intensity of 80% of RMT, a stimulation time of 2 s, and an interval of 10 s between each stimulation. The treatment duration was 20 min with a total of 100 repetitions and 1,000 stimuli. The treatment period was once a day for 5 days per week for 2 weeks.</p> <p>Concomitant therapy: All patients received the same traditional dysphagia treatment for 30 min each day after rTMS intervention, such as sensory stimulation, tongue retraction exercises, and oropharyngeal muscle strengthening exercises. An experienced physical therapist led the exercises five times each week for 10 days.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Moderate FEDSS - 4
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>For the sham stimulation group, the same parameters (including position, stimulation frequency, interval time, and pulse number) were used as in the rTMS group. However, to ensure the same stimulation sound without any effective stimulation, the coil was perpendicular to the surface of the skull during the intervention. The treatment period was once a day for 5 days per week for 2 weeks.</p> <p>Concomitant therapy: All patients received the same traditional dysphagia treatment for 30 min each day after rTMS intervention, such as sensory stimulation, tongue retraction exercises, and oropharyngeal muscle strengthening exercises. An experienced physical therapist led the exercises five times each week for 10 days.</p>
Number of participants	60
Duration of follow-up	2 weeks after 2 week intervention = 4 weeks
Indirectness	NR
Additional comments	NR

1 **1.1.62.2. Study arms**

2 **1.1.62.2.1. Repetitive transcranial magnetic stimulation (rTMS) (N = 30)**

3 10-session rTMS was given to the rTMS group for 2 weeks.

4

5 **1.1.62.2.2. Sham transcranial magnetic stimulation (rTMS) (N = 30)**

6

7 **1.1.62.3. Characteristics**

8 **1.1.62.3.1. Study-level characteristics**

Characteristic	Study (N = 49)
Ethnicity	NR
Nominal	
Comorbidities	NR to NR
Range	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

9

1 **1.1.62.3.2. Arm-level characteristics**

Characteristic	Repetitive transcranial magnetic stimulation (rTMS) (N = 30)	Sham transcranial magnetic stimulation (rTMS) (N = 30)
% Female	n = 6 ; % = 26.1	n = 6 ; % = 23.1
Sample size		
Mean age (SD)	67.61 (11.71)	67.73 (9.97)
Mean (SD)		
Severity of dysphagia (FEDSS)	4.22 (1)	4.27 (1.04)
Mean (SD)		
Time after stroke (days)	74.17 (88.2)	63.38 (59.5)
Mean (SD)		

2

3 **1.1.62.4. Outcomes**4 **1.1.62.4.1. Study timepoints**

- 5 • Baseline
- 6 • 4 week

7

1 **1.1.62.4.2. Continuous outcomes**

Outcome	Repetitive transcranial magnetic stimulation (rTMS), Baseline, N = 30	Repetitive transcranial magnetic stimulation (rTMS), 4 week, N = 23	Sham transcranial magnetic stimulation (rTMS), Baseline, N = 30	Sham transcranial magnetic stimulation (rTMS), 4 week, N = 26
Occurance of aspiration (PAS) (final value) 1-8 Mean (SD)	4.57 (1.31)	2.83 (1.47)	4.58 (1.98)	3.46 (1.66)
Swallowing ability (Standardised swallowing assessment) (final value) unclear scale range Mean (SD)	29.35 (3.83)	25.57 (4.34)	27.46 (3.35)	24.92 (3.88)

2 Occurance of aspiration (PAS) - Polarity - Lower values are better

3 Swallowing ability (Standardised swallowing assessment) - Polarity - Lower values are better

4 **1.1.62.4.3. Dichotomous outcomes**

Outcome	Repetitive transcranial magnetic stimulation (rTMS), Baseline, N = 30	Repetitive transcranial magnetic stimulation (rTMS), 4 week, N = 23	Sham transcranial magnetic stimulation (rTMS), Baseline, N = 30	Sham transcranial magnetic stimulation (rTMS), 4 week, N = 26
Mortality No serious adverse events No of events	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
Occurrence of chest infections No serious adverse events	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0

Outcome	Repetitive transcranial magnetic stimulation (rTMS), Baseline, N = 30	Repetitive transcranial magnetic stimulation (rTMS), 4 week, N = 23	Sham transcranial magnetic stimulation (rTMS), Baseline, N = 30	Sham transcranial magnetic stimulation (rTMS), 4 week, N = 26
No of events				
Dysphagia present/Return to normal diet (removal of feeding tube)	n = NA ; % = NA	n = 11 ; % = 48	n = NA ; % = NA	n = 10 ; % = 38
No of events				

- 1 Mortality - Polarity - Lower values are better
- 2 Occurrence of chest infections - Polarity - Lower values are better
- 3 Dysphagia present/Return to normal diet (removal of feeding tube) - Polarity - Higher values are better

4

5

6 **1.1.62.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.62.4.5. Continuous outcomes - Occurrence of aspiration (PAS) - Mean SD - Repetitive transcranial magnetic stimulation (rTMS) - Sham transcranial magnetic stimulation (rTMS) - t4**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.62.4.6.** *Continuous outcomes-Swallowing ability(Standardised swallowing assessment)-Mean SD- Repetitive transcranial*
 2 *magnetic stimulation (rTMS)-Sham transcranial magnetic stimulation (rTMS)-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.62.4.7.** *Dichotomous outcomes-Mortality-No Of Events- Repetitive transcranial magnetic stimulation (rTMS)-Sham*
 5 *transcranial magnetic stimulation (rTMS)-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.62.4.8.** *Dichotomous outcomes-Occurrence of chest infections-No Of Events- Repetitive transcranial magnetic stimulation*
 8 *(rTMS)-Sham transcranial magnetic stimulation (rTMS)-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.62.4.9.** *Dichotomous outcomes-Dysphagia present/Return to normal diet (removal of feeding tube)-No Of Events- Repetitive*
 2 *transcranial magnetic stimulation (rTMS)-Sham transcranial magnetic stimulation (rTMS)-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.63. Liu, 2018**

Bibliographic Reference Liu, X.; Chen, F.; Chu, J.; Bao, Y.; Effects of nape acupuncture combined with swallowing rehabilitation on dysphagia in pseudobulbar palsy; J Tradit Chin Med; 2018; vol. 38 (no. 1); 117-124

5

6 **1.1.63.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study location	China

Study setting	acupuncture out-patient clinic of Hangzhou Hospital of Traditional Chinese Medicine
Study dates	June 2014 to December 2015
Sources of funding	Supported by Zhejiang province administration of Traditional Chinese Medicine funded Project: Effects of nape acupuncture on dysphagia in pseudobulbar palsy in different stages (Project No: 2014ZA094).
Inclusion criteria	<p>Diagnostic criteria: Patients were recruited according to the diagnostic criteria for pseudobulbar palsy outlined in Jiao and Wang's "Symptomatology in diseases of the nervous system"¹⁴ as follows: (a) dysphagia, dysphasia, dysphonia; (b) positive reaction of pathological brainstem reflexes, such as sucking reflex, palmomental reflex etc.; (c) bipolar disorder, forced crying and laughter; (d) absent uvular reflex, pharyngeal reflex hyporeflexia or normality. A patient with diagnostic criterion (a) plus any one of (b), (c) or (d) was diagnosed as having pseudobulbar palsy.</p> <p>Inclusion criteria were as follows: (a) the case met the above diagnostic criteria; (b) patients were confirmed to have suffered a stroke by head CT and MRI, accompanied by pseudobulbar palsy; (c) the disease course did not exceed half a year; (d) patients were aged 40-80 years; (e) patients were proven to have symptoms of dysphagia, with a water swallow test (WST) grading of III or above; (f) patients voluntarily participated and agreed to provide informed consent.</p>
Exclusion criteria	The following individuals were excluded: (a) patients younger than 40 years or older than 80 years; (b) patients with brain stem infarction; (c) patients whose disease course exceeded half a year; (d) patients with massive brain infarctions accompanied by disturbance of consciousness; (e) patients with motor, sensory or global aphasia; (f) patients with local throat lesions, such as thyroid issues, local infection, ulceration etc.; (g) pregnant and lactating women, and those with bleeding tendency or bleeding diseases; (h) patients with hyperpiesia (BP > 180/120 mm Hg); however, after taking antihypertensive drugs, if the blood pressure decreased to 170/110 mm Hg or below, these patients were accepted; (i) patients with severe primary diseases of the heart, liver, kidneys, hematopoietic system, endocrine system or malignant tumors; and (j) patients with low intelligence or psychiatric symptoms and who would not cooperate.
Recruitment / selection of participants	From June 2014 to December 2015, 117 patients with dysphagia caused by pseudobulbar palsy visited the acupuncture out-patient clinic of Hangzhou Hospital of Traditional Chinese Medicine. One hundred of these patients were enrolled in this study (nine patients were excluded for not meeting the inclusion criteria, five patients declined to receive acupuncture therapy, and three refused to provide informed consent).
Intervention(s)	Subjects in both groups received rehabilitative swallowing training. Subjects in the experimental group also received nape acupuncture treatment. The procedure was conducted once per day, excluding weekends, over 8 weeks of treatment.

	<p>Nape acupuncture combined with rehabilitative swallowing training The experimental group received nape acupuncture treatment as well as rehabilitative swallowing training. The patients were seated, and the acupuncture procedure was conducted as follows. After normal sterilization of the points, Fengchi (GB 20), Yiming (EX-HN 14) and Gongxue [found by Gao Weibin, 1.5 cun directly inferior to Fengchi (GB 20)] were each bilaterally punctured with the tip of a 4.0 cm filiform needle (0.25 mm × 40 mm), directed towards the Adam's apple, to a depth of 25-40 cm. The twirling and rotating manipulation was conducted for 15 s, at a speed of 100/min. Needle retention time was 30 min after the De Qi, and the needles were manipulated three times during this period. Next, Lianquan (CV 23), and external Jinjing and Yuye (both extra-points) were punctured obliquely with the tip of the needle pointed towards the lingual radix to a depth of about 4.0 cm. Tunyan (between the hyoid and the Adam's apple, 0.5 cun lateral to the anterior midline, just in the depression), Zhiqiang (the depression between the hyoid and the Adam's apple), and Fayin (1.5 cun inferior to the Adam's apple, 0.3 cun lateral to the anterior midline) were punctured obliquely for about 0.8 cm. The twirling and rotating manipulation was conducted for 15 s, at a speed of 100/min, before the needles were removed. Retention of needles was forbidden for all points except Fengchi (GB 20), Yiming (EX-HN 14), and Gongxue. If the patient had a tendency to cough when the needles were manipulated, the needle was removed immediately. The entire therapy was conducted once a day for 30 min, excluding weekends, over 8 weeks of treatment.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear

Population subgroups	NR
Comparator	Rehabilitative swallowing training: Indirect training methods: (a) swallowing muscle training: patients practiced actions such as lip girdle expiration, smiling, opening or closing the mouth etc., to strengthen the muscles of the cheeks and lips; (b) pushing exercise: the thorax of the patient was fixed, and after closing the glottis, they suddenly re-opened the glottis; (c) closed glottis training: after a deep inspiration, patients held their breath for 5 s, then cleared their throat (for example: they made the long "A" sound, held the breath for 5 s, then coughed); (d) Mendelsohn maneuver: patients were required to focus on the thyroid cartilage, and to swallow saliva repeatedly. They were asked whether they could feel the movement of the Adam's apple up and down. Then, when they swallowed, if they felt the Adam's apple going up, they would contract the muscle to keep it up for a number of seconds; (e) ice-massage: frozen cotton swabs were used to lightly stimulate the bilateral soft palate, lingual radix and posterior pharyngeal wall; (f) tonguemuscle training: patients were asked to complete horizontal, back, and lateral movements of the tongue, and a dorsum raising movement, using a spatula to provide resistance, or to use the tip of the tongue to lick the lower lip, pressing on the hard palate. Direct training methods: (a) food placement: food was placed in a location in the mouth that the patient could feel, which allowed them to move the food smooth; (b) food form: food was chosen according to the severity and stage of dysphagia, starting with the easiest food to manage (gelatinous food at the beginning of training, gradually moving to paste, full diet and water); (c) feeding position: patients were seated with the neck flexed slightly forward and the body tilted about 45 degrees to the normal side (if unable to maintain a seated position, a supine position was taken, with the trunk 30 degrees to the left, head and neck bent forward, and the shoulder of the hemiplegia side propped up by a pillow); (d) progressive adjustment of food intake: patients were asked to focus on each mouthful and eat slowly, starting with a mouthful of 3-4 mL, and increasing the amount of food when appropriate up to a normal-sized mouthful of 20 mL; (e) interaction swallowing: after eating and swallowing, patients were asked to drink a little water (1-2 mL), which not only induced the swallowing reflex, but also eliminated residuum from the pharynx. The therapy was conducted one-on-one for 30 min once a day, excluding weekends, over 8 weeks of treatment.
Number of participants	100
Duration of follow-up	8 weeks
Indirectness	NR
Additional comments	NR

- 1 **1.1.63.2. Study arms**
- 2 **1.1.63.2.1. *Nape acupuncture with rehabilitative swallowing training (N = 50)***
- 3
- 4 **1.1.63.2.2. *Standard swallowing training - behavioural exercises (N = 50)***
- 5

- 6 **1.1.63.3. Characteristics**
- 7 **1.1.63.3.1. *Study-level characteristics***

Characteristic	Study (N = 87)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

8

1 **1.1.63.3.2. Arm-level characteristics**

Characteristic	Nape acupuncture with rehabilitative swallowing training (N = 50)	Standard swallowing training - behavioural exercises (N = 50)
% Female Nominal	39.58	38.78
Mean age (SD) Mean (SD)	67 (10.8)	67.1 (10.5)
Severity of dysphagia standardized swallowing assessment Mean (SD)	31 (5.4)	30.8 (5.8)
Time after stroke (days) Mean (SD)	41.1 (38.6)	40.5 (30.8)

2

3 **1.1.63.4. Outcomes**4 **1.1.63.4.1. Study timepoints**

- 5 • Baseline
- 6 • 8 week

7

1 **1.1.63.4.2. Dichotomous outcomes**

Outcome	Nape acupuncture with rehabilitative swallowing training, Baseline, N = 50	Nape acupuncture with rehabilitative swallowing training, 8 week, N = 48	Standard swallowing training - behavioural exercises, Baseline, N = 50	Standard swallowing training - behavioural exercises, 8 week, N = 49
Dysphagia present	n = NR ; % = NR	n = 34 ; % = 71	n = NR ; % = NR	n = 43 ; % = 88
No of events				

2 Dysphagia present - Polarity - Lower values are better

3 **1.1.63.4.3. Continuous outcomes**

Outcome	Nape acupuncture with rehabilitative swallowing training, Baseline, N = 50	Nape acupuncture with rehabilitative swallowing training, 8 week, N = 48	Standard swallowing training - behavioural exercises, Baseline, N = 50	Standard swallowing training - behavioural exercises, 8 week, N = 49
Swallowing ability (standardized swallowing assessment)	31 (5.4)	20.6 (3.5)	30.8 (5.8)	23.5 (4.4)
Mean (SD)				

4 Swallowing ability (standardized swallowing assessment) - Polarity - Lower values are better

5

6

1 **1.1.63.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.63.4.5. Continuous outcomes-Swallowing ability (standardized swallowing assessment)-Mean SD-Nape acupuncture with**
 3 **rehabilitative swallowing training-Standard swallowing training - behavioural exercises-t8**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.63.4.6. Dichotomous outcomes-Dysphagia present-No Of Events-Nape acupuncture with rehabilitative swallowing training-**
 6 **Standard swallowing training - behavioural exercises-t8**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.64. Love, 2012**

Bibliographic Reference Love, J.; Bath, P. M. W.; A multi-centre, double blind, randomised controlled clinical investigation to validate the EPS1 device as a treatment for stroke-induced dysphagia: a study of Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS Study); 2012

9

10 **1.1.64.1. Study details**

Secondary publication of	Bath, Philip M, Scutt, Polly, Love, Jo et al. (2016) Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial. Stroke 47(6): 1562-70
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another included study- see primary study for details	
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

1

2

3 **1.1.65. MANN, 1997**

Bibliographic Reference MANN, G; BAXTER, K; HANKEY, G; DAVIS, B; STEWART-WYNNE, E; Treatment for swallowing disorders following acute stroke: a randomised controlled trial; STROKE-SOCIETY-OF-AUSTRALASIA-ANNUAL-SCIENTIFIC-MEETING; 1997

4

5 **1.1.65.1. Study details**

Secondary publication of another included study- see primary study for details	Carnaby, Giselle; Hankey, Graeme J; Pizzi, Julia (2006) Behavioural intervention for dysphagia in acute stroke: a randomised controlled trial. The Lancet. Neurology 5(1): 31-7
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

6

7

1 **1.1.66. Mao, 2022**

Bibliographic Reference Mao, Huiwen; Lyu, Yi; Li, Yan; Gan, Lin; Ni, Jiawei; Liu, Liang; Xiao, Zhengguang; Clinical study on swallowing function of brainstem stroke by tDCS.; Neurological sciences : official journal of the Italian Neurological Society and of the Italian Society of Clinical Neurophysiology; 2022; vol. 43 (no. 1); 477-484

2

3 **1.1.66.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Rehabilitation ward in Tongren Hospital, Shanghai Jiao Tong University School of Medicine
Study dates	October 2017 to December 2018
Sources of funding	This study was supported by the Shanghai Tongren Hospital Project (TRYJ201607) "The clinical effect of different rehabilitation strategy based on the evaluation of VFSS.
Inclusion criteria	(1) The brainstem stroke was diagnosed according to the World Health Organization's definition of a stroke, with the location on the medulla oblongata confirmed by CT or MRI, with the symptom of water choking, dysphagia, and

	hoarseness; (2) Age from 50 to 80 years old; (3) The course of the disease from 2 to 12 months; (4) NIHSS score from 2 to 9; (5) No cognitive impairment, good compliance; (6) Signing informed consent; can tolerate our therapy.
Exclusion criteria	(1) The stroke site was not located in the brainstem; (2) Other diseases of the nervous system caused swallowing disorders; (3) Head and neck radiotherapy caused swallowing disorders; (4) Critical conditions such as organ failure or unconsciousness; (5) dysphagia due to previous neurological dysfunction..
Recruitment / selection of participants	No additional information
Intervention(s)	<p>tDCS training protocol: tDCS training was delivered by a constant current stimulator (IS200, Sichuan Intelligent Electronics Industry Co., Ltd.) through 2 saline-soaked electrodes. The anodal electrode with the size of 4.5cm*6.0cm was placed over the swallowing sensory motor cortex area on the nonlesional hemisphere, at the middle of C3 and T3 according to the international 10-20 EEG electrode system, and the cathodal electrode with the size of 7cm*10.0cm was placed on the opposite shoulder. The current was 1.6mA, 20 min each time, once a day, 6days each week, for a total of 8 weeks. The tDCS group cooperated with tDCS training based on routine training.</p> <p>Concomitant therapy - Patients in both groups were given secondary prevention of stroke: (1) Control of hypertension, blood pressure should be controlled below 140/90mmHg, hypotensive speed, amplitude, specific use of drugs should be individualized, to avoid hypoperfusion. (2) Control of diabetes, lifestyle and drug intervention, the control of HbA1C<7%. (3) For patients with non-cardiogenic embolic ischemic stroke, antiplatelet drugs, aspirin 100mg/day, or clopidogrel 75mg/ day were given, and for patients with cardiogenic embolic stroke, oral warfarin was given, and the target dose was maintained at the INR level of 2.0–3.0. (4) Management of lipid metabolism, the use of statins to control LDL-C ≤1.8mmol/L</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring	Not stated/unclear

enteral feeding support at baseline	
Subgroup 4: Type of stroke (using the Bamford scale)	Posterior circulation stroke (POCS)
Population subgroups	NR
Comparator	<p>The conventional comprehensive treatment group received routine swallowing rehabilitation training.</p> <p>Routine swallowing rehabilitation training: (a) Motor and sensory training of the muscles around the mouth and tongue, such as lip closure, mouth opening, sucking, and tongue extension. Using iced cotton swab to stimulate the pharyngeal posterior wall and soft palate mucosa 60min each time, once a day, 6days per week, a total of 8 weeks. (b) Breath training: teaching the patient to take abdominal breath, slowly exhale the air with a breathing trainer, and airway protection strategies, once a day, 6days per week, a total of 8 weeks. (c) External laryngeal electrical stimulation: Vital Stim neuromuscular electrical stimulation instrument was used for treatment, and body surface electrodes were placed on the skin of pharynx, once a day, 6days per week, a total of 8 weeks. (d) Balloon dilatation [10]: using No. 12 catheter inserted through the mouth slowly into the esophagus, inject 2–8 mL cold saline slowly into the balloon until the patients feel stuck, then instruct the patient to swallow while gently pulling catheter outward, once feeling the resistance of balloon has passed the cricopharyngeus muscle, quickly draw out the saline in the balloon catheter. Eight times a day, 6days per week, a total of 8</p>
Number of participants	40
Duration of follow-up	3 months
Indirectness	NR
Additional comments	NR

1 **1.1.66.2. Study arms**

2 **1.1.66.2.1. Transcranial direct current stimulation (N = 20)**

3 Transcranial direct current stimulation (tDCS) combined with conventional comprehensive rehabilitation

4

5 **1.1.66.2.2. Usual care (conventional comprehensive treatment group) (N = 20)**

6

7 **1.1.66.3. Characteristics**

8 **1.1.66.3.1. Study-level characteristics**

Characteristic	Study (N = 40)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

9

10 **1.1.66.3.2. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (N = 20)	Usual care (conventional comprehensive treatment group) (N = 20)
% Female	45	60

Characteristic	Transcranial direct current stimulation (N = 20)	Usual care (conventional comprehensive treatment group) (N = 20)
Nominal		
Mean age (SD)	59.8 (7.3)	61.3 (8)
Mean (SD)		
Severity of dysphagia Functional Dysphagia Scale (FDS)	75.4 (12.4)	75.3 (12.5)
Mean (SD)		
Time after stroke months	3.3 (2.2)	3.6 (2.5)
Mean (SD)		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
No of events		
Medullar	n = 5 ; % = 25	n = 4 ; % = 20
No of events		
Midbrain	n = 8 ; % = 40	n = 9 ; % = 45
No of events		
Pons	n = 7 ; % = 35	n = 7 ; % = 35
No of events		

1 **1.1.66.4. Outcomes**

2 **1.1.66.4.1. Study timepoints**

- 3 • Baseline
- 4 • 3 month

5

6 **1.1.66.4.2. Continuous outcomes**

Outcome	Transcranial direct current stimulation, Baseline, N = 20	Transcranial direct current stimulation, 3 month, N = 20	Usual care (conventional comprehensive treatment group), Baseline, N = 20	Usual care (conventional comprehensive treatment group), 3 month, N = 20
Swallowing ability (Functional Dysphagia Scale (FDS)) Scale range: 0-100. Final values. Mean (SD)	75.4 (12.4)	46.2 (18.9)	75.3 (12.6)	56.8 (13.8)
Nutrition (albumin) Final values. Mean (SD)	35.5 (1)	52.9 (3)	35.5 (2.1)	44.8 (0.9)

7 Swallowing ability (Functional Dysphagia Scale (FDS)) - Polarity - Lower values are better

8 Nutrition (albumin) - Polarity - Higher values are better

9

10

1 **1.1.66.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.66.4.4. Continuousoutcomes-Swallowingability(FunctionalDysphagiaScale(FDS)-MeanSD-Transcranial direct current**
 3 **stimulation-conventional comprehensive treatment group-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.66.4.5. Continuousoutcomes-Nutrition(albumin)-MeanSD-Transcranial direct current stimulation-conventional**
 6 **comprehensive treatment group-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.67. Matos, 2022**

Bibliographic Reference Matos, K.C.; de Oliveira, V.F.; de Oliveira, P.L.C.; Carvalho, F.A.; de Mesquita, M.R.M.; da Silva Queiroz, C.G.; Marques, L.M.; Lima, D.L.N.; Carvalho, F.M.M.; Braga-Neto, P.; Combined conventional speech therapy and functional electrical stimulation in acute stroke patients with dysphagia: a randomized controlled trial; BMC Neurology; 2022; vol. 22 (no. 1); 231

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10 **1.1.67.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT03649295.
Study type	Randomised controlled trial (RCT)
Study location	Brazil.
Study setting	Inpatients.
Study dates	September 2018 to July 2020.
Sources of funding	No funding received.
Inclusion criteria	People with ischaemic stroke confirmed by neuroimaging within 24 hours of the event; people with age between 40 and 70 years; Glasgow Coma Scale Score >11; people with oropharyngeal dysphagia.
Exclusion criteria	Degenerative neurological diseases, neoplasia, pacemaker, cochlear implant, feverish state, pregnancy and/or anxiety.
Recruitment / selection of participants	People admitted to the Stroke Unit at Hospital Geral de Fortaleza, a stroke reference tertiary public care hospital in the city of Fortaleza, located in Northeast of Brazil.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=20 Electrostimulation using the Neurodyn Portable TENS/FES technique. The equipment corresponds to CLASS II type BF. The program was used in 5 steps: muscle warming up (frequency 10 Hz, pulse duration 250 micrometers, TON 6s, TOFF 12s, stimulus duration 2 minutes); type I muscle fibers potentiation (frequency 30 Hz, pulse duration 250 micrometers, TON 5s, TOFF 10s, stimulus duration 8 minutes); type II muscle fibers potentiation (frequency 80 Hz, pulse duration 300 micrometers, TON 5s, TOFF 10s, stimulus duration 8 minutes), muscle toning (frequency 30Hz, pulse duration 300 micrometers, TON 5s, TOFF 7s, stimulus duration 8 minutes), relaxation (frequency 5 Hz, pulse duration 200 micrometers, TON off, TOFF off, stimulus duration 4 minutes). One channel was placed in the submental region and the others placed

	<p>over the thyroid cartilage forming a T. The treatment was started at the minimum level of intensity and increased carefully until therapeutic levels were achieved. Therapy was provided for 5 days.</p> <p>Concomitant therapy: All people received conventional speech therapy including: isotonic exercises, isometric exercises, exercises to stimulate triggering swallowing reflex, consecutive repetitions of Shaker exercise and Mendelsohn's maneuver. Training was performed once a day for five consecutive days. Enteral diet was maintained when the person was unable to have a safe oral diet. A mixed diet was possible dependent on the person.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=20</p> <p>The same therapy. However, the machine was switched on with the intensity set at 0 during therapy.</p>

	Concomitant therapy: All people received conventional speech therapy including: isotonic exercises, isometric exercises, exercises to stimulate triggering swallowing reflex, consecutive repetitions of Shaker exercise and Mendelsohn's maneuver. Training was performed once a day for five consecutive days. Enteral diet was maintained when the person was unable to have a safe oral diet. A mixed diet was possible dependent on the person.
Number of participants	40
Duration of follow-up	1 week
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis appears to be completers only.

1

2 **1.1.67.2. Study arms**3 **1.1.67.2.1. Neuromuscular electrical stimulation (NMES) (N = 20)**

4 Electrostimulation using the Neurodyn Portable TENS/FES technique. The equipment corresponds to CLASS II type BF. The program
5 was used in 5 steps: muscle warming up (frequency 10 Hz, pulse duration 250 micrometers, TON 6s, TOFF 12s, stimulus duration 2
6 minutes); type I muscle fibers potentiation (frequency 30 Hz, pulse duration 250 micrometers, TON 5s, TOFF 10s, stimulus duration 8
7 minutes); type II muscle fibers potentiation (frequency 80 Hz, pulse duration 300 micrometers, TON 5s, TOFF 10s, stimulus duration 8
8 minutes), muscle toning (frequency 30Hz, pulse duration 300 micrometers, TON 5s, TOFF 7s, stimulus duration 8 minutes), relaxation
9 (frequency 5 Hz, pulse duration 200 micrometers, TON off, TOFF off, stimulus duration 4 minutes). One channel was placed in the
10 submental region and the others placed over the thyroid cartilage forming a T. The treatment was started at the minimum level of
11 intensity and increased carefully until therapeutic levels were achieved. Therapy was provided for 5 days. Concomitant therapy: All
12 people received conventional speech therapy including: isotonic exercises, isometric exercises, exercises to stimulate triggering
13 swallowing reflex, consecutive repetitions of Shaker exercise and Mendelsohn's maneuver. Training was performed once a day for five
14 consecutive days. Enteral diet was maintained when the person was unable to have a safe oral diet. A mixed diet was possible
15 dependent on the person.

16

1 **1.1.67.2.2. Placebo/sham therapy (N = 20)**

2 The same therapy. However, the machine was switched on with the intensity set at 0 during therapy. Concomitant therapy: All people
 3 received conventional speech therapy including: isotonic exercises, isometric exercises, exercises to stimulate triggering swallowing
 4 reflex, consecutive repetitions of Shaker exercise and Mendelsohn's maneuver. Training was performed once a day for five
 5 consecutive days. Enteral diet was maintained when the person was unable to have a safe oral diet. A mixed diet was possible
 6 dependent on the person.

7

8 **1.1.67.3. Characteristics**

9 **1.1.67.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 20)	Placebo/sham therapy (N = 20)
% Female	n = 4 ; % = 25	n = 6 ; % = 35
Sample size		
Mean age (SD) (years)	n = NA ; % = NA	n = NA ; % = NA
Sample size		
40-50 years	n = 4 ; % = 25	n = 7 ; % = 41
Sample size		
51-60 years	n = 6 ; % = 38	n = 7 ; % = 41
Sample size		
61-70 years	n = 6 ; % = 38	n = 3 ; % = 18
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 20)	Placebo/sham therapy (N = 20)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Functional swallowing	n = 0 ; % = 0	n = 1 ; % = 6
Sample size		
Mild dysphagia	n = 1 ; % = 6	n = 1 ; % = 6
Sample size		
Moderate dysphagia	n = 6 ; % = 38	n = 6 ; % = 35
Sample size		
Severe dysphagia	n = 9 ; % = 56	n = 9 ; % = 53
Sample size		
Time after stroke	NR (NR)	NR (NR)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NA ; % = NA	n = NA ; % = NA

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 20)	Placebo/sham therapy (N = 20)
Sample size		
Nasogastric tube	n = 15 ; % = 94	n = 16 ; % = 94
Sample size		
Gastrostomy	n = 0 ; % = 0	n = 1 ; % = 6
Sample size		
Oral	n = 1 ; % = 6	n = 0 ; % = 0
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1 Only reports for 16 people in the intervention arm, 17 in the control arm.

2

3 1.1.67.4. Outcomes

4 1.1.67.4.1. Study timepoints

- 5 • Baseline
- 6 • 1 week (<3 months)

7

1 **1.1.67.4.2. Dichotomous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 16	Neuromuscular electrical stimulation (NMES), 1 week, N = 16	Placebo/sham therapy, Baseline, N = 17	Placebo/sham therapy, 1 week, N = 17
Dysphagia present/return to normal diet (return to oral diet)	n = 1 ; % = 6	n = 8 ; % = 50	n = 0 ; % = 0	n = 6 ; % = 35
No of events				

2 Dysphagia present/return to normal diet (return to oral diet) - Polarity - Higher values are better

3 **1.1.67.4.3. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 16	Neuromuscular electrical stimulation (NMES), 1 week, N = 16	Placebo/sham therapy, Baseline, N = 17	Placebo/sham therapy, 1 week, N = 17
Swallowing ability (FOIS scale) Scale range: 1-7. Final values.	NR (NR)	3.44 (2.28)	NR (NR)	3.18 (1.84)
Mean (SD)				

4 Swallowing ability (FOIS scale) - Polarity - Higher values are better

5

6

1 **1.1.67.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.67.4.5. Dichotomous outcomes - Dysphagia present/return to normal diet (return to oral diet) - No Of Events - Neuromuscular**
 3 **electrical stimulation (NMES) - Placebo/sham therapy-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.67.4.6. Continuous outcomes - Swallowing ability (FOIS scale) - Mean SD - Neuromuscular electrical stimulation (NMES) -**
 6 **Placebo/sham therapy-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.68. Meng, 2018**

Bibliographic Reference Meng, Pingping; Zhang, Shuchao; Wang, Qiang; Wang, Peipei; Han, Chao; Gao, Jinghui; Yue, Shouwei; The effect of surface neuromuscular electrical stimulation on patients with post-stroke dysphagia.; Journal of back and musculoskeletal rehabilitation; 2018; vol. 31 (no. 2); 363-370

9

10 **1.1.68.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	August 2013 to May 2014.
Sources of funding	The work was supported by the National Natural Science Foundation of China (81502246), Science and Technology Bureau of Qingdao (16-5-1-58-jch), Health and Family Planning Commission of Shandong Province (2015WS0353, 2016WS0255).
Inclusion criteria	People diagnosed with stroke using the classification of cerebrovascular disease released from the National Institute of Neurological Disorders and Stroke; the diagnosis of stroke was confirmed by CT or MRI examinations, and the course of disease was no more than 6 months; people aged between 18 and 85 years old, were alert and oriented, and cooperated actively in their treatment; dysphagia was diagnosed using the video fluoroscopic swallowing scan.
Exclusion criteria	People were diagnosed with severe cardiac and pulmonary dysfunction, dementia, aphasia as well as the people who had a limited ability to follow instructions and to cooperate with the rehabilitation therapy; people who had severe aspiration and who were completely unable to swallow anything; people who were implanted with a cardiac pacemaker.
Recruitment / selection of participants	People admitted to the Rehabilitation Department of the Affiliated Hospital of Qingdao University assessed using the water swallow test.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=20

	<p>Combination of two groups: group 1) NMES where 1 pair of electrodes was placed on the surface of both sides of suprahyoid (the region of the geniohyoid muscle movement) and another pair on the surface of the upper and lower edge of thyroid cartilage. Group 2) 2 pairs of electrodes placed on the surface of the suprahyoid, including 1 pair which was placed on either sides of the region of geniohyoid muscle movement, another pair was placed on either side of the region of mylohyoideus muscle movement. NMES was applied using the VitalStim hand-held device at a frequency of 80 Hz and wave amplitude of 0-25 mA. The intensity was according to the tolerability of the person and the minimum degree of stimulation to induce visible muscle contraction. Provided for 30 minutes, 5 days per week and in 10 sessions over 2 weeks (in addition to usual care).</p> <p>Concomitant therapy: All people received conventional therapy with medications, general rehabilitation therapy and traditional dysphagia therapy (a combination of therapeutic exercise, compensatory manoeuvres and diet texture modifications). This was provided for 30 minutes, 5 days a week for 10 sessions over the study.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=10

	Usual care only.
	Concomitant therapy: All people received conventional therapy with medications, general rehabilitation therapy and traditional dysphagia therapy (a combination of therapeutic exercise, compensatory manoeuvres and diet texture modifications). This was provided for 30 minutes, 5 days a week for 10 sessions over the study.
Number of participants	30
Duration of follow-up	2 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be ITT no drop outs.

1

2 **1.1.68.2. Study arms**

3 **1.1.68.2.1. Neuromuscular electrical stimulation (NMES) (N = 20)**

4 Combination of two groups: group 1) NMES where 1 pair of electrodes was placed on the surface of both sides of suprahyoid (the
 5 region of the geniohyoid muscle movement) and another pair on the surface of the upper and lower edge of thyroid cartilage. Group 2)
 6 2 pairs of electrodes placed on the surface of the suprahyoid, including 1 pair which was placed on either sides of the region of
 7 geniohyoid muscle movement, another pair was placed on either side of the region of mylohyoideus muscle movement. NMES was
 8 applied using the VitalStim hand-held device at a frequency of 80 Hz and wave amplitude of 0-25 mA. The intensity was according to
 9 the tolerability of the person and the minimum degree of stimulation to induce visible muscle contraction. Provided for 30 minutes, 5
 10 days per week and in 10 sessions over 2 weeks (in addition to usual care). Concomitant therapy: All people received conventional
 11 therapy with medications, general rehabilitation therapy and traditional dysphagia therapy (a combination of therapeutic exercise,
 12 compensatory manoeuvres and diet texture modifications). This was provided for 30 minutes, 5 days a week for 10 sessions over the
 13 study.

14

1 **1.1.68.2.2. Usual care (N = 10)**

2 Usual care only. Concomitant therapy: All people received conventional therapy with medications, general rehabilitation therapy and
3 traditional dysphagia therapy (a combination of therapeutic exercise, compensatory manoeuvres and diet texture modifications). This
4 was provided for 30 minutes, 5 days a week for 10 sessions over the study.

5

6 **1.1.68.3. Characteristics**7 **1.1.68.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 20)	Usual care (N = 10)
% Female	n = 7 ; % = 35	n = 3 ; % = 30
Sample size		
Mean age (SD) (years)	66.2 (13.55)	64.4 (9.03)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	29 (6.75)	30.8 (8.6)
Mean (SD)		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 20)	Usual care (N = 10)
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.68.4. Outcomes**

3 **1.1.68.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)

6

7 **1.1.68.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 20	Neuromuscular electrical stimulation (NMES), 2 week, N = 20	Usual care, Baseline, N = 10	Usual care, 2 week, N = 10
Swallowing ability (Dysphagia outcome and severity score) Scale range: 1-7. Final values. NMES group 1 = 5.20 (1.40). NMES group 2 = 5.10 (1.45). Mean (SD)	3.6 (1.54)	5.2 (1.43)	4 (1.05)	4.9 (1.1)

8 Swallowing ability (Dysphagia outcome and severity score) - Polarity - Higher values are better

1 **1.1.68.4.3. Dichotomous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 20	Neuromuscular electrical stimulation (NMES), 2 week, N = 20	Usual care, Baseline, N = 10	Usual care, 2 week, N = 10
Dysphagia present/return to normal diet (number of people who were not completely cured according to the water swallow test) NMES group A = 6. NMES group B = 7.	n = 20 ; % = 100	n = 13 ; % = 65	n = 10 ; % = 100	n = 9 ; % = 90
No of events				

2 Dysphagia present/return to normal diet (number of people who were not completely cured according to the water swallow test) -
3 Polarity - Lower values are better

4

5

6 **1.1.68.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.68.4.5. Continuous outcomes - Occurrence of aspiration (Dysphagia outcome and severity score) - Mean SD - Neuromuscular electrical stimulation (NMES) - Usual care - t2**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.68.4.6.** *Dichotomous outcomes-*
 2 *Dysphagia present/return to normal diet (number of people who were not completely cured according to the water swallow test)-No Of Events-Neuromuscular electrical stimulation (NMES)-Usual care-t2*
 3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.69. Moon, 2017**

Bibliographic Reference Moon, Jong Hoon; Jung, Jin-Hwa; Won, Young Sik; Cho, Hwi-Young; Cho, KiHun; Effects of expiratory muscle strength training on swallowing function in acute stroke patients with dysphagia.; Journal of physical therapy science; 2017; vol. 29 (no. 4); 609-612

6

7 **1.1.69.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information

Study type	Randomised controlled trial (RCT)
Study location	Korea
Study setting	Hospital in Korea from 2014–2015
Study dates	2014-1015
Sources of funding	No additional information
Inclusion criteria	Participant selection criteria were as follows: (1) onset of no more than 1 month, (2) the person with swallowing disorder of pharyngeal stage through videofluoroscopic swallowing study (VFSS), such as aspiration, invasion or residues of pharyngeal stage, (3) no oral stage problems, such as mastication and oral facial muscle movement, (4) MMSE of more than 24, (5) no specific medical problems, including respiratory problems.
Exclusion criteria	Exclusion criteria were as follows: (1) person without the appropriate lips closed, (2) significant facial paralysis, (3) tracheostomy and percutaneous endoscopic gastrostomy, (4) hypertension
Recruitment / selection of participants	No additional information
Intervention(s)	<p>The experimental group was trained using the EMST 150 (Aspire Products LLC., USA). First, patients were provided with a mouthpiece to blow into, after which the nasal cavity was closed using forceps. The personal maximal expiratory pressure (MEP) was then measured using a manometer. Wheeler et al. were trained with a threshold value of 70%, it based on the personal MEP11) . The training consisted of taking a deep breath and biting a mouthpiece, during which time the patient was told to blow faster and stronger. Each patient received seven trainings per session, five times a week for four weeks. Breaks of 30 seconds were provided after one session.</p> <p>Expiratory muscle strength training was only provided to the experimental group in 30 minute sessions</p> <p>All participants performed traditional swallowing rehabilitation therapy in 30 minute sessions five times a week for four weeks</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information
Comparator	Traditional swallowing treatment was composed of orofacial exercises, thermal-tactile stimulation, the Mendelson maneuver, effortful swallow, and supraglottic maneuver. All swallowing treatments were carried out by the responsible therapists
Number of participants	18
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

- 1 **1.1.69.2. Study arms**
- 2 **1.1.69.2.1. *Behavioural intervention (expiratory muscle strength training) (N = 9)***
- 3
- 4 **1.1.69.2.2. *Usual care (traditional-swallowing rehabilitation therapy) (N = 9)***
- 5

6 **1.1.69.3. Characteristics**

7 **1.1.69.3.1. *Study-level characteristics***

Characteristic	Study (N = 18)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

8

1

1.1.69.3.2.

Arm-level characteristics

Characteristic	Behavioural intervention (expiratory muscle strength training) (N = 9)	Usual care (traditional-swallowing rehabilitation therapy) (N = 9)
% Female	33.3	33.3
Nominal		
Mean age (SD)	63 (5.8)	63.1 (5.2)
Mean (SD)		
Severity of dysphagia FDS total	28.22 (5.33)	27.56 (5.64)
Mean (SD)		
Time after stroke	21.4 (5.1)	21.1 (4)
Mean (SD)		

2

3

1.1.69.4.

Outcomes

4

1.1.69.4.1.

Study timepoints

5

- Baseline

6

- 4 week

7

1 **1.1.69.4.2. Continuous outcomes**

Outcome	Behavioural intervention (expiratory muscle strength training), Baseline, N = 9	Behavioural intervention (expiratory muscle strength training), 4 week, N = 9	Usual care (traditional-swallowing rehabilitation therapy), Baseline, N = 9	Usual care (traditional-swallowing rehabilitation therapy), 4 week, N = 9
Occurrence of aspiration (PAS) Scale range: 1-8. Change scores. Mean (SD)	4.78 (1.56)	-2.67 (0.87)	3.89 (1.27)	-1.11 (1.05)
Swallowing ability (FDS) Scale range: 0-100. Change scores. Mean (SD)	28.22 (5.33)	-9.78 (2.73)	27.56 (5.64)	-5.56 (4.22)

2 Occurrence of aspiration (PAS) - Polarity - Lower values are better

3 Swallowing ability (FDS) - Polarity - Lower values are better

4

5

6 **1.1.69.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**7 **1.1.69.4.4. Continuous outcomes - Occurrence of aspiration (PAS) - Mean SD - Expiratory muscle strength training - Traditional-swallowing rehabilitation therapy - t4**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and deviations from intended interventions)

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.69.4.5. Continuous outcomes-Swallowing ability (FDS)-Mean SD-Expiratory muscle strength training-Traditional-swallowing**
 3 **rehabilitation therapy-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to randomisation and deviations from intended interventions)
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.70. Moon, 2018**

Bibliographic Reference Moon, Jong-Hoon; Hahm, Suk-Chan; Won, Young Sik; Cho, Hwi-Young; The effects of tongue pressure strength and accuracy training on tongue pressure strength, swallowing function, and quality of life in subacute stroke patients with dysphagia: a preliminary randomized clinical trial.; International journal of rehabilitation research. Internationale Zeitschrift fur Rehabilitationsforschung. Revue internationale de recherches de readaptation; 2018; vol. 41 (no. 3); 204-210

6

7 **1.1.70.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
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Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea
Study setting	
Study dates	April 2015 and March 2016
Sources of funding	This work was supported by the Gachon University research fund of 2016 (GCU-2016-0219).
Inclusion criteria	The selection criteria were as follows: (i) aspiration or penetration, oropharyngeal residue confirmed by videofluoroscopic swallowing evaluation (VFSE), (ii) initial VFSE performed during the subacute stage between 3 and 12 weeks after the onset of stroke, (iii) patients who could follow the instructions provided (a score of at least 21 on the Mini-Mental State Examination), and (iv) decreased lingual pressures with either the anterior or posterior tongue as 40 kPa.
Exclusion criteria	This study excluded any non stroke patients with dysphagia as well as those with pain during tongue movement. Patients with tongue cuts were also excluded because they were not eligible for tongue training.
Recruitment / selection of participants	No additional information
Intervention(s)	<p>The TPSAT group underwent TPSAT for 30 min in the morning and traditional dysphagia therapy for 30 min in the afternoon five times per week for 8 weeks. Dysphagia therapy was performed by an occupational therapist with 6 years of experience with dysphagia management. In both groups, standardized physical and occupational therapies were included.</p> <p>TPSAT with traditional dysphagia treatment was performed in the TPSAT group. TPSAT consisted of an anterior and posterior isometric tongue strength exercise and an isometric tongue accuracy exercise (Yeates et al., 2008). For the</p>

	anterior isometric tongue strength exercise, participants were instructed to use the tongue tip to press on the air-filled bulb of the posterior portion of the alveolar arch of the tongue; for the posterior isometric tongue strength exercise, participants were instructed to use the middle portion of the tongue to press on the air-filled bulb of the middle portion of the hard palate. The protocol involved five sets of tongue-to-palate presses, with six repetitions per set for each session. As for the isometric tongue accuracy exercise, amplitudes were set at 50, 75, and 100% of the maximum pressure measured during the first isometric strength exercise in the session for each bulb location by the occupational therapist. Participants were instructed to generate precise pressures within 10 kPa error for each amplitude. The traditional dysphagia therapy consisted of thermal tactile stimulation, the Mendelsohn maneuver, effortful swallow, and diet modification.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	The control group underwent traditional therapy for 30 min in the morning and 30 min in the afternoon, five times per week for 8 weeks. Dysphagia therapy was performed by an occupational therapist with 6 years of experience with dysphagia management. In both groups, standardized physical and occupational therapies were included.
Number of participants	19
Duration of follow-up	8 weeks

Indirectness	NR
Additional comments	NR

1

2 **1.1.70.2. Study arms**3 **1.1.70.2.1. Behavioural interventions (Tongue pressure strength and accuracy training) (N = 10)**

4 Tongue pressure strength and accuracy training with routine treatment

5

6 **1.1.70.2.2. Usual care (N = 9)**

7 routine treatment (standardised physical and occupational therapy)

8

9 **1.1.70.3. Characteristics**10 **1.1.70.3.1. Study-level characteristics**

Characteristic	Study (N = 19)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	

Characteristic	Study (N = 19)
People requiring enteral feeding support at baseline	NR
Nominal	

1

2 **1.1.70.3.2. Arm-level characteristics**

Characteristic	Behavioural interventions (Tongue pressure strength and accuracy training) (N = 10)	Usual care (N = 9)
% Female	62	50
Nominal		
Mean age (SD)	62 (4.17)	63.5 (6.05)
Mean (SD)		
Time after stroke (days)	56 (17.35)	59.88 (20.04)
Mean (SD)		
Type of stroke	NR	NR
Nominal		
Supratentorial lesion	3	4
Nominal		
Infratentorial lesion	5	4
Nominal		

3

1 **1.1.70.4. Outcomes**

2 **1.1.70.4.1. Study timepoints**

- 3 • Baseline
4 • 8 week

5

6 **1.1.70.4.2. Continuous outcomes**

Outcome	Behavioural interventions (Tongue pressure strength and accuracy training), Baseline, N = 10	Behavioural interventions (Tongue pressure strength and accuracy training), 8 week, N = 8	Usual care, Baseline, N = 9	Usual care, 8 week, N = 8
Swallowing ability (Mann Assessment of Swallowing Ability total) Scale range: 0-200. Change scores. Mean (SD)	145.5 (3.38)	27.75 (5.99)	144.13 (5.46)	22.75 (7.65)

7 Swallowing ability (Mann Assessment of Swallowing Ability total) - Polarity - Higher values are better

8

9

10 **1.1.70.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.70.4.4. Continuous outcomes-Swallowing ability(MASAtota)-MeanSD-Tongue pressure strength and accuracy training-Usual care-t8**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.71. Murray, 2016**

Bibliographic Reference Murray, Jo; Doeltgen, Sebastian; Miller, Michelle; Scholten, Ingrid; Does a Water Protocol Improve the Hydration and Health Status of Individuals with Thin Liquid Aspiration Following Stroke? A Randomized Controlled Trial.; Dysphagia; 2016; vol. 31 (no. 3); 424-33

3

4 **1.1.71.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	ACTRN12610000752066
Study type	Randomised controlled trial (RCT)
Study location	Australia
Study setting	Stroke units from two acute hospitals and three inpatient rehabilitation facilities in an Australian capital city.
Study dates	November 2009 to February 2013

Sources of funding	This research was supported by the Royal Adelaide Hospital/Institute of Medical and Veterinary Science Clinical Research Grant for Allied Health, Nursing and Pharmacy (January 2009) and a Clinical Research Development Grant awarded to the first author by the National Stroke Foundation, Australia (dated 15th December 2011).
Inclusion criteria	Over 18 years of age; an inpatient in a dedicated stroke unit; had a confirmed diagnosis of stroke (ICD-10 codes of I60, I61, I63 and I64); had a clinical dysphagia assessment indicating aspiration of thin liquid and were consuming thickened liquids.
Exclusion criteria	Known condition that may have affected swallowing pre-stroke (progressive neurological condition, brain tumour, traumatic brain injury, or head or neck cancer); had a condition that put them at increased risk of respiratory complications such as chronically suppressed immune system or chronic obstructive pulmonary disease; had an acute medical illness; required supplementary non-oral feeding or fluids; had a medical order for fluid restriction or were pregnant or breast feeding.
Recruitment / selection of participants	People recruited from the stroke units of two acute hospitals and three inpatient rehabilitation facilities in an Australian capital city.
Intervention(s)	Free water protocol N=9 Adapted from the original Frazier Water Protocol. Water was permitted anytime between meals but not at mealtime, with food, medication or for 30 minutes after a meal. People also had access to the thickened liquid that they were assessed to be safely consuming. Concomitant therapy: All people in both arms were required to adhere to a daily oral hygiene routine which involved brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring	Not stated/unclear

enteral feeding support at baseline	
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	Usual care (thickened fluids) N=7 Thickened liquid only intervention. People were allowed to drink only the mildly, moderately or extremely thickened liquid deemed safe from their VFSS. They may have consumed small amounts of water with their clinician when assessing readiness for upgrade to thin fluids. Each of the three rehabilitation facilities observed a slightly different process for providing thickened liquids (made on-site from powdered thickener or pre-packaged), but all were consistent with the Australian National Standards for fluid viscosity. Concomitant therapy: All people in both arms were required to adhere to a daily oral hygiene routine which involved brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch.
Number of participants	16
Duration of follow-up	7 days, 14 days, 21 days
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Seems to exclude people from the analysis for reasons that may not be appropriate (for example: 1 excluded from analysis as only acute patient in sample).

1 **1.1.71.2. Study arms**2 **1.1.71.2.1. Free water protocol (N = 9)**

3 Adapted from the original Frazier Water Protocol. Water was permitted anytime between meals but not at mealtime, with food,
4 medication or for 30 minutes after a meal. People also had access to the thickened liquid that they were assessed to be safely
5 consuming. Concomitant therapy: All people in both arms were required to adhere to a daily oral hygiene routine which involved
6 brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch.

7

8 **1.1.71.2.2. Usual care (thickened fluids) (N = 7)**

9 Thickened liquid only intervention. People were allowed to drink only the mildly, moderately or extremely thickened liquid deemed safe
10 from their VFSS. They may have consumed small amounts of water with their clinician when assessing readiness for upgrade to thin
11 fluids. Each of the three rehabilitation facilities observed a slightly different process for providing thickened liquids (made on-site from
12 powdered thickener or pre-packaged), but all were consistent with the Australian National Standards for fluid viscosity. Concomitant
13 therapy: All people in both arms were required to adhere to a daily oral hygiene routine which involved brushing the teeth or dentures
14 twice daily, after breakfast and in the evening, and rinsing their mouth after lunch.

15

16 **1.1.71.3. Characteristics**17 **1.1.71.3.1. Arm-level characteristics**

Characteristic	Free water protocol (N = 9)	Usual care (thickened fluids) (N = 7)
% Female	n = 3 ; % = 33.3	n = 3 ; % = 42.9
Sample size		
Mean age (SD) (years)	78 (6.8)	80 (6.4)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR

Characteristic	Free water protocol (N = 9)	Usual care (thickened fluids) (N = 7)
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Aphasia	n = 1 ; % = 11.1	n = 2 ; % = 28.6
Sample size		
Cognitive impairment	n = 3 ; % = 33.3	n = 2 ; % = 28.6
Sample size		
Not exerting to mobilise	n = 5 ; % = 55.6	n = 4 ; % = 57.1
Sample size		
Motor or ideational apraxia	n = 0 ; % = 0	n = 1 ; % = 14.3
Sample size		
Dysarthria	n = 7 ; % = 77.8	n = 5 ; % = 71.4
Sample size		
Apraxia of speech	n = 0 ; % = 0	n = 2 ; % = 28.6
Sample size		
Dependence for oral care	n = 1 ; % = 11.1	n = 3 ; % = 42.9
Sample size		
Dependence for pouring drinks	n = 0 ; % = 0	n = 2 ; % = 28.6
Sample size		

Characteristic	Free water protocol (N = 9)	Usual care (thickened fluids) (N = 7)
Dependence for drinking from a cup	n = 0 ; % = 0	n = 0 ; % = 0
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	19.1 (8.4)	19.7 (9.3)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Cortical	n = 3 ; % = 33.3	n = 4 ; % = 57.1
Sample size		
Subcortical	n = 2 ; % = 22.2	n = 2 ; % = 28.6
Sample size		
Brainstem	n = 3 ; % = 33.3	n = 0 ; % = 0
Sample size		
Cerebellar	n = 0 ; % = 0	n = 0 ; % = 0
Sample size		

1

2 **1.1.71.4. Outcomes**3 **1.1.71.4.1. Study timepoints**

- 4 • Baseline
5 • 21 day (<3 months)

6

7 **1.1.71.4.2. Dichotomous outcome**

Outcome	Free water protocol, Baseline, N = 9	Free water protocol, 21 day, N = 8	Usual care (thickened fluids), Baseline, N = 7	Usual care (thickened fluids), 21 day, N = 6
Occurrence of chest infection (pneumonia)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0
No of events				

8 Occurrence of chest infection (pneumonia) - Polarity - Lower values are better

9 **1.1.71.4.3. Continuous outcome**

Outcome	Free water protocol, Baseline, N = 9	Free water protocol, 21 day, N = 8	Usual care (thickened fluids), Baseline, N = 7	Usual care (thickened fluids), 21 day, N = 6
Hydration (fluid intake) (ml)	NR (NR)	1103 (215)	NR (NR)	1103 (247)
Mean (SD)				

10 Hydration (fluid intake) - Polarity - Higher values are better

11

12

1 **1.1.71.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.71.4.5. Dichotomous outcome - Presence of chest infection (pneumonia) - No of Events - Free water protocol - Usual care**
 3 **(thickened fluids) - t21**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.71.4.6. Continuous outcome - Hydration (fluid intake) - Mean SD - Free water protocol - Usual care (thickened fluids) - t21**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.72. Nordio, 2021**

Bibliographic Reference Nordio, S.; Arcara, G.; Berta, G.; Dellai, A.; Brisotto, C.; Koch, I.; Cazzador, D.; Aspidistria, M.; Ventura, L.; Turolla, A.; D'Imperio, D.; Battel, I.; Biofeedback as an Adjunctive Treatment for Post-stroke Dysphagia: A Pilot-Randomized Controlled Trial; Dysphagia; 2021

8

9 **1.1.72.1. Study details**

Secondary publication of another included	No additional information.
--	----------------------------

study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT03247374.
Study type	Randomised controlled trial (RCT)
Study location	Italy.
Study setting	Inpatients.
Sources of funding	No funding was received.
Inclusion criteria	First stroke; onset from stroke >6 weeks to ensure deficit stability; level of dysphagia at the Functional Oral Intake Scale (FOIS no more than 5); preserved comprehension (Token Test >53); absence of hearing or visual impairments; absence of severe concomitant medical conditions (i.e., fever, infections, metabolic problems, serious cardiac insufficiency, serious dystonia or unintentional movements); other neurological diseases to not compromise the rehabilitation.
Exclusion criteria	See inclusion criteria. No additional information.
Recruitment / selection of participants	People at IRCCS San Camillo Hospital.
Intervention(s)	Behavioural interventions (sEMG biofeedback rehabilitation) N=9 sEMG-Biofeedback applied through the ProComp5 Infiniti System. Preparation took about 10 minutes for assembly and 5 minutes for removal. Two surface electrodes were secured over the person's submental muscles for registering larynx's raising (i.e. collectively covering mylohyoid, geniohyoid, anterior belly of digastric and genioglossus) and one at the shoulder as neutral reference. The sEMG (filtered 10-370 Hz) can detect muscular electrical signals (0.2-2000 microV). They were rectified, digitized and sent to the computer via a fiber optic cable. The electromyographic signal was real time registered and depicted on a computer screen as a wave of muscular activity, which provided an online performance's feedback to the person. During the first session, participants were instructed how to keep their own movements in a range

	<p>between 5 and 30 microV, in accordance with subjective clinical level. During the rehabilitation, the people were required to swallow at a given time and to perform maneuvers for swallowing strength, coordination and efficacy, randomly including: 10 minutes of effortful swallow, 10 minutes of supraglottic swallow and 10 minutes of Masako maneuver. Specifically, during effortful swallow the person was asked to swallow and push hard with the tongue against the hard palate, to increase posterior tongue base movement and facilitate bolus clearance. For supraglottic swallow, the person had to voluntarily hold breath just before swallowing, to close the vocal folds, and immediately to produce a volitional cough. This maneuver was designed to protect the airways before and during swallowing. During Masako exercise, the person held the tongue between the teeth while swallowing, with the intent to improve movements and strength of the base of the tongue and the posterior pharyngeal wall during swallowing. When possible, the first two tasks were performed with bolus administration, whose consistency depended on each person's status, while Masako maneuver was performed without any food or liquid intake, to prevent coughing or choking. This training lasted for 40 minutes (with additional two five-minute pauses between exercises) with the support of muscle activity's visualisation on the screen through the sEMG-biofeedback and of verbal feedback about correct execution from the speech therapist. All the visual and verbal feedbacks were useful to improve the quality of performance at the specific exercise (i.e., speech therapist directs patient's attention to the height of the curve on the screen in effortful swallow, timing and coordination in supraglottic swallow, high and coordination in Masako maneuver). Additionally, the verbal feedback included positive reinforcement or encouragement to improve strength (in effortful swallow), coordination and timing of deglutition (in supraglottic swallow) or strength and coordination (in Masako maneuver). Intervention for 1 hour per day for 5 weeks (on week days only, 25 sessions in total).</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear

Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=8 The same random behavioural exercises of the experimental group (40 minutes, excluding pauses), without sEMG-biofeedback application. People only received verbal feedback. Concomitant therapy: No additional information.
Number of participants	17
Duration of follow-up	5 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information. Method of analysis appears to be mITT (people had to have received the intervention at least once).

1

2 **1.1.72.2. Study arms**3 **1.1.72.2.1. Behavioural interventions (sEMG biofeedback rehabilitation) (N = 9)**

4 sEMG-Biofeedback applied through the ProComp5 Infiniti System. Preparation took about 10 minutes for assembly and 5 minutes for
5 removal. Two surface electrodes were secured over the person's submental muscles for registering larynx's raising (i.e. collectively
6 covering mylohyoid, geniohyoid, anterior belly of digastric and genioglossus) and one at the shoulder as neutral reference. The sEMG
7 (filtered 10-370 Hz) can detect muscular electrical signals (0.2-2000 microV). They were rectified, digitized and sent to the computer
8 via a fiber optic cable. The electromyographic signal was real time registered and depicted on a computer screen as a wave of
9 muscular activity, which provided an online performance's feedback to the person. During the first session, participants were instructed

1 how to keep their own movements in a range between 5 and 30 microV, in accordance with subjective clinical level. During the
2 rehabilitation, the people were required to swallow at a given time and to perform maneuvers for swallowing strength, coordination and
3 efficacy, randomly including: 10 minutes of effortful swallow, 10 minutes of supraglottic swallow and 10 minutes of Masako maneuver.
4 Specifically, during effortful swallow the person was asked to swallow and push hard with the tongue against the hard palate, to
5 increase posterior tongue base movement and facilitate bolus clearance. For supraglottic swallow, the person had to voluntarily hold
6 breath just before swallowing, to close the vocal folds, and immediately to produce a volitional cough. This maneuver was designed to
7 protect the airways before and during swallowing. During Masako exercise, the person held the tongue between the teeth while
8 swallowing, with the intent to improve movements and strength of the base of the tongue and the posterior pharyngeal wall during
9 swallowing. When possible, the first two tasks were performed with bolus administration, whose consistency depended on each
10 person's status, while Masako maneuver was performed without any food or liquid intake, to prevent coughing or choking. This training
11 lasted for 40 minutes (with additional two five-minute pauses between exercises) with the support of muscle activity's visualisation on
12 the screen through the sEMG-biofeedback and of verbal feedback about correct execution from the speech therapist. All the visual
13 and verbal feedbacks were useful to improve the quality of performance at the specific exercise (i.e., speech therapist directs patient's
14 attention to the height of the curve on the screen in effortful swallow, timing and coordination in supraglottic swallow, high and
15 coordination in Masako maneuver). Additionally, the verbal feedback included positive reinforcement or encouragement to improve
16 strength (in effortful swallow), coordination and timing of deglutition (in supraglottic swallow) or strength and coordination (in Masako
17 maneuver). Intervention for 1 hour per day for 5 weeks (on week days only, 25 sessions in total). Concomitant therapy: No additional
18 information.

19

20 **1.1.72.2.2. Usual care (N = 8)**

21 The same random behavioural exercises of the experimental group (40 minutes, excluding pauses), without sEMG-biofeedback
22 application. People only received verbal feedback. Concomitant therapy: No additional information.

23

1 **1.1.72.3. Characteristics**2 **1.1.72.3.1. Arm-level characteristics**

Characteristic	Behavioural interventions (sEMG biofeedback rehabilitation) (N = 9)	Usual care (N = 8)
% Female	n = 2 ; % = 22	n = 3 ; % = 38
Sample size		
Mean age (SD) (years)	71 (9.77)	69 (11.72)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	7.44 (1.42)	9.57 (3.31)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 1 ; % = 11.11	n = 5 ; % = 57.14
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.72.4. Outcomes**

3 **1.1.72.4.1. Study timepoints**

- 4 • Baseline
5 • 2 month (<3 months)

6

7 **1.1.72.4.2. Continuous outcomes**

Outcome	Behavioural interventions (sEMG biofeedback rehabilitation), Baseline, N = 9	Behavioural interventions (sEMG biofeedback rehabilitation), 2 month, N = 9	Usual care, Baseline, N = 8	Usual care, 2 month, N = 8
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change scores. Taken from liquid value. Mean (SD)	3.64 (3.08)	-2 (2.36)	3.75 (2.74)	-1.83 (2.79)
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Change scores. Mean (SD)	4.14 (1.29)	1.68 (0.71)	4.06 (1.53)	1.29 (1.23)

8 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

9 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

1 **1.1.72.4.3. Dichotomous outcomes**

Outcome	Behavioural interventions (sEMG biofeedback rehabilitation), Baseline, N = 9	Behavioural interventions (sEMG biofeedback rehabilitation), 2 month, N = 9	Usual care, Baseline, N = 8	Usual care, 2 month, N = 8
Dysphagia present/return to normal diet (people who do not require enteral feeding)	n = 8 ; % = 89	n = 8 ; % = 89	n = 3 ; % = 38	n = 6 ; % = 75
No of events				

2 Dysphagia present/return to normal diet (people who do not require enteral feeding) - Polarity - Higher values are better

3

4

5 **1.1.72.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.72.4.5. Continuous outcomes-Occurrence of aspiration (Penetration Aspiration Scale)-Mean SD-Behavioural interventions (sEMG biofeedback rehabilitation)-Usual care-t2**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.72.4.6. Continuous outcomes-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Behavioural interventions (sEMG biofeedback rehabilitation)-Usual care-t2**

10

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.72.4.7.** *Dichotomous outcomes-Dysphagia present/return to normal diet (people who do not require enteral feeding)-No Of Events-*
 3 *Behavioural interventions (sEMG biofeedback rehabilitation)-Usual care-t2*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.73. Park, 2019**

Bibliographic Reference Park, Hee-Su; Oh, Dong-Hwan; Yoon, Taehyung; Park, Ji-Su; Effect of effortful swallowing training on tongue strength and oropharyngeal swallowing function in stroke patients with dysphagia: a double-blind, randomized controlled trial.; International journal of language & communication disorders; 2019; vol. 54 (no. 3); 479-484

6

7 **1.1.73.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with	No additional information.

this study included in review	
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	South Korea.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	This work was supported by BB21+ project in 2018.
Inclusion criteria	Diagnosis of stroke based on computed tomography or magnetic resonance imaging findings; oropharyngeal dysphagia after stroke confirmed by a videofluoroscopic swallowing study (VFSS); inpatient at the Paik Hospital; no significant cognitive problems (Mini Mental Status Examination Score >24); ability to perform effortful swallowing training; ability to make tongue-to-palate contact.
Exclusion criteria	Secondary stroke; trigeminal neuropathy; significant malocclusion and facial asymmetry; parafunctional oral habits (clenching, bruxing or tongue thrusting); tongue strength could not be measured; severe communication difficulties associated with dementia or aphasia; neck pain or neck surgery; presence of a tracheostomy tube.
Recruitment / selection of participants	Recruited from the dysphagia clinic at the rehabilitation department of Busan Paik Hospital.
Intervention(s)	Behavioural interventions (effortful swallowing therapy) N=15 Effortful swallowing training. People were asked to push their tongue firmly onto their palate, while squeezing the neck muscles, and to swallow as forcefully as possible. This was performed 10 times per session, with 3 sessions per day, 5 days per week for 4 weeks. This was confirmed by the therapist through visual observation and palpation during effortful swallowing. They visually confirmed their expression and the strong contraction of the orofacial and suprahyoid muscles. Additionally, intermittent palpation of the suprahyoid muscles under the jaws confirmed effortful swallowing. People were given encouragement during training, a small spray of water to induce swallowing if they found it difficult to maintain it and in cases of fatigue of the tongue and neck, rest was provided for several seconds.

	Concomitant therapy: Both groups received a the same conventional dysphagia therapy (e.g. compensatory techniques such as the chin tuck and head tilting and rotation; therapeutic techniques such as orofacial muscle exercises, thermal tactile stimulation using ice sticks, expiratory training) from occupational therapists. The therapy was administered for 30 minutes per day, consecutively for 5 days per week for 4 weeks.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	Usual care N=15 Instructed to swallow naturally without intentional force from the tongue and neck muscles, according to the same schedule as that of the experimental group. Concomitant therapy: Both groups received a the same conventional dysphagia therapy (e.g. compensatory techniques such as the chin tuck and head tilting and rotation; therapeutic techniques such as orofacial muscle exercises, thermal

	tactile stimulation using ice sticks, expiratory training) from occupational therapists. The therapy was administered for 30 minutes per day, consecutively for 5 days per week for 4 weeks.
Number of participants	30
Duration of follow-up	4 weeks (end of intervention)
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1

2 **1.1.73.2. Study arms**3 **1.1.73.2.1. Behavioural interventions (effortful swallowing therapy) (N = 15)**

4 Effortful swallowing training. People were asked to push their tongue firmly onto their palate, while squeezing the neck muscles, and to
5 swallow as forcefully as possible. This was performed 10 times per session, with 3 sessions per day, 5 days per week for 4 weeks.
6 This was confirmed by the therapist through visual observation and palpation during effortful swallowing. They visually confirmed their
7 expression and the strong contraction of the orofacial and suprahyoid muscles. Additionally, intermittent palpation of the suprahyoid
8 muscles under the jaws confirmed effortful swallowing. People were given encouragement during training, a small spray of water to
9 induce swallowing if they found it difficult to maintain it and in cases of fatigue of the tongue and neck, rest was provided for several
10 seconds. Concomitant therapy: Both groups received a the same conventional dysphagia therapy (e.g. compensatory techniques such
11 as the chin tuck and head tilting and rotation; therapeutic techniques such as orofacial muscle exercises, thermal tactile stimulation
12 using ice sticks, expiratory training) from occupational therapists. The therapy was administered for 30 minutes per day, consecutively
13 for 5 days per week for 4 weeks.

14

15 **1.1.73.2.2. Usual care (N = 15)**

16 Instructed to swallow naturally without intentional force from the tongue and neck muscles, according to the same schedule as that of
17 the experimental group. Concomitant therapy: Both groups received a the same conventional dysphagia therapy (e.g. compensatory
18 techniques such as the chin tuck and head tilting and rotation; therapeutic techniques such as orofacial muscle exercises, thermal

1 tactile stimulation using ice sticks, expiratory training) from occupational therapists. The therapy was administered for 30 minutes per
 2 day, consecutively for 5 days per week for 4 weeks.

3

4 **1.1.73.3. Characteristics**

5 **1.1.73.3.1. Arm-level characteristics**

Characteristic	Behavioural interventions (effortful swallowing therapy) (N = 15)	Usual care (N = 15)
% Female	n = 6 ; % = 50	n = 7 ; % = 58
Sample size		
Mean age (SD) (years)	66.5 (9.5)	64.8 (11.2)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	24.39 (8.65)	25.74 (6.27)
Mean (SD)		

Characteristic	Behavioural interventions (effortful swallowing therapy) (N = 15)	Usual care (N = 15)
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Middle cerebral artery	n = 6 ; % = 50	n = 6 ; % = 50
Sample size		
Midbrain	n = 1 ; % = 8	n = 1 ; % = 8
Sample size		
Frontal lobe	n = 2 ; % = 17	n = 1 ; % = 8
Sample size		
Internal capsule	n = 2 ; % = 17	n = 2 ; % = 17
Sample size		
Corona radiate	n = 1 ; % = 8	n = 2 ; % = 17
Sample size		

1 Only reports baseline characteristics for 12 people in each study arm.

2

1 **1.1.73.4. Outcomes**

2 **1.1.73.4.1. Study timepoints**

- 3 • Baseline
- 4 • 4 week (<3 months)

5

6 **1.1.73.4.2. Continuous outcomes**

Outcome	Behavioural interventions (effortful swallowing therapy), Baseline, N = 15	Behavioural interventions (effortful swallowing therapy), 4 week, N = 12	Usual care, Baseline, N = 15	Usual care, 4 week, N = 12
Swallowing ability (Videofluoroscopic Dysphagia Score) Scale range: 0-100. Final values. Mean (SD)	61.79 (9.12)	50.46 (7.4)	59.58 (9.56)	53.17 (9.56)

7 Swallowing ability (Videofluoroscopic Dysphagia Score) - Polarity - Lower values are better

8

9

10 **1.1.73.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.73.4.4. Continuous outcomes-Swallowing ability (Videofluoroscopic Dysphagia Score)-Mean SD-Behavioural interventions (effortful swallowing therapy)-Usual care-t4**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1

2

1.1.74. Park, 2017

Bibliographic Reference Park, J S; Hwang, N K; Oh, D H; Chang, M Y; Effect of head lift exercise on kinematic motion of the hyolaryngeal complex and aspiration in patients with dysphagic stroke.; Journal of oral rehabilitation; 2017; vol. 44 (no. 5); 385-391

3

4

1.1.74.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	Chang, M. Y. (2015) KCT0001901 Effect of shaker exercise on motion of hyolaryngeal complex and aspiration in stroke patients with oropharyngeal dysphagia.
Study type	Randomised controlled trial (RCT)
Study location	South Korea.
Study setting	Inpatients.
Study dates	December 2015 to April 2016.
Sources of funding	This work was supported by the 2015 Inje University research grant.
Inclusion criteria	Coughing after completion of 3-oz water swallow test; dysphagia after stroke confirmed by a videofluoroscopic swallowing study; no significant cognitive deficit (a score of >20 points in the Mini-mental Status Examination); having full range of motion on muscle testing of the neck (flexion, extension, lateral flexion) against gravity; symmetrical posture of the neck; ability to initiate a voluntary swallow and not necessarily as a response to stimulation by a bolus.

Exclusion criteria	History of a stroke; poor general condition that precluded further participation in the experiment; severe communication difficulties associated with dementia or aphasia; neck pain or neck surgery; unstable medical condition; presence of a tracheostomy tube.
Recruitment / selection of participants	Admitted to a rehabilitation department at two tertiary hospitals in the Republic of Korea.
Intervention(s)	<p>Behavioural intervention (head lift exercise) N=20</p> <p>Head lift exercise. This consisted of isometric and isokinetic types. In isometric exercise head lift exercises, the people are asked to raise their head up 3 times and look at their toes for 60 seconds without lifting their shoulder from the ground in a supine position; a 60 s rest period is allowed between each lift. In isokinetic head lift exercises, the person performs 30 consecutive repetitions of head raising without sustaining the lifted position in the same supine position. All people performed sustained head-raising exercise, followed by 30 consecutive repetitions of head raising, which were enough to observe their toes without raising their shoulders. Conducted 5 days a week for 4 weeks (20 sessions).</p> <p>Concomitant therapy: 30 minutes traditional dysphagia therapy was provided to all. This included oro-facial muscle exercises, thermal tactile stimulation using ice sticks and therapeutic manoeuvres.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear

Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	Usual care N=17 Usual care only. Concomitant therapy: 30 minutes traditional dysphagia therapy was provided to all. This included oro-facial muscle exercises, thermal tactile stimulation using ice sticks and therapeutic manoeuvres.
Number of participants	37
Duration of follow-up	4 weeks (end of intervention)
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1

2 **1.1.74.2. Study arms**3 **1.1.74.2.1. Behavioural intervention (head lift exercise) (N = 20)**

4 Head lift exercise. This consisted of isometric and isokinetic types. In isometric exercise head lift exercises, the people are asked to
5 raise their head up 3 times and look at their toes for 60 seconds without lifting their shoulder from the ground in a supine position; a 60
6 s rest period is allowed between each lift. In isokinetic head lift exercises, the person performs 30 consecutive repetitions of head
7 raising without sustaining the lifted position in the same supine position. All people performed sustained head-raising exercise,
8 followed by 30 consecutive repetitions of head raising, which were enough to observe their toes without raising their shoulders.

1 Conducted 5 days a week for 4 weeks (20 sessions). Concomitant therapy: 30 minutes traditional dysphagia therapy was provided to
 2 all. This included oro-facial muscle exercises, thermal tactile stimulation using ice sticks and therapeutic manoeuvres.

3

4 **1.1.74.2.2. Usual care (N = 17)**

5 Usual care only. Concomitant therapy: 30 minutes traditional dysphagia therapy was provided to all. This included oro-facial muscle
 6 exercises, thermal tactile stimulation using ice sticks and therapeutic manoeuvres.

7

8 **1.1.74.3. Characteristics**

9 **1.1.74.3.1. Arm-level characteristics**

Characteristic	Behavioural intervention (head lift exercise) (N = 20)	Usual care (N = 17)
% Female	n = 4 ; % = 31	n = 6 ; % = 43
Sample size		
Mean age (SD) (years)	59.26 (11.94)	61.59 (13.61)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Behavioural intervention (head lift exercise) (N = 20)	Usual care (N = 17)
Time after stroke (Weeks) Mean (SD)	21.29 (8.92)	19.2 (5.65)
People requiring enteral feeding support at baseline Sample size	n = NR ; % = NR	n = NR ; % = NR
Type of stroke Sample size	n = NA ; % = NA	n = NA ; % = NA
Middle cerebral artery Sample size	n = 8 ; % = 62	n = 10 ; % = 71
Basal ganglia Sample size	n = 2 ; % = 15	n = 1 ; % = 7
Pontine Sample size	n = 2 ; % = 15	n = 3 ; % = 21
Medullar Sample size	n = 1 ; % = 8	n = 0 ; % = 0

1 Only reports for 13 people in the experimental group, 14 people in the control group.

2

3 **1.1.74.4. Outcomes**

4 **1.1.74.4.1. Study timepoints**

- 5 • Baseline

- 4 week (<3 months)

1.1.74.4.2. Continuous outcomes

Outcome	Behavioural intervention (head lift exercise), Baseline, N = 20	Behavioural intervention (head lift exercise), 4 week, N = 13	Usual care, Baseline, N = 17	Usual care, 4 week, N = 14
Occurrence of aspiration (Penetration Aspiration Scale Liquid type) Scale range: 1-8. Change scores Mean (SD)	5 (1.53)	-2.85 (2.08)	5 (1.3)	-1.43 (2.24)

Occurrence of aspiration (Penetration Aspiration Scale Liquid type) - Polarity - Lower values are better

1.1.74.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

1.1.74.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale Liquid type) - Mean SD - Behavioural intervention (head lift exercise) - Usual care - t4

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.75. Park, 2016**

Bibliographic Reference Park, J S; Oh, D H; Chang, M Y; Kim, K M; Effects of expiratory muscle strength training on oropharyngeal dysphagia in subacute stroke patients: a randomised controlled trial.; Journal of oral rehabilitation; 2016; vol. 43 (no. 5); 364-72

2

3 **1.1.75.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Korea
Study setting	Rehabilitation centre of the Inje University Busan Paik Hospital
Study dates	No additional information
Sources of funding	This research was carried out without funding
Inclusion criteria	(i) dysphagia following a stroke, as confirmed by VFSS; (ii) stroke onset less than 6 months; and (iii) a score of ≥ 24 on the Mini-Mental State Examination

Exclusion criteria	Exclusion criteria were as follows: (i) stroke prior to that resulting in dysphagia; (ii) severe oro-facial pain including trigeminal neuropathy; (iii) significant malocclusion or facial asymmetry; (iv) unstable breathing and pulse; (v) tracheostomy; (vi) severe communication disorder such as severe aphasia; or (vii) inadequate lip closure.
Recruitment / selection of participants	no additional information
Intervention(s)	<p>Prior to training, as a means of determining the EMST threshold value of subjects, maximal expiratory pressure (MEP) was measured using a respiratory pressure meter (Micro RPM*). The EMST protocol of the experimental group was performed in a manner similar to MEP measurement, with resistance set at the 70% range of MEP for each patient. For training, subjects were asked to open their mouth following maximum inhalation and locate the EMST mouthpiece between the lips before closing their mouth. Then, they were instructed to blow strong and fast until the pressure release valve within the EMST device opens. The pressure release valve was set to open if expiratory pressure exceeded the target pressure set for the device. Evaluators confirmed whether the exercise was successful by listening to the sound of air rushing through the EMST device.</p> <p>Intervention was performed 5 days per week, with 5 sets of 5 breaths through the device for a total of 25 breaths per day. During training, less than 1 minute break was provided after each session, with consideration for muscle fatigue and dizziness.</p> <p>Concomitant therapy - all participants were given 30 minutes of traditional dysphagia therapy per day</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	NR
Comparator	<p>Placebo group performed training using a sham device with no spring loading within the device. The sham had an exterior the same as that of the real EMST device used with the experimental group, but it is a non-functional device with little effect of physiologic load on targeted muscles.</p> <p>Intervention was performed 5 days per week, with 5 sets of 5 breaths through the device for a total of 25 breaths per day. During training, less than 1 minute break was provided after each session, with consideration for muscle fatigue and dizziness.</p>
Number of participants	33
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.75.2. Study arms**3 **1.1.75.2.1. Behavioural interventions (Expiratory muscle strength training [EMST]) (N = 17)**

4 EMST with a 70% threshold value of maximal expiratory pressure, using an EMST device

1

2 **1.1.75.2.2. Placebo/Sham therapy (N = 16)**

3 Training with sham device

4

5 **1.1.75.3. Characteristics**6 **1.1.75.3.1. Study-level characteristics**

Characteristic	Study (N = 33)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	

7

8 **1.1.75.3.2. Arm-level characteristics**

Characteristic	Behavioural interventions (Expiratory muscle strength training [EMST]) (N = 17)	Placebo/Sham therapy (N = 16)
% Female	57	54
Nominal		
Mean age (SD)	64.3 (10.7)	65.8 (11.3)
Mean (SD)		

Characteristic	Behavioural interventions (Expiratory muscle strength training [EMST]) (N = 17)	Placebo/Sham therapy (N = 16)
Severity of dysphagia FOIS	3.5 (0.5)	3.8 (0.6)
Mean (SD)		
Time after stroke	27.4 (6.3)	26.6 (6.8)
Mean (SD)		
People requiring enteral feeding support at baseline	NR	NR
Nominal		
Type of stroke	NR	NR
Nominal		
Middle cerebral artery	5	4
Nominal		
Basal ganglia	2	1
Nominal		
Midbrain	2	1
Nominal		
Frontal lobe	2	2
Nominal		

Characteristic	Behavioural interventions (Expiratory muscle strength training [EMST]) (N = 17)	Placebo/Sham therapy (N = 16)
Internal capsule	1	2
Nominal		
Corona radiate	1	1
Nominal		
Pons	1	2
Nominal		

1

2 **1.1.75.4. Outcomes**3 **1.1.75.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week

6

7 **1.1.75.4.2. Continuous outcomes**

Outcome	Behavioural interventions (Expiratory muscle strength training [EMST]), Baseline, N = 17	Behavioural interventions (Expiratory muscle strength training [EMST]), 4 week, N = 14	Placebo/Sham therapy, Baseline, N = 16	Placebo/Sham therapy, 4 week, N = 13
Occurrence of aspiration (PAS) Scale range: 1-8. Change scores.	6 (0.6)	-1.1 (0.6)	5.8 (0.7)	-0.2 (1.2)

Outcome	Behavioural interventions (Expiratory muscle strength training [EMST]), Baseline, N = 17	Behavioural interventions (Expiratory muscle strength training [EMST]), 4 week, N = 14	Placebo/Sham therapy, Baseline, N = 16	Placebo/Sham therapy, 4 week, N = 13
Mean (SD)				
Swallowing ability (FOIS) Scale range: 1-7. Final values.	3.5 (0.5)	1.9 (1.9)	3.8 (0.6)	0.6 (0.9)
Mean (SD)				

1 Occurrence of aspiration (PAS) - Polarity - Lower values are better

2 Swallowing ability (FOIS) - Polarity - Higher values are better

3

4

5 **1.1.75.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.75.4.4. Continuous outcomes - Occurrence of aspiration (PAS) - Mean SD - Expiratory muscle strength training (EMST) - Sham**
7 **training - t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.75.4.5. Continuous outcomes-Swallowing ability(FOIS)-MeanSD-Expiratory muscle strength training (EMST)-Sham training-**
 2 **t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.76. Park, 2012**

Bibliographic Reference Park, Jin-Woo; Kim, Youngsun; Oh, Jong-Chi; Lee, Ho-Jun; Effortful swallowing training combined with electrical stimulation in post-stroke dysphagia: a randomized controlled study.; Dysphagia; 2012; vol. 27 (no. 4); 521-7

5

6 **1.1.76.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)

Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	July to December 2008.
Sources of funding	No additional information.
Inclusion criteria	Post-stroke dysphagia confirmed by a video-fluoroscopic swallowing study; >1 month after stroke onset; they had sufficient cognitive function to perform effortful swallow training.
Exclusion criteria	Subarachnoid haemorrhage; carotid stenosis; inability to overcome stimulation, which was determined by observation and palpation.
Recruitment / selection of participants	People with dysphagia at the hospital.
Intervention(s)	<p>Neuromuscular electrical stimulation (NMES) N=10</p> <p>Effortful swallow with infrahyoid sensory electrical stimulation delivered for 4 weeks. Electrical stimulation was performed using VitaStim. Two sets of electrodes were placed in the infrahyoid area targeting the sternohyoid muscles. A pulse rate of 80 Hz with a duration of 700 microseconds was used. The intensity was increased until muscle contraction was visible. All people received three sets of 20 minutes of exercise per week for 4 weeks. A minimum of 1 day of rest was provided between sessions. One session consisted of two 10 minute exercises with a 2 minute rest period provided between exercises for all people to avoid muscle fatigue. People were asked to forcefully swallow their saliva or a small amount of water every 10 s during stimulation to elevate the hyolaryngeal complex. Some water was provided if it was confirmed that they were able to swallow fluid safely. If not, thickened water was provided.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=10</p> <p>The same procedure except the intensity was adjusted until the person felt the tingling sense in their neck, but not enough to cause muscle contraction.</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	20.
Duration of follow-up	4 weeks
Indirectness	No additional information.
Additional comments	No additional information. Appears to be completers only.

1 **1.1.76.2. Study arms**

2 **1.1.76.2.1. Neuromuscular electrical stimulation (NMES) (N = 10)**

3 Effortful swallow with infrahyoid sensory electrical stimulation delivered for 4 weeks. Electrical stimulation was performed using
 4 VitaStim. Two sets of electrodes were placed in the infrahyoid area targeting the sternohyoid muscles. A pulse rate of 80 Hz with a
 5 duration of 700 microseconds was used. The intensity was increased until muscle contraction was visible. All people received three
 6 sets of 20 minutes of exercise per week for 4 weeks. A minimum of 1 day of rest was provided between sessions. One session
 7 consisted of two 10 minute exercises with a 2 minute rest period provided between exercises for all people to avoid muscle fatigue.
 8 People were asked to forcefully swallow their saliva or a small amount of water every 10 s during stimulation to elevate the
 9 hyolaryngeal complex. Some water was provided if it was confirmed that they were able to swallow fluid safely. If not, thickened water
 10 was provided. Concomitant therapy: No additional information.

11

12 **1.1.76.2.2. Placebo/sham therapy (N = 10)**

13 The same procedure except the intensity was adjusted until the person felt the tingling sense in their neck, but not enough to cause
 14 muscle contraction. Concomitant therapy: No additional information.

15

16 **1.1.76.3. Characteristics**

17 **1.1.76.3.1. Study-level characteristics**

Characteristic	Study (N = 18)
% Female	n = 2 ; % = 10
Sample size	
Mean age (SD) (years)	65.3 (15.1)
Mean (SD)	

18

1 **1.1.76.3.2. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 10)	Placebo/sham therapy (N = 10)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

2

3 **1.1.76.4. Outcomes**4 **1.1.76.4.1. Study timepoints**

- 5 • Baseline
- 6 • 4 week (<3 months)

1

2 **1.1.76.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 9	Neuromuscular electrical stimulation (NMES), 4 week, N = 9	Placebo/sham therapy, Baseline, N = 9	Placebo/sham therapy, 4 week, N = 9
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values. Mean (SD)	NR (NR)	3.11 (2.08)	NR (NR)	2.17 (1.37)

3 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

4

5

6 **1.1.76.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

7 **1.1.76.4.4. Continuous outcomes - Occurrence of aspiration (Penetration Aspiration Scale) - Mean SD - Neuromuscular electrical stimulation (NMES) - Placebo/sham therapy - t4**

8

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.77. Park, 2018**

Bibliographic Reference Park, Ji-Su; An, Duk-Hyun; Oh, Dong-Hwan; Chang, Moon-Young; Effect of chin tuck against resistance exercise on patients with dysphagia following stroke: A randomized pilot study.; NeuroRehabilitation; 2018; vol. 42 (no. 2); 191-197

2

3 **1.1.77.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	This work was supported by the 2016 Inje University research grant.
Inclusion criteria	Dysphagia following stroke confirmed by a videofluoroscopic swallowing study; the onset duration was <12 months; the patients were able to swallow voluntarily; the Mini-Mental State Examination score was at least 20; ability to sit without assistance; ability to perform chin tuck using the CTAR device.
Exclusion criteria	Secondary stroke; severe communication disorders, such as severe aphasia, dementia, etc.; pain in the neck region; unstable medical conditions; head and neck cancer.

Recruitment / selection of participants	People with dysphagia undergoing rehabilitation.
Intervention(s)	<p>Behavioural interventions (chin-tuck against resistance exercises) N=13</p> <p>Chin tuck against resistance performed using a chin tuck against resistance (CTAR) device in a sitting position on a chair. Applied similar to the existing head life exercise method and isometric and isotonic exercises were performed separately. In isometric CTAR, the person was asked to chin tuck against the device 3 times for 60 seconds with no repetition. In isotonic CTAR, the person performs 30 consecutive repetitions by strongly pressing against the resistance of the device and releasing it again. To perform it correctly, the therapist explained and demonstrated the exercise methods before the intervention. The emphasised the correct chin tuck posture, so that people do not flex their heads against the devices.</p> <p>Concomitant therapy: Conventional dysphagia treatment was available to all such as orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist performed this for 30 minutes/day, five days per week for 4 weeks.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	No additional information.
Comparator	Usual care N=12 Usual care only. Concomitant therapy: Conventional dysphagia treatment was available to all such as orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist performed this for 30 minutes/day, five days per week for 4 weeks.
Number of participants	25
Duration of follow-up	4 weeks.
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1

2 **1.1.77.2. Study arms**3 **1.1.77.2.1. Behavioural interventions (chin-tuck against resistance exercises) (N = 13)**

4 Chin tuck against resistance performed using a chin tuck against resistance (CTAR) device in a sitting position on a chair. Applied
5 similar to the existing head life exercise method and isometric and isotonic exercises were performed separately. In isometric CTAR,
6 the person was asked to chin tuck against the device 3 times for 60 seconds with no repetition. In isotonic CTAR, the person performs
7 30 consecutive repetitions by strongly pressing against the resistance of the device and releasing it again. To perform it correctly, the
8 therapist explained and demonstrated the exercise methods before the intervention. The emphasised the correct chin tuck posture, so
9 that people do not flex their heads against the devices. Concomitant therapy: Conventional dysphagia treatment was available to all
10 such as orofacial muscle exercises, thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced
11 occupational therapist performed this for 30 minutes/day, five days per week for 4 weeks.

1

2 **1.1.77.2.2. Usual care (N = 12)**

3 Usual care only. Concomitant therapy: Conventional dysphagia treatment was available to all such as orofacial muscle exercises,
4 thermal tactile stimulation and therapeutic or compensatory maneuvers. An experienced occupational therapist performed this for 30
5 minutes/day, five days per week for 4 weeks.

6

7 **1.1.77.3. Characteristics**8 **1.1.77.3.1. Arm-level characteristics**

Characteristic	Behavioural interventions (chin-tuck against resistance exercises) (N = 13)	Usual care (N = 12)
% Female	n = 5 ; % = 39	n = 7 ; % = 64
Sample size		
Mean age (SD) (years)	62.16 (17.27)	58.43 (12.51)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Dysarthria	n = 1 ; % = 9	n = 0 ; % = 0
Sample size		
Facial palsy	n = 2 ; % = 18	n = 2 ; % = 18

Characteristic	Behavioural interventions (chin-tuck against resistance exercises) (N = 13)	Usual care (N = 12)
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	37.24 (8.54)	32.14 (14.38)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Oral feeding	n = 4 ; % = 36	n = 5 ; % = 46
Sample size		
Tube feeding	n = 7 ; % = 64	n = 6 ; % = 55
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Middle cerebral artery	n = 7 ; % = 64	n = 9 ; % = 82
Sample size		
Internal capsule	n = 2 ; % = 18	n = 1 ; % = 9
Sample size		

Characteristic	Behavioural interventions (chin-tuck against resistance exercises) (N = 13)	Usual care (N = 12)
Basal ganglia	n = 2 ; % = 18	n = 1 ; % = 9
Sample size		

1 Only reports baseline characteristics for 11 people in the intervention group and 11 people in the control group.

2

3 **1.1.77.4. Outcomes**

4 **1.1.77.4.1. Study timepoints**

- 5 • Baseline
- 6 • 4 week (<3 months)

7

8 **1.1.77.4.2. Continuous outcomes**

Outcome	Behavioural interventions (chin-tuck against resistance exercises), Baseline, N = 13	Behavioural interventions (chin-tuck against resistance exercises), 4 week, N = 11	Usual care, Baseline, N = 12	Usual care, 4 week, N = 11
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change scores. Mean (SD)	5.73 (1.19)	-2.18 (1.83)	5.18 (1.6)	-0.45 (1.63)
Swallowing ability (Functional dysphagia scale)	38.64 (18.41)	-16.27 (9.79)	33.18 (16.23)	-6 (7.14)

Outcome	Behavioural interventions (chin-tuck against resistance exercises), Baseline, N = 13	Behavioural interventions (chin-tuck against resistance exercises), 4 week, N = 11	Usual care, Baseline, N = 12	Usual care, 4 week, N = 11
Scale range: 0-100. Change scores.				
Mean (SD)				

1 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better
2 Swallowing ability (Functional dysphagia scale) - Polarity - Lower values are better

3

4

5 **1.1.77.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.77.4.4. Continuous outcomes-Swallowing ability (Functional dysphagia scale)-Mean SD-Behavioural interventions (chin-tuck against resistance exercises)-Usual care-t4**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.77.4.5. Continuous outcomes-Occurrence of aspiration (Penetration Aspiration Scale)-Mean SD-Behavioural interventions (chin-tuck against resistance exercises)-Usual care-t4**

10

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.78. Park, 2016**

Bibliographic Reference	Park, J-S; Oh, D-H; Hwang, N-K; Lee, J-H; Effects of neuromuscular electrical stimulation combined with effortful swallowing on post-stroke oropharyngeal dysphagia: a randomised controlled trial.; Journal of oral rehabilitation; 2016; vol. 43 (no. 6); 426-34
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3

4 **1.1.78.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	KCT0001641.
Study type	Randomised controlled trial (RCT)
Study location	South Korea.
Study setting	Inpatients.
Study dates	January 2015 to April 2015.

Sources of funding	This research was carried out without funding.
Inclusion criteria	Dysphagia from a stroke that was confirmed by a videofluoroscopic swallowing study; onset duration >6 months; able to swallow against resistance applied by using electrical stimulation and cooperate actively in training; Mini-Mental State Examination score of at least 24.
Exclusion criteria	Psychiatric disorders or dementia; implanted cardiac pacemaker; severe communication disorder such as severe aphasia; history of seizure or epilepsy; unstable medical conditions; skin problems associated with electrode placement.
Recruitment / selection of participants	People were recruited from the rehabilitation centre of a local university hospital.
Intervention(s)	<p>Neuromuscular electrical stimulation (NMES) N=31</p> <p>30 minutes of neuromuscular electrical stimulation with effortful swallowing and conventional dysphagia therapy. Electrical stimulation was performed using the VitalStim. Electrodes were placed on the anterior neck region in the infrahyoid area targeting the sternohyoid muscles. The electrical stimulation unit provided two channels of bipolar electrical stimulation at a fixed 80 Hz pulse rate and a fixed biphasic pulse duration of 700 microseconds. The stimulation intensity was set to a level to induce a strong muscle contraction. The intensity ranged from 9.0 to 14.0mA with it being increased gradually at an interval of 0.5mA until the person felt a grabbing sensation in their neck. People were asked to perform an effortful swallow with their saliva or a small amount of water during the stimulation (viscosity was adjusted using a thickener as required). Therapy was provided for 30 minutes per session, 5 sessions per week for 6 weeks.</p> <p>Concomitant therapy: All people received effortful swallowing exercises and conventional dysphagia therapy (additional information not provided).</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=30</p> <p>Described as placebo NMES in the study, where sensory stimulation only was provided (intensity averaging from 3.0 to 5.0 mA). Otherwise the same procedure.</p> <p>Concomitant therapy: All people received effortful swallowing exercises and conventional dysphagia therapy (additional information not provided).</p>
Number of participants	61
Duration of follow-up	6 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be completers only.

1 **1.1.78.2. Study arms**

2 **1.1.78.2.1. Neuromuscular electrical stimulation (NMES) (N = 31)**

3 30 minutes of neuromuscular electrical stimulation with effortful swallowing and conventional dysphagia therapy. Electrical
 4 stimulationw as performed using the VitalStim. Electrodes were placed on the anterior neck region in the infrahyoid area targeting the
 5 sternohyoid muscles. The electrical stimulation unit provided two channels of bipolar electrical stimulation at a fixed 80 Hz pulse rate
 6 and a fixed biphasic pulse duration of 700 microseconds. The stimulation intensity was set to a level to induce a strong muscle
 7 contraction. The intensity ranged from 9.0 to 14.0mA with it being increased gradually at an interval of 0.5mA until the person felt a
 8 grabbing sensation in their neck. People were asked to perform an effortful swallow with their saliva or a small amount of water during
 9 the stimulation (viscosity was adjusted using a thickener as required). Therapy was provided for 30 minutes per session, 5 sessions
 10 per week for 6 weeks. Concomitant therapy: All people received effortful swallowing exercises and conventional dysphagia therapy
 11 (additional information not provided).

13 **1.1.78.2.2. Placebo/sham therapy (N = 30)**

14 Described as placebo NMES in the study, where sensory stimulation only was provided (intensity averaging from 3.0 to 5.0 mA).
 15 Otherwise the same procedure. Concomitant therapy: All people received effortful swallowing exercises and conventional dysphagia
 16 therapy (additional information not provided).

18 **1.1.78.3. Characteristics**

19 **1.1.78.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 31)	Placebo/sham therapy (N = 30)
% Female	n = 13 ; % = 52	n = 11 ; % = 44
Sample size		
Mean age (SD) (years)	54 (11.93)	55.8 (12.23)
Mean (SD)		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 31)	Placebo/sham therapy (N = 30)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	35.44 (5.63)	36 (6.05)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1 Only 25 participants are reported for each group.

2

3 **1.1.78.4. Outcomes**

4 **1.1.78.4.1. Study timepoints**

- 5 • Baseline
- 6 • 6 week (<3 months)

1

2 **1.1.78.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 31	Neuromuscular electrical stimulation (NMES), 6 week, N = 25	Placebo/sham therapy, Baseline, N = 30	Placebo/sham therapy, 6 week, N = 25
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Change scores. Mean (SD)	4.96 (1.4)	-1.36 (1.5)	4.72 (1.57)	-0.2 (0.5)
Swallowing ability (Videofluoroscopic Dysphagia Scale) Scale range: 0-100. Change scores. Mean (SD)	59.28 (7.49)	-14.14 (8.8)	59.52 (10.59)	-2.1 (4.04)

3 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

4 Swallowing ability (Videofluoroscopic Dysphagia Scale) - Polarity - Lower values are better

5

6

1 **1.1.78.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.78.4.4. Continuousoutcomes-Occurrenceofaspiration(PenetrationAspirationScale)-MeanSD-Neuromuscular electrical**
 3 **stimulation (NMES)-Placebo/sham therapy-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.78.4.5. Continuousoutcomes-Swallowingability(VideofluoroscopicDysphagiaScale)-MeanSD-Neuromuscular electrical**
 6 **stimulation (NMES)-Placebo/sham therapy-t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.79. Park, 2013**

Bibliographic Reference Park, J-W; Oh, J-C; Lee, J-W; Yeo, J-S; Ryu, K H; The effect of 5Hz high-frequency rTMS over contralesional pharyngeal motor cortex in post-stroke oropharyngeal dysphagia: a randomized controlled study.; Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society; 2013; vol. 25 (no. 4); 324-e250

9

10 **1.1.79.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Republic of Korea.
Study setting	Inpatients.
Study dates	November 2010 to January 2012.
Sources of funding	Research was supported by Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education, Science and Technology (grant number: 2010-0003964).
Inclusion criteria	Unilateral hemispheric stroke; oropharyngeal dysphagia confirmed by a videofluoroscopic swallowing study; oropharyngeal dysphagia that persisted over 1 month after stroke onset.
Exclusion criteria	Metal implants or a pacemaker in their body; history of seizures.
Recruitment / selection of participants	No additional information.
Intervention(s)	Transcranial magnetic stimulation (TMS) N=9 10 minutes of real 5Hz transcranial magnetic stimulation. A session of stimulation consisted of 10 trains of 5 Hz stimulation, each lasting for 10 seconds and then repeated every minute given through a 70 mm figure-of-eight coil positioned over the pharyngeal hot spot of the intact hemisphere. The intensity of stimulation was set at 90% of the thenar motor threshold of the same hemisphere. Delivered for 2 weeks.

	Concomitant therapy: No additional information.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=9</p> <p>Sham TMS for the same time period. Same protocol except the coil was tilted 90 degrees to produce the same noise but not produce motor cortical stimulation.</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	18
Duration of follow-up	4 weeks (2 weeks after the end of intervention).

Indirectness	No additional information.
Additional comments	Method of analysis appears to be ITT no drop outs.

1

2 **1.1.79.2. Study arms**

3 **1.1.79.2.1. Transcranial magnetic stimulation (TMS) (N = 9)**

4 10 minutes of real 5Hz transcranial magnetic stimulation. A session of stimulation consisted of 10 trains of 5 Hz stimulation, each
 5 lasting for 10 seconds and then repeated every minute given through a 70 mm figure-of-eight coil positioned over the pharyngeal hot
 6 spot of the intact hemisphere. The intensity of stimulation was set at 90% of the thenar motor threshold of the same hemisphere.
 7 Delivered for 2 weeks. Concomitant therapy: No additional information.

8

9 **1.1.79.2.2. Placebo/sham therapy (N = 9)**

10 Sham TMS for the same time period. Same protocol except the coil was tilted 90 degrees to produce the same noise but not produce
 11 motor cortical stimulation. Concomitant therapy: No additional information.

12

13 **1.1.79.3. Characteristics**

14 **1.1.79.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 9)	Placebo/sham therapy (N = 9)
% Female	n = 4 ; % = 44	n = 4 ; % = 44
Sample size		
Mean age (SD) (years)	73.7 (3.8)	68.9 (9.3)
Mean (SD)		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 9)	Placebo/sham therapy (N = 9)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	59.9 (16.3)	63.9 (26.8)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.79.4. Outcomes**3 **1.1.79.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)
- 6 • 4 week (<3 months)

7

1 **1.1.79.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 9	Transcranial magnetic stimulation (TMS), 2 week, N = 9	Transcranial magnetic stimulation (TMS), 4 week, N = 9	Placebo/sham therapy, Baseline, N = 9	Placebo/sham therapy, 2 week, N = 9	Placebo/sham therapy, 4 week, N = 9
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values. Mean (SD)	3.41 (2.32)	NA (NA)	1.37 (0.87)	3.3 (2.03)	NA (NA)	3.11 (2.15)
Swallowing ability (video fluoroscopic dysphagia score) Scale range: 0-100. Final values. Reports value for the control group at 4 weeks only. Mean (SD)	33.6 (12.1)	25.3 (9.8)	NR (NR)	23.4 (14.6)	21.2 (15.6)	NA (NA)

2 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

3 Swallowing ability (video fluoroscopic dysphagia score) - Polarity - Lower values are better

4

5

1 **1.1.79.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.79.4.4. Continuousoutcomes-Occurrenceofaspiration(PenetrationAspirationScale)-MeanSD-Transcranial magnetic**
 3 **stimulation (TMS)-Placebo/sham therapy-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.79.4.5. Continuousoutcomes-Swallowingability(videofluoroscopicdysphagiascore)-MeanSD-Transcranial magnetic**
 6 **stimulation (TMS)-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.80. Perez, 1998**

Bibliographic Reference Perez, I; Smithard, D G; Davies, H; Kalra, L; Pharmacological treatment of dysphagia in stroke.; Dysphagia; 1998; vol. 13 (no. 1); 12-6

9

10 **1.1.80.1. Study details**

Secondary publication of another included	No additional information
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study- see primary study for details	
Other publications associated with this study included in review	Smithard, D.; Perez, I.; Kalra, L. (1997) Pharmacological Treatment of Dysphagia in Stroke. Cerebrovascular Diseases 7(suppl4): 36 This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	UK
Study setting	Queen Mary's NHS Trust
Study dates	No additional information
Sources of funding	No additional information
Inclusion criteria	No additional information
Exclusion criteria	Inability to sit, high clinical risk of aspiration, receptive dysphasia, cognitive impairment, pre-stroke dysphagia, existing neurological or psychiatric disease, current treatment with calcium channel blockers or aminophyllin
Recruitment / selection of participants	No additional information
Intervention(s)	Slow release nifedipine 30 mg orally, treatment for 4 weeks
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Placebo - matching tablet; treatment for 4 weeks
Number of participants	17
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.80.2. Study arms**3 **1.1.80.2.1. *Nifedipine (N = 8)***

4 30 mg orally daily, Bayer, UK

5

6 **1.1.80.2.2. *Placebo (N = 9)***

7

1 **1.1.80.3. Characteristics**2 **1.1.80.3.1. Study-level characteristics**

Characteristic	Study (N = 17)
% Female	NR
Nominal	
Mean age (SD)	NR
Nominal	
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

1 **1.1.80.4. Outcomes**2 **1.1.80.4.1. Study timepoints**

- 3 • Baseline
- 4 • 4 week

5

6 **1.1.80.4.2. dichotomous outcomes**

Outcome	Nifedipine, Baseline, N = 8	Nifedipine, 4 week, N = 8	Placebo, Baseline, N = 9	Placebo, 4 week, N = 9
Mortality	n = NR ; % = NR	n = 1 ; % = 12.5	n = NR ; % = NR	n = 1 ; % = 11.1
No of events				
Dysphagia present	n = NR ; % = NR	n = 3 ; % = 37	n = NR ; % = NR	n = 5 ; % = 56
No of events				

7 Mortality - Polarity - Lower values are better

8 Dysphagia present - Polarity - Lower values are better

9

10

11 **1.1.80.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**12 **1.1.80.4.4. dichotomousoutcomes-Mortality-NoOfEvents-Nifedipine-Placebo-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (due to randomisation process)

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.80.4.5. dichotomousoutcomes-Dysphagiapresent-NoOfEvents-Nifedipine-Placebo-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (<i>due to randomisation process</i>)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.81. Sawan, 2020**

Bibliographic Reference Sawan, S.A.E.; Reda, A.M.; Kamel, A.H.; Ali, M.A.M.; Transcranial direct current stimulation (tDCS): its effect on improving dysphagia in stroke patients; Egyptian Journal of Neurology, Psychiatry and Neurosurgery; 2020; vol. 56 (no. 1); 111

5

6 **1.1.81.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.

Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Egypt.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No specific grant from any funding agency in the public, commercial or not-for-profit sectors.
Inclusion criteria	Acute or subacute ischaemic stroke.
Exclusion criteria	Severe impairment of swallowing before the stroke; difficulty communicating; impaired cognition; neurodegenerative disorder; major psychiatric illness such as depression; unstable health issues such as severe cardiac disease or renal failure; intracranial device and/or metal excluding tDCS application; chronic drug use that could affect brain activity such as anti-epileptics or antipsychotics; alcohol abuse; epilepsy; pregnancy; pacemaker or other implanted electrically sensitive device.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Transcranial direct current stimulation (tDCS) N=20</p> <p>Anodal tDCS on pharyngeal motor cortex and a selected physiotherapy program to improve swallowing. For anodal stimulation of the pharyngeal motor cortex, the anode was placed over the healthy hemisphere at mid-distance between C3 and T3 on the left or C4 and T4 on the right according to international 10/20 EEG electrode system. A reference electrode was placed over the contralateral supraorbital region. A constant current of 2mA intensity was applied for 30 minutes. Stimulation was applied for five consecutive sessions for 2 weeks.</p> <p>Concomitant therapy: Everyone received a selected physiotherapy program.</p>
Subgroup 1: Severity of	Not stated/unclear

dysphagia (as stated by category)	
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=20</p> <p>Sham therapy applied for the same amount of time. The sham produced the same tingling sensation but had no other active effect through the use of a different machine.</p> <p>Concomitant therapy: Everyone received a selected physiotherapy program.</p>
Number of participants	40
Duration of follow-up	2 weeks (end of intervention)
Indirectness	Outcome indirectness - Dichotomous reporting of an outcome specified to be continuous in the protocol.
Additional comments	No additional information. Appears to be ITT no drop outs.

1 **1.1.81.2. Study arms**

2 **1.1.81.2.1. Transcranial direct current stimulation (tDCS) (N = 20)**

3 Anodal tDCS on pharyngeal motor cortex and a selected physiotherapy program to improve swallowing. For anodal stimulation of the
4 pharyngeal motor cortex, the anode was placed over the healthy hemisphere at mid-distance between C3 and T3 on the left or C4 and
5 T4 on the right according to international 10/20 EEG electrode system. A reference electrode was placed over the contralateral
6 supraorbital region. A constant current of 2mA intensity was applied for 30 minutes. Stimulation was applied for five consecutive
7 sessions for 2 weeks. Concomitant therapy: Everyone received a selected physiotherapy program.

8

9 **1.1.81.2.2. Placebo/sham therapy (N = 20)**

10 Sham therapy applied for the same amount of time. The sham produced the same tingling sensation but had no other active effect
11 through the use of a different machine. Concomitant therapy: Everyone received a selected physiotherapy program.

12

13 **1.1.81.3. Characteristics**

14 **1.1.81.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 20)	Placebo/sham therapy (N = 20)
% Female	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Mean age (SD) (years)	53.3 (5.04)	50.3 (5.22)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial direct current stimulation (tDCS) (N = 20)	Placebo/sham therapy (N = 20)
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	2 to 10	2 to 25
Range		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.81.4. Outcomes**3 **1.1.81.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)

6

1 **1.1.81.4.2. Dichotomous outcome**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 20	Transcranial direct current stimulation (tDCS), 2 week, N = 20	Placebo/sham therapy, Baseline, N = 20	Placebo/sham therapy, 2 week, N = 20
Occurrence of aspiration (positive aspiration) Dichotomous reporting of an outcome specified to be continuous in the protocol.	n = 20 ; % = 100	n = 6 ; % = 30	n = 16 ; % = 80	n = 17 ; % = 85
No of events				

2 Occurrence of aspiration (positive aspiration) - Polarity - Lower values are better

3

4

5 **1.1.81.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.81.4.4. Dichotomous outcome - Occurrence of aspiration (positive aspiration) - No of Events - Transcranial direct current stimulation (tDCS) - Placebo/sham therapy - t2**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable (Outcome indirectness - Dichotomous reporting of an outcome specified to be continuous in the protocol.)

8

1 **1.1.82. Shigematsu, 2013**

Bibliographic Reference Shigematsu, Takashi; Fujishima, Ichiro; Ohno, Kikuo; Transcranial direct current stimulation improves swallowing function in stroke patients.; Neurorehabilitation and neural repair; 2013; vol. 27 (no. 4); 363-9

2

3 **1.1.82.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Japan.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No financial support for the research.
Inclusion criteria	Occurrence of stroke at least 4 weeks prior to enrollment; admitted to hospital for rehabilitation after stroke; chronic, severe poststroke dysphagia; the need for tube feeding therapy.
Exclusion criteria	Subarachnoid haemorrhage; history of epileptic seizures; severe consciousness disturbance; organic neck disease; history of surgery, except for tracheostomy.

Recruitment / selection of participants	People admitted to the hospital.
Intervention(s)	<p>Transcranial direct current stimulation (tDCS) N=10</p> <p>Anodal tDCS for 10 days. The anodal electrodes were placed over the ipsilesional hemisphere, 15 cm from Cz to A1 and 2cm in the front direction on the right and from Cz to A2 in the front direction on the left according to the international 10-20 EEG electrode system; the cathode was placed over the contralesional supraorbital region. The current was 1mA and was provided for 20 minutes a day for 10 days (over 2 weeks).</p> <p>Concomitant therapy: People who were at risk of aspiration and could not meet the safety conditions required for oral intake were tube fed and underwent oral intake rehabilitation. People who could eat and drink safely with compensatory conditions received both oral intake rehabilitation and indirect therapy. Indirect therapy consisted of blowing, ice massage, pushing exercises, supraglottic swallowing, Shaker exercise, effortful swallow and K-point stimulation. People with swallow delay received training to induce the swallow reflex, such as ice massage and K-point stimulation. People with pharyngeal residue received muscle strengthening exercise, such as the Shaker exercise.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=10</p> <p>Sham tDCS. Same procedure but the current was put up to 1mA and then reduced over 40 seconds (so people felt an initial sensation but then there was no active treatment afterwards).</p> <p>Concomitant therapy: People who were at risk of aspiration and could not meet the safety conditions required for oral intake were tube fed and underwent oral intake rehabilitation. People who could eat and drink safely with compensatory conditions received both oral intake rehabilitation and indirect therapy. Indirect therapy consisted of blowing, ice massage, pushing exercises, supraglottic swallowing, Shaker exercise, effortful swallow and K-point stimulation. People with swallow delay received training to induce the swallow reflex, such as ice massage and K-point stimulation. People with pharyngeal residue received muscle strengthening exercise, such as the Shaker exercise.</p>
Number of participants	20
Duration of follow-up	10 weeks (2 months after end of treatment)
Indirectness	No additional information.
Additional comments	Method of analysis appears to be ITT no drop outs.

1

2 **1.1.82.2. Study arms**3 **1.1.82.2.1. Transcranial direct current stimulation (tDCS) (N = 10)**

4 Anodal tDCS for 10 days. The anodal electrodes were placed over the ipsilesional hemisphere, 15 cm from Cz to A1 and 2cm in the
5 front direction on the right and from Cz to A2 in the front direction on the left according to the international 10-20 EEG electrode
6 system; the cathode was placed over the contralesional supraorbital region. The current was 1mA and was provided for 20 minutes a
7 day for 10 days (over 2 weeks). Concomitant therapy: People who were at risk of aspiration and could not meet the safety conditions
8 required for oral intake were tube fed and underwent oral intake rehabilitation. People who could eat and drink safely with

1 compensatory conditions received both oral intake rehabilitation and indirect therapy. Indirect therapy consisted of blowing, ice
 2 massage, pushing exercises, supraglottic swallowing, Shaker exercise, effortful swallow and K-point stimulation. People with swallow
 3 delay received training to induce the swallow reflex, such as ice massage and K-point stimulation. People with pharyngeal residue
 4 received muscle strengthening exercise, such as the Shaker exercise.

5

6 **1.1.82.2.2. Placebo/sham therapy (N = 10)**

7 Sham tDCS. Same procedure but the current was put up to 1mA and then reduced over 40 seconds (so people felt an initial sensation
 8 but then there was no active treatment afterwards). Concomitant therapy: People who were at risk of aspiration and could not meet the
 9 safety conditions required for oral intake were tube fed and underwent oral intake rehabilitation. People who could eat and drink safely
 10 with compensatory conditions received both oral intake rehabilitation and indirect therapy. Indirect therapy consisted of blowing, ice
 11 massage, pushing exercises, supraglottic swallowing, Shaker exercise, effortful swallow and K-point stimulation. People with swallow
 12 delay received training to induce the swallow reflex, such as ice massage and K-point stimulation. People with pharyngeal residue
 13 received muscle strengthening exercise, such as the Shaker exercise.

14

15 **1.1.82.3. Characteristics**

16 **1.1.82.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 10)	Placebo/sham therapy (N = 10)
% Female	n = 3 ; % = 30	n = 3 ; % = 30
Sample size		
Mean age (SD) (years)	66.9 (6.3)	64.7 (8.9)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Transcranial direct current stimulation (tDCS) (N = 10)	Placebo/sham therapy (N = 10)
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	12.9 (7.8)	12.1 (9)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 10 ; % = 100	n = 10 ; % = 100
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Putamen	n = 2 ; % = 20	n = 1 ; % = 10
Sample size		
Internal capsule	n = 1 ; % = 10	n = 1 ; % = 10
Sample size		
Medulla oblongata	n = 2 ; % = 20	n = 0 ; % = 0
Sample size		
Frontotemporal	n = 1 ; % = 10	n = 0 ; % = 0
Sample size		

Characteristic	Transcranial direct current stimulation (tDCS) (N = 10)	Placebo/sham therapy (N = 10)
Sample size		
Corona radiata	n = 1 ; % = 10	n = 0 ; % = 0
Sample size		
Corona radiata	n = 1 ; % = 10	n = 0 ; % = 0
Sample size		
Pons	n = 1 ; % = 10	n = 4 ; % = 40
Sample size		
Thalamus	n = 1 ; % = 10	n = 1 ; % = 10
Sample size		
Frontoparietal	n = 1 ; % = 10	n = 2 ; % = 20
Sample size		
Caudate nucleus	n = 0 ; % = 0	n = 1 ; % = 10
Sample size		

1

2 **1.1.82.4. Outcomes**3 **1.1.82.4.1. Study timepoints**

- 4 • Baseline
- 5 • 10 week (<3 months)

6

1 **1.1.82.4.2. Continuous outcomes**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 10	Transcranial direct current stimulation (tDCS), 10 week, N = 10	Placebo/sham therapy, Baseline, N = 10	Placebo/sham therapy, 10 week, N = 10
Swallowing ability (Dysphagia Outcome Severity Scale) Scale range: 1-7. Final values. Mean (SD)	1.9 (0.7)	4.7 (0.9)	2.3 (1)	3.5 (0.9)

2 Swallowing ability (Dysphagia Outcome Severity Scale) - Polarity - Lower values are better

3

4

5 **1.1.82.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.82.4.4. Continuous outcomes-Swallowing ability (Dysphagia Outcome Severity Scale)-Mean SD-Transcranial direct current stimulation (tDCS)-Placebo/sham therapy-t10**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.83. Smithard, 1997**

Bibliographic Reference Smithard, D.; Perez, I.; Kalra, L.; Pharmacological Treatment of Dysphagia in Stroke; Cerebrovascular Diseases; 1997; vol. 7 (no. suppl4); 36

1

2 **1.1.83.1. Study details**

Secondary publication of another included study- see primary study for details	Perez, I, Smithard, D G, Davies, H et al. (1998) Pharmacological treatment of dysphagia in stroke. <i>Dysphagia</i> 13(1): 12-6
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. <i>The Cochrane database of systematic reviews</i> 10: cd000323

3

4

5 **1.1.84. Song, 2004**

Bibliographic Reference	Song, Q-L; Swallowing and ingesting training and nursing in patients with swallowing disorder after stroke; <i>Chinese journal of clinical rehabilitation</i> ; 2004; vol. 8 (no. 19); 3722-3723
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6

7 **1.1.84.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
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Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	No additional information.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	People with dysphagia identified by water swallow test.
Exclusion criteria	No additional information.
Recruitment / selection of participants	No additional information.
Intervention(s)	Behavioural intervention (nurse-led swallowing exercises) N=29 Nurse-led swallowing exercises, oral stimulation and oral care. Concomitant therapy: No additional information.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=24 Not explicitly stated. Concomitant therapy: No additional information.
Number of participants	53
Duration of follow-up	1 month.
Indirectness	No additional information.
Additional comments	No additional information.

1 **1.1.84.2. Study arms**2 **1.1.84.2.1. Behavioural intervention (nurse-led swallowing exercises) (N = 29)**

3 Nurse-led swallowing exercises, oral stimulation and oral care. Concomitant therapy: No additional information.

4

5 **1.1.84.2.2. Usual care (N = 24)**

6 Not explicitly stated. Concomitant therapy: No additional information.

7

8 **1.1.84.3. Characteristics**9 **1.1.84.3.1. Arm-level characteristics**

Characteristic	Behavioural intervention (nurse-led swallowing exercises) (N = 29)	Usual care (N = 24)
% Female	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Mean age (SD)	NR (NR)	NR (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Behavioural intervention (nurse-led swallowing exercises) (N = 29)	Usual care (N = 24)
Time after stroke	NR (NR)	NR (NR)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.84.4. Outcomes**3 **1.1.84.4.1. Study timepoints**

- 4 • Baseline
- 5 • 1 month (<3 months)

6

7 **1.1.84.4.2. Dichotomous outcomes**

Outcome	Behavioural intervention (nurse-led swallowing exercises), Baseline, N = 29	Behavioural intervention (nurse-led swallowing exercises), 1 month, N = 35	Usual care, Baseline, N = 24	Usual care, 1 month, N = 24
Dysphagia present/return to normal diet (Dysphagia at end of	n = NA ; % = NA	n = 6 ; % = 21	n = NA ; % = NA	n = 10 ; % = 42

Outcome	Behavioural intervention (nurse-led swallowing exercises), Baseline, N = 29	Behavioural intervention (nurse-led swallowing exercises), 1 month, N = 35	Usual care, Baseline, N = 24	Usual care, 1 month, N = 24
trial)				
No of events				
Occurrence of chest infections (chest infection or pneumonia)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 3 ; % = 13
No of events				

1 Dysphagia present/return to normal diet (Dysphagia at end of trial) - Polarity - Lower values are better
 2 Occurrence of chest infections (chest infection or pneumonia) - Polarity - Lower values are better

3
4

5 **1.1.84.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.84.4.4. Dichotomous outcomes-Dysphagia present/return to normal diet (Dysphagia at end of trial)-No Of Events-Behavioural**
 7 **intervention (nurse-led swallowing exercises)-Usual care-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.84.4.5. Dichotomous outcomes-Occurrence of chest infections (chest infection or pneumonia)-No Of Events-Behavioural**
 2 **intervention (nurse-led swallowing exercises)-Usual care-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.85. Su, 2011**

Bibliographic Reference Su, X; Lai, X; The clinical study on 'Tongduliaoshen' (an acupuncture treatment) for the treatment of dysphagia after stroke; International Journal of Clinical Acupuncture; 2011; vol. 20 (no. 3); 104-8

5

6 **1.1.85.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)

Study location	China.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	All people meet the diagnosis standards of cerebrovascular diseases set by the Fourth National Conference on Cerebrovascular Disease; all people diagnosed with stroke are confirmed with a head CT and MRI; people are evaluated with the grading standards of the Video Fluoroscopic Swallowing Study and the Kubota Water Swallowing Function Test; the course of disease is longer than 30 days; the vital signs are stable and are awake enough to respond well to treatment.
Exclusion criteria	People also have disorders of consciousness and obvious cognition difficulties; people have a severe organic disease, such as heart disease; dysphagia is caused by bulbar paralysis.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Acupuncture N=30</p> <p>Acupoints along the head and neck regions of the Du Meridian, including: Fengu (DU16), Yamen (DU15), Dazhui (DU14), Baihui (DU20), Shangxing (DU23) and Shuigou (DU26), etc. were used. Needles were inserted and twirled for 1-2 minutes with a frequency of 200 r/min until deqi sensation. After obtaining the correct Qi sensations, Shuigou and Fengfu, Shangxing and Baihui, and Yamen and Dazhui were connected to positive and negative electrodes of a pulse electro-instrument. A continuous wave was applied with a frequency of 120 times/min. Total time of electroacupuncture was 30 minutes. People received two treatment courses (15 days for each course, 30 days in total).</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Usual care N=30</p> <p>Includes basic swallowing training and food intake training. Basic swallow training included movements of the lips, lower jaw and tongue. Major movements were combined with supplementary movements. Breathing exercises including abdominal breathing and shrink mouth breathing. Cold stimulation: a frozen cotton stick to touch and excite the palatine arch. Coughing exercise: Method to cough consciousness. Food intake training: Eating several types of food to train different styles of eating. People received two treatment courses (15 days for each course, 30 days in total).</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	60
Duration of follow-up	30 days (end of intervention).
Indirectness	No additional information.
Additional comments	No additional information.

1 **1.1.85.2. Study arms**2 **1.1.85.2.1. Acupuncture (N = 30)**

3 Acupoints along the head and neck regions of the Du Meridian, including: Fengu (DU16), Yamen (DU15), Dazhui (DU14). Baihui
 4 (DU20), Shangxing (DU23) and Shuigou (DU26), etc. were used. Needles were inserted and twirled for 1-2 minutes with a frequency
 5 of 200 r/min until deqi sensation. After obtaining the correct Qi sensations, Shuigou and Fengfu, Shangxing and Baihui, and Yamen
 6 and Dazhui were connected to positive and negative electrodes of a pulse electro-instrument. A continuous wave was applied with a
 7 frequency of 120 times/min. Total time of electroacupuncture was 30 minutes. People received two treatment courses (15 days for
 8 each course, 30 days in total). Concomitant therapy: No additional information.

9

10 **1.1.85.2.2. Usual care (N = 30)**

11 Includes basic swallowing training and food intake training. Basic swallow training included movements of the lips, lower jaw and
 12 tongue. Major movements were combined with supplementary movements. Breathing exercises including abdominal breathing and
 13 shrink mouth breathing. Cold stimulation: a frozen cotton stick to touch and excite the palatine arch. Coughing exercise: Method to
 14 cough consciousness. Food intake training: Eating several types of food to train different styles of eating. People received two
 15 treatment courses (15 days for each course, 30 days in total). Concomitant therapy: No additional information.

16

17 **1.1.85.3. Characteristics**18 **1.1.85.3.1. Arm-level characteristics**

Characteristic	Acupuncture (N = 30)	Usual care (N = 30)
% Female	n = 13 ; % = 43	n = 10 ; % = 33
Sample size		
Mean age (SD) (years)	35 to <i>empty data</i>	50 to 79
Range		

Characteristic	Acupuncture (N = 30)	Usual care (N = 30)
Mean age (SD) (years)	67.5 (NR)	67.4 (NR)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	40 to 365	30 to 365
Range		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.85.4. Outcomes**3 **1.1.85.4.1. Study timepoints**

- 4 • Baseline
- 5 • 30 day (<3 months)

1

2 **1.1.85.4.2. Dichotomous outcomes**

Outcome	Acupuncture, Baseline, N = 30	Acupuncture, 30 day, N = 30	Usual care, Baseline, N = 30	Usual care, 30 day, N = 30
Occurrence of chest infection (aspiration pneumonia)	n = NA ; % = NA	n = 8 ; % = 26.67	n = NA ; % = NA	n = 10 ; % = 33.33
No of events				
Dysphagia present/return to normal diet (people not cured from the treatment)	n = NA ; % = NA	n = 19 ; % = 63	n = NA ; % = NA	n = 25 ; % = 83
No of events				

3 Occurrence of chest infection (aspiration pneumonia) - Polarity - Lower values are better

4 Dysphagia present/return to normal diet (people not cured from the treatment) - Polarity - Lower values are better

5 **1.1.85.4.3. Continuous outcomes**

Outcome	Acupuncture, Baseline, N = 30	Acupuncture, 30 day, N = 30	Usual care, Baseline, N = 30	Usual care, 30 day, N = 30
Swallowing ability (videofluoroscopic swallowing study) Scale range: 0-8. Change scores.	2 (1.26)	4.9 (2.64)	2.57 (1.41)	3.03 (2.65)
Mean (SD)				

6 Swallowing ability (videofluoroscopic swallowing study) - Polarity - Higher values are better

7

8

1 **1.1.85.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.85.4.5. Dichotomous outcomes - Occurrence of chest infection (aspiration pneumonia) - No of Events - Acupuncture - Usual care -**
 3 **t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.85.4.6. Dichotomous outcomes - Dysphagia present/return to normal diet (people not cured from the treatment) - No of Events -**
 6 **Acupuncture - Usual care - t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.85.4.7. Continuous outcomes - Swallowing ability (video fluoroscopic swallowing study) - Mean SD - Acupuncture - Usual care - t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.86. Suntrup, 2015**

Bibliographic Reference Suntrup, Sonja; Marian, Thomas; Schroder, Jens Burchard; Suttrup, Inga; Muhle, Paul; Oelenberg, Stephan; Hamacher, Christina; Minnerup, Jens; Warnecke, Tobias; Dziewas, Rainer; Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial.; Intensive care medicine; 2015; vol. 41 (no. 9); 1629-37

2

3 **1.1.86.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	Dziewas, R. (2014) DRKS00005509 A single-centre, double blind, randomised controlled clinical trial to evaluate the effect of electrical pharyngeal stimulation as a treatment for stroke related dysphagia in tracheotomized stroke patients.
Trial name / registration number	Trial registration: ClinicalTrials.gov NCT01956175.
Study type	Randomised controlled trial (RCT)
Study location	Turkey
Study setting	neurological intensive care unit (ICU) at the University Hospital Muenster
Study dates	June 2013 and August 2014
Sources of funding	No additional information
Inclusion criteria	Patients were eligible to be included if they were tracheotomized and suffered from severe persistent dysphagia (as defined in Sect. "Dysphagia assessment") rendering decannulation impossible.
Exclusion criteria	Exclusion criteria were pre-existing dysphagia or presence of implanted electronic devices of any kind.

Recruitment / selection of participants	Between June 2013 and August 2014 consecutive acute stroke patients from our neurological intensive care unit (ICU) at the University Hospital Muenster, who were completely weaned from the ventilator and able stay alert for at least 15 min, were screened for possible inclusion in this study. Patient recruitment was stopped once the target sample size was reached.
Intervention(s)	<p>Stimulation was delivered via the Phagenyx™ catheter system and base station (Phagenesis Ltd, UK). The system consists of a nasogastric feeding tube housing a pair of bipolar titanium ring electrodes with a distance of 10 mm in between. The electrodes were positioned in the middle pharynx. Correct positioning of the electrodes was visually confirmed by fiberoptic endoscopic evaluation of swallowing (FEES). The catheter was connected to the base station to deliver stimuli of 0.2 ms pulse duration at a frequency of 5 Hz with 280 V, which had previously been found to be the most effective stimulation parameters [13]. The current intensity (mA) was individually adjusted in every session. Therefore prior to the actual intervention the perceptual threshold (PT) and the maximum tolerated threshold (MTT) were determined repeatedly by slowly increasing the current. The average values of three trials were taken into account for the calculation of the optimal stimulation intensity according to the formula $PT + 0.75 \times (MTT - PT)$ [13]. Thresholds as well as calculated optimal stimulation intensities were documented at each session. In the treatment condition stimulation was afterwards delivered for a total of 10 min at this intensity.</p> <p>The intervention was repeated daily for three consecutive days. The stimulation catheter remained in place over this period of time and was used as a regular feeding tube between treatment sessions.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Very severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed

Population subgroups	NR
Comparator	The intervention was the same as the study group but In the sham condition the catheter was left connected to the base station for 10 min without current flow between the electrodes.
Number of participants	30
Duration of follow-up	3 days
Indirectness	NR
Additional comments	NR

1

2 **1.1.86.2. Study arms**

3 **1.1.86.2.1. *Pharyngeal electrical stimulation (PES) (N = 20)***

4

5 **1.1.86.2.2. *Sham stimulation (N = 10)***

6

7 **1.1.86.3. Characteristics**

8 **1.1.86.3.1. *Study-level characteristics***

Characteristic	Study (N = 30)
Ethnicity	NR to NR
Range	

Characteristic	Study (N = 30)
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
People requiring enteral feeding support at baseline	n = 30 ; % = 100
No of events	

1

2 **1.1.86.3.2. Arm-level characteristics**

Characteristic	Pharyngeal electrical stimulation (PES) (N = 20)	Sham stimulation (N = 10)
% Female	55	40
Nominal		
Mean age (SD)	63 (14.5)	66.7 (14.5)
Mean (SD)		
Time after stroke (hours)	644 (221)	572 (406)
Mean (SD)		

3

4 **1.1.86.4. Outcomes**

5 **1.1.86.4.1. Study timepoints**

- 6 • Baseline

- 3 day

1.1.86.4.2. continuous outcomes

Outcome	Pharyngeal electrical stimulation (PES), Baseline, N = 20	Pharyngeal electrical stimulation (PES), 3 day, N = 20	Sham stimulation, Baseline, N = 10	Sham stimulation, 3 day, N = 10
Length of hospital stay (hours) Mean (SD)	NA (NA)	1028 (409)	NA (NA)	1017 (493)
Dysphagia present/Return to normal diet (FOIS score at discharge - return to normal diet) No of events	n = NR ; % = NR	n = 12 ; % = 60	n = NR ; % = NR	n = 4 ; % = 40
Tube-dependent (1–3) No of events	n = NR ; % = NR	n = 8 ; % = 40	n = NR ; % = NR	n = 6 ; % = 60
Total oral intake (4–7) No of events	n = NR ; % = NR	n = 12 ; % = 60	n = NR ; % = NR	n = 4 ; % = 40

Length of hospital stay - Polarity - Lower values are better

Dysphagia present/Return to normal diet (FOIS score at discharge - return to normal diet) - Polarity - Higher values are better

1 **1.1.86.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.86.4.4. continuousoutcomes-Dysphagiapresent/Returntonormaldiet(FOISscoreatdischarge)-NoOfEvents-Electrical**
 3 **pharyngeal stimulation (EPS)-Sham stimulation-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to bias in selection of reported result)</i>
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.86.4.5. continuousoutcomes-Dysphagiapresent/Returntonormaldiet(FOISscoreatdischarge)-Tube-dependent(1-3)-**
 6 **NoOfEvents-Electrical pharyngeal stimulation (EPS)-Sham stimulation-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to bias in selection of reported result)</i>
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.86.4.6. continuousoutcomes-Dysphagiapresent/Returntonormaldiet(FOISscoreatdischarge)-Totaloralintake(4-7)-**
 9 **NoOfEvents-Electrical pharyngeal stimulation (EPS)-Sham stimulation-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to bias in selection of reported result)</i>
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.86.4.7. continuous outcomes- Length of hospital stay- Mean SD- Electrical pharyngeal stimulation (EPS)- Sham stimulation-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

2

3 **1.1.87. Suntrup-Krueger, 2018**

Bibliographic Reference Suntrup-Krueger, Sonja; Ringmaier, Corinna; Muhle, Paul; Wollbrink, Andreas; Kemmling, Andre; Hanning, Uta; Claus, Inga; Warnecke, Tobias; Teismann, Inga; Pantev, Christo; Dziewas, Rainer; Randomized trial of transcranial direct current stimulation for poststroke dysphagia.; Annals of neurology; 2018; vol. 83 (no. 2); 328-340

4

5 **1.1.87.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	(2013) NCT01970384 Transcranial direct current stimulation for dysphagia therapy in acute stroke patients.
Trial name / registration number	NCT01970384.
Study type	Randomised controlled trial (RCT)

Study location	Germany.
Study setting	Inpatients.
Study dates	June 2012 to December 2014.
Sources of funding	This work was supported by the German Research Foundation (TE 840/1-1, SU 922/1-1).
Inclusion criteria	People older than 18 years; >24 hours from stroke onset if diagnosed with dysphagia due to acute ischaemic stroke, confirmed by brain imaging.
Exclusion criteria	Preexisting swallowing difficulties unrelated to stroke; history of seizures; previous or current need for skull surgery; metallic implants of any kind; presence of a tracheal cannula; unstable medical condition; inability to stay alert and give informed consent.
Recruitment / selection of participants	Patients from the stroke unit at the University Hospital Munster.
Intervention(s)	<p>Transcranial direct current stimulation (tDCS) N=30</p> <p>Stimulation delivered by a battery-drive constant current stimulator through a pair of electrodes. The center of the anode was positioned approximately 3.5cm lateral and 1cm anterior to the vertex with its long axis parallel to the central sulcus. The reference electrode was placed over the contralateral orbit. Anodal tDCS was performed at 1mA for 20 minutes, once daily on 4 consecutive days. If the person's condition allowed, swallowing exercises (dry swallows, effortful swallows, administration of fluids or pudding, depending on the person's swallowing abilities) were performed during stimulation. People not able to perform any exercises were asked to stay relaxed with their eyes open.</p> <p>Concomitant therapy: No additional information.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear

Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=30</p> <p>The same approach. However, stimulation was only applied for 30 seconds with the electrodes left in place for a further 20 minutes. In any case, the current was gradually ramped up and down over 30 seconds at the beginning and end of stimulation to mimic the transient skin sensation of real therapy.</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	60
Duration of follow-up	Until discharge (the maximum time before discharge was 3 weeks).
Indirectness	No additional information.
Additional comments	Intention-to-treat analysis conducted.

1 **1.1.87.2. Study arms**2 **1.1.87.2.1. Transcranial direct current stimulation (tDCS) (N = 30)**

3 Stimulation delivered by a battery-drive constant current stimulator through a pair of electrodes. The center of the anode was
 4 positioned approximately 3.5cm lateral and 1cm anterior to the vertex with its long axis parallel to the central sulcus. The reference
 5 electrode was placed over the contralateral orbit. Anodal tDCS was performed at 1mA for 20 minutes, once daily on 4 consecutive
 6 days. If the person's condition allowed, swallowing exercises (dry swallows, effortful swallows, administration of fluids or pudding,
 7 depending on the person's swallowing abilities) were performed during stimulation. People not able to perform any exercises were
 8 asked to stay relaxed with their eyes open. Concomitant therapy: No additional information.

9

10 **1.1.87.2.2. Placebo/sham therapy (N = 30)**

11 The same approach. However, stimulation was only applied for 30 seconds with the electrodes left in place for a further 20 minutes. In
 12 any case, the current was gradually ramped up and down over 30 seconds at the beginning and end of stimulation to mimic the
 13 transient skin sensation of real therapy. Concomitant therapy: No additional information.

14

15 **1.1.87.3. Characteristics**16 **1.1.87.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 30)	Placebo/sham therapy (N = 30)
% Female	n = 12 ; % = 41.4	n = 13 ; % = 43.3
Sample size		
Mean age (SD) (years)	68.9 (11.5)	67.2 (14.5)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR

Characteristic	Transcranial direct current stimulation (tDCS) (N = 30)	Placebo/sham therapy (N = 30)
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (hours)	116.3 (98.9)	116.8 (64.9)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Total anterior circulation	n = 0 ; % = 0	n = 0 ; % = 0
Sample size		
Partial anterior circulation	n = 21 ; % = 72.4	n = 24 ; % = 80
Sample size		
Lacunar	n = 0 ; % = 0	n = 0 ; % = 0
Sample size		

Characteristic	Transcranial direct current stimulation (tDCS) (N = 30)	Placebo/sham therapy (N = 30)
Posterior circulation	n = 8 ; % = 27.6	n = 6 ; % = 20
Sample size		

1 Only reports 29 people in the intervention group.

2

3 1.1.87.4. Outcomes

4 1.1.87.4.1. Study timepoints

- 5 • Baseline
- 6 • 3 week (<3 months)

7

8 1.1.87.4.2. Continuous outcomes

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 29	Transcranial direct current stimulation (tDCS), 3 week, N = 29	Placebo/sham therapy, Baseline, N = 30	Placebo/sham therapy, 3 week, N = 30
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Change score. Mean (SD)	3.2 (1.8)	1.8 (1.6)	3.8 (1.9)	1 (1.4)
Length of hospital stay (days) Mean (SD)	NA (NA)	16.2 (6.8)	NA (NA)	13.4 (5.1)

- 1 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better
- 2 Length of hospital stay - Polarity - Lower values are better

3 **1.1.87.4.3. Dichotomous outcomes**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 30	Transcranial direct current stimulation (tDCS), 3 week, N = 29	Placebo/sham therapy, Baseline, N = 30	Placebo/sham therapy, 3 week, N = 30
Occurrence of chest infections (pneumonia)	n = NA ; % = NA	n = 11 ; % = 37.9	n = NA ; % = NA	n = 16 ; % = 53.3
No of events				

- 4 Occurrence of chest infections (pneumonia) - Polarity - Lower values are better

- 5
- 6

7 **1.1.87.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

8 **1.1.87.4.5. Continuous outcomes-Swallowing ability(Functional Oral Intake Scale)-MeanSD-Transcranial direct current stimulation (tDCS)-Placebo/sham therapy-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

- 10

1 **1.1.87.4.6. Continuous outcomes- Length of hospital stay- Mean SD- Transcranial direct current stimulation (tDCS)-Placebo/sham**
 2 **therapy-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

3
 4 **1.1.87.4.7. Dichotomous outcomes- Occurrence of chest infections (pneumonia)- No Of Events- Transcranial direct current**
 5 **stimulation (tDCS)-Placebo/sham therapy-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

6
 7 **1.1.88. Tageldin, 2020**

Bibliographic Reference Tageldin, Elsayed; Khalil, Mohamed; Elbahnasy, Wafik; Fouda, Basem; The possible role of repetitive transcranial magnetic stimulation in dysphagia following brain stem infarctions; TMJ update; 2020; vol. 47; 68

8
 9 **1.1.88.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
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Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	Egypt.
Study setting	Inpatients.
Study dates	A 6 month period started in June 2016.
Sources of funding	No financial support or sponsorship.
Inclusion criteria	Fully conscious adults with first-ever brain stem infarction.
Exclusion criteria	Haemorrhagic stroke; recurrent or severe stroke (NIHSS >22); epilepsy; heavy smokers; chronic chest patients; those older than 70 years; people with disturbed consciousness; people who needed assisted ventilation; people with contraindications to rTMS (including people with epilepsy, people with prosthetic valves, people with cardiac pacemakers, people with arterial stenting, people with metallic material as joint replacement and internal orthopedic fixations).
Recruitment / selection of participants	People with brain stem infarctions attending the Neurovascular Unit and ICUs of the Neurology Department and The Center of Neurology and Psychiatry, Tanta University Hospitals.
Intervention(s)	<p>Transcranial magnetic stimulation (TMS) N=15</p> <p>Transcranial magnetic stimulation using a Magstim Rapid second-generation double 70-mm coil stimulators produced in the United Kingdom. The stimulation sites were the swallowing areas in the premotor cortices of both hemispheres, which were located 3cm lateral and 6cm anterior to the vertex. People received bilateral 10 sessions repeated five times per week for 2 successive weeks. Ten trains of real TMS were done per session in bilateral sequential manner. Each train was 120% of the motor threshold intensity, 3-Hz frequency and 10s duration, with 50s inter-train intervals. The total number of pulses in each session was 300 (3 Hz x 10s x 10 trains) pulses in each side.</p>

	Concomitant therapy: No additional information.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=15</p> <p>The same procedure except the coil was angled 90 degrees away by lifting the lateral aspect of the coil which delivers a very small proportion of the dose (<25%).</p> <p>Concomitant therapy: No additional information.</p>
Number of participants	30
Duration of follow-up	2 weeks (end of intervention).

Indirectness	No additional information.
Additional comments	No additional information. No information about the method of analysis.

1

2 **1.1.88.2. Study arms**

3 **1.1.88.2.1. Transcranial magnetic stimulation (TMS) (N = 15)**

4 Transcranial magnetic stimulation using a Magstim Rapid second-generation double 70-mm coil stimulators produced in the United
 5 Kingdom. The stimulation sites were the swallowing areas in the premotor cortices of both hemispheres, which were located 3cm
 6 lateral and 6cm anterior to the vertex. People received bilateral 10 sessions repeated five times per week for 2 successive weeks. Ten
 7 trains of real TMS were done per session in bilateral sequential manner. Each train was 120% of the motor threshold intensity, 3-Hz
 8 frequency and 10s duration, with 50s inter-train intervals. The total number of pulses in each session was 300 (3 Hz x 10s x 10 trains)
 9 pulses in each side. Concomitant therapy: No additional information.

10

11 **1.1.88.2.2. Placebo/sham therapy (N = 15)**

12 The same procedure except the coil was angled 90 degrees away by lifting the lateral aspect of the coil which delivers a very small
 13 proportion of the dose (<25%). Concomitant therapy: No additional information.

14

15 **1.1.88.3. Characteristics**

16 **1.1.88.3.1. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Placebo/sham therapy (N = 15)
% Female	n = 7 ; % = 47	n = 8 ; % = 53
Sample size		
Mean age (SD) (years)	57.47 (7.68)	55.6 (10.24)

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Placebo/sham therapy (N = 15)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	4.33 (1.75)	4.16 (1.17)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.88.4. Outcomes**3 **1.1.88.4.1. Study timepoints**

- 4 • Baseline
- 5 • 2 week (<3 months)

6

1 **1.1.88.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 15	Transcranial magnetic stimulation (TMS), 2 week, N = 15	Placebo/sham therapy, Baseline, N = 15	Placebo/sham therapy, 2 week, N = 15
Swallowing ability (Dysphagia Outcome and Severity scale) Scale range: unclear. Final values. Mean (SD)	3.13 (0.81)	4.13 (0.74)	3.2 (0.77)	3.33 (0.72)

2 Swallowing ability (Dysphagia Outcome and Severity scale) - Polarity - Higher values are better

3

4

5 **1.1.88.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.88.4.4. Continuous outcomes-Swallowing ability (Dysphagia Outcome and Severity scale)-Mean SD-Transcranial magnetic stimulation (TMS)-Placebo/sham therapy-t2**

7

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.89. Tarihci Cakmak, 2022**

Bibliographic Reference Tarihci Cakmak, Elif; Sen, Ekin Ilke; Doruk, Can; Sen, Comert; Sezikli, Selim; Yaliman, Ayse; The Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Post-stroke Dysphagia: A Randomized Controlled Trial.; Dysphagia; 2022

1

2 **1.1.89.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NCT04421937.
Study type	Randomised controlled trial (RCT)
Study location	Turkey.
Study setting	Outpatient follow up.
Study dates	April 2020 to October 2020.
Sources of funding	Funded by Istanbul University Scientific Research Projects Coordination Unit (Project Number 37068).
Inclusion criteria	Diagnosis of stroke by MRI or CT scans; over the age of 18; detection of dysphagia by bedside water swallow test in patients who have passed 1 week or longer after stroke; having unassisted sitting balance; a score above 20 on the MMSE; no swallowing problems before stroke.
Exclusion criteria	Having had multiple strokes; presence of global aphasia or cognitive impairments that would affect comprehension of the instructions; having major medical issues that may affect participation in the program; presence of tracheostomy or cardiac pacemaker; history of epilepsy; having had a previous surgical operation or radiotherapy to the head or neck area.
Recruitment / selection of participants	No additional information.

Intervention(s)	<p>Neuromuscular electrical stimulation (NMES) N=19</p> <p>45 minutes of NMES was provided via a VitalStim unit. The pulse rate was 80Hz using a biphasic pulse duration of 700 microseconds and stimulation intensity not exceeding 25 mA. The upper electrodes were placed on the mylohyoid muscle while the lower electrodes were placed horizontally on the thyrohyoid muscle. The stimulation intensity was started at 2mA and increased by 0.5mA increments until the person felt vibration in their neck.</p> <p>Concomitant therapy: Traditional dysphagia therapy was provided to everyone for 45 minutes, 5 days a week for 3 weeks. This included diet modifications, oral hygiene education, compensatory methods (postural techniques and oral sensorimotor enhancement techniques including thermal-tactile stimulation) and exercises.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Chronic (>6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed Mixture of people with hemisphere and brainstem stroke
Population subgroups	No additional information.
Comparator	Usual care N=19

	Usual care.
	Concomitant therapy: Traditional dysphagia therapy was provided to everyone for 45 minutes, 5 days a week for 3 weeks. This included diet modifications, oral hygiene education, compensatory methods (postural techniques and oral sensorimotor enhancement techniques including thermal-tactile stimulation) and exercises.
Number of participants	38
Duration of follow-up	3 weeks (post-intervention) and 15 weeks (3 months after post-intervention)
Indirectness	No additional information.
Additional comments	Method of analysis unclear (appears to be completers only).

1

2 **1.1.89.2. Study arms**

3 **1.1.89.2.1. Neuromuscular electrical stimulation (NMES) (N = 19)**

4 45 minutes of NMES was provided via a VitalStim unit. The pulse rate was 80Hz using a biphasic pulse duration of 700 microseconds
 5 and stimulation intensity not exceeding 25 mA. The upper electrodes were placed on the mylohyoid muscle while the lower electrodes
 6 were placed horizontally on the thyrohyoid muscle. The stimulation intensity was started at 2mA and increased by 0.5mA increments
 7 until the person felt vibration in their neck. Concomitant therapy: Traditional dysphagia therapy was provided to everyone for 45
 8 minutes, 5 days a week for 3 weeks. This included diet modifications, oral hygiene education, compensatory methods (postural
 9 techniques and oral sensorimotor enhancement techniques including thermal-tactile stimulation) and exercises.

10

11 **1.1.89.2.2. Usual care (N = 19)**

12 Usual care. Concomitant therapy: Traditional dysphagia therapy was provided to everyone for 45 minutes, 5 days a week for 3 weeks.
 13 This included diet modifications, oral hygiene education, compensatory methods (postural techniques and oral sensorimotor
 14 enhancement techniques including thermal-tactile stimulation) and exercises.

1

2 **1.1.89.3. Characteristics**3 **1.1.89.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 19)	Usual care (N = 19)
% Female	n = 6 ; % = 35	n = 8 ; % = 47
Sample size		
Mean age (SD) (years)	62.9 (9.8)	63.6 (10)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (Weeks)	48.3 (92.6)	52.2 (92.2)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
NG tube use	n = 10 ; % = 59	n = 11 ; % = 65
Sample size		

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 19)	Usual care (N = 19)
PEG use	n = 1 ; % = 6	n = 1 ; % = 6
Sample size		
Type of stroke	n = NA ; % = NA	n = NA ; % = NA
Sample size		
Hemisphere	n = 11 ; % = 65	n = 10 ; % = 59
Sample size		
Brainstem	n = 6 ; % = 35	n = 7 ; % = 41
Sample size		

1 Only reports the baseline characteristics for 17 people in each treatment arm.

2

3 **1.1.89.4. Outcomes**

4 **1.1.89.4.1. Study timepoints**

- 5 • Baseline
- 6 • 3 week (<3 months)
- 7 • 15 week (≥3 months)

8

1 **1.1.89.4.2. Dichotomous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 19	Neuromuscular electrical stimulation (NMES), 3 week, N = 19	Neuromuscular electrical stimulation (NMES), 15 week, N = 19	Usual care, Baseline, N = 19	Usual care, 3 week, N = 19	Usual care, 15 week, N = 19
Mortality No adverse events were reported No of events	n = NA ; % = NA	n = 0 ; % = 0	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0	n = 0 ; % = 0
Occurrence of chest infections No adverse events were reported No of events	n = NA ; % = NA	n = 0 ; % = 0	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0	n = 0 ; % = 0

2 Mortality - Polarity - Lower values are better

3 Occurrence of chest infections - Polarity - Lower values are better

4 **1.1.89.4.3. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 17	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Neuromuscular electrical stimulation (NMES), 15 week, N = 17	Usual care, Baseline, N = 17	Usual care, 3 week, N = 17	Usual care, 15 week, N = 17
Swallowing ability (Functional Oral Intake Scale)	4.3 (1.9)	6 (1.5)	6.2 (1.4)	4.5 (1.8)	5.8 (1.6)	6 (1.4)

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 17	Neuromuscular electrical stimulation (NMES), 3 week, N = 17	Neuromuscular electrical stimulation (NMES), 15 week, N = 17	Usual care, Baseline, N = 17	Usual care, 3 week, N = 17	Usual care, 15 week, N = 17
Scale range: 1-7. Final values.						
Mean (SD)						
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values.	4 (3)	2.6 (2.4)	NR (NR)	3.5 (2.9)	2.3 (2.4)	NR (NR)
Mean (SD)						

1 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better
 2 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

3

4

5 **1.1.89.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.89.4.5. Dichotomous outcomes-Mortality-NoOfEvents-Neuromuscular electrical stimulation (NMES)-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

1 **1.1.89.4.6. Dichotomous outcomes-Mortality-NoOfEvents-Neuromuscular electrical stimulation (NMES)-Usual care-t15**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

2

3 **1.1.89.4.7. Dichotomous outcomes-Occurrence of chest infections-NoOfEvents-Neuromuscular electrical stimulation (NMES)-**
 4 **Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

5

6 **1.1.89.4.8. Dichotomous outcomes-Occurrence of chest infections-NoOfEvents-Neuromuscular electrical stimulation (NMES)-**
 7 **Usual care-t15**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.89.4.9.** *Continuous outcomes-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Neuromuscular electrical stimulation*
 2 *(NMES)-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.89.4.10.** *Continuous outcomes-Swallowing ability (Functional Oral Intake Scale)-Mean SD-Neuromuscular electrical stimulation*
 5 *(NMES)-Usual care-t15*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.89.4.11.** *Continuous outcomes-Occurrence of aspiration (Penetration Aspiration Scale)-Mean SD-Neuromuscular electrical*
 8 *stimulation (NMES)-Usual care-t3*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.89.4.12. Continuous outcomes-Occurrence of aspiration (Penetration Aspiration Scale)-Mean SD-Neuromuscular electrical**
 2 **stimulation (NMES)-Usual care-t15**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.90. Umay, 2017**

Bibliographic Reference Umay, Ebru K; Yaylaci, Atilay; Saylam, Guleser; Gundogdu, Ibrahim; Gurcay, Eda; Akcapinar, Dehen; Kirac, Zeynep; The effect of sensory level electrical stimulation of the masseter muscle in early stroke patients with dysphagia: A randomized controlled study.; Neurology India; 2017; vol. 65 (no. 4); 734-742

5

6 **1.1.90.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)

Study location	Turkey
Study setting	This study was conducted at the Physical Medicine and Rehabilitation (PMR) and Otolaryngology-Head and Neck Surgery Clinics
Study dates	Between 2013 and 2015
Sources of funding	Financial support and sponsorship Nil.
Inclusion criteria	The inclusion criteria were the following: patients aged between 45 and 75 years, who were admitted for any problem such as motor function impairment or disability, within the first month after ischemic stroke confirmed by magnetic resonance imaging (MRI). The diagnosis of dysphagia was obtained by evaluation of swallowing.
Exclusion criteria	
Recruitment / selection of participants	Patients with a history of malignancy, head and/or neck surgery, previous stroke, known pulmonary or swallowing disorder, gastroesophageal reflux disease, dementia or psychiatric disorder, hemorrhagic infarction, bilateral involvement, and smoking, were excluded from the study. In addition, the exclusion criteria for flexible fiberoptic endoscopic evaluation of swallowing (FEES) method were the presence of contagious or infectious diseases such as human immunodeficiency virus (HIV) and hepatitis types B and C; the risk of bleeding; the presence of nasal obstruction; and, the presence of decompensated heart disease. The exclusion criteria for electrical stimulation were the presence of biomedical devices such as a cardiac pacemaker sensitive to electrical field in the body; and, the presence of serious infectious diseases similar to pneumonia.
Intervention(s)	<p>Patients in group 1 received intermittent galvanic stimulation to bilateral masseter muscles for 60 minutes a day, 5 days per week, for 4 weeks up to a total of 20 sessions (Intelect Advanced- Chattonooga, UK). In this method, after the patients were positioned in 90° supported/unsupported seating, 2 pieces of 4 × 5 cm surface electrodes were placed, one over the ramus of the mandible, and another over the masseter muscle (the chin being in the intercuspal position and in the midline). The current stimulation intensity was established by determining the threshold sensibility using an incremental protocol and fixed during the treatment session. The sensory approach, i.e., the sensory threshold, was identified as the lowest current level at which the patient felt a tingling sensation on the skin. The amplitude of the electrical current level was approximately 4–6 mA. Patients were not instructed to perform any oropharyngeal exercises or swallowing training during the electrical stimulation treatment.</p> <p>Concomitant therapy- All patients under the supervision of the same physiotherapist received daily care for oral hygiene, thermal (cold) and tactile stimulation, swallowing maneuvers, head and trunk positioning, dietary modification, and oral</p>

	motor exercises including lips, tongue, and jaw movements. This was in accordance with the different patient swallowing characteristics and were given for 60 minutes a day, 5 days a week, for 4 weeks; cognitive, respiratory, and sensorimotor functional rehabilitation programs were added to this program.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	NR
Comparator	<p>Patients in group 2 received sham stimulation, the electrodes were placed at the same positions as in active stimulation; however, the stimulator was turned off. Therefore, the patients received no current stimulation for the treatment period.</p> <p>Concomitant therapy- All patients under the supervision of the same physiotherapist received daily care for oral hygiene, thermal (cold) and tactile stimulation, swallowing maneuvers, head and trunk positioning, dietary modification, and oral motor exercises including lips, tongue, and jaw movements. This was in accordance with the different patient swallowing characteristics and were given for 60 minutes a day, 5 days a week, for 4 weeks; cognitive, respiratory, and sensorimotor functional rehabilitation programs were added to this program.</p>
Number of participants	98

Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.90.2. Study arms**3 **1.1.90.2.1. *Neuromuscular electrical stimulation (Sensory-level electrical stimulation [SES]) (N = 58)***

4

5 **1.1.90.2.2. *Sham stimulation (N = 40)***

6

7 **1.1.90.3. Characteristics**8 **1.1.90.3.1. *Study-level characteristics***

Characteristic	Study (N = 98)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

Characteristic	Study (N = 98)
Type of stroke	NR
Nominal	

1

2 **1.1.90.3.2. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (Sensory-level electrical stimulation [SES]) (N = 58)	Sham stimulation (N = 40)
% Female	29.3	12.5
Nominal		
Mean age (SD)	61.03 (10.05)	62.4 (9.93)
Mean (SD)		
Severity of dysphagia MASA Mann assessment swallowing ability	141.6 (26.98)	143.51 (28.59)
Mean (SD)		
Time after stroke (days)	14 (5.51)	15.27 (5.53)
Mean (SD)		

3

4 **1.1.90.4. Outcomes**5 **1.1.90.4.1. Study timepoints**

- 6
- Baseline

- 4 week

1.1.90.4.2. Continuous outcomes

Outcome	Neuromuscular electrical stimulation (Sensory-level electrical stimulation [SES]), Baseline, N = 58	Neuromuscular electrical stimulation (Sensory-level electrical stimulation [SES]), 4 week, N = 58	Sham stimulation, Baseline, N = 40	Sham stimulation, 4 week, N = 40
Swallowing ability (Mann Assessment of Swallowing Ability) Scale range: 38-200. Change score. Mean (SD)	141.6 (26.98)	46.2 (27.11)	143.51 (28.59)	25.5 (18.47)

Swallowing ability (Mann Assessment of Swallowing Ability) - Polarity - Higher values are better

1.1.90.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

1.1.90.4.4. Continuous outcomes-Swallowing ability-Mann Assessment of Swallowing Ability-change score-Mean SD-Sensory-level electrical stimulation (SES)-Sham stimulation-t4

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to missing outcome data)</i>
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.91. Unluer, 2019**

Bibliographic Reference Unluer, Nezehat Ozgul; Temucin, Cagri Mesut; Demir, Numan; Serel Arslan, Selen; Karaduman, Aynur Ayse; Effects of Low-Frequency Repetitive Transcranial Magnetic Stimulation on Swallowing Function and Quality of Life of Post-stroke Patients.; Dysphagia; 2019; vol. 34 (no. 3); 360-371

2

3 **1.1.91.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NR
Study type	Randomised controlled trial (RCT)
Study location	Turkey
Study setting	Physiotherapy and Rehabilitation and Hacettepe University Faculty of Medicine, Department of Neurology in Turkey.
Study dates	No additional information
Sources of funding	No additional information
Inclusion criteria	Stroke patients with dysphagia were included. The inclusion criteria were as follows: confirmed diagnosis of unilateral hemispheric stroke, oropharyngeal dysphagia continuing 2–6 months after the stroke, and no prior dysphagia rehabilitation and/ or cortical stimulation therapy.

Exclusion criteria	The exclusion criteria were as follows: having dysphagia before the stroke, history of any other neurogenic disease, epilepsy, tumor, radiotherapy in the head and neck prior to the stroke, unstable medical condition, severe cognitive impairment, severe aphasia, contraindication to magnetic or electrical stimulation, and treatment with any cortical stimulation techniques before participating in this study.
Recruitment / selection of participants	A total of 40 post-stroke dysphagic patients were assessed for eligibility, of which 30 patients matching with the inclusion/exclusion criteria were included. Thirty patients were equally randomized into two groups. Two patients in the control group gave up the treatment due to transportation problems.
Intervention(s)	<p>All patients received conventional dysphagia rehabilitation under the control of a trained physical therapist 3 days per week. In addition, a home program was implemented 2 days per week.</p> <p>At the same time, the study group also received 1 Hz rTMS applied to the unaffected hemisphere during the final week.</p> <p>Before performing the rTMS, the cortical motor representation area related to swallowing was determined. Thus, the potentials in the mylohyoid muscle (representing the oral swallowing musculature) were recorded using silver–silver chloride surface electrodes. A Keypoint electromyography device was used for recording (Medtronic A/S, Copenhagen, Denmark). The figure eight coil (MMC-140, 33 kT/s) was first placed at the vertex of the cranium, then it was positioned 2–4 cm anteriorly and 4–6 cm laterally, and then it was moved around in this region using the MagPro stimulator (Medtronic A/S) to obtain the highest motor-evoked potential recording to locate the mylohyoid cortical area of the hemisphere. This site was marked on the scalp as the “hot spot,” and we delivered the magnetic stimulation to that point. Then, a single-pulse TMS was delivered to the hot spot. After induction was detected at this site, the resting motor threshold was determined as the minimal stimulus intensity creating a response >100 μV. For the treatment, each patient received 1 Hz at 90% of the resting motor threshold intensity at the hot spot for 20 min daily for five consecutive days (for a total of 1200 pulses each day). The rTMS application was done by the same neurologist at the Hacettepe University Faculty of Medicine, Neurology Department.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Mixed

Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>Conventional dysphagia rehabilitation included oropharyngeal muscle strengthening exercises, thermal tactile stimulation, Masako and Mendelson maneuvers, vocal cord exercises, Shaker exercises, and tongue retraction exercises for 4 weeks. These exercises were performed actively under the control of a trained physical therapist 3 days per week. In addition, a home program was implemented 2 days per week. The conventional dysphagia rehabilitation took 30–45 min in the control group. All exercises were done by same physical therapist (N.Ö.Ü.).</p> <p>All patients received conventional dysphagia rehabilitation.</p>
Number of participants	30
Duration of follow-up	post treatment, 1 month and 3 months
Indirectness	NR
Additional comments	NR

1 **1.1.91.2. Study arms**

2 **1.1.91.2.1. *Transcranial magnetic stimulation (TMS) (N = 15)***

3 conventional dysphagia rehabilitation for 3 days a week for 4 weeks plus 1 Hz rTMS to unaffected hemisphere in the final week

4

5 **1.1.91.2.2. *Usual care (conventional dysphagia rehabilitation) (N = 15)***

6 3 days a week for 4 weeks

7

8 **1.1.91.3. Characteristics**

9 **1.1.91.3.1. *Study-level characteristics***

Characteristic	Study (N = 28)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Type of stroke	NR
Nominal	

10

1 **1.1.91.3.2. Arm-level characteristics**

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Usual care (conventional dysphagia rehabilitation) (N = 15)
% Female	40	46
Nominal		
Mean age (SD)	67.8 (11.88)	69.31 (12.89)
Mean (SD)		
Severity of dysphagia PAS liquid	6.87 (1.45)	7.15 (1.34)
Mean (SD)		
Time after stroke (days)	105.93 (49.02)	101.38 (42.06)
Mean (SD)		
People requiring enteral feeding support at baseline	<i>empty data</i>	n = NR ; % = NR
No of events		
Oral	n = 0 ; % = 0	n = 3 ; % = 23
No of events		
NG	n = 2 ; % = 13	n = 1 ; % = 8
No of events		
PEG	n = 5 ; % = 33	n = 2 ; % = 15
No of events		

Characteristic	Transcranial magnetic stimulation (TMS) (N = 15)	Usual care (conventional dysphagia rehabilitation) (N = 15)
ME	n = 1 ; % = 7	n = 2 ; % = 23
No of events		
MO	n = 7 ; % = 47	n = 4 ; % = 31
No of events		

1

2 **1.1.91.4. Outcomes**3 **1.1.91.4.1. Study timepoints**

- 4 • Baseline
- 5 • 1 month
- 6 • 3 month

7

8 **1.1.91.4.2. Continuous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 15	Transcranial magnetic stimulation (TMS), 1 month, N = 15	Transcranial magnetic stimulation (TMS), 3 month, N = 15	Usual care (conventional dysphagia rehabilitation), Baseline, N = 15	Usual care (conventional dysphagia rehabilitation), 1 month, N = 13	Usual care (conventional dysphagia rehabilitation), 3 month, N = 13
Occurrence of aspiration (PAS liquid) Scale range: 1-8. Final values	6.87 (1.45)	3.53 (3.18)	3.6 (3.24)	7.17 (1.34)	3.69 (2.84)	3.62 (2.9)

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 15	Transcranial magnetic stimulation (TMS), 1 month, N = 15	Transcranial magnetic stimulation (TMS), 3 month, N = 15	Usual care (conventional dysphagia rehabilitation), Baseline, N = 15	Usual care (conventional dysphagia rehabilitation), 1 month, N = 13	Usual care (conventional dysphagia rehabilitation), 3 month, N = 13
Mean (SD)						
Swallowing ability (SAFE - Swallowing Ability and Function Evaluation) Scale range: 0-3. Final values. The values reported for the physical examination, oral phase and pharyngeal phases were combined. Reported intervention 1 month PE = 7.20 (1.52), OP = 7.60 (1.68), PP = 6.20 (2.27). 3 months PE = 7.53 (1.88). OP = 8.20 (1.20). PP = 6.73 (2.31). Control 1 month PE = 6.92 (2.17). OP = 7.46 (2.10). PP = 6.69 (1.65). 3 months PE = 7.15 (2.03). OP = 7.46 (2.06). PP = 6.69 (1.35). Mean (SD)	4.73 (1.89)	7 (1.94)	7.49 (1.95)	3.77 (2.34)	7.02 (1.92)	7.1 (1.87)

- 1 Occurrence of aspiration (PAS liquid) - Polarity - Lower values are better
- 2 Swallowing ability (SAFE - Swallowing Ability and Function Evaluation) - Polarity - Higher values are better

1 **1.1.91.4.3. Dichotomous outcomes**

Outcome	Transcranial magnetic stimulation (TMS), Baseline, N = 15	Transcranial magnetic stimulation (TMS), 1 month, N = 15	Transcranial magnetic stimulation (TMS), 3 month, N = 15	Usual care (conventional dysphagia rehabilitation), Baseline, N = 15	Usual care (conventional dysphagia rehabilitation), 1 month, N = 15	Usual care (conventional dysphagia rehabilitation), 3 month, N = 15
Dysphagia present/return to normal diet (number of people receiving oral nutrition)	n = 0 ; % = 0	n = 9 ; % = 60	n = 10 ; % = 67	n = 3 ; % = 23	n = 9 ; % = 69	n = 9 ; % = 68
No of events						

2 Dysphagia present/return to normal diet (number of people receiving oral nutrition) - Polarity - Higher values are better

3

4

5 **1.1.91.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.91.4.5. Continuous outcomes-Swallowing ability(PASliquid)-MeanSD-Repetitive transcranial magnetic stimulation-**
 7 **conventional dysphagia rehabilitation-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

8

1 **1.1.91.4.6.** ***Continuousoutcomes-Swallowingability(PASliquid)-MeanSD-Repetitive transcranial magnetic stimulation-***
 2 ***conventional dysphagia rehabilitation-t3***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

3
 4 **1.1.91.4.7.** ***Continuousoutcomes-Swallowingability(SAFE-SwallowingAbilityandFunctionEvaluation)-MeanSD-Transcranial***
 5 ***magnetic stimulation (TMS)-Usual care (conventional dysphagia rehabilitation)-t1***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

6
 7 **1.1.91.4.8.** ***Continuousoutcomes-Swallowingability(SAFE-SwallowingAbilityandFunctionEvaluation)-MeanSD-Transcranial***
 8 ***magnetic stimulation (TMS)-Usual care (conventional dysphagia rehabilitation)-t3***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.91.4.9. Dichotomous outcomes-Dysphagia present/return to normal diet (number of people receiving oral nutrition)-No Of Events-**
 2 **Transcranial magnetic stimulation (TMS)-Usual care (conventional dysphagia rehabilitation)-t1**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.91.4.10. Dichotomous outcomes-Dysphagia present/return to normal diet (number of people receiving oral nutrition)-No Of Events-**
 5 **Transcranial magnetic stimulation (TMS)-Usual care (conventional dysphagia rehabilitation)-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (Due to missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

6

7 **1.1.92. Vasant, 2014**

Bibliographic Reference Vasant, D.H.; Michou, E.; Tyrrell, P.; Jayasekeran, V.; Mistry, S.; O'Leary, N.; Vail, A.; Anwar, S.; Gamble, E.; Hamdy, S.; Pharyngeal electrical stimulation (PES) in dysphagia post-acute stroke: A double-blind, randomised trial; Gut; 2014; vol. 63 (no. suppl1); a31

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9 **1.1.92.1. Study details**

Secondary publication of another included	Vasant DH, Michou E, O LN, Vail A, Mistry S, Hamdy S. Pharyngeal Electrical Stimulation in Dysphagia Poststroke. <i>Neurorehabilitation & Neural Repair</i> . 2016;30(9):866-875.
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study- see primary study for details	
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

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3 **1.1.93. Vasant, 2016**

Bibliographic Reference Vasant, Dipesh H.; Michou, Emilia; O'Leary, Neil; Vail, Andy; Mistry, Satish; Hamdy, Shaheen; Pharyngeal Electrical Stimulation in Dysphagia Poststroke.; *Neurorehabilitation & Neural Repair*; 2016; vol. 30 (no. 9); 866-875

4

5 **1.1.93.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	Vasant D, Michou E, Tyrrell P, <i>et al</i> OC-063 Pharyngeal Electrical Stimulation (pes) In Dysphagia Post-acute Stroke: A Double-blind, Randomised Trial <i>Gut</i> 2014; 63 :A31. This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323

Trial name / registration number	Clinical Trial Registration: ISRCTN 83103698.
Study type	Randomised controlled trial (RCT)
Study location	Stroke units in 3 Greater Manchester hospitals (Salford Royal, University Hospital of South Manchester, and Trafford General)
Study setting	UK
Study dates	No additional information
Sources of funding	The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This article presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0107-12076). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.
Inclusion criteria	Patients included (no age limit) were those with newonset dysphagia following anterior or posterior cerebral circulation, within 6 weeks of ictus. Patients with both ischemic stroke and hemorrhagic stroke were included. All recruited patients were medically stable at inclusion. None of the included patients had been intubated/trachiotomized during hospitalization prior to recruitment.
Exclusion criteria	Exclusion criteria included advanced dementia, other neurological conditions that may explain dysphagia, previous history of dysphagia, presence of cardiac pacemaker or implanted cardiac defibrillator, a diagnosis other than stroke (eg, brain tumor), any severe concomitant chronic medical condition that compromises cardiac or respiratory status (severe emphysema or heart failure that may render catheter intubation unsafe), and significant structural abnormalities of the mouth or throat. Patients requiring continuous oxygen treatment were also excluded.
Recruitment / selection of participants	Stroke patients who fulfilled inclusion criteria were identified and approached on the stroke units in 3 Greater Manchester hospitals (Salford Royal, University Hospital of South Manchester, and Trafford General). All recruited participants either provided informed written consent, or if they lacked capacity as a result of stroke, they were recruited if a named consultee declared that in their opinion, the patient would not have objected to participation in the trial.
Intervention(s)	Interventions were delivered at the patient's bedside. Based on previous pharyngeal electrode placement experience in clinically dysphagic patients, the intraluminal pharyngeal "stimulation" catheter (Gaeltec, Dunvegan, Isle of Skye, UK) was inserted either orally or nasally (depending on patient preference) such that its bipolar electrodes were secured at the midpharyngeal level (17 cm from the nasal flare or 15 cm aboral). The catheter was connected to a stimulator (Model DS7; Digitimer, Welwyn-Garden City, Herts, UK) via a trigger generator (Neurolog System, Digitimer), and stimuli were delivered (0.2 ms pulses, maximum 280 V) at the previously defined optimal parameters (5 Hz frequency and an intensity [current]

	75% of the maximum tolerated). The maximum tolerated intensity was determined from each patient's perception and pain thresholds; these values were calculated from an average of 3 consecutive measurements on each of the 3 days. Group 1 received 3 sessions of PES for 10 minutes on 3 consecutive days.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Group 2 received sham stimulation (catheter in situ with stimulator turned off) for the same period. Concomitant therapy - Both groups continued to receive standard swallowing treatments as decided by SaLTs of the respective hospitals.
Number of participants	36
Duration of follow-up	2 weeks and 3 months
Indirectness	NR

Additional comments	NR
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2 **1.1.93.2. Study arms**3 **1.1.93.2.1. Pharyngeal electrical stimulation (N = 18)**

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5 **1.1.93.2.2. Sham PES (N = 18)**

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7 **1.1.93.3. Characteristics**8 **1.1.93.3.1. Study-level characteristics**

Characteristic	Study (N = 36)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	

9

10 **1.1.93.3.2. Arm-level characteristics**

Characteristic	Pharyngeal electrical stimulation (N = 18)	Sham PES (N = 18)
% Female	50	28
Nominal		

Characteristic	Pharyngeal electrical stimulation (N = 18)	Sham PES (N = 18)
Mean age (SD)	71 (56 to 79)	71 (61 to 78)
Median (IQR)		
Severity of dysphagia	NR	NR
Nominal		
Time after stroke	16 (9 to 23)	11 (7 to 17)
Median (IQR)		
People requiring enteral feeding support at baseline	NR	NR
Nominal		
NG	11	9
Nominal		
PEG	5	5
Nominal		
None	2	4
Nominal		
Type of stroke	NR	NR
Nominal		

1 **1.1.93.4. Outcomes**2 **1.1.93.4.1. Study timepoints**

- 3 • Baseline
4 • 3 month

5

6 **1.1.93.4.2. Dichotomous outcomes (1)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 18	Pharyngeal electrical stimulation, 3 month, N = 18	Sham PES, Baseline, N = 18	Sham PES, 3 month, N = 18
Mortality	n = 0 ; % = 0	n = 1 ; % = 6	n = 0 ; % = 0	n = 1 ; % = 6
No of events				

7 Mortality - Polarity - Lower values are better

8 **1.1.93.4.3. Continuous outcomes (1)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 18	Pharyngeal electrical stimulation, 3 month, N = 6	Sham PES, Baseline, N = 18	Sham PES, 3 month, N = 7
Occurrence of aspiration (PAS) Scale range: 1-8.	NR (NR)	2.64 (1.8)	NR (NR)	4.31 (2.5)
Mean (SD)				

9 Occurrence of aspiration (PAS) - Polarity - Lower values are better

1 **1.1.93.4.4. Dichotomous outcomes (2)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 18	Pharyngeal electrical stimulation, 3 month, N = 14	Sham PES, Baseline, N = 18	Sham PES, 3 month, N = 14
Dysphagia present/return to normal diet (return to normal diet - removal of NG and PEG tubes)	n = NA ; % = NA	n = 8 ; % = 57	n = NA ; % = NA	n = 4 ; % = 29
No of events				

2 Dysphagia present/return to normal diet (return to normal diet - removal of NG and PEG tubes) - Polarity - Higher values are better

3 **1.1.93.4.5. Continuous outcomes (2)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 18	Pharyngeal electrical stimulation, 3 month, N = 14	Sham PES, Baseline, N = 18	Sham PES, 3 month, N = 14
Length of hospital stay (days)	NR (NR)	56.07 (25.86)	NR (NR)	66.43 (35.97)
Mean (SD)				

4 Length of hospital stay - Polarity - Lower values are better

5 **1.1.93.4.6. Continuous outcomes (3)**

Outcome	Pharyngeal electrical stimulation, Baseline, N = 18	Pharyngeal electrical stimulation, 3 month, N = 18	Sham PES, Baseline, N = 18	Sham PES, 3 month, N = 17
Swallowing ability (Dysphagia Severity Rating) Scale range: 0-12. Final values.	NR (NR)	4.28 (3.97)	NR (NR)	4.59 (4.39)
Mean (SD)				

6 Swallowing ability (Dysphagia Severity Rating) - Polarity - Lower values are better

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1.1.93.4.7. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

1.1.93.4.8. Continuousoutcomes-Occurrenceofaspiration(PAS)-MeanSD-Pharyngeal electrical stimulation-Sham PES-t3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

1.1.93.4.9. Swallowingability-Swallowingability(unclearwhichscalereported)-MeanSD-Pharyngeal electrical stimulation-Sham PES-t3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

1.1.93.4.10. Continuousoutcome-Lengthofhospitalstay-MeanSD-Pharyngeal electrical stimulation-Sham PES-t3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.93.4.11. Dichotomous outcomes-Mortality-NoOfEvents-Pharyngeal electrical stimulation-Sham PES-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

2

3 **1.1.93.4.12. Dichotomous outcomes-Dysphagia present/return to normal diet (return to normal diet-removal of NG and PEG tubes)-**
 4 **NoOfEvents-Pharyngeal electrical stimulation-Sham PES-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

5

6 **1.1.94. Wang, 2017**

Bibliographic Reference Wang, Ling; Qiu, Xiao-Ping; Ye, Li-Juan; Effects of Rood intervention and routine oral intervention on malnutrition in stroke patients with dysphagia; World Chinese Journal of Digestology; 2017; vol. 25; 1980-1984

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8 **1.1.94.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
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Other publications associated with this study included in review	No additional information.
Trial name / registration number	NR
Study location	China
Study setting	Affiliated Hospital of Hangzhou Normal University
Study dates	July 2011 to June 2016
Sources of funding	NR
Inclusion criteria	Inclusion criteria: (1) stroke patients with dysphagia; (2) stable vital signs; (3) all patients' families signed the informed consent.
Exclusion criteria	Exclusion criteria: (1) patients with oral lesions; (2) Serious dysfunction of heart, liver and kidney; (3) Patients with pulmonary infection; (4) Family members are reluctant to participate in this study; (5) Poor treatment compliance.
Recruitment / selection of participants	NR
Intervention(s)	The patients in the observation group received Rood technology intervention, and the pharyngeal and palatal arches and tongue were rapidly stimulated with ice cotton sticks For the root, in order to avoid nausea, each part was stimulated back and forth 5 times, 5 min/time, 3 times/d, and the intervention was continued for 14 d.
Subgroup 1: Severity of dysphagia (as stated by category)	Mixed
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	The patients in the control group received routine oral intervention, regular oral massage, 3 times/d, and continued intervention for 14 days.
Number of participants	96
Duration of follow-up	14 days
Indirectness	NR
Additional comments	NR

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2 **1.1.94.2. Study arms**3 **1.1.94.2.1. *Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment (N = 48)***

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5 **1.1.94.2.2. *Routine treatment (oral exercises and massage) (N = 48)***

6

1 **1.1.94.3. Characteristics**2 **1.1.94.3.1. Study-level characteristics**

Characteristic	Study (N = 96)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

4 **1.1.94.3.2. Arm-level characteristics**

Characteristic	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment (N = 48))	Routine treatment (oral exercises and massage) (N = 48)
% Female	39.5	41.6

Characteristic	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment (N = 48))	Routine treatment (oral exercises and massage) (N = 48)
Nominal		
Mean age (SD)	51.3 (4.7)	52.4 (5.1)
Mean (SD)		

1

2 **1.1.94.4. Outcomes**

3 **1.1.94.4.1. Study timepoints**

- 4 • Baseline
- 5 • 14 day

6

7 **1.1.94.4.2. Dichotomous outcomes**

Outcome	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, Baseline, N = 48)	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, 14 day, N = 48)	Routine treatment (oral exercises and massage), Baseline, N = 48	Routine treatment (oral exercises and massage), 14 day, N = 48
occurrence of chest infections	n = NR ; % = NR	n = 3 ; % = 6.25	n = NR ; % = NR	n = 12 ; % = 25
No of events				
Occurance of aspiration	n = NR ; % = NR	n = 6 ; % = 12.5	n = NR ; % = NR	n = 17 ; % = 35.42

Outcome	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, Baseline, N = 48	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, 14 day, N = 48	Routine treatment (oral exercises and massage), Baseline, N = 48	Routine treatment (oral exercises and massage), 14 day, N = 48
No of events				
Presence of dysphagia	n = NR ; % = NR	n = 19 ; % = 39.5	n = NR ; % = NR	n = 37 ; % = 77.1
No of events				

1 occurrence of chest infections - Polarity - Lower values are better

2 Occurance of aspiration - Polarity - Lower values are better

3 Presence of dysphagia - Polarity - Lower values are better

4 **1.1.94.4.3. Continuous outcomes**

Outcome	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, Baseline, N = 48	Rood intervention (thermal and tactile stimulation of the pharyngeal palatine arch + routine treatment, 14 day, N = 48	Routine treatment (oral exercises and massage), Baseline, N = 48	Routine treatment (oral exercises and massage), 14 day, N = 48
Nutrition (albumin)	25.12 (2.36)	36.07 (3.36)	26.88 (2.74)	30.37 (3.06)
Mean (SD)				

5 Nutrition (albumin) - Polarity - Higher values are better

6

7

1 **1.1.94.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.94.4.5. Continuousoutcomes-Nutrition(albumin)-MeanSD-Rood intervention (thermal and tactile stimulation of the**
 3 **pharyngeal palatine arch + routine treatment-Routine treatment (oral exercises and massage)-t14**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.94.4.6. Dichotomousoutcomes-Presenceofdysphagia-NoOfEvents-Rood intervention (thermal and tactile stimulation of the**
 6 **pharyngeal palatine arch + routine treatment-Routine treatment (oral exercises and massage)-t14**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.94.4.7. Dichotomousoutcomes-Occuranceofaspiration-NoOfEvents-Rood intervention (thermal and tactile stimulation of**
 9 **the pharyngeal palatine arch + routine treatment-Routine treatment (oral exercises and massage)-t14**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.94.4.8. Dichotomous outcomes-occurrence of chest infections-No Of Events-Rood intervention (thermal and tactile stimulation**
 2 **of the pharyngeal palatine arch + routine treatment-Routine treatment (oral exercises and massage)-t14**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to randomisation and missing data)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.95. Wang, 2022**

Bibliographic Reference Wang, Tingwei; Tai, Jiahui; Hu, Ruiping; Fan, Shunjuan; Li, Haozheng; Zhu, Yulian; Wu, Yi; Wu, Junfa; Effect of Tongue-Pressure Resistance Training in Poststroke Dysphagia Patients with Oral Motor Dysfunction-A Randomized Controlled Trial.; American journal of physical medicine & rehabilitation; 2022

5

6 **1.1.95.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	ChiCTR2000032129.

Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	June 2019 to December 2020.
Sources of funding	Funded by the Shanghai Commission of Science and Technology of China (No. 19411968700, 20412420200), General Program of National Natural Science Foundation of China (No. 81972140), the National Key R&D Program of China (No. 2018YFC2001700) and the Shanghai Municipal Key Clinical Speciality (No. shslczdzk02702).
Inclusion criteria	People diagnosed with stroke that were confirmed by CT or MRI, according to the Diagnostic Key Points of Various Major Cerebrovascular Diseases in China (2019); presence of dysphagia after stroke confirmed by FEES; assessment of oral motor dysfunction with 6 codes of the ICF (e.g. b5100 sucking, b5101 biting, b5102 chewing, b5103 manipulation of food in mouth, b5104 salivation, b51050 oral swallowing); aged between 45 and 75 years old; people without unconsciousness, dementia or sensory aphasia.
Exclusion criteria	Existence of other neurological conditions; local oral lesions, such as oral ulcers in lips, buccal, tongue, hard and soft palates; unstable vital signs, severe cardiopulmonary insufficiency, or critically ill patients who cannot cooperate with TPRT.
Recruitment / selection of participants	People recruited from the rehabilitation department, Huashan Hospital, Fudan University.
Intervention(s)	<p>Behavioural intervention (tongue-pressure resistance training) N=19</p> <p>Tongue-pressure resistance training by a JMS tongue pressure measurement device according to the standard protocols. People sat on chairs and look forward with their head in a neutral position. In the manometer, the probe was filled with air to make inter pressure at 20 kPa and positioned on the middle of their tongues with the lips closed. People were encouraged to use their tongues to squeeze the probe upward. The maximal tongue pressure on the manometer was recorded. 50% of MTP was set at the initial training value. During training, people were asked to squeeze the probe as hard as possible, receiving real-time dynamic feedback by observing the change in the pressure value. The same experienced Speech and Language Pathologist performed training for 20 minutes/day, 5 days a week for 4 weeks.</p> <p>Concomitant therapy: Conventional dysphagia rehabilitation training, including oro-facial motor control exercises, oro-facial muscles sensory stimulation, respiratory training and airway protection manipulation. The oro-facial motor control exercises</p>

	consisted of occlusion, cheek blowing, tongue protrusion, lip shrink and bolus control exercises. The oro-facial muscles sensory stimulation included electrical stimulation or cold stimulation with ice. Respiratory training includes shrinking breathing, abdominal breathing and cough training. The airway protection manipulation consisted of Mendelsohn maneuver, effortful swallow, supraglottic swallow and super-supraglottic swallow. An experienced Speech-Language Pathologist performed conventional dysphagia rehabilitation training for 30 minutes/day, 5 days a week for 4 weeks.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Mixed
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=18 Usual care only. Concomitant therapy: Conventional dysphagia rehabilitation training, including oro-facial motor control exercises, oro-facial muscles sensory stimulation, respiratory training and airway protection manipulation. The oro-facial motor control exercises consisted of occlusion, cheek blowing, tongue protrusion, lip shrink and bolus control exercises. The oro-facial muscles sensory stimulation included electrical stimulation or cold stimulation with ice. Respiratory training includes shrinking breathing, abdominal breathing and cough training. The airway protection manipulation consisted of Mendelsohn maneuver,

	effortful swallow, supraglottic swallow and super-supraglottic swallow. An experienced Speech-Language Pathologist performed conventional dysphagia rehabilitation training for 30 minutes/day, 5 days a week for 4 weeks.
Number of participants	37
Duration of follow-up	

1

2 **1.1.95.2. Study arms**3 **1.1.95.2.1. Behavioural intervention (tongue-pressure resistance training) (N = 19)**

4 Tongue-pressure resistance training by a JMS tongue pressure measurement device according to the standard protocols. People sat
5 on chairs and look forward with their head in a neutral position. In the manometer, the probe was filled with air to make inter pressure
6 at 20 kPa and positioned on the middle of their tongues with the lips closed. People were encouraged to use their tongues to squeeze
7 the probe upward. The maximal tongue pressure on the manometer was recorded. 50% of MTP was set at the initial training value.
8 During training, people were asked to squeeze the probe as hard as possible, receiving real-time dynamic feedback by observing the
9 change in the pressure value. The same experienced Speech and Language Pathologist performed training for 20 minutes/day, 5
10 days a week for 4 weeks. Concomitant therapy: Conventional dysphagia rehabilitation training, including oro-facial motor control
11 exercises, oro-facial muscles sensory stimulation, respiratory training and airway protection manipulation. The oro-facial motor control
12 exercises consisted of occlusion, cheek blowing, tongue protrusion, lip shrink and bolus control exercises. The oro-facial muscles
13 sensory stimulation included electrical stimulation or cold stimulation with ice. Respiratory training includes shrinking breathing,
14 abdominal breathing and cough training. The airway protection manipulation consisted of Mendelsohn maneuver, effortful swallow,
15 supraglottic swallow and super-supraglottic swallow. An experienced Speech-Language Pathologist performed conventional
16 dysphagia rehabilitation training for 30 minutes/day, 5 days a week for 4 weeks.

17

18 **1.1.95.2.2. Usual care (N = 18)**

19 Usual care only. Concomitant therapy: Conventional dysphagia rehabilitation training, including oro-facial motor control exercises, oro-
20 facial muscles sensory stimulation, respiratory training and airway protection manipulation. The oro-facial motor control exercises
21 consisted of occlusion, cheek blowing, tongue protrusion, lip shrink and bolus control exercises. The oro-facial muscles sensory
22 stimulation included electrical stimulation or cold stimulation with ice. Respiratory training includes shrinking breathing, abdominal

1 breathing and cough training. The airway protection manipulation consisted of Mendelsohn maneuver, effortful swallow, supraglottic
 2 swallow and super-supraglottic swallow. An experienced Speech-Language Pathologist performed conventional dysphagia
 3 rehabilitation training for 30 minutes/day, 5 days a week for 4 weeks.

4

5 **1.1.95.3. Characteristics**

6 **1.1.95.3.1. Arm-level characteristics**

Characteristic	Behavioural intervention (tongue-pressure resistance training) (N = 19)	Usual care (N = 18)
People requiring enteral feeding support at baseline	n = 13 ; % = 68	n = 14 ; % = 78
Sample size		

7

8 **1.1.95.4. Outcomes**

9 **1.1.95.4.1. Study timepoints**

- 10 • Baseline
- 11 • 4 week (<3 months)

12

13 **1.1.95.4.2. Dichotomous outcomes**

Outcome	Behavioural intervention (tongue-pressure resistance training), Baseline, N = 19	Behavioural intervention (tongue-pressure resistance training), 4 week, N = 19	Usual care, Baseline, N = 18	Usual care, 4 week, N = 18
Occurrence of chest infections (pneumonia)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 0 ; % = 0

Outcome	Behavioural intervention (tongue-pressure resistance training), Baseline, N = 19	Behavioural intervention (tongue-pressure resistance training), 4 week, N = 19	Usual care, Baseline, N = 18	Usual care, 4 week, N = 18
15 in the intervention group, 14 in the control group were diagnosed before the study. No new cases during treatment.				
No of events				

1 Occurrence of chest infections (pneumonia) - Polarity - Lower values are better

2

3

4 **1.1.95.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.95.4.4. Dichotomous outcomes - Occurrence of pneumonia - No of events - Behavioural intervention (tongue-pressure**
 6 **resistance training) - Usual care - t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.96. Wang, 2020**

Bibliographic Reference Wang, Zhi-Yong; Chen, Jian-Min; Lin, Zheng-Kun; Ni, Guo-Xin; Transcranial direct current stimulation improves the swallowing function in patients with cricopharyngeal muscle dysfunction following a brainstem stroke.; Neurological sciences : official journal of the Italian Neurological Society and of the Italian Society of Clinical Neurophysiology; 2020; vol. 41 (no. 3); 569-574

1

2 **1.1.96.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.
Trial name / registration number	NR
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Department of Rehabilitation Medicine, the First Affiliated Hospital of Fujian Medical University, China
Study dates	October 2016 and September 2018
Sources of funding	The study was supported by Startup Fund for scientific research, Fujian Medical University (Grant number, 2016QH071), and National Natural Science Foundation of China (81572219).
Inclusion criteria	(1) onset duration was more than 1 month prior to enrolment; (2) dysphagia was caused by CPD, confirmed by a videofluoroscopic swallowing study (VFSS); (3) received aspiration during the VFSS; (4) used a nasogastric tube for nutrition supply; and (5) had a MiniMental State Examination (MMSE) score of 23 or above
Exclusion criteria	(1) severely decreased consciousness; (2) history of epilepsy; (3) unstable medical conditions such as severe pneumonia and decompensated congestive heart failure; (4) history of previous dysphagia; (5) history of radiotherapy for nasopharyngeal carcinoma, head and neck cancer and oral cancer or other head and neck diseases; and (6) had an intracranial metallic device.

Recruitment / selection of participants	Brainstem stroke patients were recruited between October 2016 and September 2018
Intervention(s)	<p>All patients received 20 intervention sessions (five times per week for 4 weeks).</p> <p>tDCS stimulation was delivered through a direct current stimulator (IS300; Zhineng Electronics Industrial Co. Ltd; Sichuan province, China), with two saline-soaked sponge surface electrodes (dimension of 5 cm × 5 cm for both the anode and reference electrodes). The anodal electrode was placed over the bilateral cerebral hemispheres, about 3 cm anterior and 6 cm lateral to the vertex, with stimuli projecting towards the oesophageal cortical area; a reference electrode was placed over the contralesional supraorbital region. For the tDCS group, the direct current was gradually increased to 1 mA within 5 s and subsequently maintained for 20 min. Each hemisphere was stimulated consecutively for 20 min with an interval of 30 min. The treatment protocol for the sham tDCS group was identical to that for the tDCS group, except that the direct current was gradually increased to 1 mA within 5 s and turned off 30 s later in order to produce an initial tingling sensation.</p> <p>Patients in both groups received catheter balloon dilatation and conventional swallowing therapy.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline

Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	All patients received 20 intervention sessions (five times per week for 4 weeks). Patients in both groups received catheter balloon dilatation and conventional swallowing therapy. The conventional swallowing therapy was conducted based on the results of the VFSS and administered by a speech language therapist (Cui Cui-Zhang), who was blind to the swallowing assessment and data analysis.
Number of participants	28
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.96.2. Study arms**3 **1.1.96.2.1. *transcranial direct current stimulation (tDCS) (N = 14)***

4

5 **1.1.96.2.2. *Sham tDCS (N = 14)***

6

1 **1.1.96.3. Characteristics**2 **1.1.96.3.1. Study-level characteristics**

Characteristic	Study (N = 28)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

4 **1.1.96.3.2. Arm-level characteristics**

Characteristic	transcranial direct current stimulation (tDCS) (N = 14)	Sham tDCS (N = 14)
% Female	21	29
Nominal		
Mean age (SD)	61.43 (11.24)	62 (10.46)
Mean (SD)		
Severity of dysphagia FOIS	1.43 (0.9)	1.64 (1)

Characteristic	transcranial direct current stimulation (tDCS) (N = 14)	Sham tDCS (N = 14)
Mean (SD)		
Time after stroke (days)	66.79 (38.63)	67.5 (47.62)
Mean (SD)		

1

2 **1.1.96.4. Outcomes**3 **1.1.96.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week

6

7 **1.1.96.4.2. Continuous outcomes**

Outcome	transcranial direct current stimulation (tDCS), Baseline, N = 14	transcranial direct current stimulation (tDCS), 4 week, N = 14	Sham tDCS, Baseline, N = 14	Sham tDCS, 4 week, N = 14
Swallowing ability (FOIS) Scale range: 1-7. Final values. Mean (SD)	1.43 (0.9)	6.07 (1.1)	1.64 (1)	4.71 (1.4)

8 Swallowing ability (FOIS) - Polarity - Higher values are better

9

10

1 **1.1.96.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.96.4.4. Continuousoutcomes-Swallowingability(FOIS)-MeanSD-transcranial direct current stimulation (tDCS)-Sham tDCS-**
 3 **t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High <i>(due to randomisation and missing outcome data)</i>
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.97. Wang, 2019**

Bibliographic Reference Wang, Zhuo; Wu, Lingling; Fang, Qi; Shen, Meifen; Zhang, Lulu; Liu, Xueyun; Effects of capsaicin on swallowing function in stroke patients with dysphagia: A randomized controlled trial.; Journal of Stroke & Cerebrovascular Diseases; 2019; vol. 28 (no. 6); 1744-1751

6

7 **1.1.97.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	No additional information.

Trial name / registration number	The Clinical Trial registration number of this study is [2018]-(K015).
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Yancheng City No.1 People's Hospital, China
Study dates	January to September 2018
Sources of funding	Funding: This work was funded by Postgraduate Research & Practice Innovation Program of Jiangsu Province; Integrated Care Model for Patients with Dysphagia after Stroke grant number KYCX18_254
Inclusion criteria	Hemorrhagic or ischemic stroke patients within 1-week of admission were included with the following selection criteria. Patients must be clinically assessed with the Volume-Viscosity Swallowing Test (V-VST), presenting clinical signs of dysphagia, older than 55 years of age, scoring above a 7 on the Abbreviated mental test scale, and able to give informed consent and follow study procedures.
Exclusion criteria	Exclusion criteria were unstable health conditions such as pyrexia or heart and respiratory disease, history of previous other diseases that might be associated with the presence of dysphagia, refusal to participate, and bronchial asthma or chronic coughs
Recruitment / selection of participants	No additional information
Intervention(s)	Thermal tactile stimulation N=30 By adding 1 g of Sichuan red pepper powder to 50 mL of mineral water, a capsaicin concentration of 150 mg/L was obtained, based on the Chinese Pharmacopoeia. A cotton swab soaked in the capsaicin solution at cold (4°C) temperature was used to dab the oropharyngeal mucosa region in the thermal tactile stimulation. A soft, fast touch no longer than 5 minutes was performed to minimize the mechanical effect of the stimulus. In addition, a 1mL nectar bolus of 150 mg/L capsaicin was administered to patients before each meal, as previous researches demonstrated that 150 mg/L was the most effective concentration for natural capsaicinoids. Nectar viscosity was obtained by adding 3.5 g of thickener Resource ThickenUp (Nestle Nutrition, Barcelona, Spain) to 100 mL of mineral water. Treatment was administered to patients three times per day before each meal for 3 weeks. The capsaicin and placebo solutions were prepared once weekly and preserved under refrigeration (4°C).

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information
Comparator	Control group N=30 In the control group, the solution and the nectar bolus were made to be identical to that in the intervention group, except for capsaicin. The randomization and supply of capsaicin were performed by a blinded pharmacist who was not involved in the study. Concomitant therapy - Both groups received the same conventional dysphagia treatments such as orofacial muscle exercises, thickeners, postures, and therapeutic or compensatory maneuvers.
Number of participants	30
Duration of follow-up	3 weeks
Indirectness	NR
Additional comments	NR

1 **1.1.97.2. Study arms**

2 **1.1.97.2.1. Thermal tactile stimulation (N = 30)**

3 By adding 1 g of Sichuan red pepper powder to 50 mL of mineral water, a capsaicin concentration of 150 mM/L was obtained,
 4 based on the Chinese Pharmacopoeia. A cotton swab soaked in the capsaicin solution at cold (4°C) temperature was used to dab the
 5 oropharyngeal mucosa region in the thermal tactile stimulation. A soft, fast touch no longer than 5 minutes was performed to minimize
 6 the mechanical effect of the stimulus. In addition, a 1mL nectar bolus of 150 mM/L capsaicin was administered to patients before each
 7 meal, as previous researches demonstrated that 150 mM/L was the most effective concentration for natural capsaicinoids. Nectar
 8 viscosity was obtained by adding 3.5 g of thickener Resource ThickenUp (Nestle Nutrition, Barcelona, Spain) to 100 mL of mineral
 9 water. Treatment was administered to patients three times per day before each meal for 3 weeks. The capsaicin and placebo solutions
 10 were prepared once weekly and preserved under refrigeration (4°C).

11

12 **1.1.97.2.2. Control group (N = 30)**

13 In the control group, the solution and the nectar bolus were made to be identical to that in the intervention group, except for capsaicin.
 14 The randomization and supply of capsaicin were performed by a blinded pharmacist who was not involved in the study. Concomitant
 15 therapy - Both groups received the same conventional dysphagia treatments such as orofacial muscle exercises, thickeners, postures,
 16 and therapeutic or compensatory maneuvers.

17

18 **1.1.97.3. Characteristics**

19 **1.1.97.3.1. Study-level characteristics**

Characteristic	Study (N = 30)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	

Characteristic	Study (N = 30)
Severity of dysphagia	NR
Nominal	
Time after stroke	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

1

2

1.1.97.3.2. *Arm-level characteristics*

Characteristic	Thermal tactile stimulation (N = 30)	Control group (N = 30)
% Female	46.6	33.3
Nominal		
Mean age (SD)	63.77 (12.18)	66.23 (11.91)
Mean (SD)		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
No of events		
Cortical	n = 5 ; % = 16.7	n = 5 ; % = 16.7
No of events		
Subcortical	n = 18 ; % = 60	n = 20 ; % = 66.7

Characteristic	Thermal tactile stimulation (N = 30)	Control group (N = 30)
No of events		
Brain stem/cerebellar	n = 7 ; % = 23.3	n = 5 ; % = 16.7
No of events		

1

2 **1.1.97.4. Outcomes**3 **1.1.97.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 week

6

7 **1.1.97.4.2. Dichotomous outcomes**

Outcome	Thermal tactile stimulation , Baseline, N = 30	Thermal tactile stimulation , 3 week, N = 30	Control group, Baseline, N = 30	Control group, 3 week, N = 30
Occurrence of chest infections	n = 0 ; % = 0	n = 1 ; % = 3.3	n = 0 ; % = 0	n = 1 ; % = 3.3
No of events				
Dysphagia present (water swallow test) number with effective swallow	n = NR ; % = NR	n = 27 ; % = 90	n = NR ; % = NR	n = 9 ; % = 30
No of events				

8 Occurrence of chest infections - Polarity - Lower values are better

9 Dysphagia present (water swallow test) - Polarity - Higher values are better

1 **1.1.97.4.3. Continuous outcomes**

Outcome	Thermal tactile stimulation , Baseline, N = 30	Thermal tactile stimulation , 3 week, N = 30	Control group, Baseline, N = 30	Control group, 3 week, N = 30
Swallowing ability (Eat-10) Scale range: 0-40. Change score Mean (95% CI)	NR (NR to NR)	-11.77 (-12.69 to -10.84)	NR (NR to NR)	-9.4 (-10.43 to -8.37)

2 Swallowing ability (Eat-10) - Polarity - Lower values are better

3
4

5 **1.1.97.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

6 **1.1.97.4.5. Dichotomous outcomes-Dysphagiapresent(waterswallowtest)-NoOfEvents-Thermal tactile stimulation -Control group-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to issues arising from the randomisation process)</i>
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.97.4.6. Dichotomous outcomes-Occurrenceofchestinfections-NoOfEvents-Thermal tactile stimulation -Control group-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns <i>(due to issues arising from the randomisation process)</i>

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.97.4.7. Continuous outcomes-Swallowing ability (Eat-10)-Mean Nine Five Percent CI-Thermal tactile stimulation -Control**
3 **group-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (due to issues arising from the randomisation process)
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.98. Warusevitane, 2015**

Bibliographic Reference Warusevitane, Anushka; Karunatilake, Dumin; Sim, Julius; Lally, Frank; Roffe, Christine; Safety and effect of metoclopramide to prevent pneumonia in patients with stroke fed via nasogastric tubes trial.; Stroke; 2015; vol. 46 (no. 2); 454-60

6

7 **1.1.98.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
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Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	ISRCTN 18034911/18034911.
Study type	Randomised controlled trial (RCT)
Study location	United Kingdom.
Study setting	Inpatients.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	People within 7 days of acute ischaemic or haemorrhagic stroke confirmed by computer tomographic scan of the brain who required nasogastric feeds for >24 hours, and could be recruited within 48 hours of nasogastric tube insertion.
Exclusion criteria	Signs and symptoms of pneumonia after stroke onset; a history of chronic neurodegenerative diseases that could affected swallowing (eg, Parkinson disease and motor neuron disease); oesophageal disorders; contraindications to metoclopramide.
Recruitment / selection of participants	People at the acute stroke unit of the University Hospital of North Staffordshire, United Kingdom.
Intervention(s)	Metoclopramide N=30 10mg metoclopramide (colourless solution 10mL) 3 times a day via a nasogastric tube. Treatment was continued until nasogastric feeding was no longer necessary or for a maximum of 21 days. Concomitant therapy: No additional information.

Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	People requiring enteral feeding support at baseline
Subgroup 4: Type of stroke (using the Bamford scale)	Mixed
Population subgroups	No additional information.
Comparator	Placebo N=30 Normal saline for the same timing and duration. Concomitant therapy: No additional information.
Number of participants	60
Duration of follow-up	21 days (follow up on day 7, 14 and 21).
Indirectness	No additional information.
Additional comments	Method of analysis appears to be ITT no drop outs.

1

2 **1.1.98.2. Study arms**3 **1.1.98.2.1. Metoclopramide (N = 30)**

4 10mg metoclopramide (colourless solution 10mL) 3 times a day via a nasogastric tube. Treatment was continued until nasogastric
5 feeding was no longer necessary or for a maximum of 21 days. Concomitant therapy: No additional information.

6

7 **1.1.98.2.2. Placebo (N = 30)**

8 Normal saline for the same timing and duration. Concomitant therapy: No additional information.

9

10 **1.1.98.3. Characteristics**11 **1.1.98.3.1. Arm-level characteristics**

Characteristic	Metoclopramide (N = 30)	Placebo (N = 30)
% Female	n = 19 ; % = 63	n = 19 ; % = 63
Sample size		
Mean age (SD) (years)	76.9 (6.3)	79.2 (10.8)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		

Characteristic	Metoclopramide (N = 30)	Placebo (N = 30)
Diabetes mellitus	n = 7 ; % = 23	n = 10 ; % = 33
Sample size		
Hypertension	n = 18 ; % = 60	n = 22 ; % = 73
Sample size		
Atrial fibrillation	n = 20 ; % = 66	n = 17 ; % = 57
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	NR (NR)	NR (NR)
Mean (SD)		
People requiring enteral feeding support at baseline	n = 30 ; % = 100	n = 30 ; % = 100
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.98.4. Outcomes**3 **1.1.98.4.1. Study timepoints**

- 4 • Baseline
- 5 • 21 day (<3 months)

- 1 • 30 day (<3 months)

2

3 **1.1.98.4.2. Dichotomous outcomes**

Outcome	Metoclopramide, Baseline, N = 30	Metoclopramide, 21 day, N = 30	Metoclopramide, 30 day, N = 30	Placebo, Baseline, N = 30	Placebo, 21 day, N = 30	Placebo, 30 day, N = 30
Mortality	n = NA ; % = NA	n = NR ; % = NR	n = 8 ; % = 27	n = NA ; % = NA	n = NR ; % = NR	n = 12 ; % = 40
No of events						
Occurrence of chest infections (pneumonia)	n = NA ; % = NA	n = 8 ; % = 27	n = NR ; % = NR	n = NA ; % = NA	n = 26 ; % = 87	n = NR ; % = NR
Number of people with any episodes of pneumonia (not counting the average number of episodes of pneumonia).						
No of events						
Dysphagia present/return to normal diet (swallow improved and treatment withdrawal)	n = NA ; % = NA	n = 23 ; % = 77	n = NR ; % = NR	n = NA ; % = NA	n = 17 ; % = 57	n = NR ; % = NR
No of events						

4 Mortality - Polarity - Lower values are better

5 Occurrence of chest infections (pneumonia) - Polarity - Lower values are better

6 Dysphagia present/return to normal diet (swallow improved and treatment withdrawal) - Polarity - Higher values are better

1 **1.1.98.4.3. Continuous outcomes**

Outcome	Metoclopramide, Baseline, N = 30	Metoclopramide, 21 day, N = 30	Metoclopramide, 30 day, N = 30	Placebo, Baseline, N = 30	Placebo, 21 day, N = 30	Placebo, 30 day, N = 30
Occurrence of aspiration (number of episodes of aspiration) Final values. Mean (SD)	NA (NA)	0.03 (0.18)	NR (NR)	NA (NA)	0.73 (0.91)	NR (NR)

2 Occurrence of aspiration (number of episodes of aspiration) - Polarity - Lower values are better

3

4

5 **1.1.98.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**6 **1.1.98.4.5. Dichotomous outcomes-Mortality-NoOfEvents-Metoclopramide-Placebo-t30**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.98.4.6. Dichotomous outcomes-Occurrence of chest infections (pneumonia)-NoOfEvents-Metoclopramide-Placebo-t21**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.98.4.7. Dichotomous outcomes-Dysphagiapresent/returntonormaldiet(swallowimprovedandtreatmentwithdrawal)-**
 3 **NoOfEvents-Metoclopramide-Placebo-t21**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.98.4.8. Continuous outcomes-Occurrenceofaspiration(numberofepisodesofaspiration)-MeanSD-Metoclopramide-Placebo-**
 6 **t21**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.99. Xia, 2011**

Bibliographic Reference Xia, Wenguang; Zheng, Chanjuan; Lei, Qingtao; Tang, Zhouping; Hua, Qiang; Zhang, Yangpu; Zhu, Suiqiang; Treatment of post-stroke dysphagia by vitalstim therapy coupled with conventional swallowing training.; Journal of Huazhong University of Science and Technology. Medical sciences = Hua zhong ke ji da xue xue bao. Yi xue Ying De wen ban = Huazhong keji daxue xuebao. Yixue Yingdewen ban; 2011; vol. 31 (no. 1); 73-76

9

1 1.1.99.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	December 2007 to June 2010.
Sources of funding	The project was supported by a grant from the Health Bureau of Hubei Province, China (No. JX5B36).
Inclusion criteria	Fulfilling the diagnostic criteria for various cerebrovascular diseases formulated by the Fourth Academic Conference of National Cerebrovascular Diseases in 1995; being finally diagnosed as having cerebral infarction or cerebral haemorrhage by CT or MRI; having swallowing disorder as confirmed by water drinking test; no pulmonary diseases; being 40-80 years old; possessing clear consciousness and being able to cooperate; being willing to provide written informed consent.
Exclusion criteria	No additional information.
Recruitment / selection of participants	People who had received treatment at the Department of Neurology and Department of Rehabilitation, Hubei Xinhua Hospital.
Intervention(s)	Neuromuscular electrical stimulation (NMES) N=40

	<p>Neuromuscular electrical simulation with conventional swallowing therapy. VitalStim devices were used. These contained two direction square waves, with a wave width being 700 microseconds, frequency 80 Hz and wave amplitude 0-25 mA. The system has two channels, each being equipped with 2 discharge electrodes. The surface electrodes were placed on the surface of swallowing muscles. Treatment was administered twice a day, lasting 30 minutes each time, 5 days a week for 4 successive weeks.</p> <p>Concomitant therapy: Conventional swallowing training including basic training and direct food intake training. The basic training, i.e. functional recovery training, referred to indirect training. Direct food intake training involved several aspects including food intake environment, body posture for swallowing and removal of pharyngeal food residue. Direct food intake training was used primarily for mild dysphagia.</p> <p>A third intervention arm (n = 40) received only neuromuscular electrical stimulation. This was not included as a comparator because it would not be comparable to the control group.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear

Population subgroups	No additional information.
Comparator	Usual care N=40 Conventional swallowing training only. Concomitant therapy: Conventional swallowing training including basic training and direct food intake training. The basic training, i.e. functional recovery training, referred to indirect training. Direct food intake training involved several aspects including food intake environment, body posture for swallowing and removal of pharyngeal food residue. Direct food intake training was used primarily for mild dysphagia.
Number of participants	80 (additional 40 who are not included in this analysis).
Duration of follow-up	4 weeks (end of intervention).
Indirectness	No additional information.
Additional comments	Method of analysis unclear. Appears to be ITT no dropouts.

1

2 **1.1.99.2. Study arms**3 **1.1.99.2.1. Neuromuscular electrical stimulation (NMES) (N = 40)**

4 Neuromuscular electrical stimulation with conventional swallowing therapy. VitalStim devices were used. These contained two direction
5 square waves, with a wave width being 700 microseconds, frequency 80 Hz and wave amplitude 0-25 mA. The system has two
6 channels, each being equipped with 2 discharge electrodes. The surface electrodes were placed on the surface of swallowing
7 muscles. Treatment was administered twice a day, lasting 30 minutes each time, 5 days a week for 4 successive weeks. Concomitant
8 therapy: Conventional swallowing training including basic training and direct food intake training. The basic training, i.e. functional
9 recovery training, referred to indirect training. Direct food intake training involved several aspects including food intake environment,
10 body posture for swallowing and removal of pharyngeal food residue. Direct food intake training was used primarily for mild dysphagia.

1 A third intervention arm (n = 40) received only neuromuscular electrical stimulation. This was not included as a comparator because it
 2 would not be comparable to the control group.

3

4 **1.1.99.2.2. Usual care (N = 40)**

5 Conventional swallowing training only. Concomitant therapy: Conventional swallowing training including basic training and direct food
 6 intake training. The basic training, i.e. functional recovery training, referred to indirect training. Direct food intake training involved
 7 several aspects including food intake environment, body posture for swallowing and removal of pharyngeal food residue. Direct food
 8 intake training was used primarily for mild dysphagia.

9

10 **1.1.99.3. Characteristics**

11 **1.1.99.3.1. Arm-level characteristics**

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 40)	Usual care (N = 40)
% Female	n = 12 ; % = 30	n = 15 ; % = 38
Sample size		
Mean age (SD) (years)	65.85 (14.63)	65.32 (14.29)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR

Characteristic	Neuromuscular electrical stimulation (NMES) (N = 40)	Usual care (N = 40)
Sample size		
Time after stroke (days)	8.37 (3.12)	8.94 (3.62)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.99.4. Outcomes**3 **1.1.99.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week (<3 months)

6

7 **1.1.99.4.2. Continuous outcomes**

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 40	Neuromuscular electrical stimulation (NMES), 4 week, N = 40	Usual care, Baseline, N = 40	Usual care, 4 week, N = 40
Swallowing ability (standardised swallow assessment)	39.5 (7.1)	21.4 (3.5)	40.9 (6.4)	30.1 (3.8)

Outcome	Neuromuscular electrical stimulation (NMES), Baseline, N = 40	Neuromuscular electrical stimulation (NMES), 4 week, N = 40	Usual care, Baseline, N = 40	Usual care, 4 week, N = 40
Scale range: Unclear. Final values.				
Mean (SD)				

1 Swallowing ability (standardised swallow assessment) - Polarity - Lower values are better

2

3

4 **1.1.99.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.99.4.4. Continuous outcomes-Swallowing ability (standardised swallow assessment)-Mean SD-Neuromuscular electrical**
 6 **stimulation (NMES)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.100.Xia, 2016**

Bibliographic Reference Xia, Wenguang; Zheng, Chanjuan; Zhu, Suiqiang; Tang, Zhouping; Does the addition of specific acupuncture to standard swallowing training improve outcomes in patients with dysphagia after stroke? a randomized controlled trial.; Clinical rehabilitation; 2016; vol. 30 (no. 3); 237-46

9

1 1.1.100.1. Study details

Secondary publication of another included study- see primary study for details	NR
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	(Registration number: ChiCTR-10R-14005249)
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Departments of Neurology and Physical Medicine and Rehabilitation, Hubei Xinhua Hospital in Wuhan, China
Study dates	June 2012 and May 2014.
Sources of funding	This study was supported by a grant from Hubei province health department of China [NO.JX5B36].
Inclusion criteria	Inclusion criteria included a primary diagnosis of stroke by magnetic resonance imaging or computerized tomography scans. A video fluoroscopic swallowing study (VFSS) identified dysphagia and then severity at the time of participation (between four and 12 days after stroke) was rated using the Dysphagia Outcome Severity Scale (DOSS). Patients ranged between 40 and 80 years of age. Assessments were based on their ability to follow instructions and engage in study procedures as well as their ability to give informed consent.
Exclusion criteria	Exclusion criteria included the presence of serious diseases of the liver, kidney, hematological system, or endocrine system, psychiatric disorders, severe cognitive impairment, severe aphasia, or other diseases that potentially impaired swallowing function, such as head and neck tumors, esophageal neoplasms, craniocerebral injury, myasthenia gravis, and Guillain-Barre syndrome.

Recruitment / selection of participants	NR
Intervention(s)	<p>Acupuncture treatment. The nape, scalp, and tongue acupuncture were conducted by an acupuncturist using Traditional Chinese Medicine (TCM) theory. The TCM theory believes the core of disease onset is the disruption of “qi”, specifically “vital energies” of the body. Stroke patients were divided into three syndrome patterns based on TCM:19 phlegm turbidity syndrome; blood stasis syndrome due to qi stagnation; and the liver–kidney yin deficiency syndrome. The phlegm turbidity syndrome is a pathological change characterized by impaired diffusion and the down bearing of lung qi owing to phlegmdampness obstruction. The blood stasis syndrome owing to qi stagnation is a pathological change in which a long-standing or severe qi stagnation impedes blood flow; this condition is characterized by the coexistence of qi stagnation and blood stasis. The liver–kidney yin deficiency syndrome is a pathological change in which insufficient yin (liver and kidney fluid) fails to nourish the related body constituents and organs, giving rise to deficiencyfire symptoms. The main acupoints were fengchi (GB 20, unilateral), jiaji (C2-C4) (EX-B2, bilateral), lianquan (CV 23, unilateral), jiajianquan (left CV 23 and right CV 23, bilateral), and baihui (GV 20, unilateral), and the combination acupoints were lieque (LV 07, bilateral), fenglong (ST 40, bilateral), sanyinjiao (SP 06, bilateral), jinjin and yuye (Z- 20, unilateral), taixi (K 103, bilateral), and zhaohai (K 106, bilateral). The main acupoints were used in all patients (Figures 2, 3, and 4, available online). The originally prescribed acupuncture treatment points were made according to the disease state. Points were added or subtracted based on patient presentation. Empirical acupuncture treatment, involving the use of multiple needles in various locations, was also used to complement the original treatment paradigm. Patients laid supine on a massage table or sat in a comfortable chair with their arms and legs exposed. The skin on the acupuncture points was prepared with 70% ethyl alcohol. One-time-use disposable sterile steel needles(0.20–0.25 × 25–75 mm) were inserted into acupuncture points. The depth of insertion at each point was between 10–30 mm, except for points on Z-20 and GV20, which were between 5–10 mm. After insertion, acupuncture needles were manually manipulated to obtain the de qi sensation. The de qi sensation is defined as the acupuncturist feeling the muscle twitch response and the patient feeling an ache or heaviness in the area surrounding the needle. The needles remained in place for 30 minutes. After 30 minutes of treatment, needles were manually manipulated again before removal. An average of 16.2 needles (range 12–23) were used during each acupuncture session for each patient. Acupuncture was performed after swallowing training for 24 sessions, which comprised of sessions six times a week for a period of four weeks.</p> <p>Concomitant therapy - All patients were given general medication, supportive mental health treatment (i.e. psychotherapy and health education), and standard swallowing training.</p>

Subgroup 1: Severity of dysphagia (as stated by category)	Very severe
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	Standard swallowing training. This process was used to improve patient dysphagia. Functional training was applied to the feeding and swallowing organs (lip, cheek, tongue, soft palate, pharynx, throat, and esophageal sphincter). This included active or passive exercise of the oral, facial, and lingual muscles, sensory stimuli, and some specialized methods such as the Mendelsohn maneuver, supraglottic and supraglottic maneuvers, swallowing efforts, and the Shaker exercise. ¹⁸ Feeding–swallowing training occurred in a quiet room, where patients were placed in a safe and appropriate position as per their medical conditions and personal preference. They were instructed to swallow boluses of an appropriate volume of different consistencies. Patients were treated with standard swallowing training according to information obtained from their VFSS tests. These training regimens were adjusted based on patient swallowing function. Each patient had one-on-one treatment for 30 minutes per session. A training intervention consisted of 24 sessions six times a week for four weeks. Standard swallowing training was performed by qualified and experienced speech–language therapists.
Number of participants	124
Duration of follow-up	4 weeks
Indirectness	NR

Additional comments	NR
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1

2 **1.1.100.2. Study arms**

3 **1.1.100.2.1. *Acupuncture (Acupuncture + swallowing training) (N = 62)***

4

5 **1.1.100.2.2. *Usual care (Swallowing training control group) (N = 62)***

6

7 **1.1.100.3. Characteristics**

8 **1.1.100.3.1. *Study-level characteristics***

Characteristic	Study (N = 124)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	

9

1 **1.1.100.3.2. Arm-level characteristics**

Characteristic	Acupuncture (Acupuncture + swallowing training) (N = 62)	Usual care (Swallowing training control group) (N = 62)
% Female	44	42
Nominal		
Mean age (SD)	65.3 (14.2)	66.1 (14.3)
Mean (SD)		
Severity of dysphagia	1.8 (0.7)	1.6 (0.6)
Mean (SD)		
Time after stroke (days)	9.3 (2.3)	8.7 (2.5)
Mean (SD)		
basal ganglia or thalamus	n = 48 ; % = 77.4	n = 46 ; % = 74.2
No of events		
MCA	n = 10 ; % = 16.1	n = 13 ; % = 21
No of events		
Brainstem	n = 4 ; % = 6.5	n = 3 ; % = 4.8
No of events		

2

1 **1.1.100.4. Outcomes**

2 **1.1.100.4.1. Study timepoints**

- 3 • Baseline
4 • 4 week

5

6 **1.1.100.4.2. Continuous outcomes**

Outcome	Acupuncture (Acupuncture + swallowing training), Baseline, N = 62	Acupuncture (Acupuncture + swallowing training), 4 week, N = 62	Usual care (Swallowing training control group), Baseline, N = 62	Usual care (Swallowing training control group), 4 week, N = 62
Swallowing ability (dysphagia outcome severity scale VFS) Scale range: 0-7. Final values. Mean (SD)	1.8 (0.7)	5.8 (1.3)	1.6 (0.6)	3.7 (1.1)

7 Swallowing ability (dysphagia outcome severity scale VFS) - Polarity - Higher values are better

8

9

10 **1.1.100.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

11 **1.1.100.4.4. Continuous outcomes-Swallowing ability (dysphagia outcome severity scale VFS) final value-Mean SD-Acupuncture + swallowing training-Swallowing training control group-t4**

12

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns (due to issues arising from randomisation)

Section	Question	Answer
Overall bias and Directness	Overall Directness	Directly applicable

1

2 **1.1.101. Yang, 2012**

Bibliographic Reference Yang, Eun Joo; Baek, So-Ra; Shin, Joonho; Lim, Jong Youb; Jang, Hye Jin; Kim, Yu Kyeong; Paik, Nam-Jong; Effects of transcranial direct current stimulation (tDCS) on post-stroke dysphagia.; Restorative neurology and neuroscience; 2012; vol. 30 (no. 4); 303-11

3

4 **1.1.101.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	South Korea.
Study setting	Inpatients.
Study dates	April 2008 to November 2009.

Sources of funding	This work was supported by grant no (03-2008-004) from the SNUBH Research Fund.
Inclusion criteria	First-ever ischaemic stroke within the previous 2 months; history of indirect aspiration symptoms, such as coughing and choking during eating; clinical signs that indicated dysphagia, including reduced tongue movement, reduced laryngeal elevation, reduced gag reflex or vocal cord palsy; coughing or speaking with a wet voice when asked to drink 5mL water in a bedside swallowing evaluation; use of a nasogastric tube to alleviate swallowing difficulties.
Exclusion criteria	Bilateral brain lesion; presence of a metallic foreign body implant, such as a pacemaker or artificial cochlea; history of seizure or another unstable medical condition; severe language disturbance; neglect, depression or cognitive deficits (based on the mini-mental state examination, no more than 10 out of 30 points) that would limit participation; history of severe alcohol or drug abuse; taking sodium or calcium channel blockers or NMDA receptor antagonists; previous stroke that resulted in residual disability.
Recruitment / selection of participants	People were recruited from a neurorehabilitation unit at a tertiary university hospital.
Intervention(s)	<p>Transcranial direct current stimulation (tDCS) N=9</p> <p>Anodal transcranial direct current stimulation (1mA for 20 minutes for 10 days). This was delivered to the affected hemisphere by a battery-driven, direct current stimulation through two sponge surface electrodes. The direct current was increased to 1mA incrementally over several seconds and maintained for 20 minutes. The electrodes were placed a) over the scalp of the affected hemisphere in the region which was reported to induce maximal pharyngeal response (anterior 4.6cm, lateral 6.15cm from the vertex in the right hemisphere. Anterior 4cm and lateral 7.1cm in the left hemisphere), 2) over the contralateral supraorbital region.</p> <p>Concomitant therapy: All people received 30 minutes of conventional swallowing training during the sessions (20 minutes with the intervention, 10 minutes without the intervention). Swallowing training consisted of a structured program including direct therapies such as diet modification, positioning, behavioural maneuvers (including Mendelsohn maneuver, supraglottic and effortful swallowing) and indirect therapies such as physical maneuver such as oral motor exercise and thermal tactile stimulation.</p>
Subgroup 1: Severity of	Not stated/unclear

dysphagia (as stated by category)	
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Placebo/sham therapy N=7</p> <p>Sham tDCS using the same procedure except the current was increased and then tapered down and turned off after 30s of stimulation.</p> <p>Concomitant therapy: All people received 30 minutes of conventional swallowing training during the sessions (20 minutes with the intervention, 10 minutes without the intervention). Swallowing training consisted of a structured program including direct therapies such as diet modification, positioning, behavioural maneuvers (including Mendelsohn maneuver, supraglottic and effortful swallowing) and indirect therapies such as physical maneuver such as oral motor exercise and thermal tactile stimulation.</p>
Number of participants	16
Duration of follow-up	2 weeks.
Indirectness	No additional information.

Additional comments	Intention-to-treat analysis.
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1

2 **1.1.101.2. Study arms**3 **1.1.101.2.1. Transcranial direct current stimulation (tDCS) (N = 9)**

4 Anodal transcranial direct current stimulation (1mA for 20 minutes for 10 days). This was delivered to the affected hemisphere by a
5 battery-driven, direct current stimulation through two sponge surface electrodes. The direct current was increased to 1mA
6 incrementally over several seconds and maintained for 20 minutes. The electrodes were placed a) over the scalp of the affected
7 hemisphere in the region which was reported to induce maximal pharyngeal response (anterior 4.6cm, lateral 6.15cm from the vertex
8 in the right hemisphere. Anterior 4cm and lateral 7.1cm in the left hemisphere), 2) over the contralateral supraorbital region.
9 Concomitant therapy: All people received 30 minutes of conventional swallowing training during the sessions (20 minutes with the
10 intervention, 10 minutes without the intervention). Swallowing training consisted of a structured program including direct therapies
11 such as diet modification, positioning, behavioural maneuvers (including Mendelsohn maneuver, supraglottic and effortful swallowing)
12 and indirect therapies such as physical maneuver such as oral motor exercise and thermal tactile stimulation.

13

14 **1.1.101.2.2. Placebo/sham therapy (N = 7)**

15 Sham tDCS using the same procedure except the current was increased and then tapered down and turned off after 30s of
16 stimulation. Concomitant therapy: All people received 30 minutes of conventional swallowing training during the sessions (20 minutes
17 with the intervention, 10 minutes without the intervention). Swallowing training consisted of a structured program including direct
18 therapies such as diet modification, positioning, behavioural maneuvers (including Mendelsohn maneuver, supraglottic and effortful
19 swallowing) and indirect therapies such as physical maneuver such as oral motor exercise and thermal tactile stimulation.

20

1 **1.1.101.3. Characteristics**2 **1.1.101.3.1. Arm-level characteristics**

Characteristic	Transcranial direct current stimulation (tDCS) (N = 9)	Placebo/sham therapy (N = 7)
% Female	n = 3 ; % = 33	n = 4 ; % = 57
Sample size		
Mean age (SD) (years)	70.44 (12.59)	70.57 (8.46)
Mean (SD)		
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke (days)	25.2 (11.5)	26.9 (7.8)
Mean (SD)		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.101.4. Outcomes**3 **1.1.101.4.1. Study timepoints**

- 4 • Baseline
 5 • 2 week (<3 months)
 6 • 3 month (≥3 months)

7

8 **1.1.101.4.2. Continuous outcomes**

Outcome	Transcranial direct current stimulation (tDCS), Baseline, N = 9	Transcranial direct current stimulation (tDCS), 2 week, N = 9	Transcranial direct current stimulation (tDCS), 3 month, N = 9	Placebo/sham therapy, Baseline, N = 7	Placebo/sham therapy, 2 week, N = 7	Placebo/sham therapy, 3 month, N = 7
Swallowing ability (Functional dysphagia scale) Scale range: 0-100. Final value for 2 weeks, change score at 3 months. Mean (SD)	16.78 (13.85)	9.11 (9)	-13 (12.18)	21.71 (8.42)	12.57 (7.91)	9.83 (7.06)

9 Swallowing ability (Functional dysphagia scale) - Polarity - Lower values are better

10

11

1 **1.1.101.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.101.4.4. Continuousoutcomes-Swallowingability(Functionaldysphagiascale)-MeanSD-Transcranial direct current**
 3 **stimulation (tDCS)-Placebo/sham therapy-t2**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.101.4.5. Continuousoutcomes-Swallowingability(Functionaldysphagiascale)-MeanSD-Transcranial direct current**
 6 **stimulation (tDCS)-Placebo/sham therapy-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.102.Youssef, 2015**

Bibliographic Reference Youssef, Gamal; Albanna, Manal; The Outcome of Intraluminal Electrical Pharyngeal stimulation (EPS) on Oropharyngeal Dysphagia in Acute Stroke Patients; AL AZHAR ASSIUT MEDICAL JOURNAL; 2015; vol. 13; 67-72

9

10 **1.1.102.1. Study details**

Secondary publication of another included	No additional information
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study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information
Study type	Randomised controlled trial (RCT)
Study location	Egypt
Study setting	No additional information
Study dates	No additional information
Sources of funding	No additional information
Inclusion criteria	Inclusion criteria: Recent attack with not more than 10 days post-stroke; First attack with no history of previous stroke attacks: Severe dysphagia as approved by bedside swallowing assessment and confirmed by FEES recording penetration aspiration score (PAS) of three or above; Hemispheric stroke without brainstem affection as proved by CT or MRI: No associative receptive aphasia or obvious cognitive impairment.
Exclusion criteria	Dysphagic patients with history of recurrent attacks of strokes, brainstem stroke and/or prohibiting factors of PES such as implantable electrical devices were excluded.
Recruitment / selection of participants	NR
Intervention(s)	PES group received intraluminal PES therapy for three consecutive days. PES comprises a Controller Unit to optimize and deliver the required level of stimulation and a single use sterile disposable PES NG tube. The Controller Unit constituted of a touch screen menu driven user interface and a connector cable to the PES NG tube. Once the PES tube is put in place, it fulfils all of the normal functions of the NG tube. The controller unit connected to the stimulator port on the PES NG tube. Stimulation parameters are tested and optimised. The maximum tolerated PES intensity was predetermined from each participant's first perceived sensation and pain threshold (the point when the pharyngeal sensation became uncomfortable), which were calculated from an average of three trials. Pharyngeal electrical stimuli (0.2-ms pulses, 280 V) was delivered at

	<p>a set frequency (5 Hz), intensity (75% of maximal tolerated), and duration (10 minutes) for a period of 10 minutes. The treatment regime in total comprises three stimulation sessions, once a day for three consecutive days. Patient and treatment details are stored on the unit and can be printed out or exported electronically for inclusion in the patients records.</p> <p>Concomitant therapy - All patients continued to receive standard clinical care throughout the study as deemed appropriate by the clinicians responsible for the patient, and independent of the researchers. Only spontaneous maneuvers were allowed. No other maneuvers or treatments were added or included, only the patient instructed to swallow hard and fast.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Acute (72 hours - 7 days)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	The control group received sham therapy for three consecutive days. During Sham pharyngeal stimulation, the same method was used, including the titration steps for determining the pharyngeal stimulation intensity. However, on commencement of stimulation, the constant current generator was switched off and the intraluminal pharyngeal catheter was left in situ in the subject for the duration of intervention.

Number of participants	18
Duration of follow-up	3 days
Indirectness	NR
Additional comments	NR

1

2 **1.1.102.2. Study arms**

3 **1.1.102.2.1. *Electrical Pharyngeal stimulation (N = 9)***

4

5 **1.1.102.2.2. *Sham control (N = 9)***

6

7 **1.1.102.3. Characteristics**

8 **1.1.102.3.1. *Study-level characteristics***

Characteristic	Study (N = 18)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR

Characteristic	Study (N = 18)
Nominal	
Type of stroke	NR
Nominal	

1

2 **1.1.102.3.2. Arm-level characteristics**

Characteristic	Electrical Pharyngeal stimulation (N = 9)	Sham control (N = 9)
% Female	22.2	33.3
Nominal		
Mean age (SD)	64.3 (11.3)	66.7 (8.5)
Mean (SD)		
Severity of dysphagia PAS	5.7 (1.1)	5.1 (0.9)
Mean (SD)		
Time after stroke	6.3 (3.2)	5.7 (2.9)
Mean (SD)		

3

4 **1.1.102.4. Outcomes**5 **1.1.102.4.1. Study timepoints**

- 6 • Baseline
- 7 • 3 day

1

2 **1.1.102.4.2. Continuous outcomes**

Outcome	Electrical Pharyngeal stimulation, Baseline, N = 9	Electrical Pharyngeal stimulation, 3 day, N = 9	Sham control, Baseline, N = 9	Sham control, 3 day, N = 9
Occurrence of aspiration (Penetration Aspiration Scale) Scale range: 1-8. Final values. Mean (SD)	5.7 (1.1)	2.3 (3.7)	5.1 (0.9)	3.58 (0.78)
Swallowing ability (Functional Oral Intake Scale) Scale range: 1-7. Final values. Mean (SD)	2.8 (1.54)	5.18 (1.7)	2.58 (1.79)	4.33 (0.98)

3 Occurrence of aspiration (Penetration Aspiration Scale) - Polarity - Lower values are better

4 Swallowing ability (Functional Oral Intake Scale) - Polarity - Higher values are better

5

6

7 **1.1.102.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**8 **1.1.102.4.4. Continuous outcomes - Penetration Aspiration Scale - Mean SD - Electrical Pharyngeal stimulation - Sham control - t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to lack of details on randomisation and allocation concealment)
Overall bias and Directness	Overall Directness	Directly applicable

9

1 **1.1.102.4.5. Continuous outcomes-Swallowing ability-(Functional oral intake scale)-Mean SD-Electrical Pharyngeal stimulation-**
 2 **Sham control-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (due to lack of details on randomisation and allocation concealment)
Overall bias and Directness	Overall Directness	Directly applicable

3

4 **1.1.103. Yuan, 2003**

Bibliographic Reference Yuan, Z-M; Huang, L-R; Chen, Z-L; Coagulant and enteral nutrition agent in the rehabilitation of deglutition disorders for patients with acute stroke; Chinese journal of clinical rehabilitation; 2003; vol. 7 (no. 28); 3834-3835

5

6 **1.1.103.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)

Study location	China.
Study setting	No additional information.
Study dates	No additional information.
Sources of funding	No additional information.
Inclusion criteria	People after stroke with dysphagia defined by Watian Swallow Test.
Exclusion criteria	Terminal illness, organ failure.
Recruitment / selection of participants	No additional information.
Intervention(s)	<p>Adaptations for oral feeding - Thickened fluids N=18</p> <p>Enteral nutrition agent with thickener and swallowing therapy. This arm was not included in the analysis as this is a type of thickened enteral fluid and so was not related to the protocol.</p> <p>Concomitant therapy: No additional information.</p> <p>Behavioural intervention (swallowing therapy) N=22</p> <p>Traditional liquid diet and swallowing therapy.</p> <p>Concomitant therapy: No additional information.</p>

	(Note: This is the usual care comparison for thickened fluids vs. usual care. When combined with thickened fluids this is the behavioural intervention (swallowing therapy) which can be compared with usual care (liquid diet only). In this data extraction the three groups are separated, but they will be combined in this manner when analysed).
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Not stated/unclear
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=24 Liquid diet only and no swallowing therapy. Concomitant therapy: No additional information.
Number of participants	64
Duration of follow-up	Unclear.

Indirectness	No additional information.
Additional comments	No additional information.

1

2 **1.1.103.2. Study arms**3 **1.1.103.2.1. Adaptations for oral feeding - Thickened fluids (N = 18)**

4 Enteral nutrition agent with thickener and swallowing therapy. This arm was not included in the analysis as this is a type of thickened
5 enteral fluid and so was not related to the protocol. Concomitant therapy: No additional information.

6

7 **1.1.103.2.2. Behavioural intervention (swallowing therapy) (N = 22)**

8 Traditional liquid diet and swallowing therapy. Concomitant therapy: No additional information. (Note: This is the usual care
9 comparison for thickened fluids vs. usual care. When combined with thickened fluids this is the behavioural intervention (swallowing
10 therapy) which can be compared with usual care (liquid diet only). In this data extraction the three groups are separated, but they will
11 be combined in this manner when analysed).

12

13 **1.1.103.2.3. Usual care (N = 24)**

14 Liquid diet only and no swallowing therapy. Concomitant therapy: No additional information.

15

1 **1.1.103.3. Characteristics**2 **1.1.103.3.1. Arm-level characteristics**

Characteristic	Adaptations for oral feeding - Thickened fluids (N = 18)	Behavioural intervention (swallowing therapy) (N = 22)	Usual care (N = 24)
% Female	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR
Mean age (SD)	NR (NR)	NR (NR)	NR (NR)
Mean (SD)			
Ethnicity	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR
Comorbidities	n = NR ; % = NR	n = NR	n = NR ; % = NR
Sample size			NR
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR
Time after stroke	NR (NR)	NR (NR)	NR (NR)
Mean (SD)			
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR
Type of stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			NR

1

2 **1.1.103.4. Outcomes**

3 **1.1.103.4.1. Study timepoints**

- 4 • Baseline
 5 • 4 week (Timing unclear. Given the length of hospital stay is reported at around 4 weeks, will use this information. <3 months.)

6

7 **1.1.103.4.2. Continuous outcomes**

Outcome	Adaptations for oral feeding - Thickened fluids, Baseline, N = 18	Adaptations for oral feeding - Thickened fluids, 4 week, N = 18	Behavioural intervention (swallowing therapy), Baseline, N = 22	Behavioural intervention (swallowing therapy), 4 week, N = 22	Usual care, Baseline, N = 24	Usual care, 4 week, N = 24
Length of hospital stay (days)	NA (NA)	24 (8.5)	NA (NA)	31 (9.4)	NA (NA)	37 (14.7)
Mean (SD)						
Nutrition (albumin) (unclear)	NR (NR)	37 (6.7)	NR (NR)	36.8 (10.32)	NR (NR)	36.6 (9.8)
Mean (SD)						

8 Length of hospital stay - Polarity - Lower values are better

9 Nutrition (albumin) - Polarity - Higher values are better

1 **1.1.103.4.3. Dichotomous outcomes**

Outcome	Adaptations for oral feeding - Thickened fluids, Baseline, N = 18	Adaptations for oral feeding - Thickened fluids, 4 week, N = 18	Behavioural intervention (swallowing therapy), Baseline, N = 22	Behavioural intervention (swallowing therapy), 4 week, N = 22	Usual care, Baseline, N = 24	Usual care, 4 week, N = 24
Dysphagia present/return to normal diet (Dysphagia at end of trial)	n = NA ; % = NA	n = 6 ; % = 33	n = NA ; % = NA	n = 17 ; % = 77	n = NA ; % = NA	n = 22 ; % = 92
No of events						
Occurrence of chest infection (chest infection or pneumonia)	n = NA ; % = NA	n = 0 ; % = 0	n = NA ; % = NA	n = 3 ; % = 14	n = NA ; % = NA	n = 10 ; % = 42
No of events						

2 Dysphagia present/return to normal diet (Dysphagia at end of trial) - Polarity - Lower values are better

3 Occurrence of chest infection (chest infection or pneumonia) - Polarity - Lower values are better

4

5

1 **1.1.103.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.103.4.5. Continuous outcomes-Length of hospital stay-**
 3 **Thickened fluids(thickened fluids and swallowing therapy) vs. usual care (swallowing therapy)-Mean SD-Adaptations for**
 4 **oral feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

5

6 **1.1.103.4.6. Dichotomous outcomes-Presence of dysphagia/return to normal diet (dysphagia at end of trial)-**
 7 **Thickened fluids(thickened fluids and swallowing therapy) vs. usual care (swallowing therapy)-No of Events-Adaptations**
 8 **for oral feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

9

10 **1.1.103.4.7. Dichotomous outcomes-Presence of dysphagia/return to normal diet (dysphagia at end of trial)-**
 11 **Swallowing therapy(thickened fluids and behavioural intervention) vs. usual care-No of Events-Adaptations for oral**
 12 **feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

13

1 **1.1.103.4.8.** ***Continuous outcomes-Length of hospital stay-***
 2 ***Swallowing therapy (thickened fluids and behavioural intervention) vs. usual care-Mean SD-Adaptations for oral feeding -***
 3 ***Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4
 5 **1.1.103.4.9.** ***Continuous outcomes-Nutrition (albumin)-***
 6 ***Thickened fluids (thickened fluids and swallowing therapy) vs. usual care (swallowing therapy)-Mean SD-Adaptations for***
 7 ***oral feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8
 9 **1.1.103.4.10.** ***Continuous outcomes-Nutrition (albumin)-***
 10 ***Swallowing therapy (thickened fluids and behavioural intervention) vs. usual care-Mean SD-Adaptations for oral feeding -***
 11 ***Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4***

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

1 **1.1.103.4.11.** *Dichotomous outcomes-Occurrence of chest infection (chest infection or pneumonia)-*
 2 *Thickened fluids (thickened fluids and swallowing therapy) vs. usual care (swallowing therapy)-No Of Events-Adaptations*
 3 *for oral feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.103.4.12.** *Dichotomous outcomes-Occurrence of chest infection (chest infection or pneumonia)-*
 6 *Swallowing therapy (thickened fluids and behavioural intervention) vs. usual care-No Of Events-Adaptations for oral*
 7 *feeding - Thickened fluids-Behavioural intervention (swallowing therapy)-Usual care-t4*

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

8

9 **1.1.104.Zhang, 2021**

Bibliographic Reference Zhang, Qian; Wu, Shuang; Effects of Synchronized Neuromuscular Electrical Stimulation (NMES) on the Submental Muscles During Ingestion of a Specified Volume of Soft Food in Patients with Mild-to-Moderate Dysphagia Following Stroke.; Medical science monitor : international medical journal of experimental and clinical research; 2021; vol. 27; e928988

10

11 **1.1.104.1. Study details**

Secondary publication of	No additional information.
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another included study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	People attending the Affiliated Hospital of Guizhou Medical University.
Study dates	June 1st 2018 to May 31st 2020.
Sources of funding	No additional information.
Inclusion criteria	Clinical diagnosis of initial cerebral infarction or cerebral haemorrhage, confirmed by brain computer tomography or magnetic resonance imaging; disease course of 1 to 3 months; age 40 to 80 years old; stable vital signs; ability to swallow at least 50mL of soft food for 30 min; a simple intelligence test scale AMTS score >7 points; a DOSS score of 2 to 6, suggesting mild-to-moderate dysphagia; pharyngeal dysphagia or oropharynx dysphagia diagnosed with a modified barium swallow; achievement of direct eating.
Exclusion criteria	Malignant tumours, serious medical diseases or other neurological diseases; mental disorders or cognitive dysfunction; dysphagia not triggered by stroke; head, neck or gastroesophageal surgery; dysphagia combined with an uncontrolled lung infection.
Recruitment / selection of participants	No additional information.
Intervention(s)	Diet modification N=28 In addition to the conventional swallowing training, this group was given direct training with soft food (viscosity 4750 to 5113 cP), depending on their willingness to eat it. The food was prepared with thickener and water at a temperature of 25

	<p>degrees centigrade. With a person seated, the therapist applied a 5mL food bolus onto the middle of the tongue using a spoon. The person was allowed to swallow, and an additional 1 to 2 swallowing actions were performed to clean the food that remained in the pharynx. During the first week, the training time was gradually increased, based on patient tolerance; a maximum of 100mL of food was fed. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days a week for 6 weeks, for a total of 30 days.</p> <p>Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intellect VitalStim model 5900 was performed. Before treatment, a person's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a person's tolerance for an choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful before taking the next one, and not to eat too fast.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	<p>Mixed</p> <p>Inclusion criteria states mild-moderate</p>
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring	Not stated/unclear

enteral feeding support at baseline	
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	<p>Usual care N=28</p> <p>Usual care only.</p> <p>Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intellect VitalStim model 5900 was performed. Before treatment, a person's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a person's tolerance for an choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful before taking the next one, and not to eat too fast.</p>

	<p>Behavioural interventions N=27</p> <p>Intensive swallowing training with tongue-hold swallow. During direct eating/swallowing training, a person was asked to hold their tongue gently between their teeth. The therapist then applied a 5-mL food bolus onto the middle of the tongue using a spoon, and the person swallowed it with their tongue in a straight position when they felt the maximum intensity of current stimulation in the submental muscles with synchronized electrical stimulation using the VitalStim neuromuscular stimulator. The NMES treatment was performed the same as in the control group. The people in this group were asked to finish swallowing the soft food bolus within 30 minutes, and they received no more than 100mL of the food. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days.</p> <p>Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intellect VitalStim model 5900 was performed. Before treatment, a person's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a person's tolerance for an choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful before taking the next one, and not to eat too fast.</p>
Number of participants	83
Duration of follow-up	6 weeks (end of treatment)

Indirectness	No additional information.
Additional comments	No additional information.

1

2 **1.1.104.2. Study arms**3 **1.1.104.2.1. Diet modification (N = 28)**

4 In addition to the conventional swallowing training, this group was given direct training with soft food (viscosity 4750 to 5113 cP),
5 depending on their willingness to eat it. The food was prepared with thickener and water at a temperature of 25 degrees centigrade.
6 With a person seated, the therapist applied a 5mL food bolus onto the middle of the tongue using a spoon. The person was allowed to
7 swallow, and an additional 1 to 2 swallowing actions were performed to clean the food that remained in the pharynx. During the first
8 week, the training time was gradually increased, based on patient tolerance; a maximum of 100mL of food was fed. Each training
9 session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days a week for 6 weeks, for a
10 total of 30 days. Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal
11 swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise,
12 gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic
13 swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning
14 strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of
15 specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing
16 examination. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of
17 30 training sessions. In addition, NMES treatment with the Intelect VitalStim model 5900 was performed. Before treatment, a person's
18 neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and
19 increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the
20 submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the
21 electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people
22 were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon
23 a person's tolerance for an choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful
24 before taking the next one, and not to eat too fast.

25

1.1.104.2.2. Usual care (N = 28)

Usual care only. Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 minutes and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intellect VitalStim model 5900 was performed. Before treatment, a person's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a person's tolerance for a choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful before taking the next one, and not to eat too fast.

1.1.104.2.3. Behavioural interventions (N = 27)

Intensive swallowing training with tongue-hold swallow. During direct eating/swallowing training, a person was asked to hold their tongue gently between their teeth. The therapist then applied a 5-mL food bolus onto the middle of the tongue using a spoon, and the person swallowed it with their tongue in a straight position when they felt the maximum intensity of current stimulation in the submental muscles with synchronized electrical stimulation using the VitalStim neuromuscular stimulator. The NMES treatment was performed the same as in the control group. The people in this group were asked to finish swallowing the soft food bolus within 30 minutes, and they received no more than 100mL of the food. Each training session lasted for 30 minutes and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days. Concomitant therapy: Each person received the following conventional swallowing training: oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); instruction in airway protection maneuvers (supraglottic swallow or suprasupraglottic swallow); thermal/tactile stimulation; oral hygiene education; direct eating training as per each individual's willingness; positioning strategies (eg, chin tuck, head turn or head tilt) and practice with swallowing maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 minutes and were

performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions. In addition, NMES treatment with the Intelect VitalStim model 5900 was performed. Before treatment, a person's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a person could withstand, which was usually 6.3 and 13.2 mA (average 11.6 mA). During direct eating therapy, people were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a person's tolerance for an choice of paste food to eat. During direct exercise therapy, people were asked to swallow the first mouthful before taking the next one, and not to eat too fast.

1.1.104.3. Characteristics

1.1.104.3.1. Arm-level characteristics

Characteristic	Diet modification (N = 28)	Usual care (N = 28)	Behavioural interventions (N = 27)
% Female	n = 14 ; % = 50	n = 17 ; % = 61	n = 13 ; % = 48
Sample size			
Mean age (SD) (years)	63.14 (6.56)	62.31 (8.07)	63.72 (6.29)
Mean (SD)			
Ethnicity	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Comorbidities	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR	n = NR
Sample size			

Characteristic	Diet modification (N = 28)	Usual care (N = 28)	Behavioural interventions (N = 27)
Time after stroke (Months)	2.06 (0.54)	2.16 (0.5)	2.1 (0.54)
Mean (SD)			
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			
Type of stroke	n = NR ; % = NR	n = NR ; % = NR	n = NR ; % = NR
Sample size			

1

2 **1.1.104.4. Outcomes**3 **1.1.104.4.1. Study timepoints**

- 4 • Baseline
- 5 • 6 week (<3 months)

6

7 **1.1.104.4.2. Dichotomous outcome**

Outcome	Diet modification, Baseline, N = 28	Diet modification, 6 week, N = 28	Usual care, Baseline, N = 28	Usual care, 6 week, N = 28	Behavioural interventions, Baseline, N = 27	Behavioural interventions, 6 week, N = 27
Occurrence of chest infection (incidence of stroke-associated pneumonia)	n = NA ; % = NA	n = 15 ; % = 53.6	n = NA ; % = NA	n = 6 ; % = 21.4	n = NA ; % = NA	n = 2 ; % = 7.4

Outcome	Diet modification, Baseline, N = 28	Diet modification, 6 week, N = 28	Usual care, Baseline, N = 28	Usual care, 6 week, N = 28	Behavioural interventions, Baseline, N = 27	Behavioural interventions, 6 week, N = 27
No of events						

1 Occurrence of chest infection (incidence of stroke-associated pneumonia) - Polarity - Lower values are better

2

3

4 **1.1.104.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

5 **1.1.104.4.4. Dichotomous outcome - Occurrence of chest infection (incidence of stroke-associated pneumonia) - No of Events - Diet**
 6 **modification - Usual care - Behavioural interventions - t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.105. Zhang, 2020**

Bibliographic Reference Zhang, W.; Yang, H.; Yao, T.; Effect of bundles of care on rehabilitation effect of stroke patients with dysphagia; Acta Medica Mediterranea; 2020; vol. 36 (no. 6); 3601-3606

9

1 1.1.105.1. Study details

Secondary publication of another included study- see primary study for details	No additional information.
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	China.
Study setting	Inpatients.
Study dates	April 2016 and March 2018.
Sources of funding	No additional information.
Inclusion criteria	People who were following the stroke diagnostic criteria formulated by the Fourth National Cerebrovascular Disease Conference and diagnosed by MRI/CT; people who were at the first onset, duration of disease no more than 3 months and had stable vital signs; people had swallowing disorders indicated by a water swallow test; people who had no obvious mental or cognitive dysfunction and could cooperate with rehabilitation treatment and protection; people who had no dysphagia, endocrine disease, metabolic disease or another important organ disease before the onset of disease.
Exclusion criteria	Those with swallowing disorders or completely unable to eat for other reasons; those with transient ischaemic attacks and reversible neurological deficits; those with endocrine system, liver and kidney dysfunction or other serious primary diseases; people with psychiatric disorders, unconsciousness, malignancy and unstable vital signs.
Recruitment / selection of participants	People after stroke with dysphagia treated in the hospital.

<p>Intervention(s)</p>	<p>Behavioural intervention (bundle of care including exercises) N=40</p> <p>Bundle of care delivered by neuropsychologists, chief nurses, supervising nurses and rehabilitation trained nurses. This included psychological protection (counselling), health education, an eating intervention (food intake of 3-5 mL/min in a semi-recumbant position, people who needed to be supine could lie in a lateral position, for people seated their head and neck should be slightly forward and tilt 30 degrees to the healthy side. Gradual transition from soft food to harder foods. Instruction on eating), rehabilitation training (monophonic method used to conduct lip movement training. The main measures included lip shrinking, breathing, whistling etc. while people were guided to perform sucking, drum gills and other actions to carry out buccal muscle movement. People were also guided to stick out their tongues and move them to the corner of the mouth, left and right, and then use the tip of the tongue to click the lower lip, turn the upper lip and then press the hard palate. Ice cotton swabs were used to stimulate the person's cheek and around the pharyngeal arch, and they were asked to do a short swallow) and quality control of the package.</p> <p>Concomitant therapy: Routine rehabilitation included basic protection (oral hygiene care more than twice a day for people unable to support themselves, generally tidy ward environment), specialist protection (closely observed changes in illness, vital signs, consciousness and pupils, dynamic assessment for dysphagia and limb therapy) and eating guidance (semi-recumbant position and mainly eating soft food, researcher guided eating skills).</p>
<p>Subgroup 1: Severity of dysphagia (as stated by category)</p>	<p>Not stated/unclear</p>
<p>Subgroup 2: Time after stroke at the start of the trial</p>	<p>Not stated/unclear</p>
<p>Subgroup 3: People requiring enteral feeding support at baseline</p>	<p>Not stated/unclear</p>

Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	No additional information.
Comparator	Usual care N=40 Usual care only. Concomitant therapy: Routine rehabilitation included basic protection (oral hygiene care more than twice a day for people unable to support themselves, generally tidy ward environment), specialist protection (closely observed changes in illness, vital signs, consciousness and pupils, dynamic assessment for dysphagia and limb therapy) and eating guidance (semi-recumbant position and mainly eating soft food, researcher guided eating skills).
Number of participants	80
Duration of follow-up	3 days (appears to be assessed initially and then 2 days after starting protection).
Indirectness	No additional information.
Additional comments	No additional information. Reported as no drop outs.

1

2 **1.1.105.2. Study arms**3 **1.1.105.2.1. Behavioural intervention (bundle of care including exercises) (N = 40)**

4 Bundle of care delivered by neuropsychologists, chief nurses, supervising nurses and rehabilitation trained nurses. This included
5 psychological protection (counselling), health education, an eating intervention (food intake of 3-5 mL/min in a semi-recumbant
6 position, people who needed to be supine could lie in a lateral position, for people seated their head and neck should be slightly
7 forward and tilt 30 degrees to the healthy side. Gradual transition from soft food to harder foods. Instruction on eating), rehabilitation

1 training (monophonic method used to conduct lip movement training. The main measures included lip shrinking, breathing, whistling
 2 etc. while people were guided to perform sucking, drum gills and other actions to carry out buccal muscle movement. People were
 3 also guided to stick out their tongues and move them to the corner of the mouth, left and right, and then use the tip of the tongue to
 4 click the lower lip, turn the upper lip and then press the hard palate. Ice cotton swabs were used to stimulate the person's cheek and
 5 around the pharyngeal arch, and they were asked to do a short swallow) and quality control of the package. Concomitant therapy:
 6 Routine rehabilitation included basic protection (oral hygiene care more than twice a day for people unable to support themselves,
 7 generally tidy ward environment), specialist protection (closely observed changes in illness, vital signs, consciousness and pupils,
 8 dynamic assessment for dysphagia and limb therapy) and eating guidance (semi-recumbant position and mainly eating soft food,
 9 researcher guided eating skills).

10

11 **1.1.105.2.2. Usual care (N = 40)**

12 Usual care only. Concomitant therapy: Routine rehabilitation included basic protection (oral hygiene care more than twice a day for
 13 people unable to support themselves, generally tidy ward environment), specialist protection (closely observed changes in illness, vital
 14 signs, consciousness and pupils, dynamic assessment for dysphagia and limb therapy) and eating guidance (semi-recumbant position
 15 and mainly eating soft food, researcher guided eating skills).

16

17 **1.1.105.3. Characteristics**

18 **1.1.105.3.1. Arm-level characteristics**

Characteristic	Behavioural intervention (bundle of care including exercises) (N = 40)	Usual care (N = 40)
% Female	n = 16 ; % = 40	n = 15 ; % = 38
Sample size		
Mean age (SD) (years)	64.02 (5.27)	63.79 (5.8)
Mean (SD)		

Characteristic	Behavioural intervention (bundle of care including exercises) (N = 40)	Usual care (N = 40)
Ethnicity	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Comorbidities	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Severity of dysphagia	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Time after stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		
People requiring enteral feeding support at baseline	n = NR ; % = NR	n = NR ; % = NR
Sample size		
Type of stroke	n = NR ; % = NR	n = NR ; % = NR
Sample size		

1

2 **1.1.105.4. Outcomes**

3 **1.1.105.4.1. Study timepoints**

- 4 • Baseline
- 5 • 3 day (<3 months)

6

1 **1.1.105.4.2. Continuous outcomes**

Outcome	Behavioural intervention (bundle of care including exercises), Baseline, N = 40	Behavioural intervention (bundle of care including exercises), 3 day, N = 40	Usual care, Baseline, N = 40	Usual care, 3 day, N = 40
Length of hospital stay (days) Mean (SD)	NA (NA)	7.53 (2.24)	NA (NA)	7.44 (2.19)
Swallowing ability (Water Swallowing test) Scale range: 1-5. Calculated from number of participants reported in each category. Final values. Mean (SD)	3.83 (0.98)	2.2 (0.91)	3.88 (0.97)	2.98 (1.29)

2 Length of hospital stay - Polarity - Lower values are better

3 Swallowing ability (Water Swallowing test) - Polarity - Lower values are better

4 **1.1.105.4.3. Dichotomous outcomes**

Outcome	Behavioural intervention (bundle of care including exercises), Baseline, N = 40	Behavioural intervention (bundle of care including exercises), 3 day, N = 40	Usual care, Baseline, N = 40	Usual care, 3 day, N = 40
Dysphagia present/return to normal diet (number of people with water swallowing test grade >1) No of events	n = 40 ; % = 100	n = 30 ; % = 75	n = 40 ; % = 100	n = 34 ; % = 85

5 Dysphagia present/return to normal diet (number of people with water swallowing test grade >1) - Polarity - Lower values are better

6

7

1 **1.1.105.4.4. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.105.4.5. Continuousoutcomes-Lengthofhospitalstay-MeanSD-Behavioural intervention (bundle of care including exercises)-**
 3 **Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.105.4.6. Continuousoutcomes-Swallowingability(WaterSwallowingtest)-MeanSD-Behavioural intervention (bundle of care**
 6 **including exercises)-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

7

8 **1.1.105.4.7. Dichotomousoutcomes-Dysphagiapresent/returntonormaldiet(numberofpeoplewithwaterswallowingtestgrade>1)-**
 9 **NoOfEvents-Behavioural intervention (bundle of care including exercises)-Usual care-t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable

10

1 **1.1.106.ZHENG, 2022**

Bibliographic Reference ZHENG, C.; WU, W.-B.; FAN, D.-F.; LIAN, Q.-Q.; GUO, F.; TANG, L.-L.; Acupuncture's effect on nerve remodeling among patients with dysphagia after cerebral infarction: a study based on diffusion tensor imaging; World Journal of Acupuncture - Moxibustion; 2022

2

3 **1.1.106.1. Study details**

Secondary publication of another included study- see primary study for details	NR
Other publications associated with this study included in review	NR
Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Department of Neurology of Longyan First Hospital
Study dates	NR
Sources of funding	The authors declare that there is no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
Inclusion criteria	The cases were eligible if they met the diagnostic criteria of cerebral infarction according to the Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke (2014 edition) and the criteria of dysphagia measured by Water Swallowing Test Scale from Chinese Expert Consensus Group on Assessment and Treatment of Dysphagia. 1) cases should have stable condition, no consciousness disorder, and be able to cooperate with examination and treatment; 2) cases aged 40 to 75 years with no sex limitation, should have acute infarction with large infarct area for 2 to 6

	weeks; 3) cases should participate voluntarily, providing signed consent form; 4) cases should have correct understanding of this trial and be compliant with the trial.
Exclusion criteria	1) cases who were complicated with aphasia, audio-visual disorders or other mental disorders; 2) cases who were women in pregnancy or lactation; 3) cases who were in extremely poor nutritional status, combined with serious primary diseases of the heart, liver, kidney, hematopoietic and endocrine systems.
Recruitment / selection of participants	During December 2018 to December 2019, one hundred and twenty cases with lasting dysphagia two weeks after cerebral infarction confirmed by cranial MRI were enrolled from the Department of Neurology of Longyan First Hospital. All cases signed informed consent form before enrollment.
Intervention(s)	Acupuncture was applied at Sishéncōng (EX-HN1), Baihuì (GV20), Tàiyáng (EX-HN5), Fengchí (GB20) and Shésanzhēn (three-tongue needling points, Extra) in acupuncture group. Using acupuncture needles of 0.30 mm × 25 mm (Suzhou Tianxi Acupuncture & Moxibustion Equipment Company), GV20 and EX-HN1 were punctured transversely about 30 mm in depth with single-hand needle insertion method. The needles of 0.30 mm × 40 mm were inserted at EX-HN5, bilateral GB20 and three tongue points vertically around 30 mm in depth at each point, respectively. Even need twirling technique was adopted at all of the above acupoints. After deqi, electric stimulation was added at GV20 and EX-HN5 (one pair), EX-HN1 and GB20 of each side (two pairs), and one pair of three tongue points, using G6805 electroacupuncture apparatus (Qingdao Xinsheng Industrial Co., Ltd.), with continuous wave, 1-2 mA in current intensity and 2Hz in frequency. The 3-week treatment was as 1 course and 2 consecutive courses of treatment were required. The needles were retained for 30 min each time, once daily and five times a week for three weeks as a course of treatment. Two courses of treatments were required in total. Concomitant therapy: All the patients received usual care and swallowing function training of neurology department. In accordance with the specified secondary prevention for cerebrovascular disease, the symptomatic treatment and supportive treatment were administered. Besides, swallowing training was combined, i.e. selective respiratory training, exercise training for perioral and lingual muscles, Shaker exercise; swallowing exercise and Mendelsohn maneuver. The treatment was provided once daily, 30 min each time, 5 treatments a week, for 6 consecutive weeks.
Subgroup 1: Severity of dysphagia (as stated by category)	Not stated/unclear
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)

Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>In sham-acupuncture group, the blunt needles were put into the needle sleeve, and the top of needle was fixed on the skin. During treatment the blunt needle tip only had slight contact with the skin without any penetration. The blunt needle tips were placed on EXHN1, GV20, EX-HN5, GB20 and three-tongue needling points, respectively. The duration of treatment in sham-acupuncture group was the same as that in acupuncture group.</p> <p>Concomitant therapy: All the patients received usual care and swallowing function training of neurology department. In accordance with the specified secondary prevention for cerebrovascular disease, the symptomatic treatment and supportive treatment were administered. Besides, swallowing training was combined, i.e. selective respiratory training, exercise training for perioral and lingual muscles, Shaker exercise; swallowing exercise and Mendelsohn maneuver. The treatment was provided once daily, 30 min each time, 5 treatments a week, for 6 consecutive weeks.</p>
Number of participants	120
Duration of follow-up	6 weeks
Indirectness	NR
Additional comments	NR

1 **1.1.106.2. Study arms**

2 **1.1.106.2.1. Acupuncture (N = 60)**

3 Acupuncture was applied at Sishéncong (EX-HN1), Baihuì (GV20), Tàiyáng (EX-HN5), Fengchí (GB20) and Shésanzhēn (three-tongue needling points, Extra) in acupuncture group. Using acupuncture needles of 0.30 mm × 25 mm (Suzhou Tianxi Acupuncture & Moxibustion Equipment Company), GV20 and EX-HN1 were punctured transversely about 30 mm in depth with single-hand needle insertion method. The needles of 0.30 mm × 40 mm were inserted at EX-HN5, bilateral GB20 and three tongue points vertically around 30 mm in depth at each point, respectively. Even need twirling technique was adopted at all of the above acupoints. After deqi, electric stimulation was added at GV20 and EX-HN5 (one pair), EX-HN1 and GB20 of each side (two pairs), and one pair of three tongue points, using G6805 electroacupuncture apparatus (Qingdao Xincheng Industrial Co., Ltd.), with continuous wave, 1-2 mA in current intensity and 2Hz in frequency. The 3-week treatment was as 1 course and 2 consecutive courses of treatment were required. The needles were retained for 30 min each time, once daily and five times a week for three weeks as a course of treatment. Two courses of treatments were required in total. Concomitant therapy: All the patients received usual care and swallowing function training of neurology department. In accordance with the specified secondary prevention for cerebrovascular disease, the symptomatic treatment and supportive treatment were administered. Besides, swallowing training was combined, i.e. selective respiratory training, exercise training for perioral and lingual muscles, Shaker exercise; swallowing exercise and Mendelsohn maneuver. The treatment was provided once daily, 30 min each time, 5 treatments a week, for 6 consecutive weeks.

17

18 **1.1.106.2.2. Sham acupuncture (N = 60)**

19 In sham-acupuncture group, the blunt needles were put into the needle sleeve, and the top of needle was fixed on the skin. During treatment the blunt needle tip only had slight contact with the skin without any penetration. The blunt needle tips were placed on EXHN1, GV20, EX-HN5, GB20 and three-tongue needling points, respectively. The duration of treatment in sham-acupuncture group was the same as that in acupuncture group. Concomitant therapy: All the patients received usual care and swallowing function training of neurology department. In accordance with the specified secondary prevention for cerebrovascular disease, the symptomatic treatment and supportive treatment were administered. Besides, swallowing training was combined, i.e. selective respiratory training, exercise training for perioral and lingual muscles, Shaker exercise; swallowing exercise and Mendelsohn maneuver. The treatment was provided once daily, 30 min each time, 5 treatments a week, for 6 consecutive weeks.

27

1 **1.1.106.3. Characteristics**2 **1.1.106.3.1. Study-level characteristics**

Characteristic	Study (N = 120)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
Severity of dysphagia	NR
Nominal	
People requiring enteral feeding support at baseline	NR
Nominal	
Type of stroke	NR
Nominal	

3

4 **1.1.106.3.2. Arm-level characteristics**

Characteristic	Acupuncture (N = 60)	Sham acupuncture (N = 60)
% Female	n = 28 ; % = 46.6	n = 24 ; % = 40
Sample size		
Mean age (SD)	60.61 (6.75)	59.72 (7.32)
Mean (SD)		

Characteristic	Acupuncture (N = 60)	Sham acupuncture (N = 60)
Time after stroke weeks	3.37 (0.27)	3.25 (0.41)
Mean (SD)		

1

2 **1.1.106.4. Outcomes**

3 **1.1.106.4.1. Study timepoints**

- 4 • Baseline
- 5 • 6 week

6

7 **1.1.106.4.2. Dichotomous outcomes**

Outcome	Acupuncture, Baseline, N = 60	Acupuncture, 6 week, N = 60	Sham acupuncture , Baseline, N = 60	Sham acupuncture , 6 week, N = 60
Dysphagia present/Return to normal diet (presnce of dysphagia on water swallow test)	n = 60 ; % = 100	n = 22 ; % = 36.6	n = 60 ; % = 100	n = 45 ; % = 75
No of events				

8 Dysphagia present/Return to normal diet (presnce of dysphagia on water swallow test) - Polarity - Lower values are better

9

10

1 **1.1.106.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**

2 **1.1.106.4.4. Dichotomous outcomes - Dysphagia present/Return to normal diet (presence of dysphagia on water swallow test) -**
 3 **No Of Events - Acupuncture - Sham acupuncture - t6**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable

4

5 **1.1.107. Zheng, 2014**

Bibliographic Reference Zheng, L.; Li, Y.; Liu, Y.; The individualized rehabilitation interventions for dysphagia: A multidisciplinary case control study of acute stroke patients; International Journal of Clinical and Experimental Medicine; 2014; vol. 7 (no. 10); 3789-3794

6

7 **1.1.107.1. Study details**

Secondary publication of another included study- see primary study for details	No additional information
Other publications associated with this study included in review	This study was included in and the data extraction may be supported by information provided within: Bath, Philip M; Lee, Han Sean; Everton, Lisa F (2018) Swallowing therapy for dysphagia in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323
Trial name / registration number	No additional information

Study type	Randomised controlled trial (RCT)
Study location	China
Study setting	Inpatient department of Neurology, Qilu Hospital of Shan- dong University
Study dates	December 2011 to February 2013
Sources of funding	No additional information
Inclusion criteria	They were all suffered from primary acute stroke as diagnosed according to the criteria of the Chinese Medical Association in 1995 and the criteria amended in the fourth national cerebrovascular disease conference. Diagnoses were further confirmed by brain computerized tomography (CT) or magnetic resonance imaging (MRI). All the patients were definitely diagnosed as dysphagia with alertness, and ones with comprehension difficulty, such as Wernicke aphasia, that may affect training were excluded from this study
Exclusion criteria	All the patients were definitely diagnosed as dysphagia with alertness, and ones with comprehension difficulty, such as Wernicke aphasia, that may affect training were excluded from this study
Recruitment / selection of participants	Patients included in this study were inpatients of our hospital from December 2011 to February 2013.
Intervention(s)	Swallow training: In the experimental group, oropharyngeal exercises deriving from speech language pathology and including soft palate, tongue, and facial muscle exercises as well as stomatognathic function exercises were performed as described previously. Pharynx and Larynx Exercises were also carried out to strengthen the swallowing musculature according to the method described by Tang et al. These rehabilitation training exercises were performed 2 times per day, and each exercise was repeatedly practiced for about 30 minutes. Eating training: The attending physician or nurse determined the type of diet, eating position and times after evaluating each patient's eating difficulties. (1) Eating position: Patients that can only stay in bed were putted at contralateral positions, the eating position was facing upwards at an angle of 30° and with the neck bent forwards. The hemiplegic ipsilateral was boosted with a pillow for food transit and to avoid the food leakage from the oral cavity. For patients that can sit by themselves, they were at the upright seated positions with the body leaned toward the contralateral sides. After the meal, they were asked to sit up for about 15 min to prevent food reflux and aspiration. (2) Type of Diet: The type of food was managed by using modified diet consistencies according to each patient's clinical condition, ranging from liquid diet to regular diet. A jelly medium such as steamed egg custard was generally administered for patients with serious swallowing disorders. (3) Volume and rate of food delivery: Small amount of meals should be given at short time intervals. Patients were advised to chew carefully and swallow slowly, and their daily food intake was selected after evaluating each patient's dysphagia, ranging from 1/2 to 1 soup spoon (1~4 mL) at the rate

	<p>of consumption 70% food within the 30 min. After each swallowing movement, they were suggested to repeat empty swallowing act for at least 8 times.</p> <p>Each patient received the individualized rehabilitation training and the corresponding plan was developed according to his or her condition. Weekly team conferences evaluated the patient's status and timely adjustments in rehabilitation program were made in appropriate.</p>
Subgroup 1: Severity of dysphagia (as stated by category)	Moderate
Subgroup 2: Time after stroke at the start of the trial	Subacute (7 days - 6 months)
Subgroup 3: People requiring enteral feeding support at baseline	Not stated/unclear
Subgroup 4: Type of stroke (using the Bamford scale)	Not stated/unclear
Population subgroups	NR
Comparator	<p>The control group patients were treated according to the traditional neurology or internal medicine practices, and were assisted to feed in accordance with their will.</p> <p>Each patient received the individualized rehabilitation training and the corresponding plan was developed according to his or her condition. Weekly team conferences evaluated the patient's status and timely adjustments in rehabilitation program were made in appropriate.</p>

Number of participants	88
Duration of follow-up	4 weeks
Indirectness	NR
Additional comments	NR

1

2 **1.1.107.2. Study arms**

3 **1.1.107.2.1. *Behavioural intervention (Individualised multi-disciplinary rehabilitation programme) (N = 44)***

4

5 **1.1.107.2.2. *Usual care (Conventional rehabilitation programme) (N = 44)***

6

7 **1.1.107.3. Characteristics**

8 **1.1.107.3.1. *Study-level characteristics***

Characteristic	Study (N = 88)
Ethnicity	NR
Nominal	
Comorbidities	NR
Nominal	
People requiring enteral feeding support at baseline	NR

Characteristic	Study (N = 88)
Nominal	
Type of stroke	NR
Nominal	

1

2

1.1.107.3.2. Arm-level characteristics

Characteristic	Behavioural intervention (Individualised multi-disciplinary rehabilitation programme) (N = 44)	Usual care (Conventional rehabilitation programme) (N = 44)
% Female	34	38
Nominal		
Mean age (SD)	65 (3)	67 (2)
Mean (SD)		
Severity of dysphagia	NR	NR
Dysphagia scale		
Nominal		
Moderate	10	11
Nominal		
Severe	10	11
Nominal		

Characteristic	Behavioural intervention (Individualised multi-disciplinary rehabilitation programme) (N = 44)	Usual care (Conventional rehabilitation programme) (N = 44)
Time after stroke (days)	8.4 (2.8)	7.1 (2.6)
Mean (SD)		

1

2 **1.1.107.4. Outcomes**3 **1.1.107.4.1. Study timepoints**

- 4 • Baseline
- 5 • 4 week

6

7 **1.1.107.4.2. Dichotomous outcome**

Outcome	Behavioural intervention (Individualised multi-disciplinary rehabilitation programme), Baseline, N = 44	Behavioural intervention (Individualised multi-disciplinary rehabilitation programme), 4 week, N = 44	Usual care (Conventional rehabilitation programme), Baseline, N = 44	Usual care (Conventional rehabilitation programme), 4 week, N = 44
Dysphagia present/return to normal diet (number of people not cured at the end of trial)	n = NR ; % = NR	n = 19 ; % = 43.2	n = NR ; % = NR	n = 32 ; % = 72.7
No of events				

8 Dysphagia present/return to normal diet (number of people not cured at the end of trial) - Polarity - Lower values are better

9

1

2 **1.1.107.4.3. Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**3 **1.1.107.4.4. Dichotomousoutcome-Dysphagiapresent-NoOfEvents-Individualised multi-disciplinary rehabilitation programme-**
4 **Conventional rehabilitation programme-t4**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High (Due to randomisation, deviation from intended interventions and missing outcome data)
Overall bias and Directness	Overall Directness	Directly applicable

5

6

7

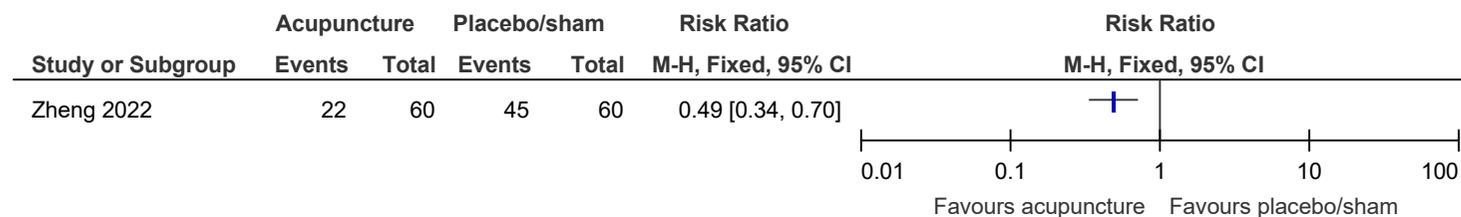
8

Appendix E Forest plots

E.1 Interventions for oropharyngeal dysphagia

E.1.1 Acupuncture/electroacupuncture compared to placebo/sham therapy

Figure 2: Dysphagia present/return to normal diet (dysphagia present) at <3 months



E.1.2 Acupuncture/electroacupuncture compared to usual care

Figure 3: Occurrence of chest infections at <3 months

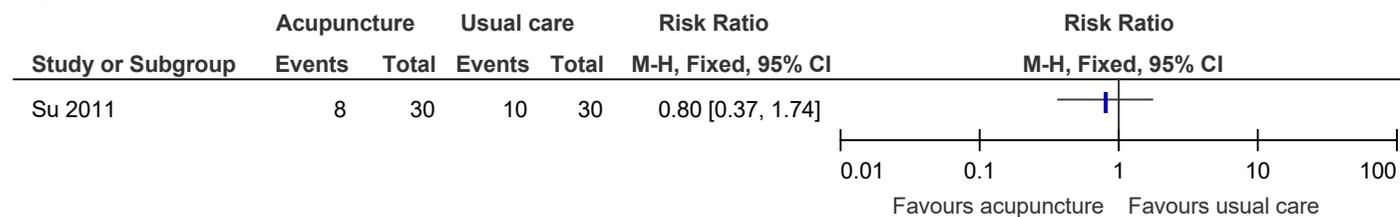


Figure 4: Dysphagia present/return to normal diet (dysphagia present) at <3 months

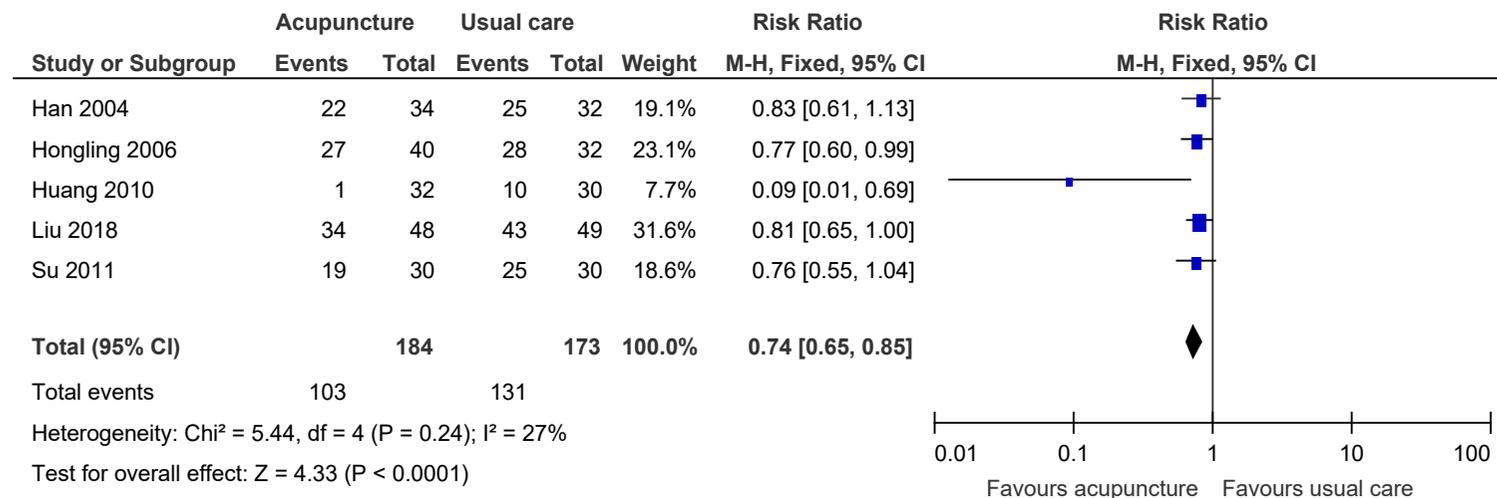


Figure 5: Swallowing ability (videofluoroscopic swallowing study, 0-8, higher values are better, change score) at <3 months

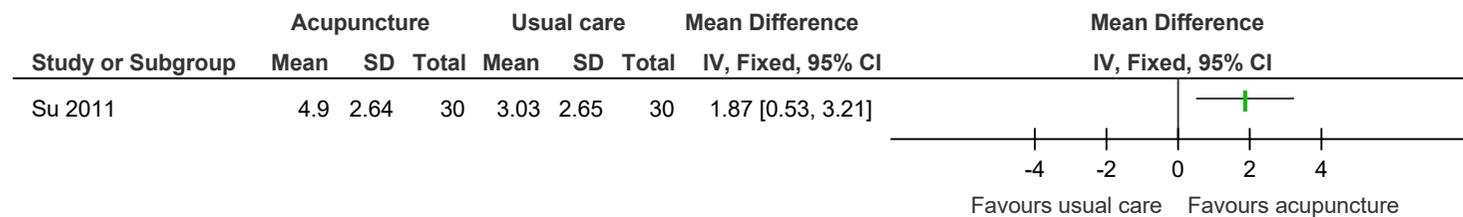
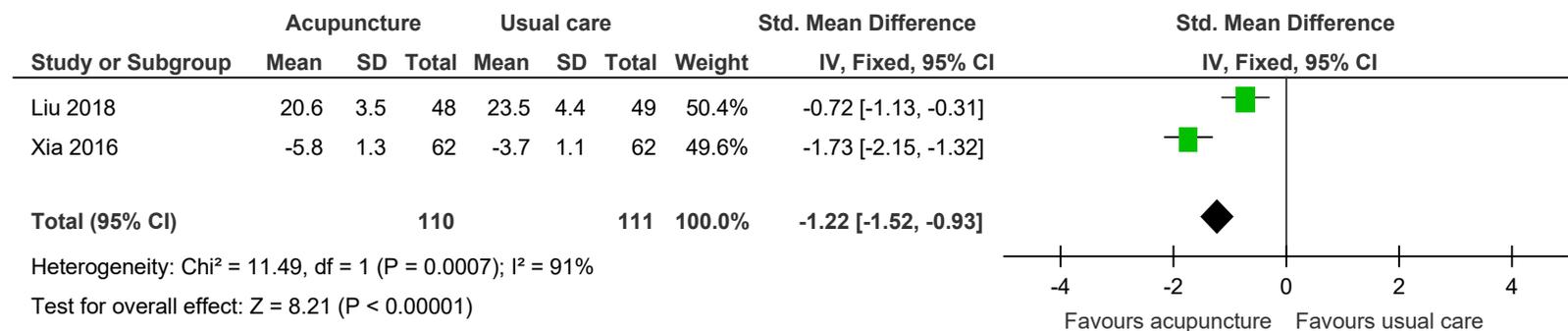


Figure 6: Swallowing ability (Standardised swallowing assessment, dysphagia outcome severity scale [different scale ranges], lower values are better, final values) at <3 months



E.1.3 Behavioural interventions compared to placebo/sham therapy

Figure 7: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score) at <3 months

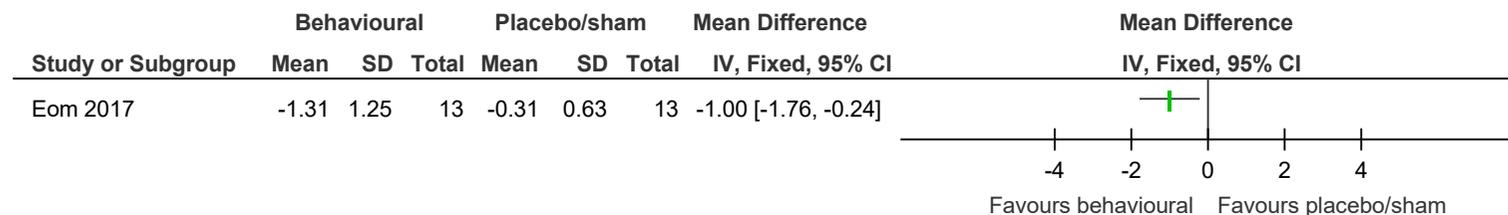


Figure 8: Swallowing ability (videofluoroscopic dysphagia scale, 0-100, lower values are better, change score) at <3 months

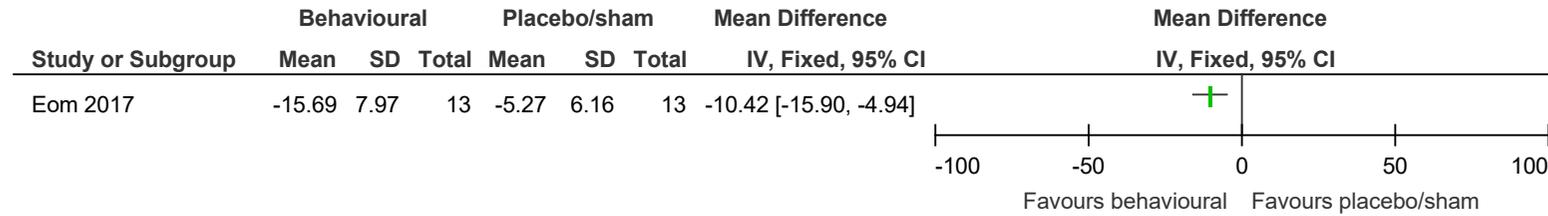
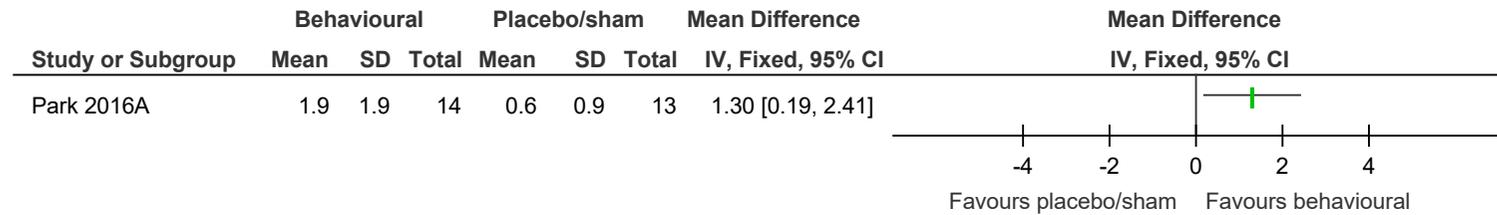


Figure 9: Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months



E.1.4 Behavioural interventions compared to usual care

Figure 10: Occurrence of chest infections at <3 months

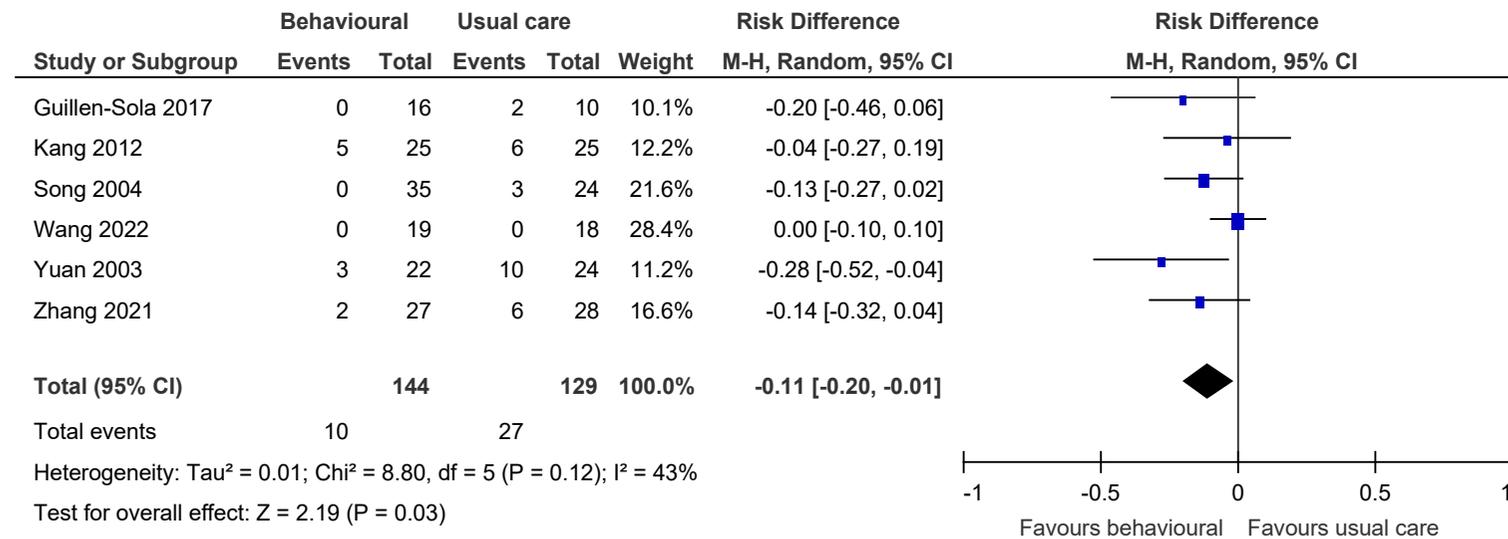


Figure 11: Occurrence of chest infections at ≥3 months

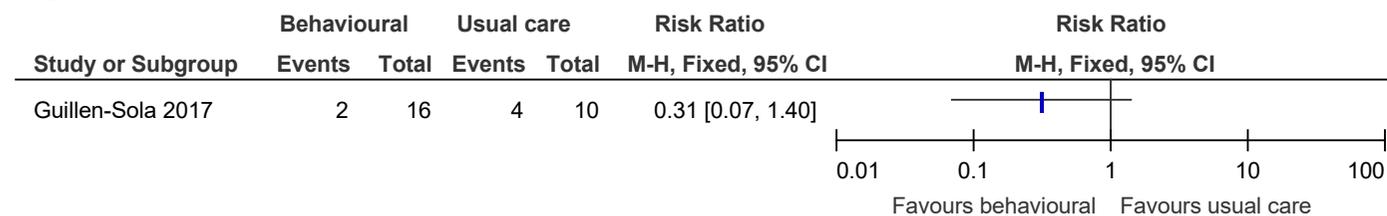


Figure 12: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final values) at <3 months

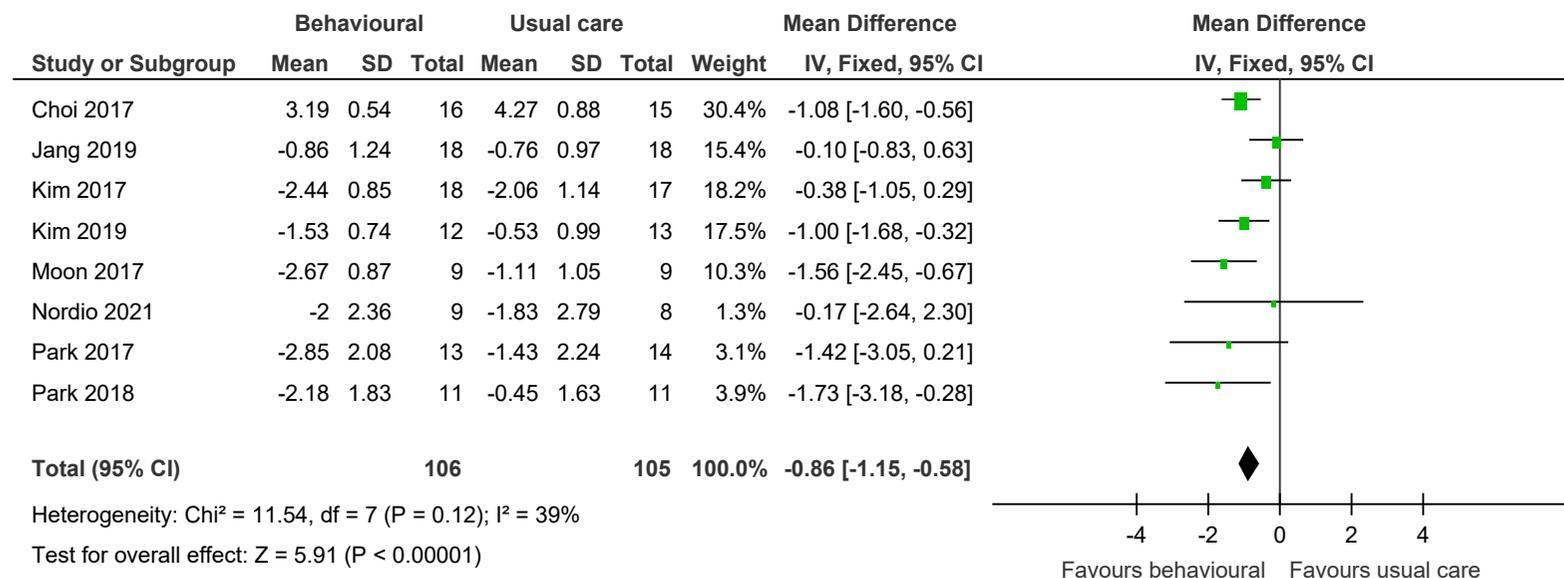


Figure 13: Occurrence of aspiration at ≥3 months

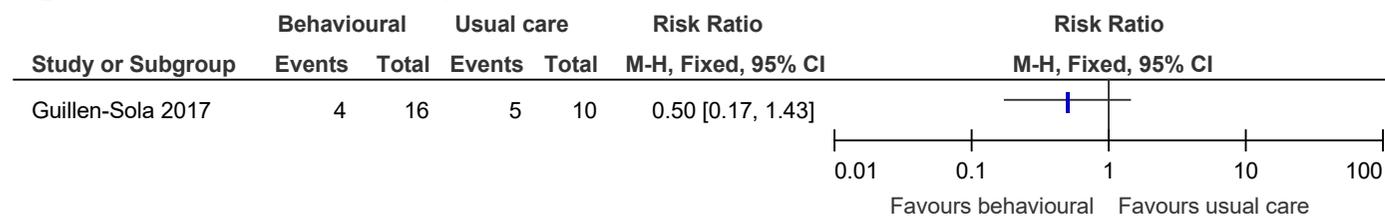


Figure 14: Dysphagia present/return to normal diet (dysphagia present) at <3 months

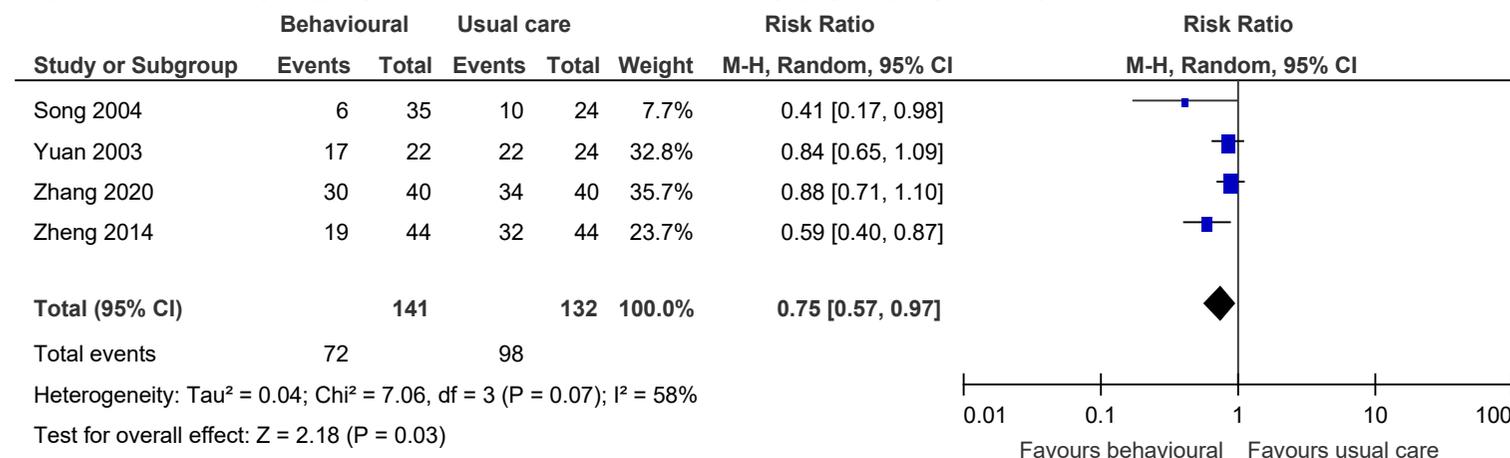


Figure 15: Dysphagia present/return to normal diet (return to normal diet) at <3 months

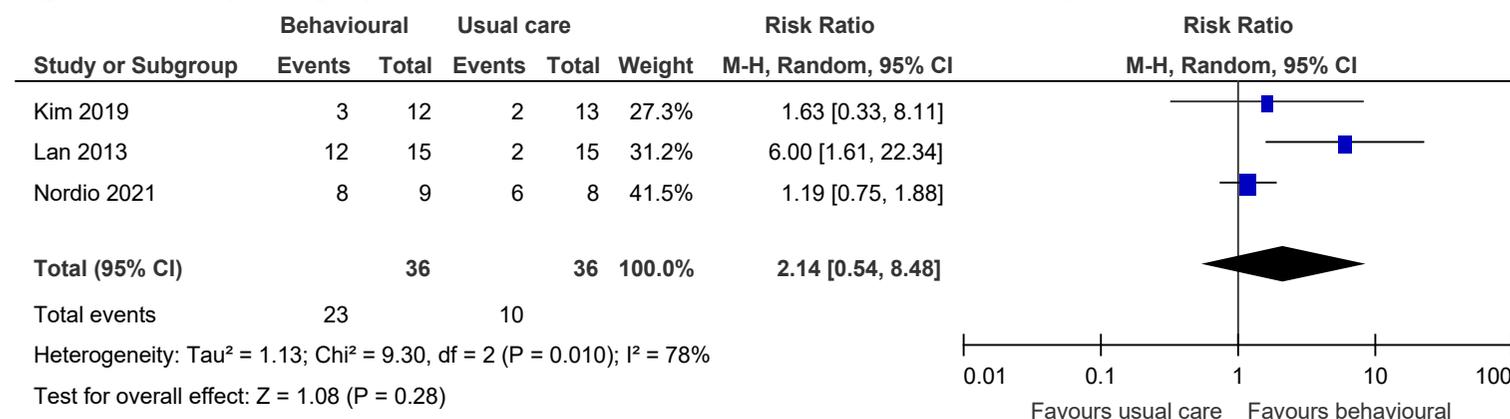


Figure 16: Length of hospital stay (days, lower values are better, final values) at <3 months

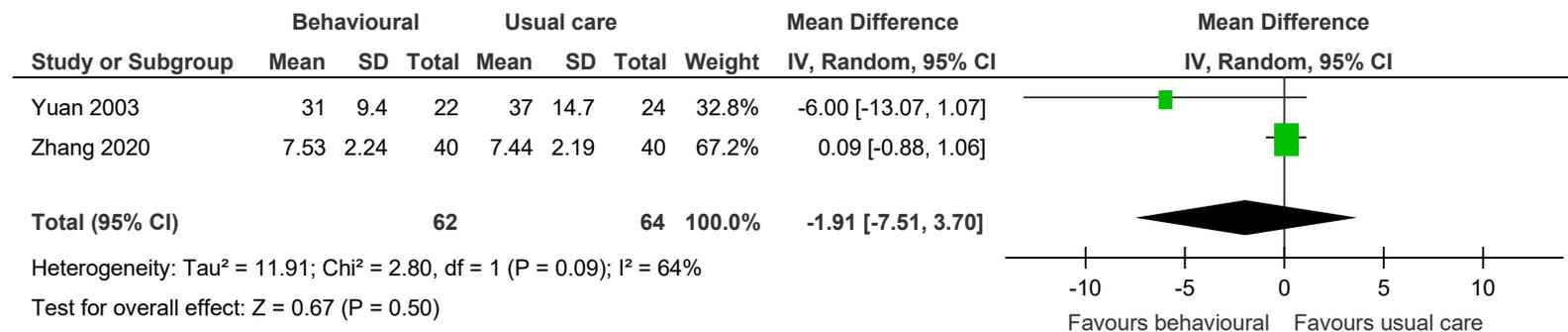


Figure 17: Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale, Mann Assessment of Swallowing, ASHA-NOMS [different scale ranges], higher values are better, change scores) at <3 months

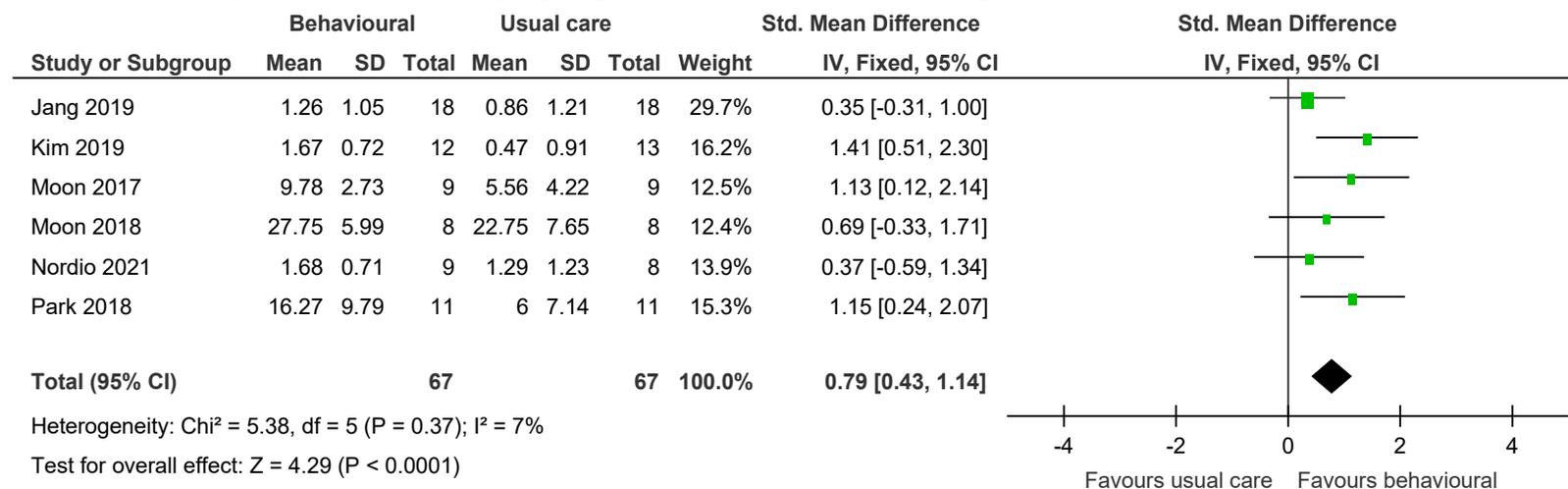


Figure 18: Swallowing ability (Functional Oral Intake Scale, Videofluoroscopic Dysphagia Rating Scale, Water swallowing test [different scale ranges], higher values are better, final values) at <3 months

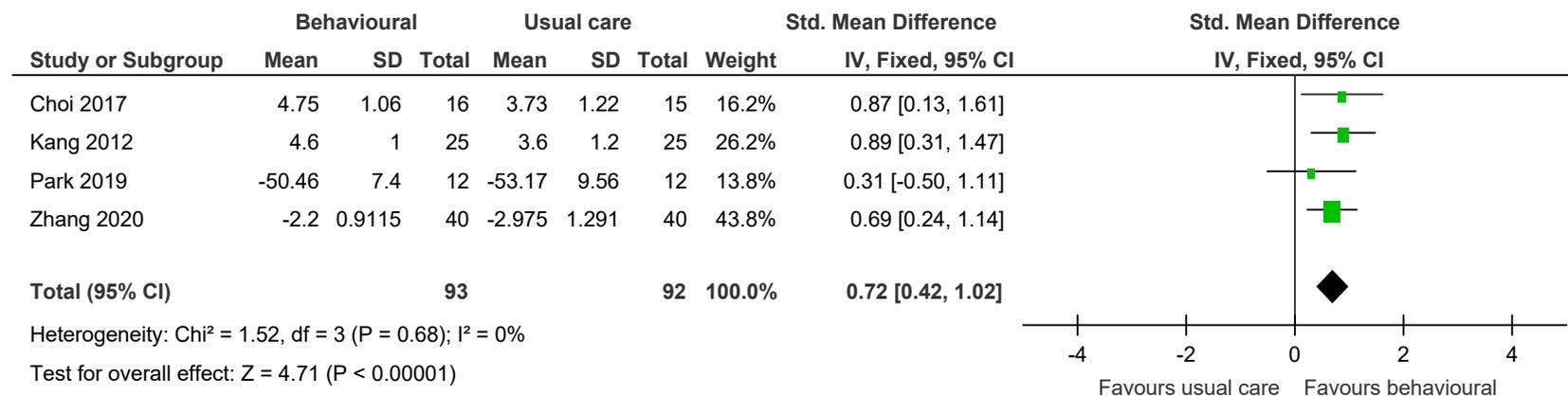
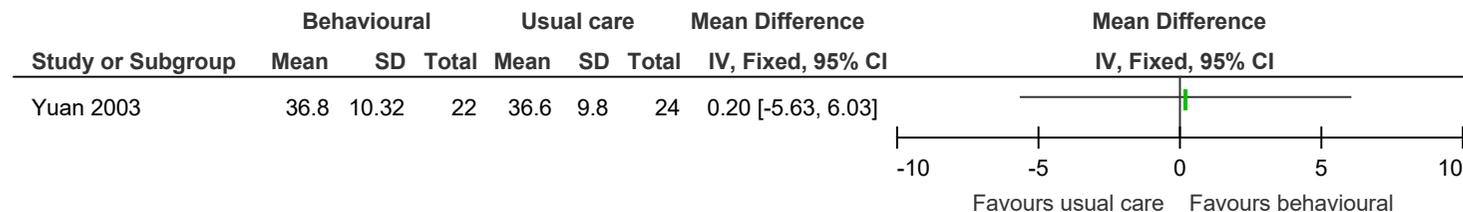


Figure 19: Nutrition (units unclear, final values) at <3 months



E.1.5 Drug interventions (metoclopramide) compared to placebo/sham therapy

Figure 20: Mortality at <3 months

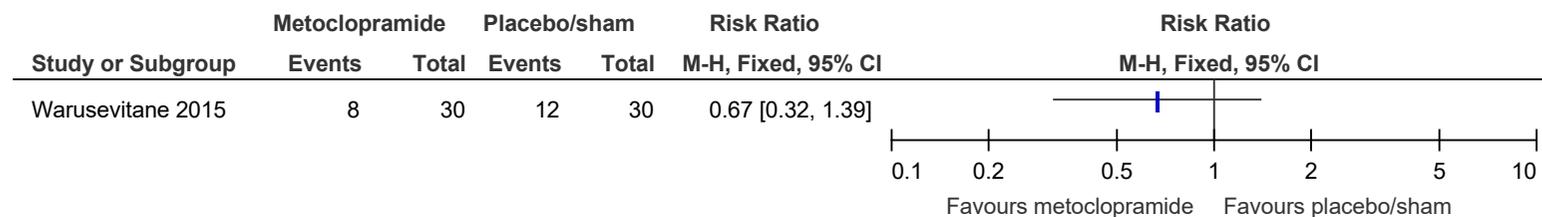


Figure 21: Occurrence of chest infections at <3 months

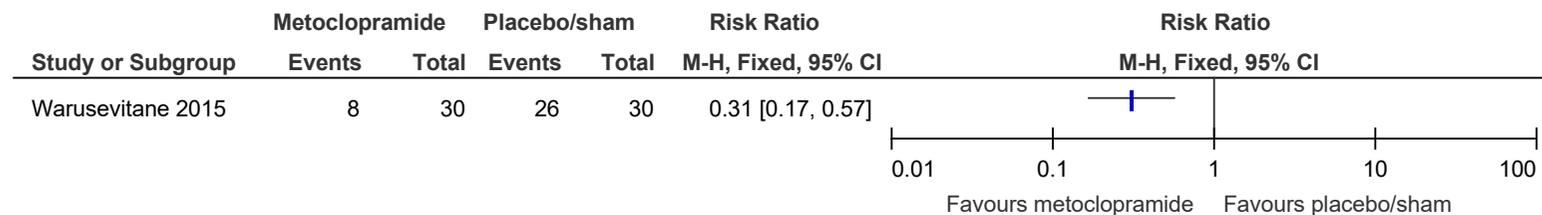


Figure 22: Occurrence of aspiration (number of episodes of aspiration, lower values are better, final value) at <3 months

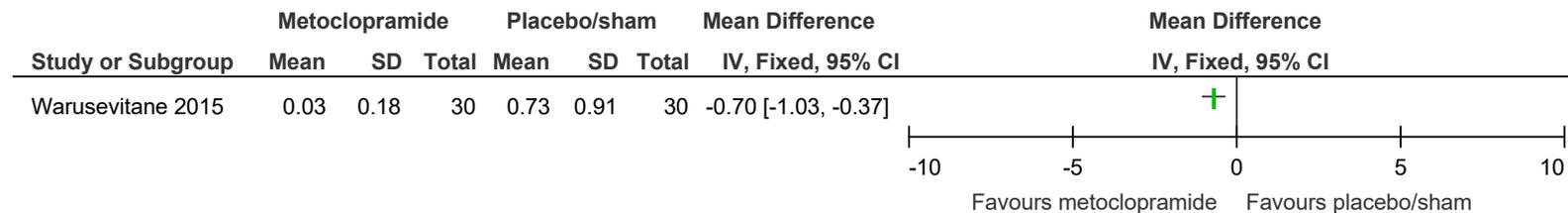
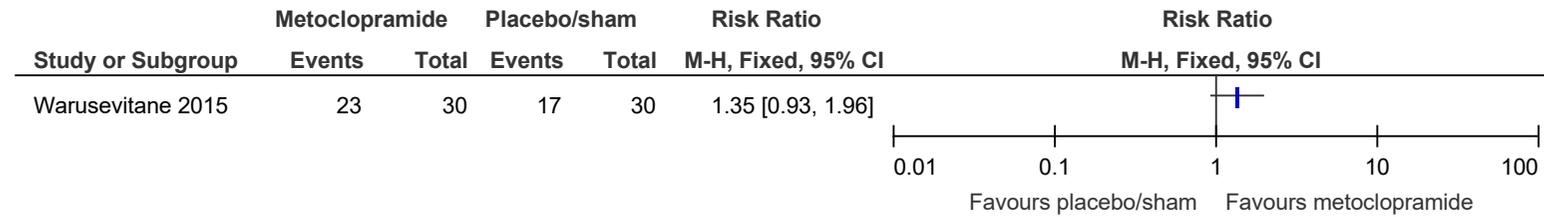


Figure 23: Dysphagia present/return to normal diet (return to normal diet) at <3 months



E.1.6 Drug interventions (domperidone) compared to placebo/sham therapy

Figure 24: Mortality at <3 months

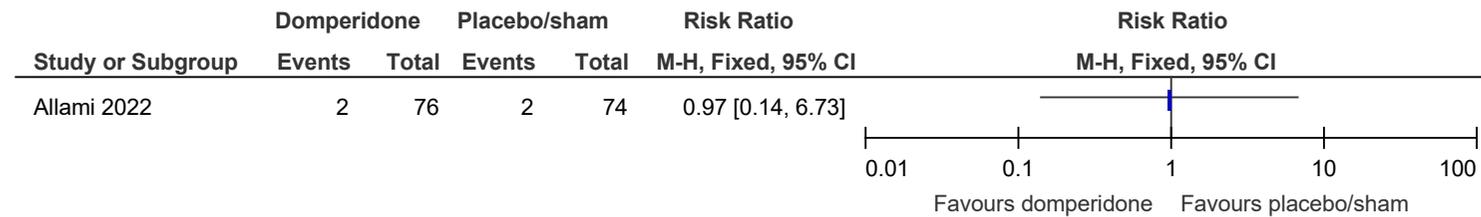


Figure 25: Occurrence of aspiration at <3 months

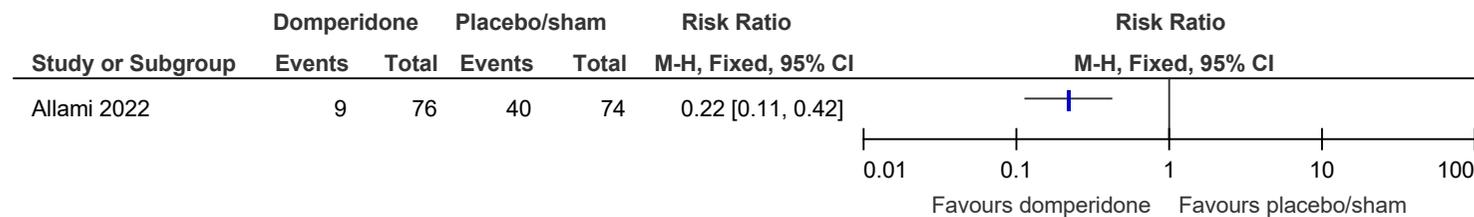
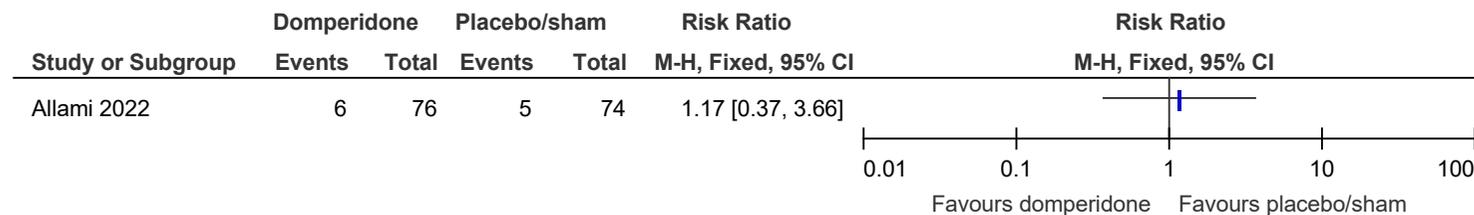


Figure 26: Dysphagia present/return to normal diet (dysphagia present) at <3 months



E.1.7 Drug interventions (lisinopril) compared to placebo/sham therapy

Figure 27: Mortality at ≥3 months

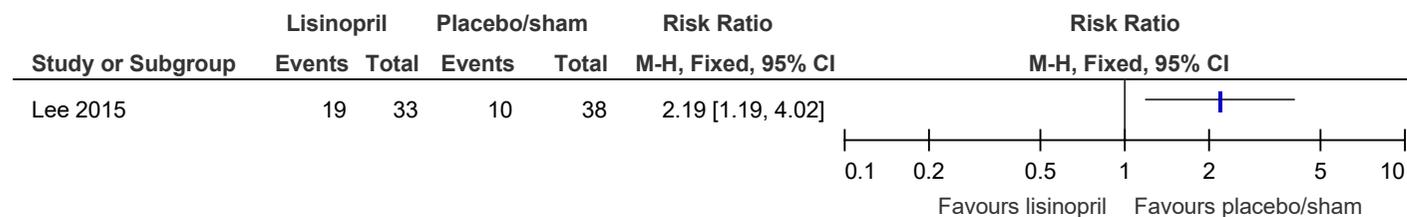


Figure 28: Occurrence of chest infections at ≥3 months

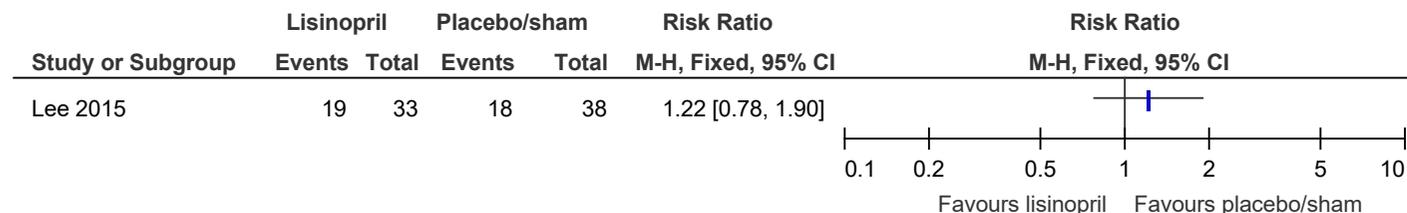
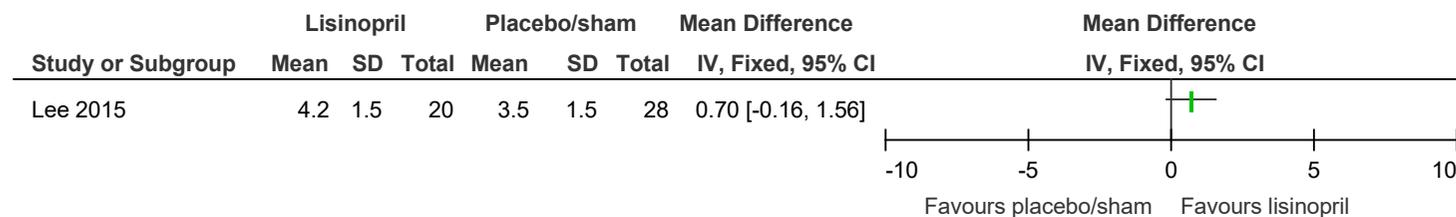


Figure 29: Swallowing ability (Royal Brisbane Hospital Outcome Measure for Swallowing, scale range unclear, higher values are better, final value) at <3 month



E.1.8 Drug interventions (nifedipine) compared to placebo/sham therapy

Figure 30: Mortality at <3 months

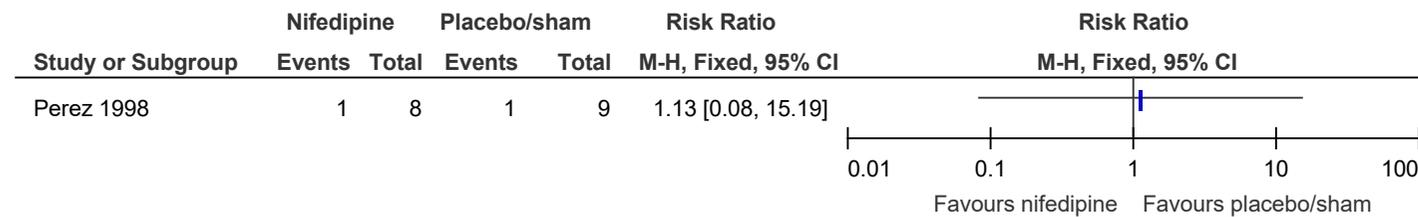
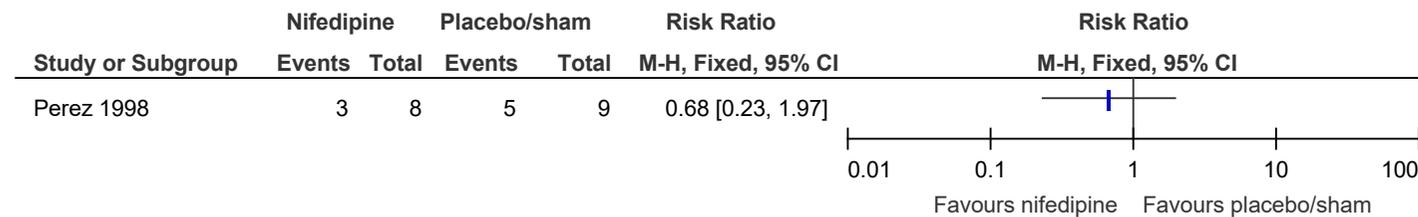


Figure 31: Dysphagia present/return to normal diet (dysphagia present) at <3 months



E.1.9 Neuromuscular electrical stimulation (NMES) compared to placebo/sham therapy

Figure 32: Mortality at <3 months

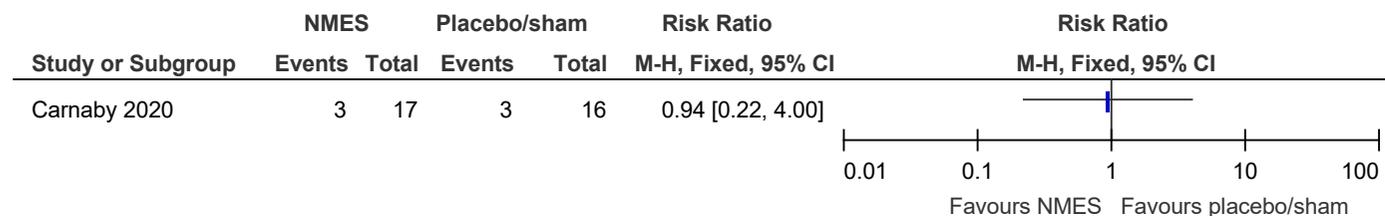


Figure 33: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final value) at <3 months

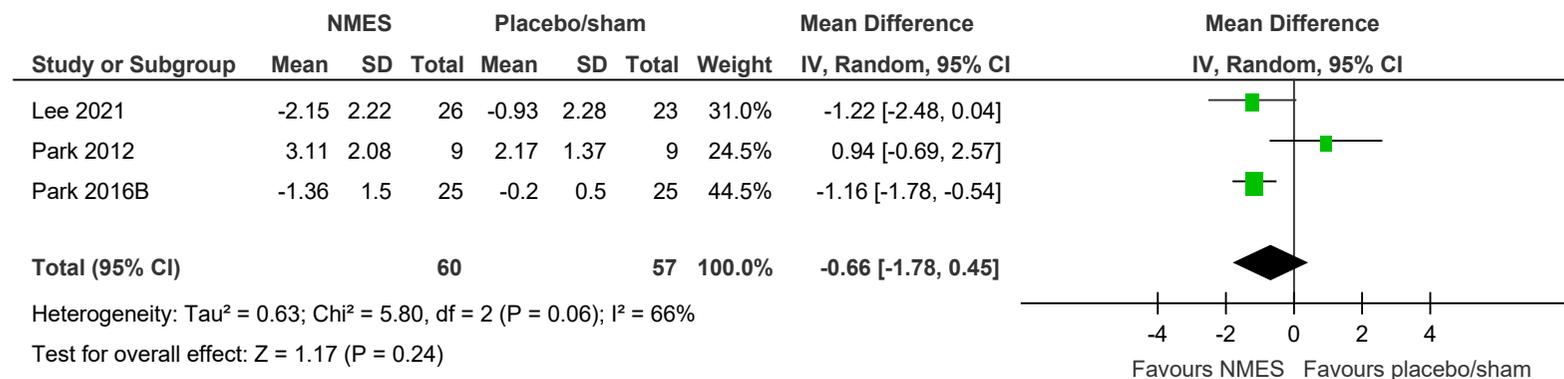


Figure 34: Occurrence of aspiration at <3 months

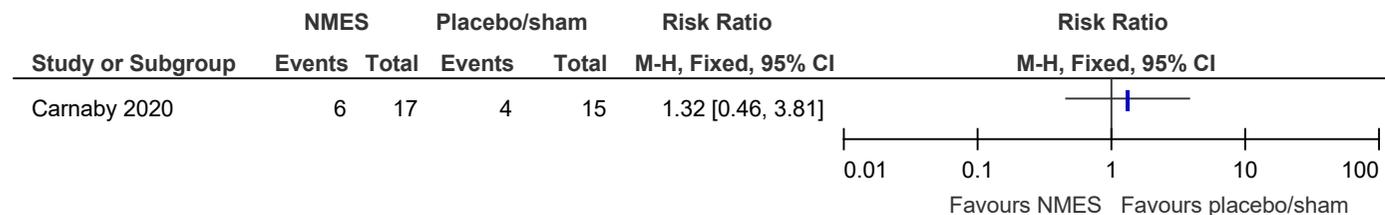


Figure 35: Dysphagia present/return to normal diet (dysphagia present) at <3 months

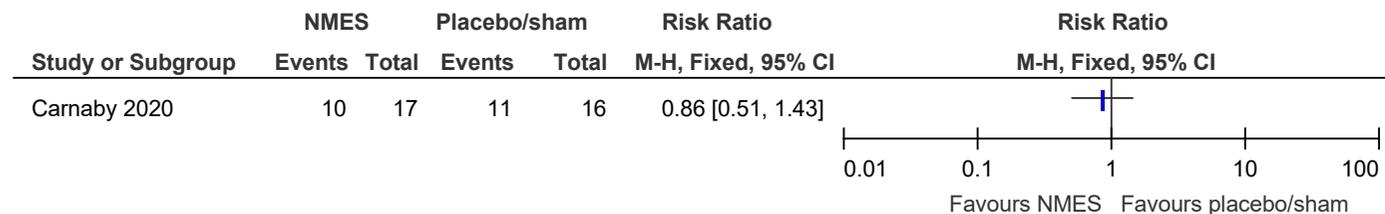


Figure 36: Dysphagia present/return to normal diet (return to normal diet) at <3 months

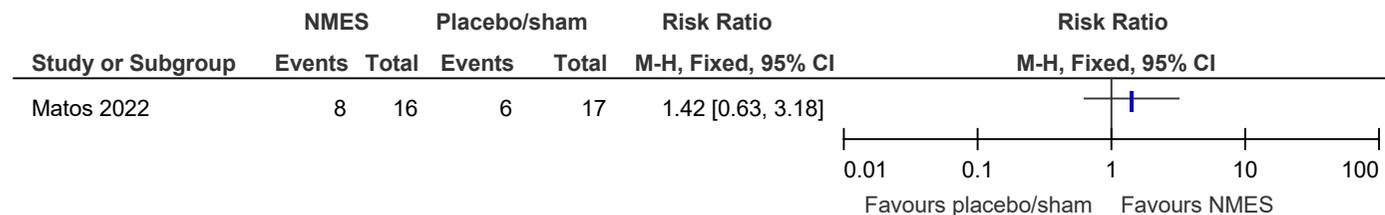


Figure 37: Length of hospital stay (days, lower values are better, final value) at <3 months

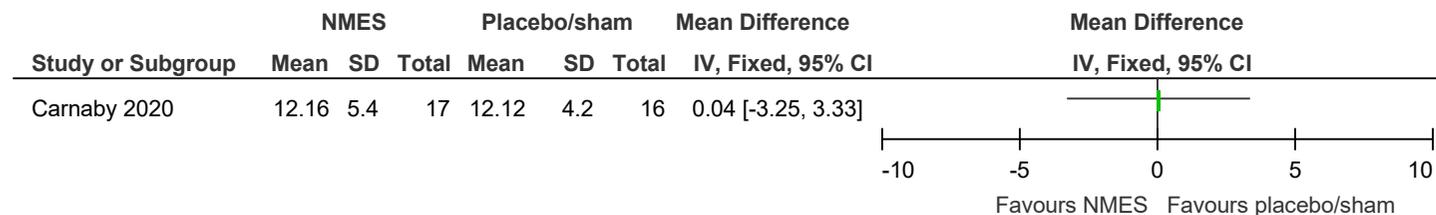


Figure 38: Swallowing ability (Functional Oral Intake Scale, Videofluoroscopic Dysphagia Scale, Mann Assessment of Swallowing Ability [different scale ranges], higher values are better, change scores) at <3 months

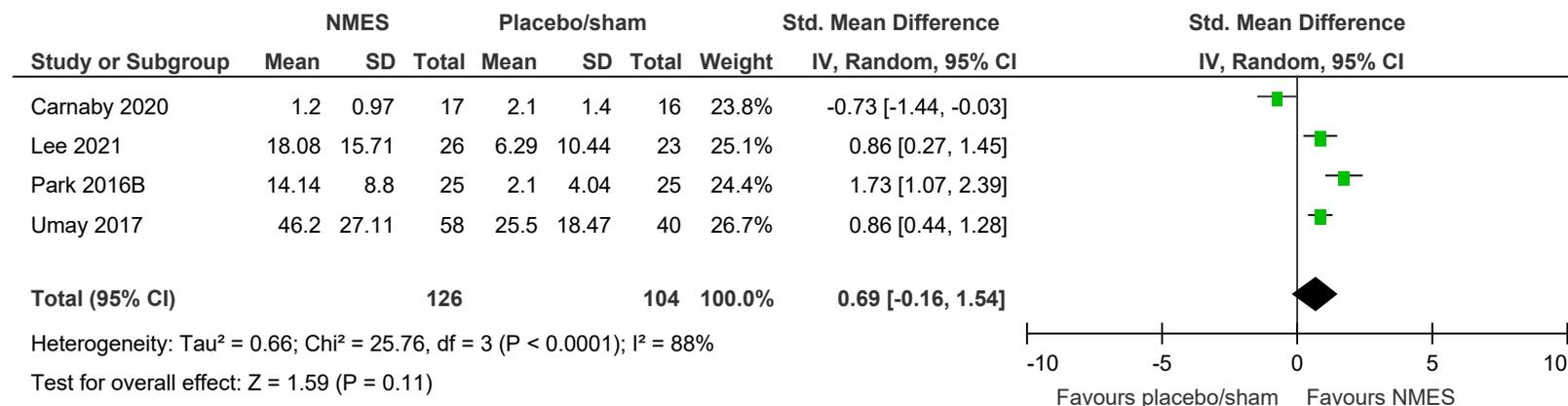
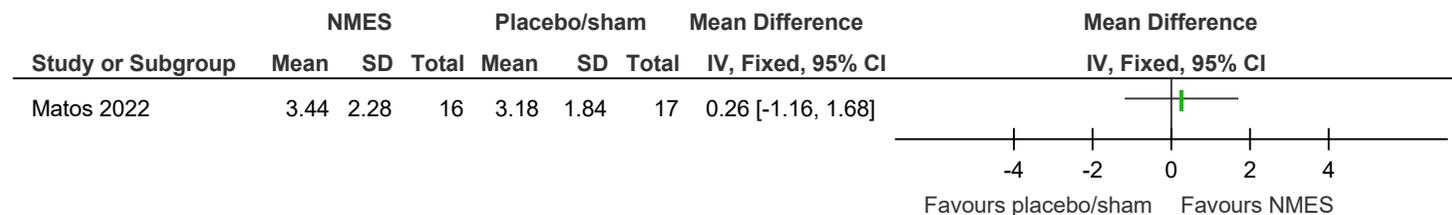


Figure 39: Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months



E.1.10 Neuromuscular electrical stimulation (NMES) compared to usual care

Figure 40: Mortality at <3 months

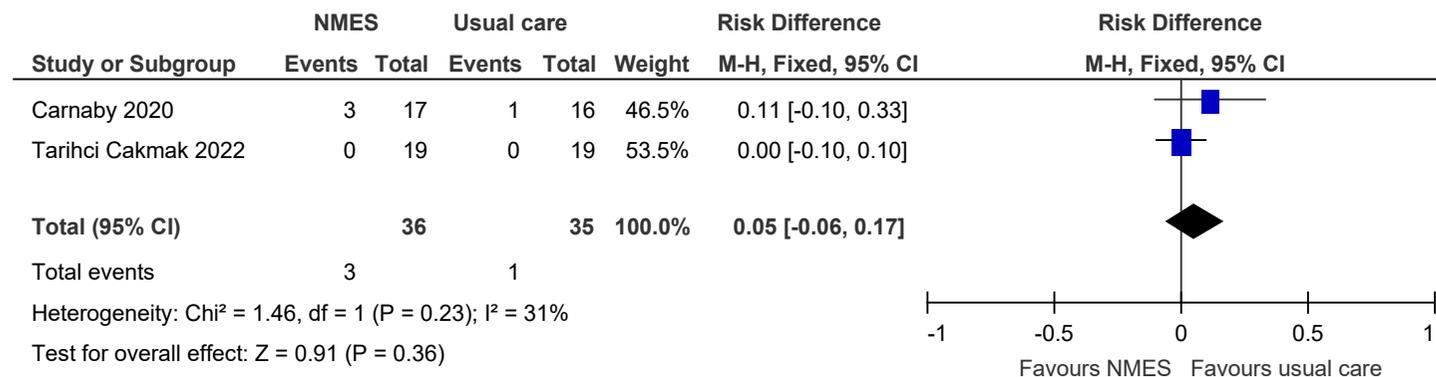


Figure 41: Mortality at ≥3 months

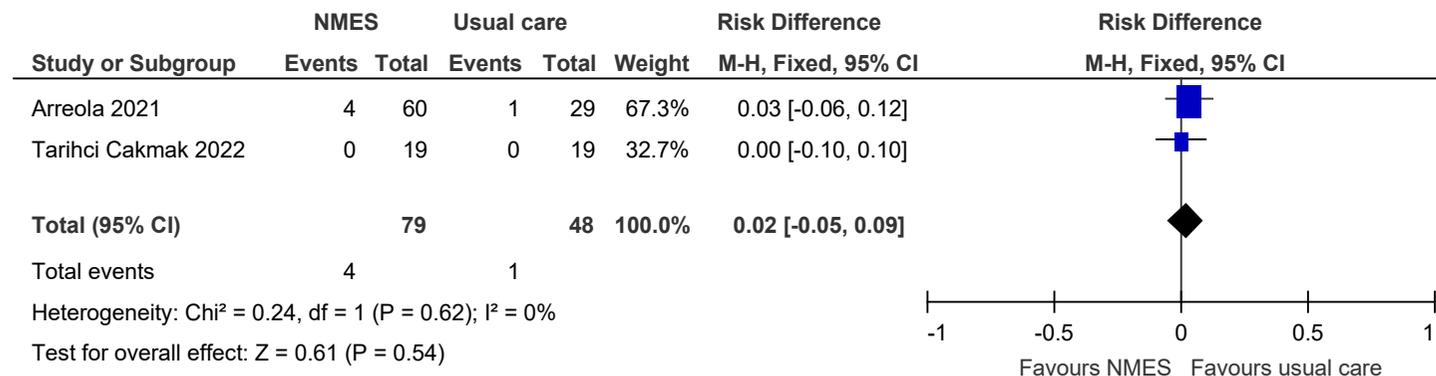


Figure 42: Person/participant generic health-related quality of life (EQ-VAS, 0-100, higher values are better, final value) at ≥3 months

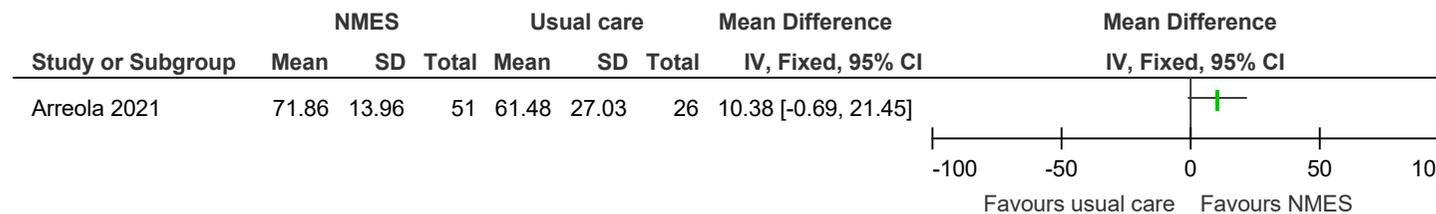


Figure 43: Occurrence of chest infections at <3 months

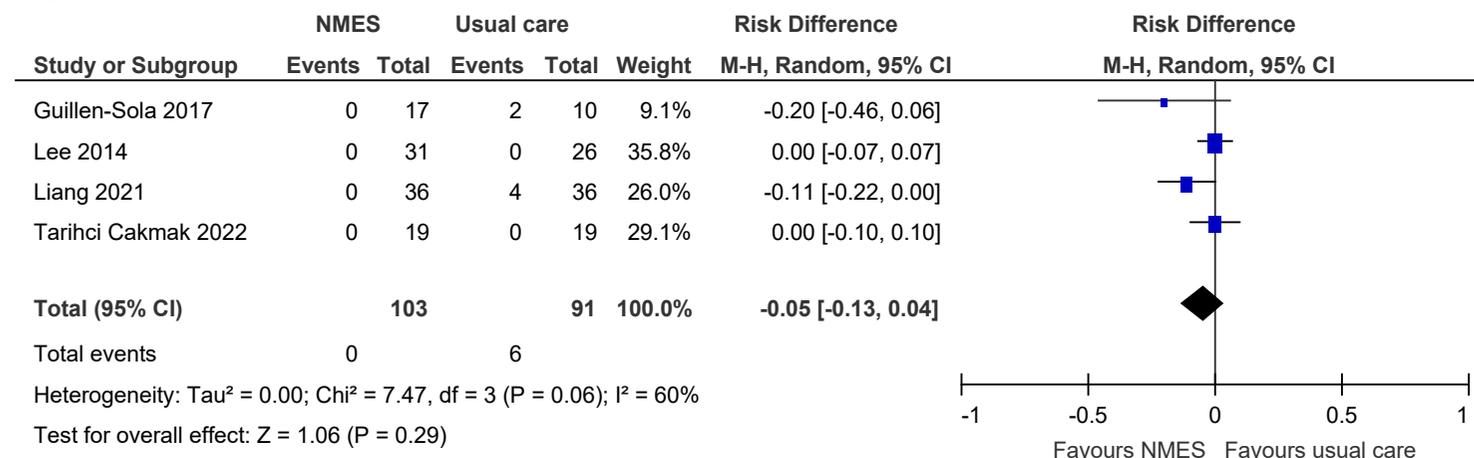


Figure 44: Occurrence of chest infections at ≥3 months

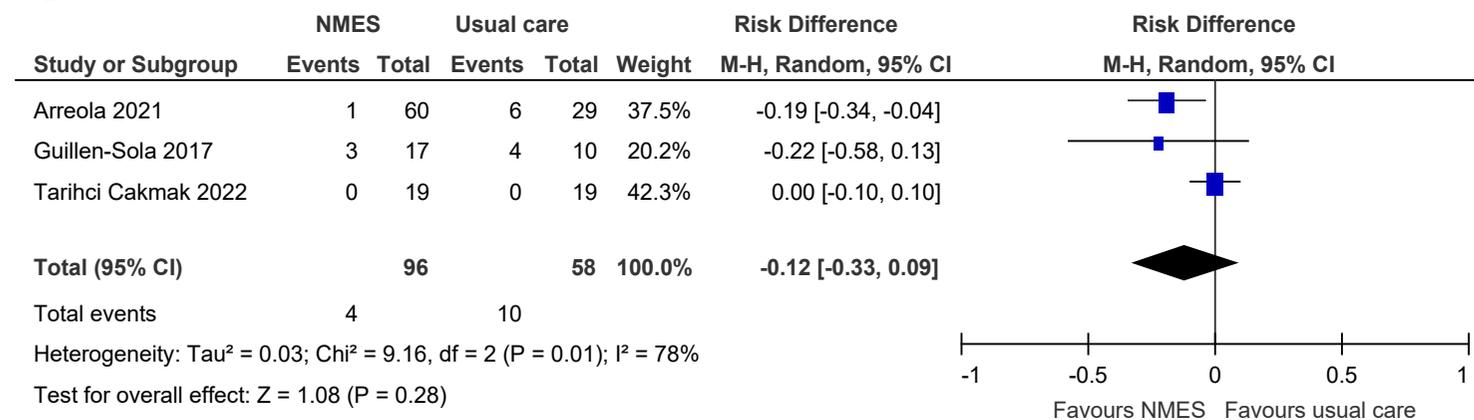


Figure 45: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months

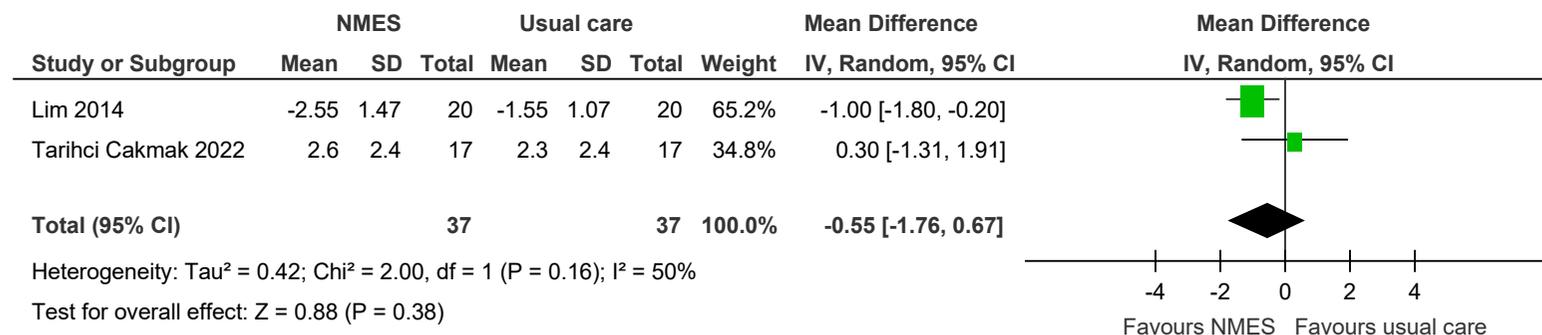


Figure 46: Occurrence of aspiration at <3 months

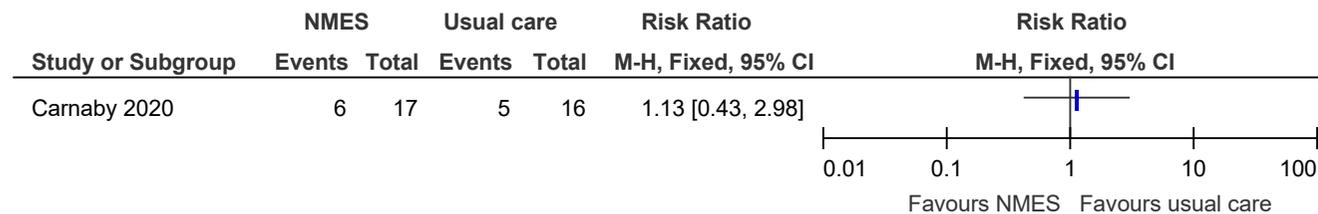


Figure 47: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months

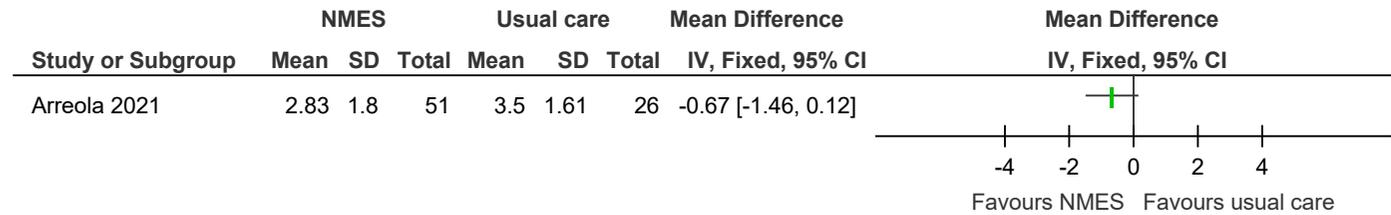


Figure 48: Occurrence of aspiration at ≥3 months

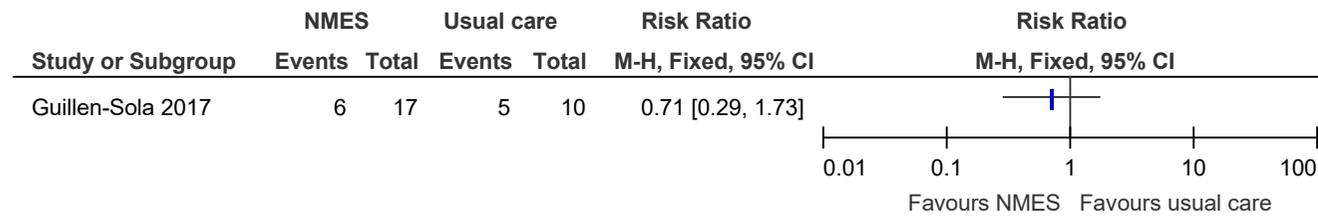


Figure 49: Dysphagia present/return to normal diet (dysphagia present) at <3 months

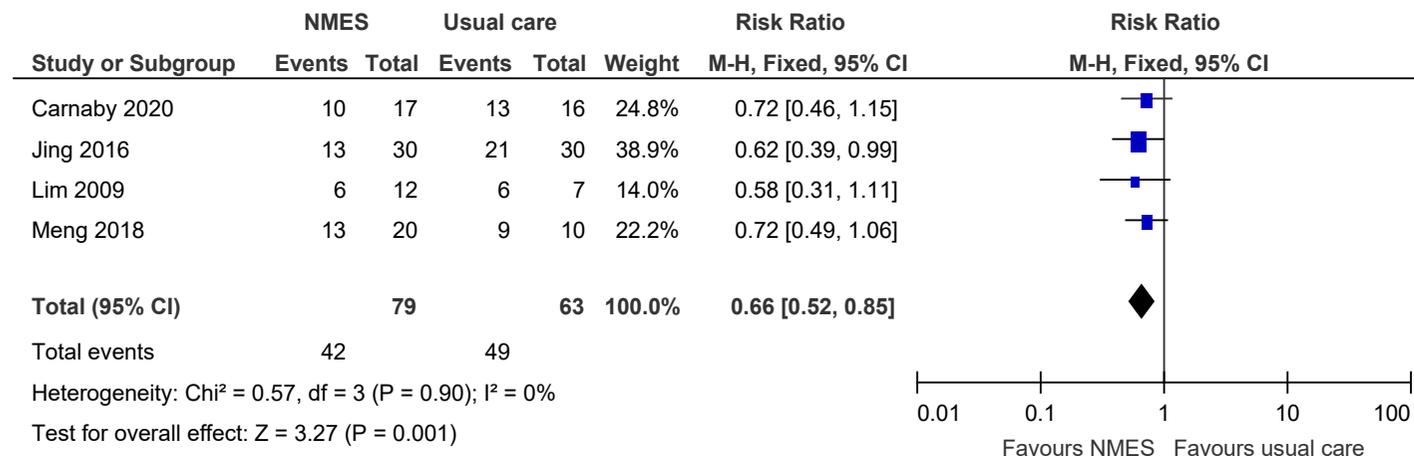


Figure 50: Dysphagia present/return to normal diet (return to normal diet) at <3 months

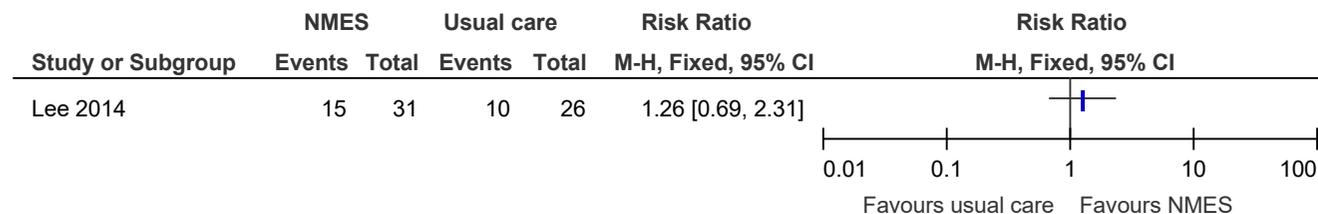


Figure 51: Dysphagia present/return to normal diet (dysphagia present) at ≥3 months

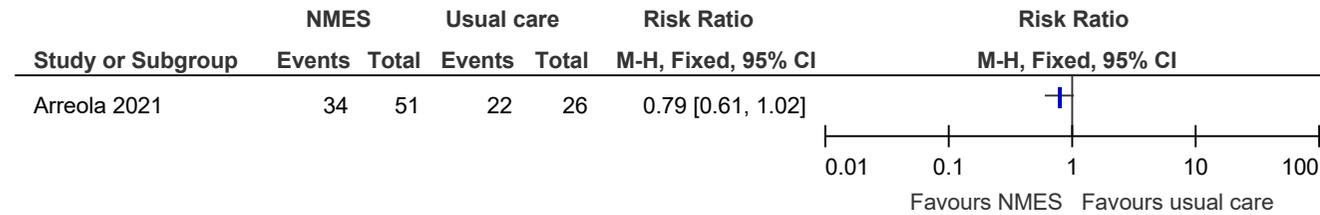


Figure 52: Length of hospital stay (days, lower values are better, final value) at <3 months

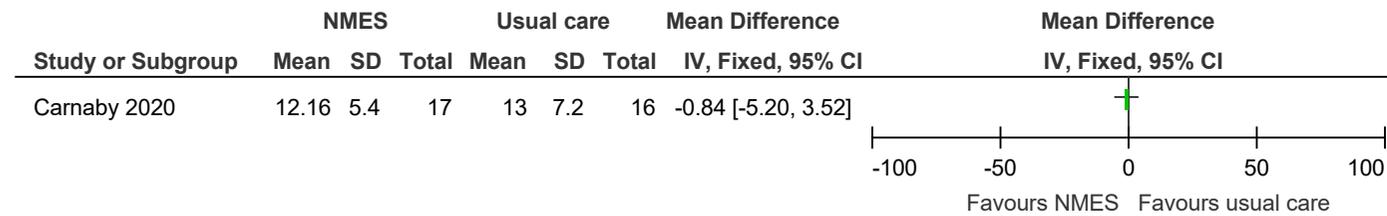


Figure 53: Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months

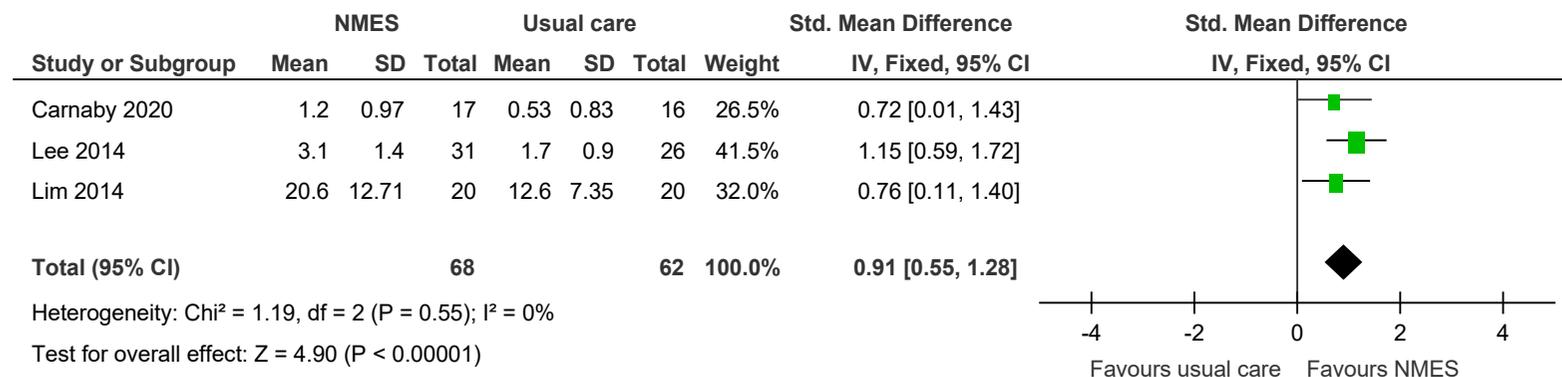


Figure 54: Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome and Severity Scale, Standardised swallowing assessment, Dysphagia severity [different scale ranges], higher values are better, final values) at <3 months

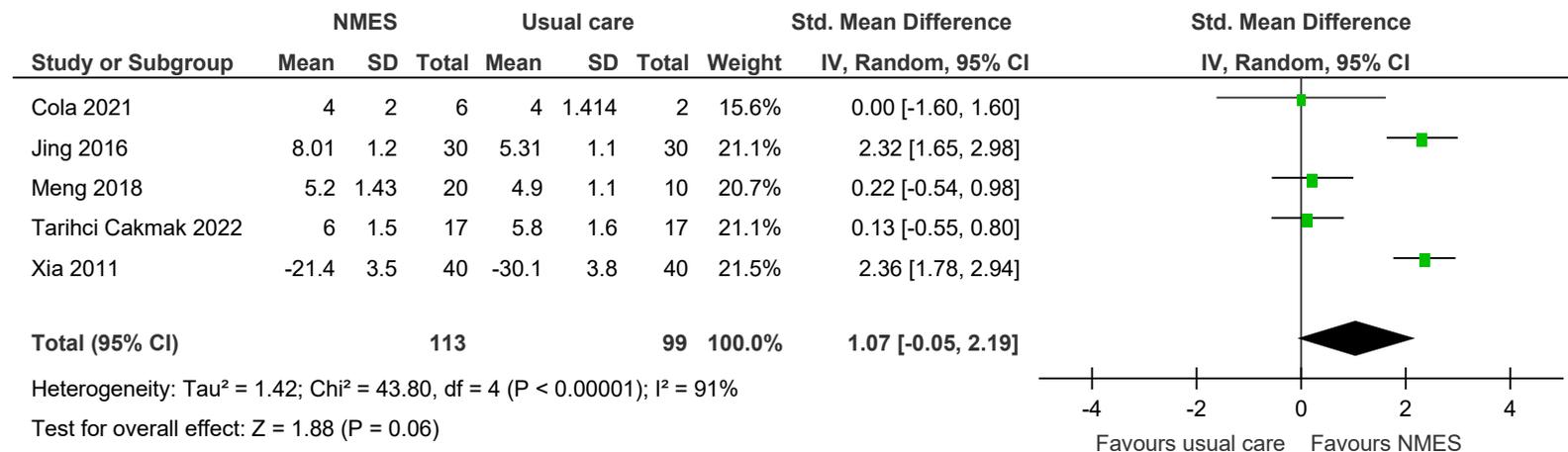


Figure 55: Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at ≥3 months

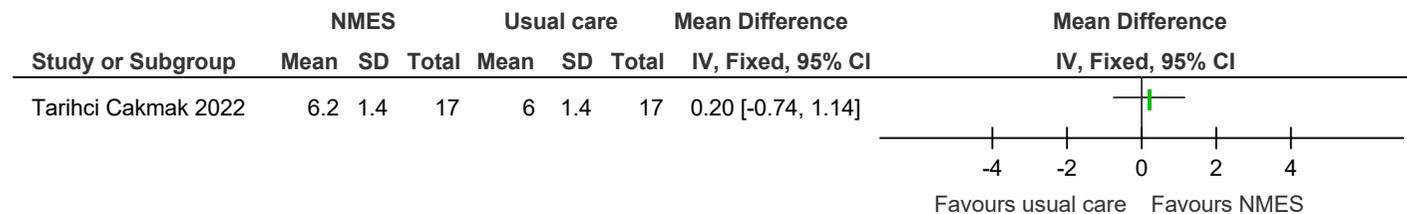
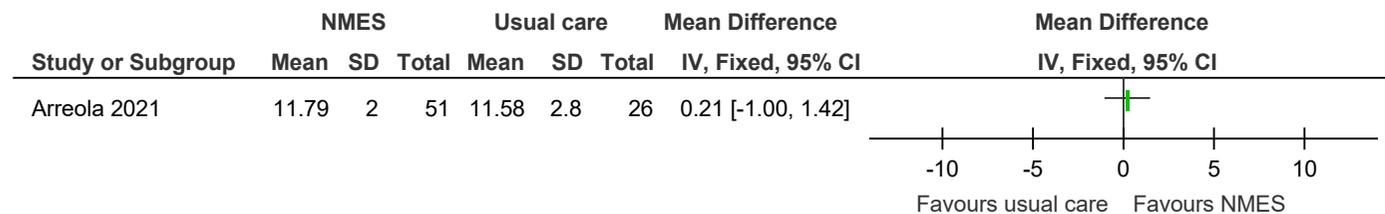


Figure 56: Nutrition (Mini Nutritional Assessment-short form, 0-14, higher values are better, final value) at ≥3 months



E.1.11 Pharyngeal electrical stimulation (PES) compared to placebo/sham therapy

Figure 57: Mortality at <3 months

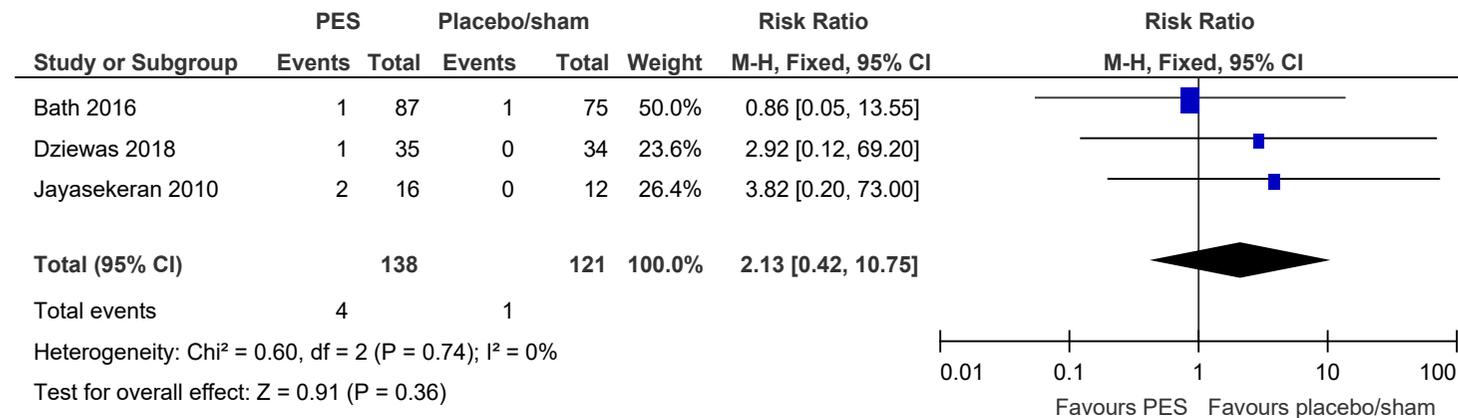


Figure 58: Mortality at ≥3 months

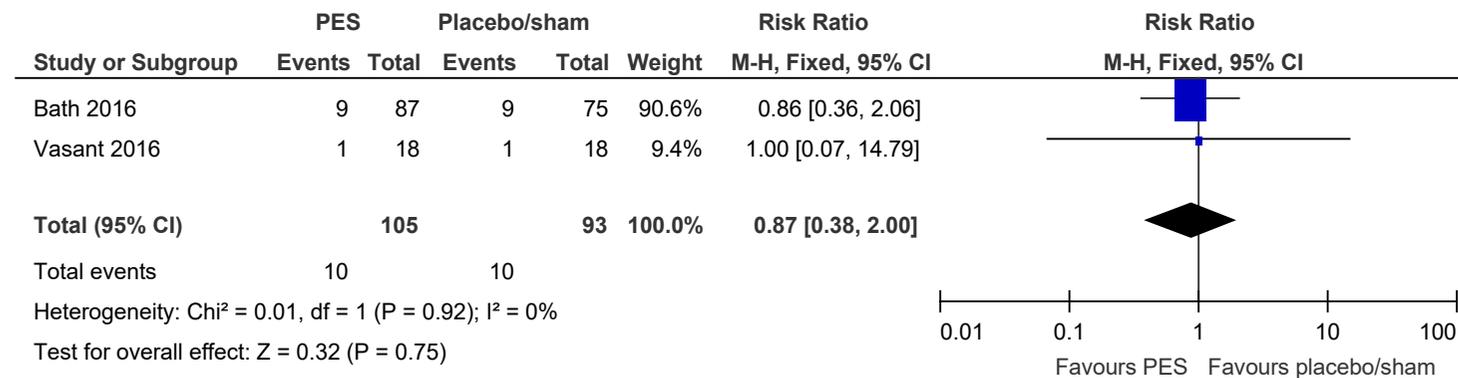


Figure 59: Person/participant generic health-related quality of life (EQ-5D, -0.11-1, higher values are better, change score) at ≥3 months

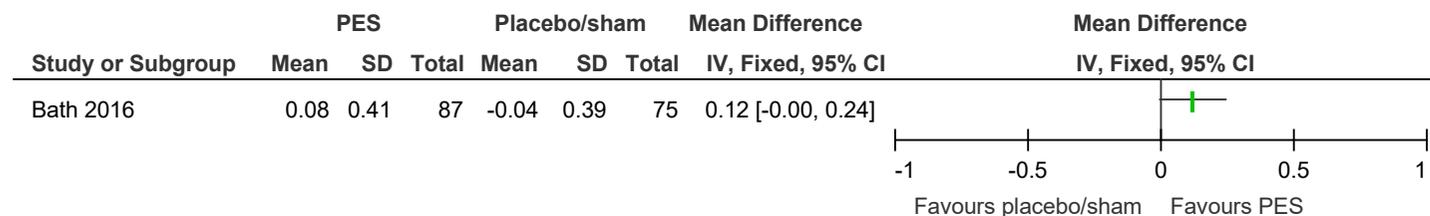


Figure 60: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final values) at <3 months

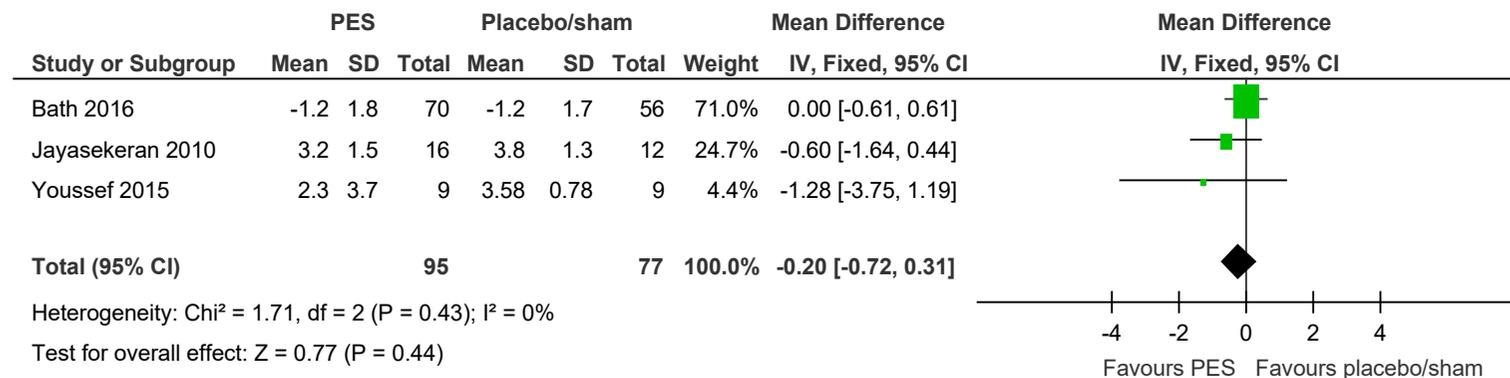


Figure 61: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at ≥3 months

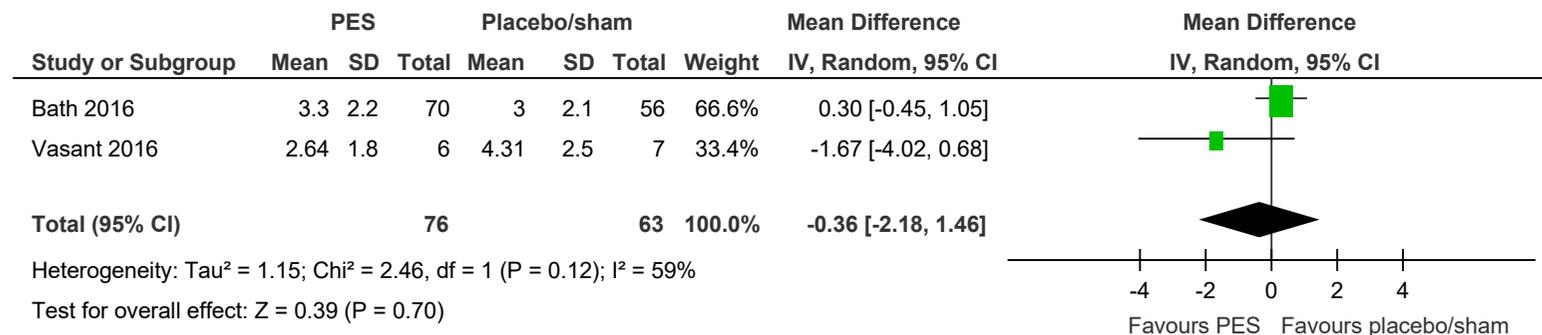


Figure 62: Dysphagia present/return to normal diet (dysphagia present) at <3 months

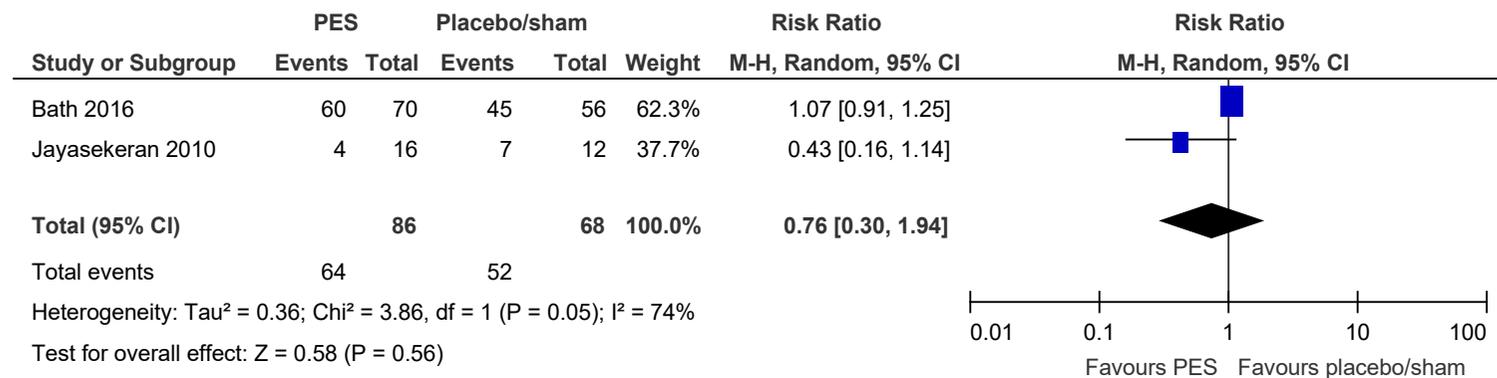


Figure 63: Dysphagia present/return to normal diet (return to normal diet) at <3 months

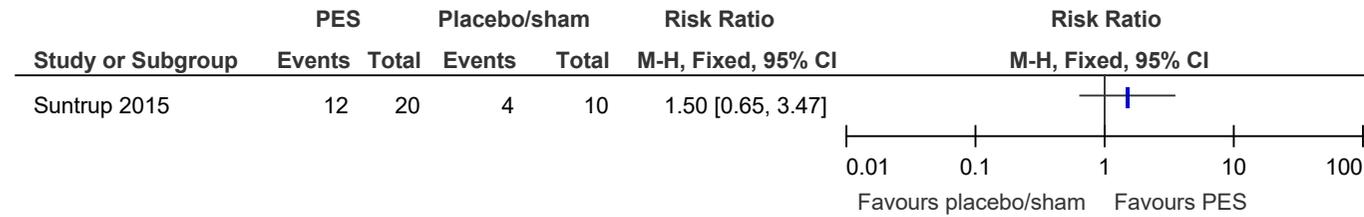


Figure 64: Dysphagia present/return to normal diet (dysphagia present) at ≥3 months

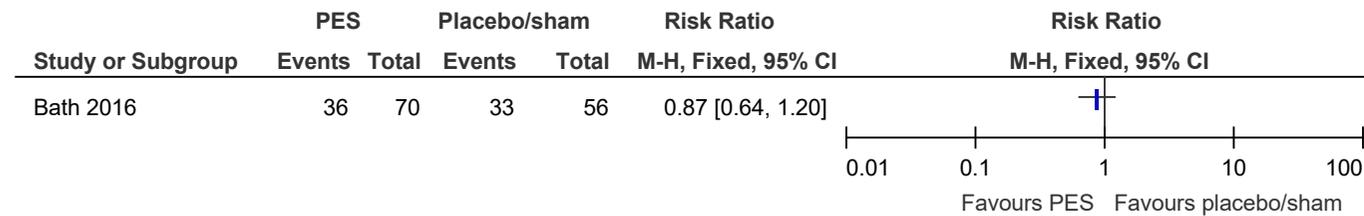


Figure 65: Dysphagia present/return to normal diet (return to normal diet) at ≥3 months

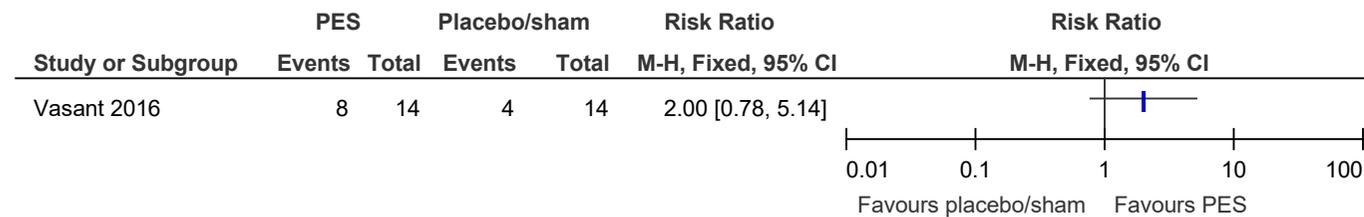


Figure 66: Discharge to residential service at ≥3 months

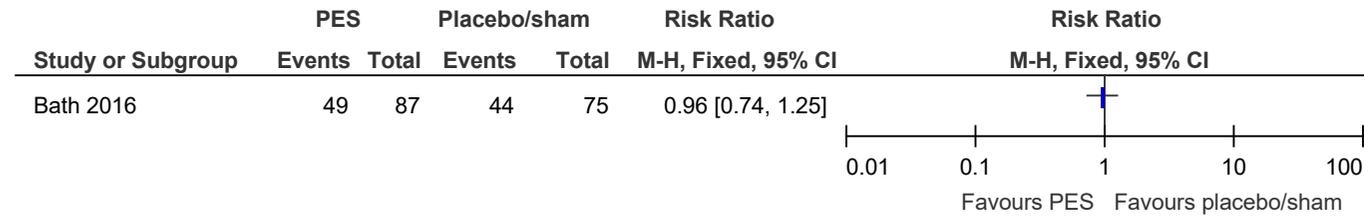


Figure 67: Length of hospital stay (hours, lower values are better, final values) at <3 months

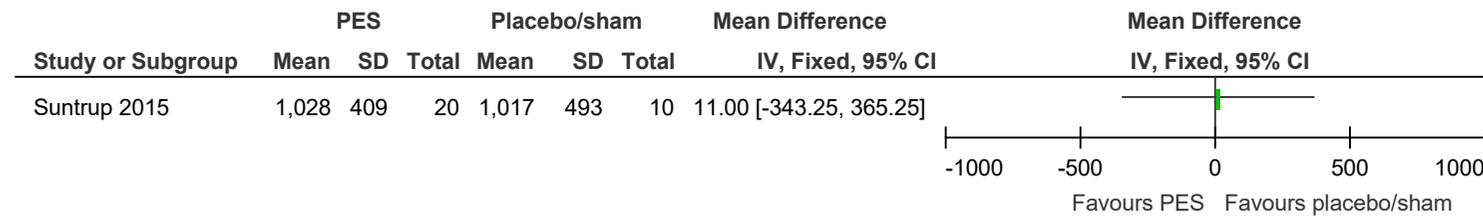


Figure 68: Length of hospital stay (days, lower values are better, final values) at <3 months

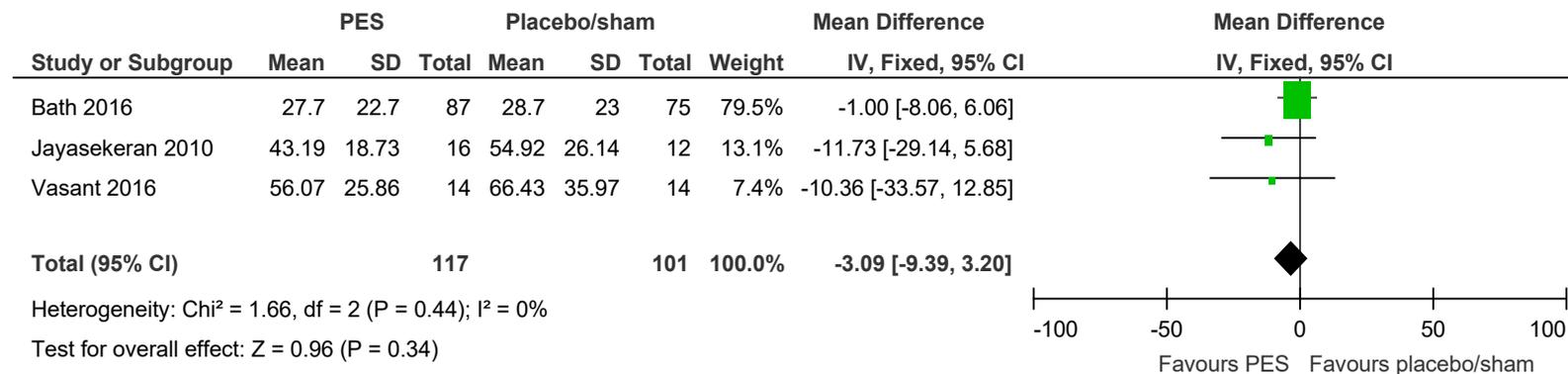


Figure 69: Swallowing ability (Functional Oral Intake Scale, Dysphagia Severity Rating Scale [different scale ranges], higher values are better, final values) at <3 months

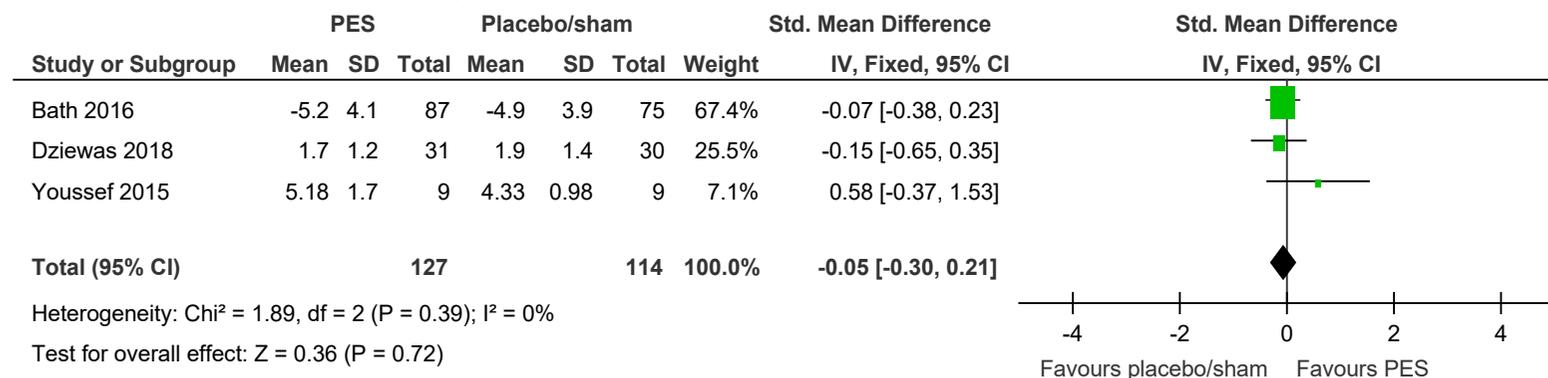


Figure 70: Swallowing ability (Dysphagia Severity Rating Scale, 0-12, lower values are better, final values) at ≥3 months

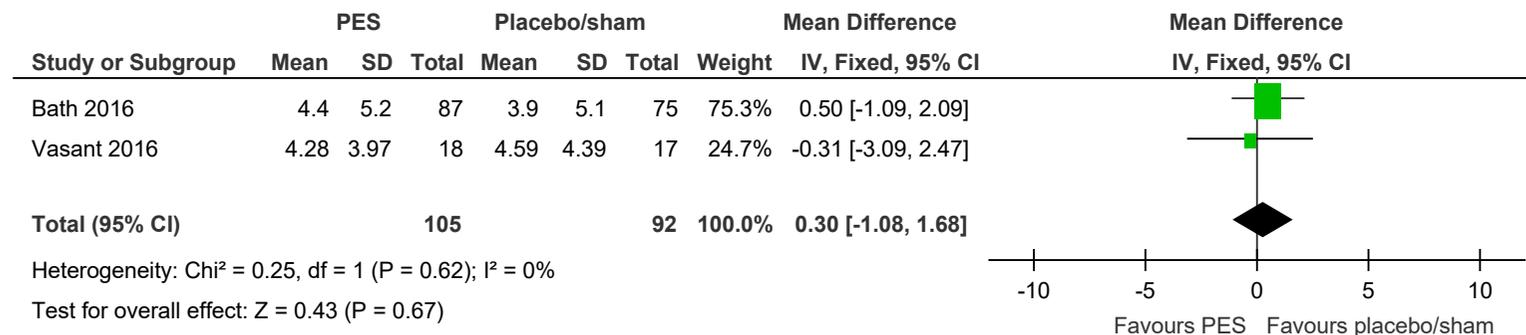


Figure 71: Nutrition (albumin, g/L, higher values are better, final value) at <3 months

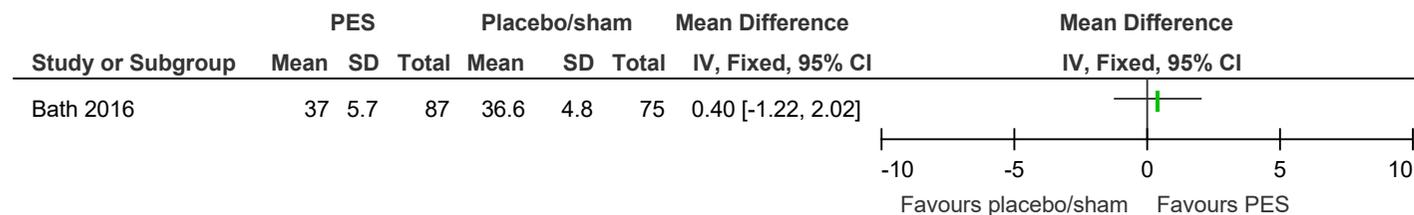
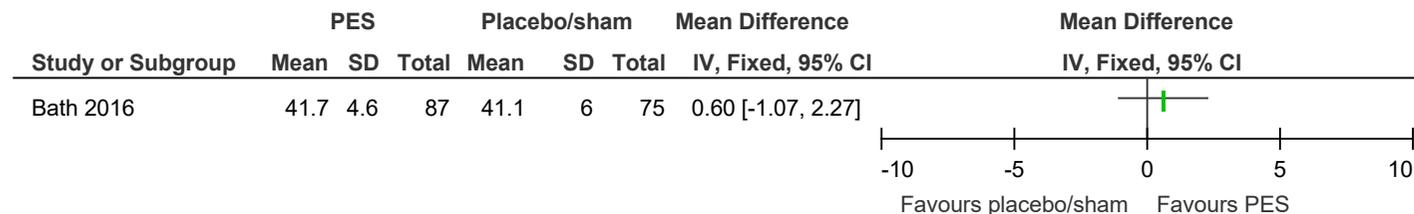


Figure 72: Nutrition (albumin, g/L, higher values are better, final value) at ≥3 months



E.1.12 Physical stimulation compared to placebo/sham therapy

Figure 73: Dysphagia present/return to normal diet (return to normal diet) at <3 months

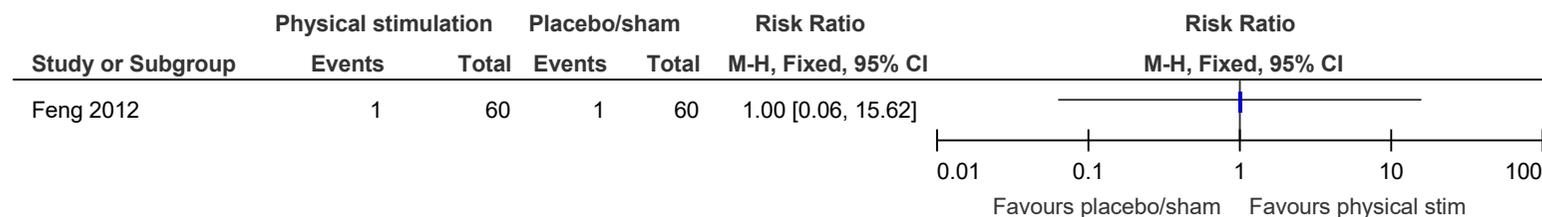
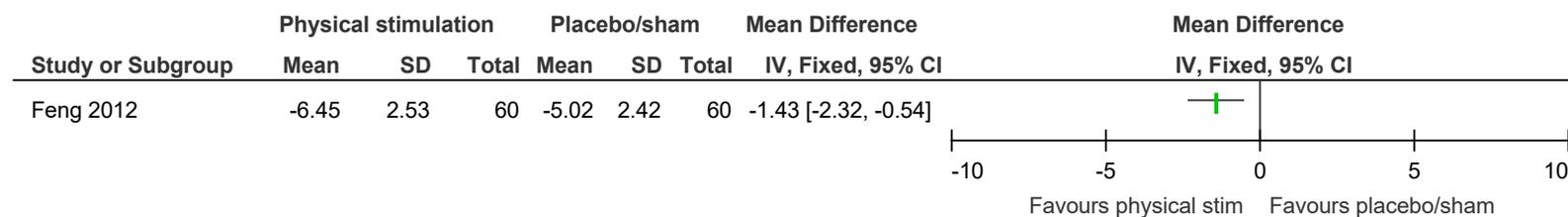


Figure 74: Swallowing ability (standardised swallowing assessment, scale range unclear, lower values are better, change score) at <3 months



E.1.13 Physical stimulation compared to usual care

Figure 75: Occurrence of chest infections at <3 months

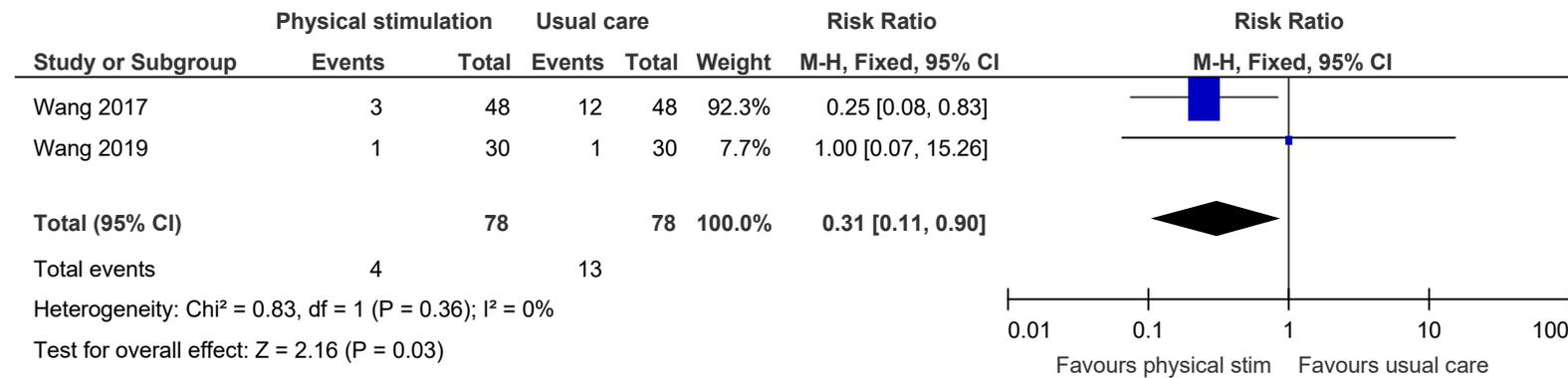


Figure 76: Occurrence of aspiration at <3 months

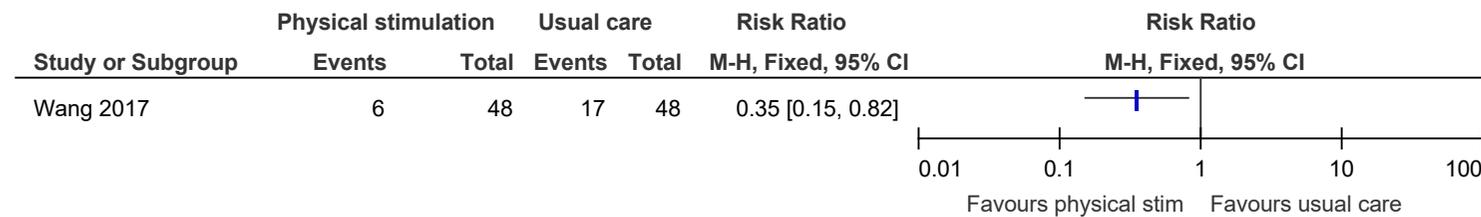


Figure 77: Dysphagia present/return to normal diet (dysphagia present) at <3 months

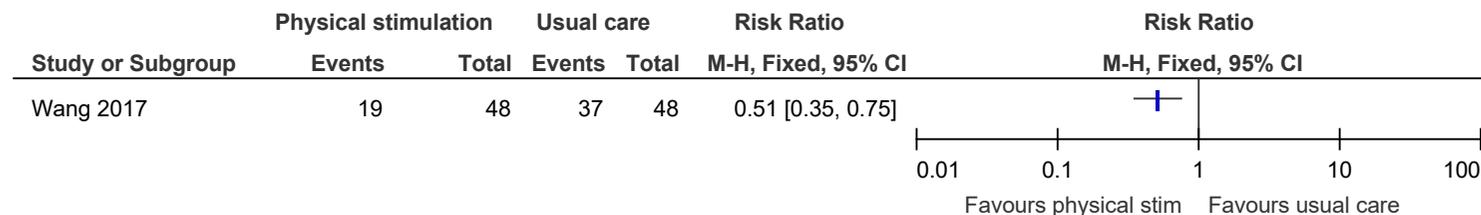


Figure 78: Dysphagia present/return to normal diet (return to normal diet) at <3 months

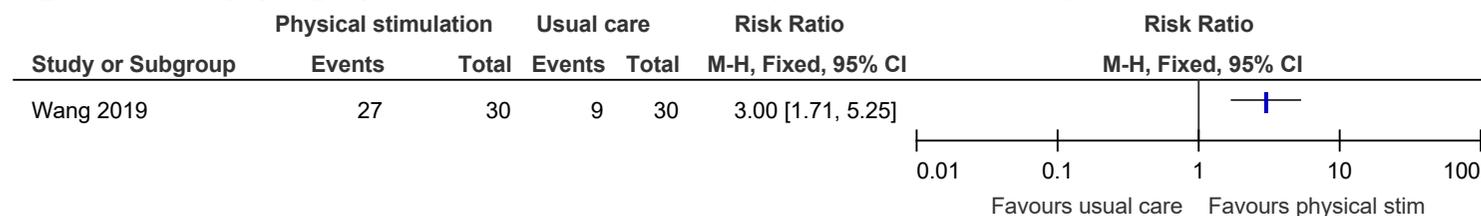


Figure 79: Swallowing ability (Eat-10, 0-40, lower values are better, change score) at <3 months

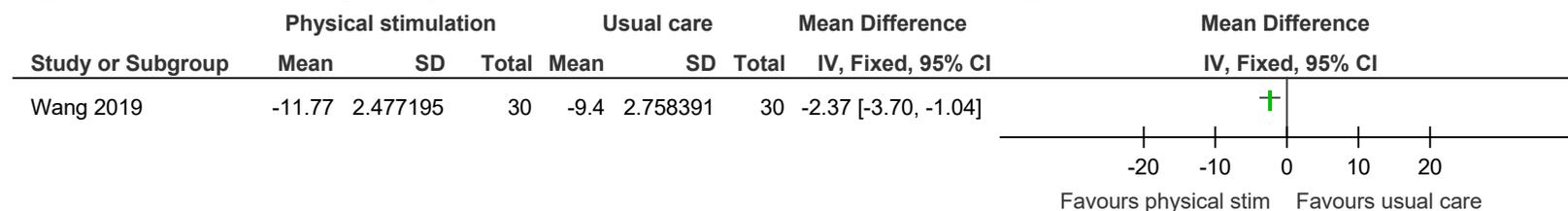
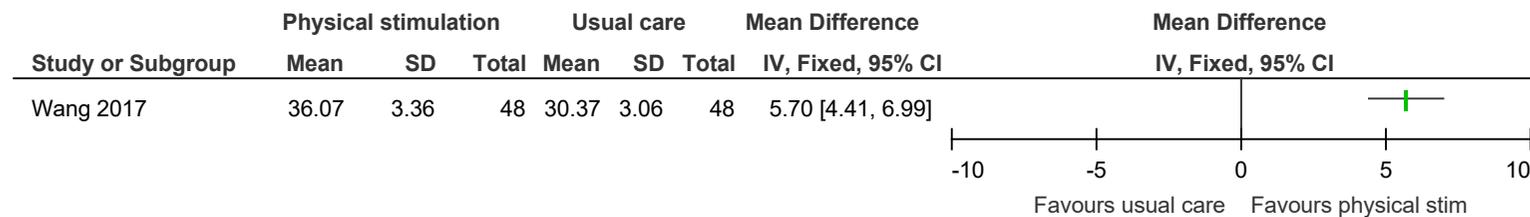


Figure 80: Nutrition (albumin, units unclear, higher values are better, final value) at <3 months



E.1.14 Transcranial direct current stimulation (TDCS) compared to placebo/sham therapy

Figure 81: Mortality at <3 months

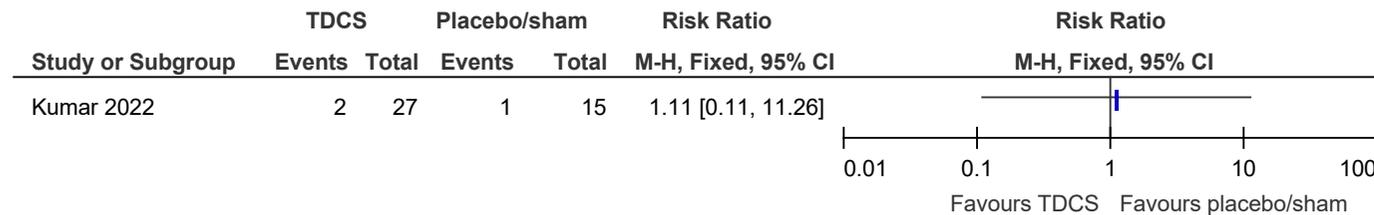


Figure 82: Occurrence of chest infection at <3 months

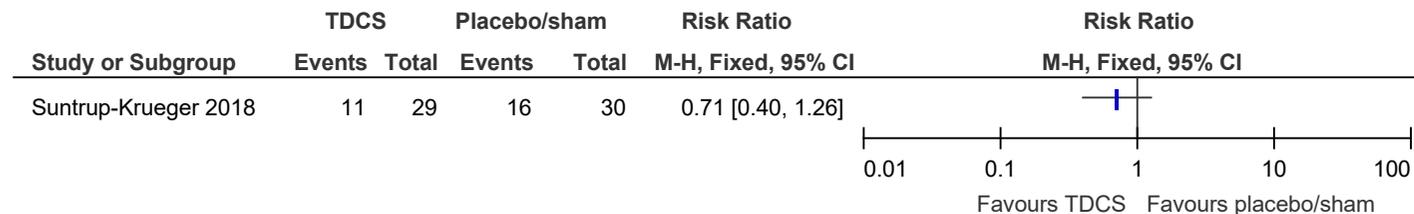


Figure 83: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score) at <3 months

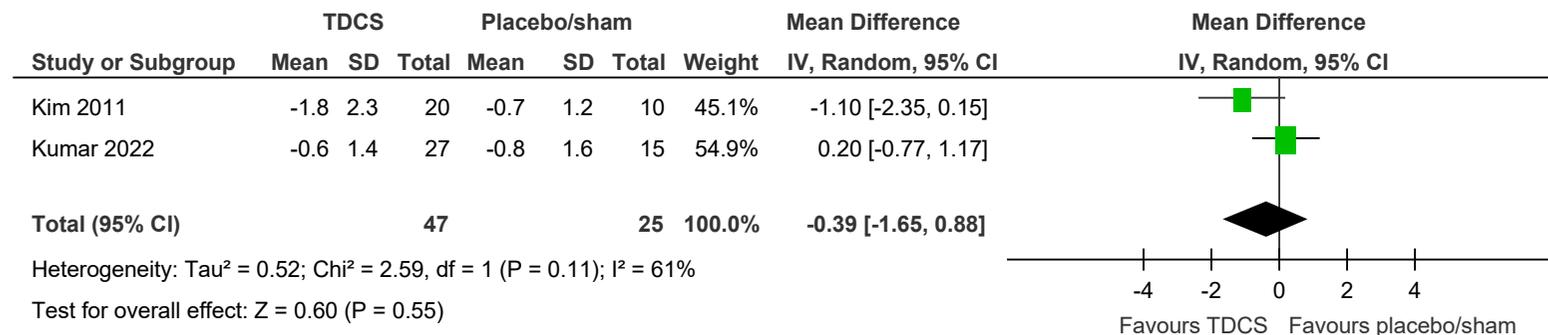


Figure 84: Occurrence of aspiration at <3 months

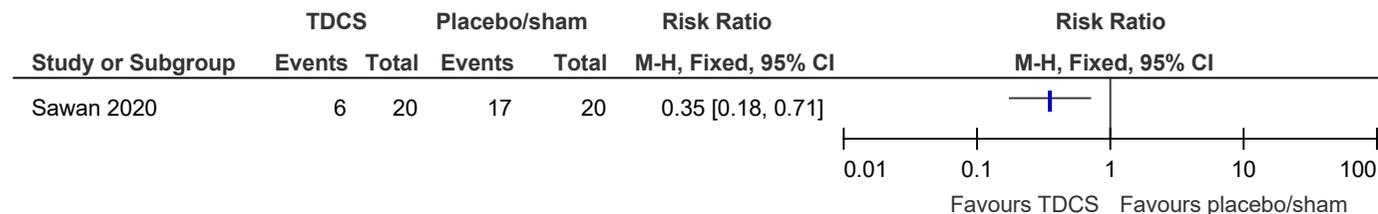


Figure 85: Dysphagia present/return to normal diet (dysphagia present) at <3 months

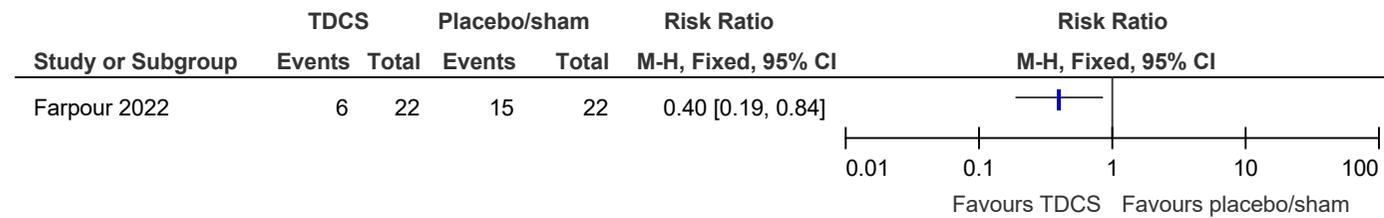


Figure 86: Length of hospital stay (days, lower values are better, final value) at <3 months

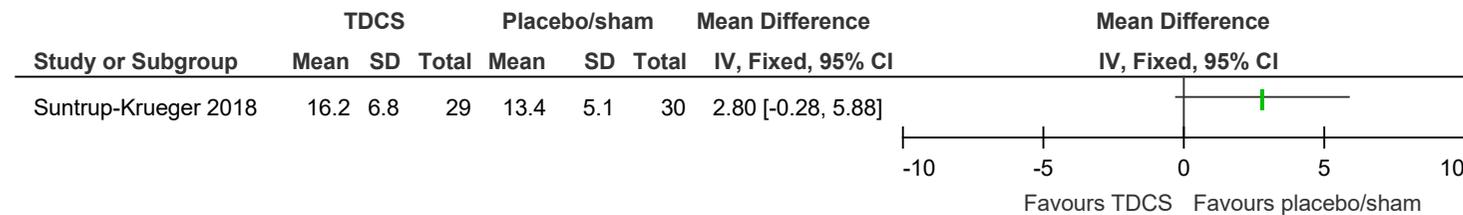


Figure 87: Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months

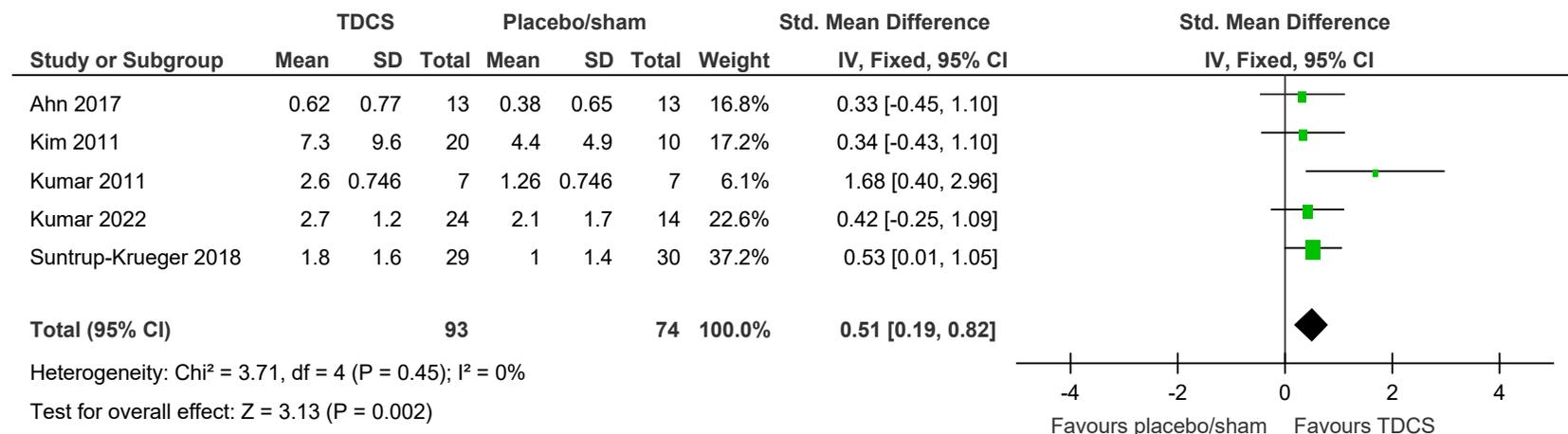


Figure 88: Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, final values) at <3 months

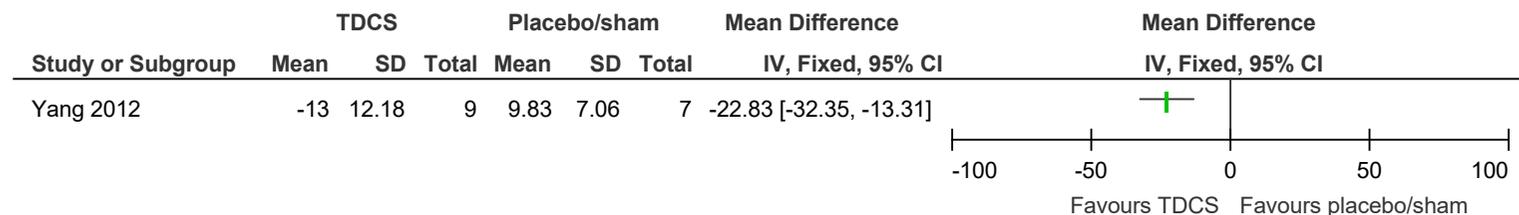
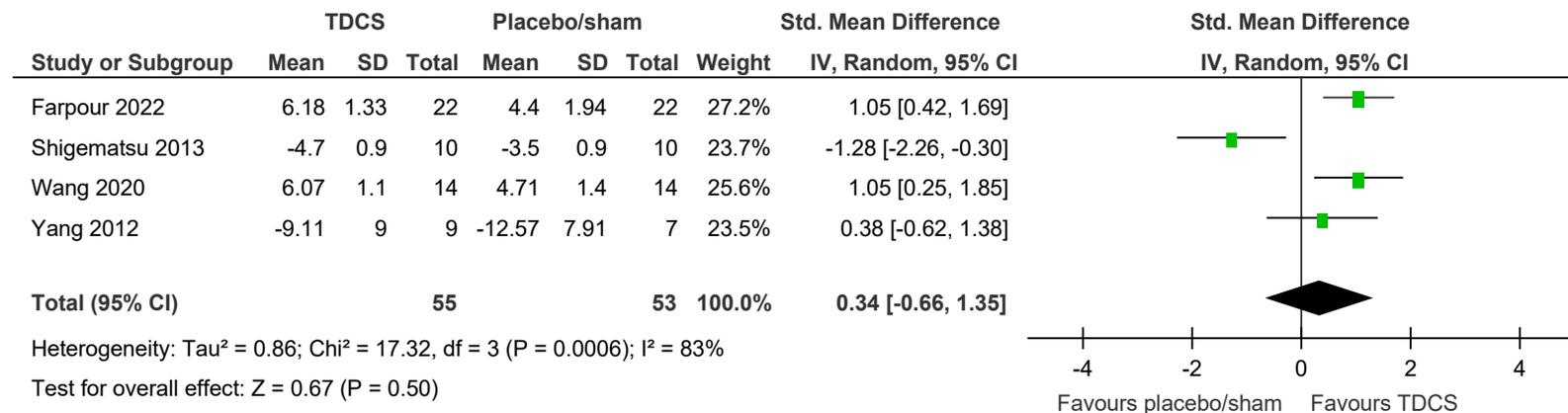


Figure 89: Swallowing ability (Functional dysphagia scale, 0-100, lower values are better, change score) at ≥3 months



E.1.15 Transcranial direct current stimulation (TDCS) compared to usual care

Figure 90: Dysphagia present/return to normal diet (dysphagia present) at <3 months



Figure 91: Swallowing ability (functional oral intake scale, 1-7, higher values are better, final value) at <3 months

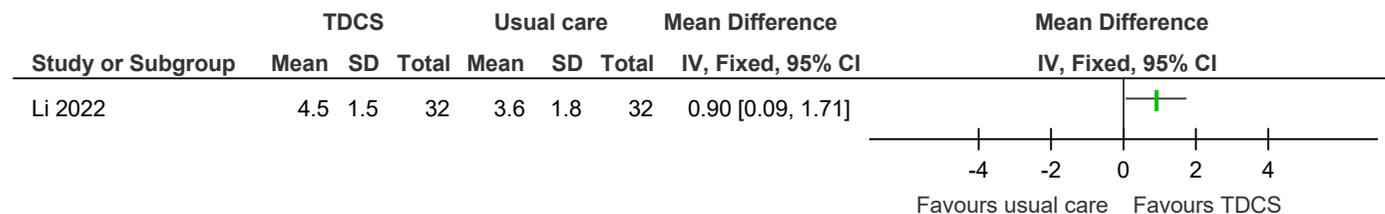


Figure 92: Swallowing ability (functional dysphagia scale, 0-100, lower values are better, final value) at ≥3 months

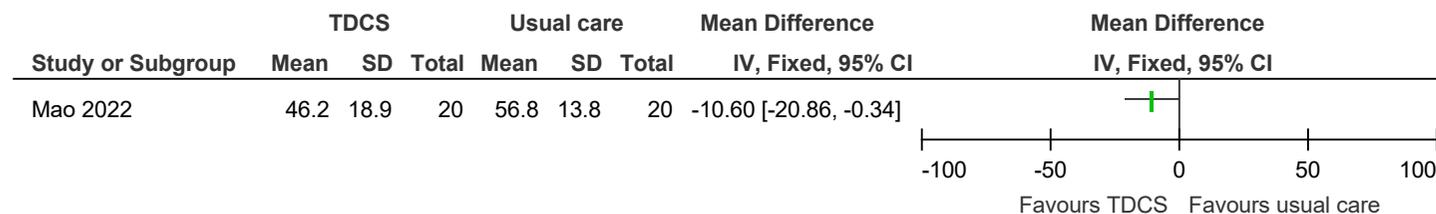
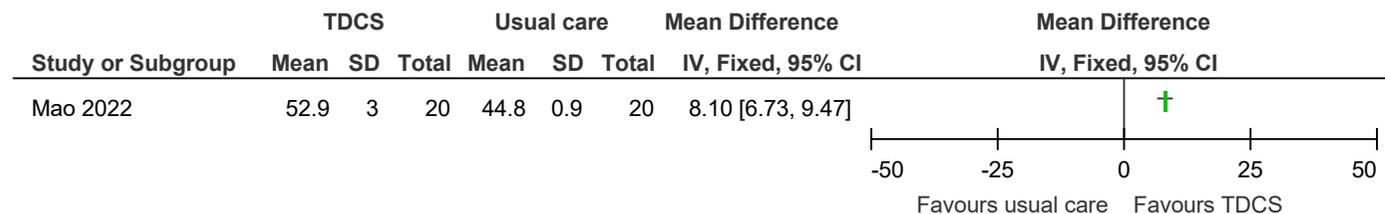


Figure 93: Nutrition (albumin, units unclear, higher values are better, final value) at ≥3 months



E.1.16 Transcranial magnetic stimulation (TMS) compared to placebo/sham therapy

Figure 94: Mortality at <3 months

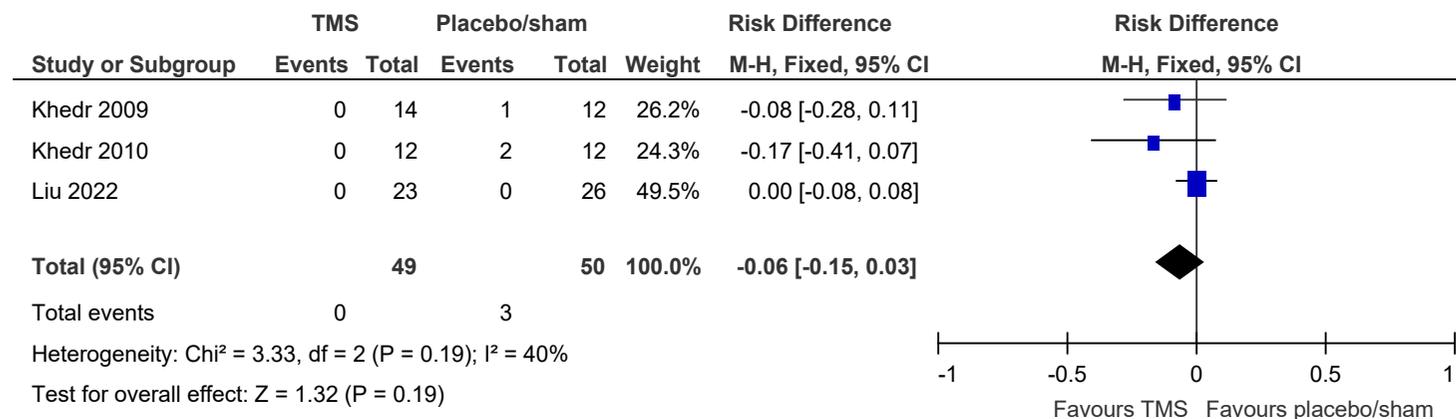


Figure 95: Occurrence of chest infections at <3 months

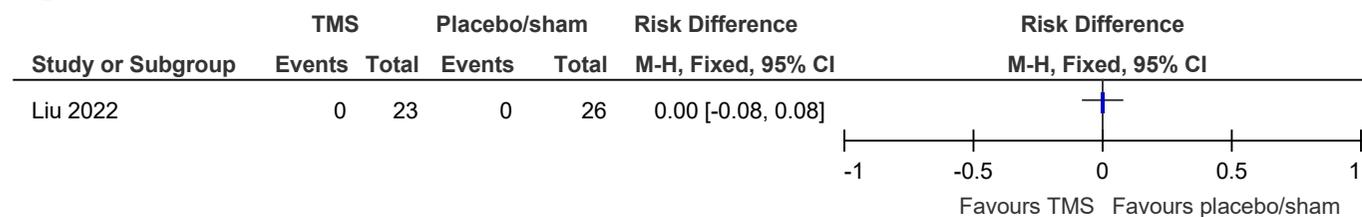


Figure 96: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at <3 months

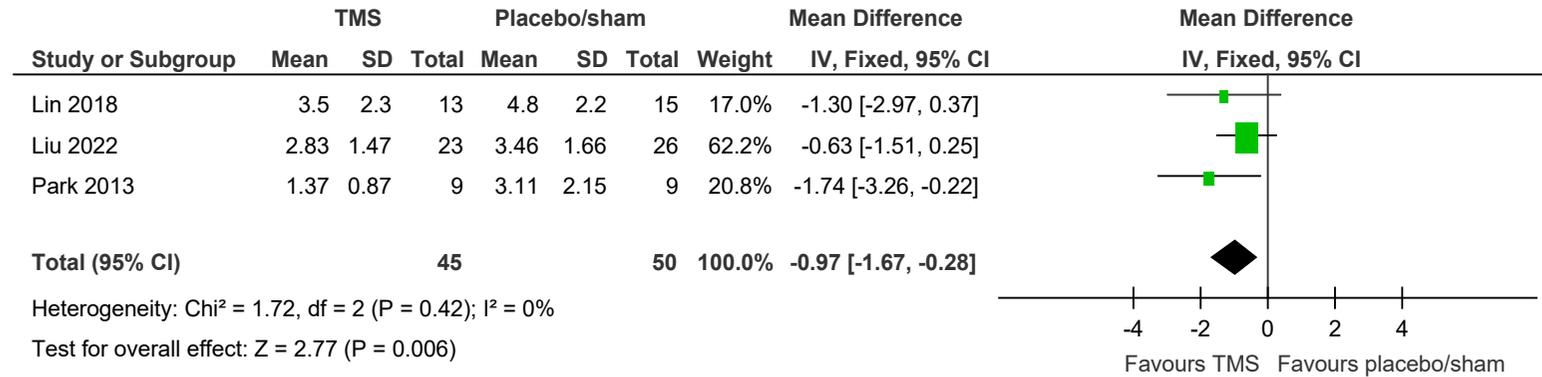


Figure 97: Dysphagia present/return to normal diet (removal of feeding tube) at <3 months

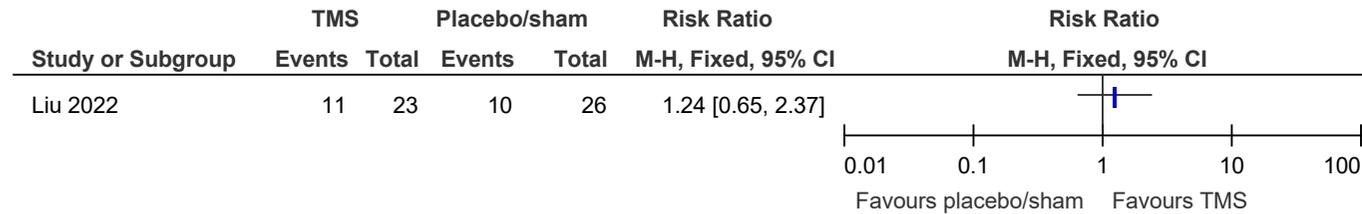


Figure 98: Swallowing ability (dysphagia outcome and severity scale, dysphagia grade, videofluoroscopic dysphagia scale, swallowing activity and participation profile scores [different scale ranges], lower values are better, final values) at <3 months

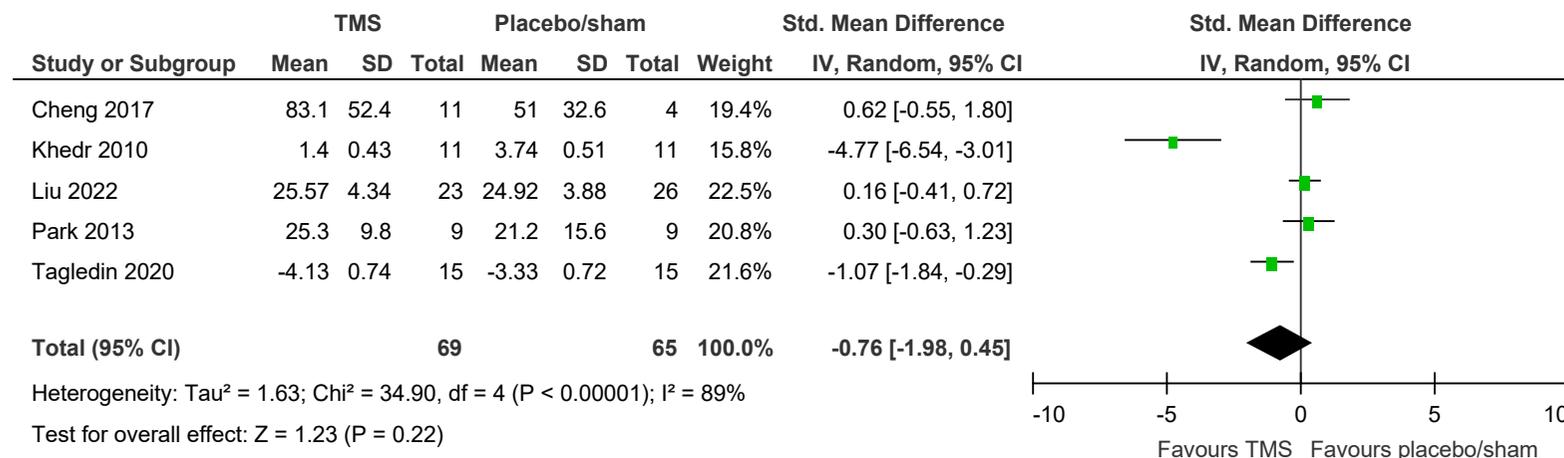
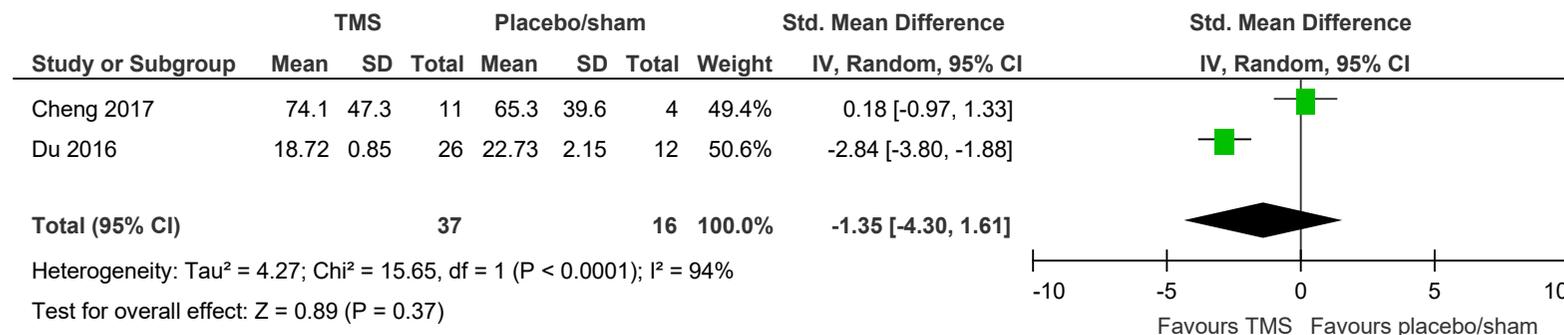


Figure 99: Swallowing ability (standardised swallowing assessment, swallowing activity and participation scale [different scale ranges], lower values are better, final values) at <3 months



E.1.17 Transcranial magnetic stimulation (TMS) compared to usual care

Figure 100: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months

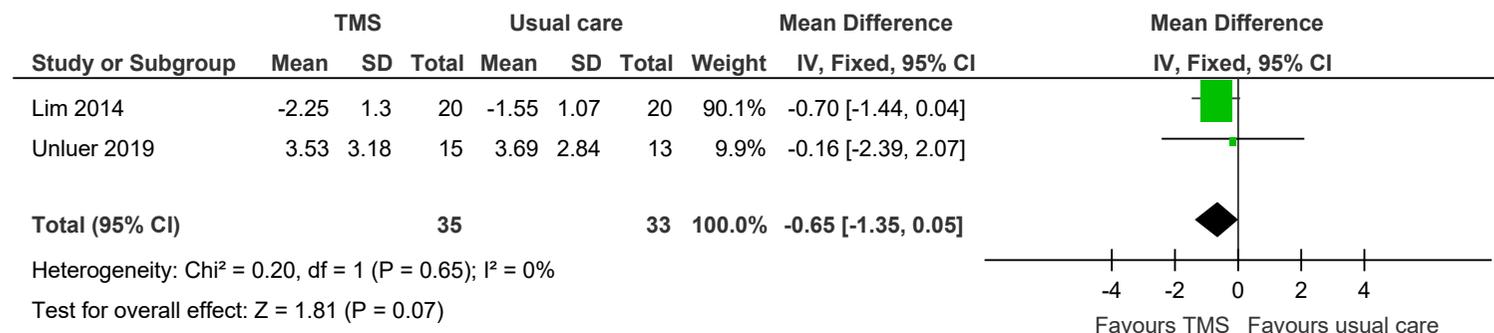


Figure 101: Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months

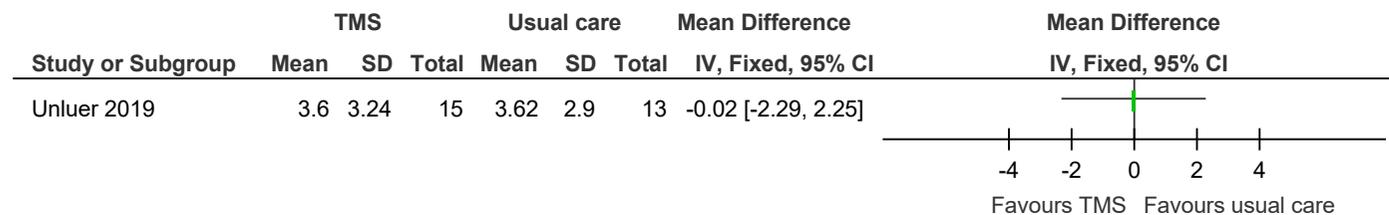


Figure 102: Dysphagia present/return to normal diet (dysphagia present) at <3 months

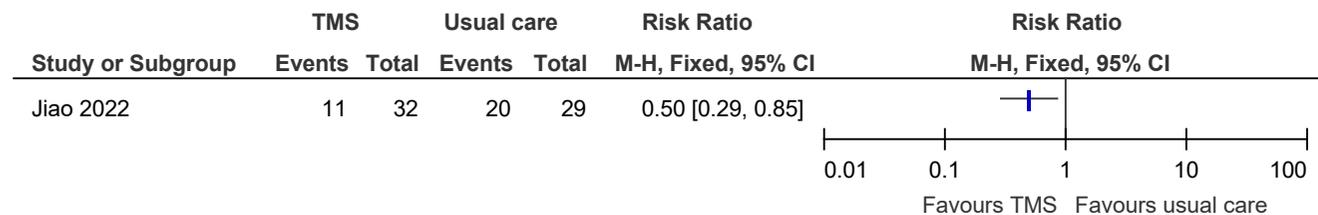


Figure 103: Dysphagia present/return to normal diet (return to normal diet) at <3 months

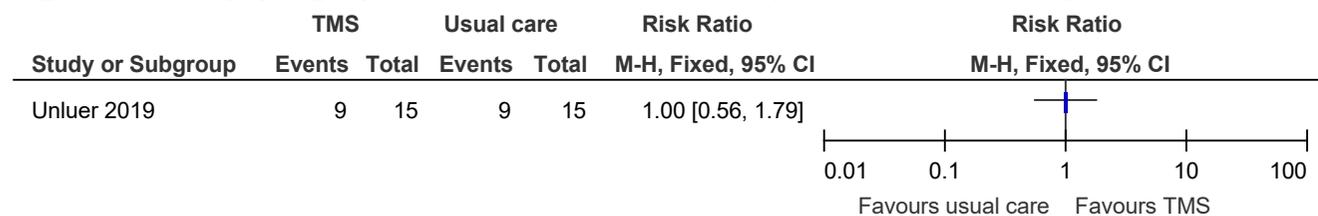


Figure 104: Dysphagia present/return to normal diet (return to normal diet) at ≥3 months

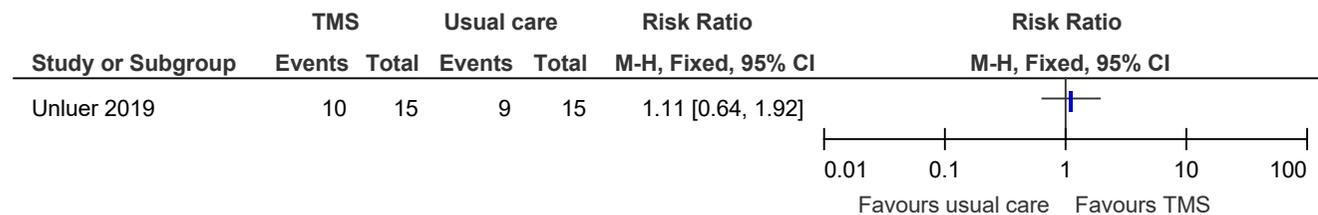


Figure 105: Swallowing ability (water swallow test, swallowing ability and function evaluation [different scale ranges], higher values are better, final values) at <3 months

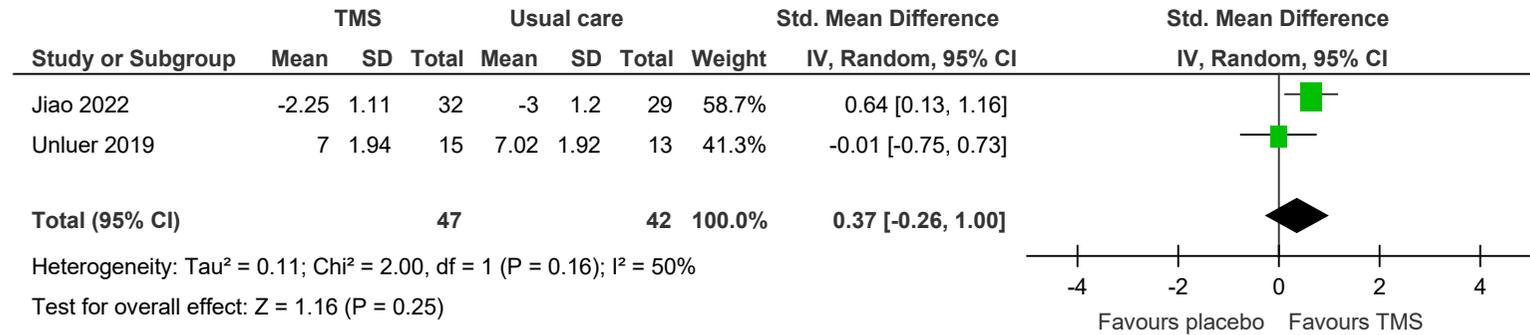


Figure 106: Swallowing ability (functional dysphagia scale, 0-100, lower values are better, change score) at <3 months

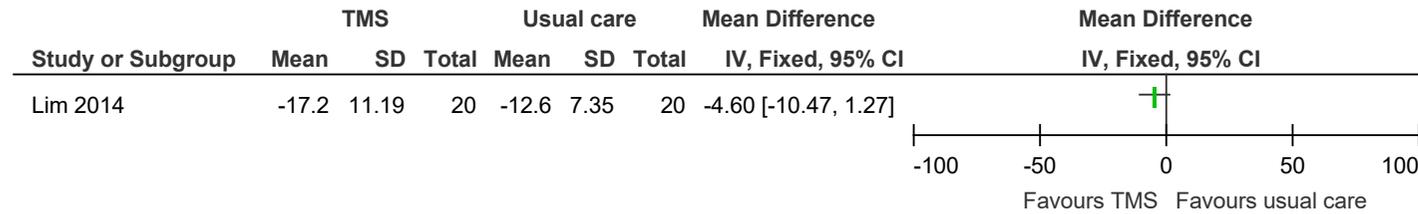
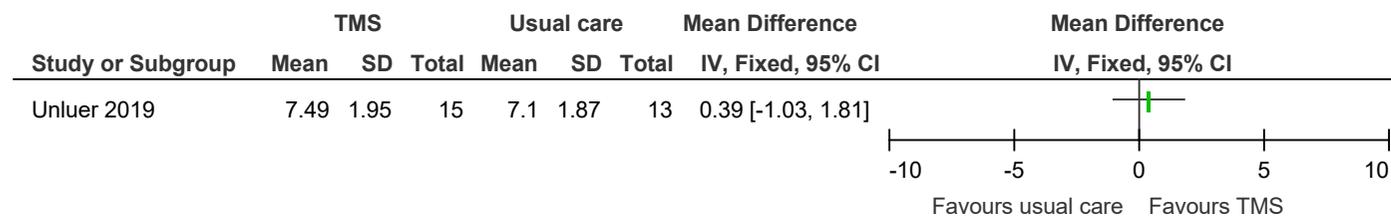


Figure 107: Swallowing ability (swallowing ability and functional evaluation, scale range unclear, higher values are better, final value) at >3 months



E.2 Interventions for oesophageal dysphagia

E.2.1 Drug interventions (domperidone) compared to placebo/sham therapy

Figure 108: Mortality at <3 months

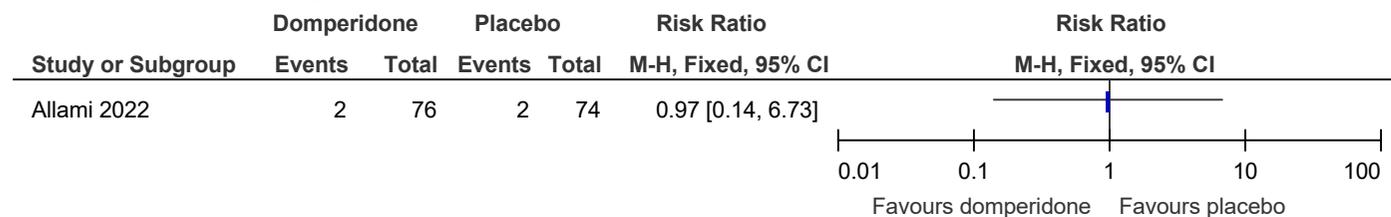


Figure 109: Occurrence of aspiration at <3 months

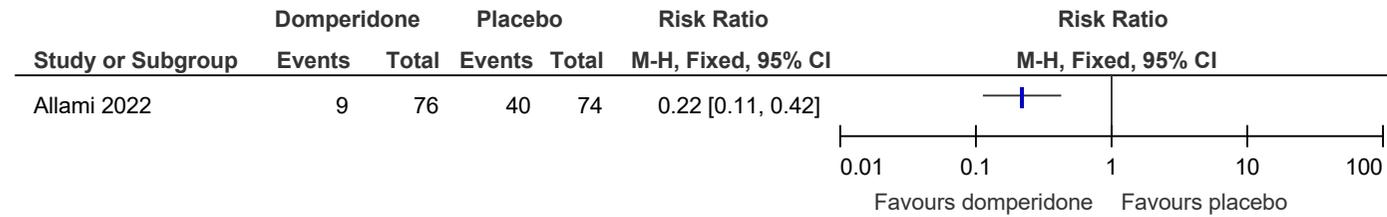


Figure 110: Dysphagia present/Return to normal diet (presence of nasogastric tube) at <3 months



E.3 Adaptations to support people with dysphagia

E.3.1 Diet modification compared to usual care

Figure 111: Mortality at <3 months

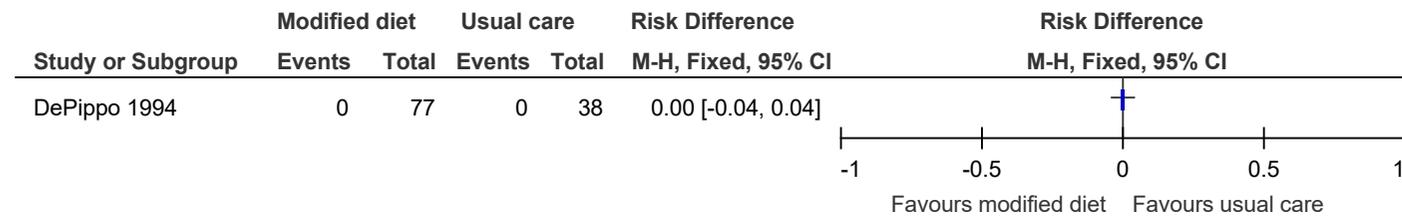


Figure 112: Occurrence of chest infections at <3 months

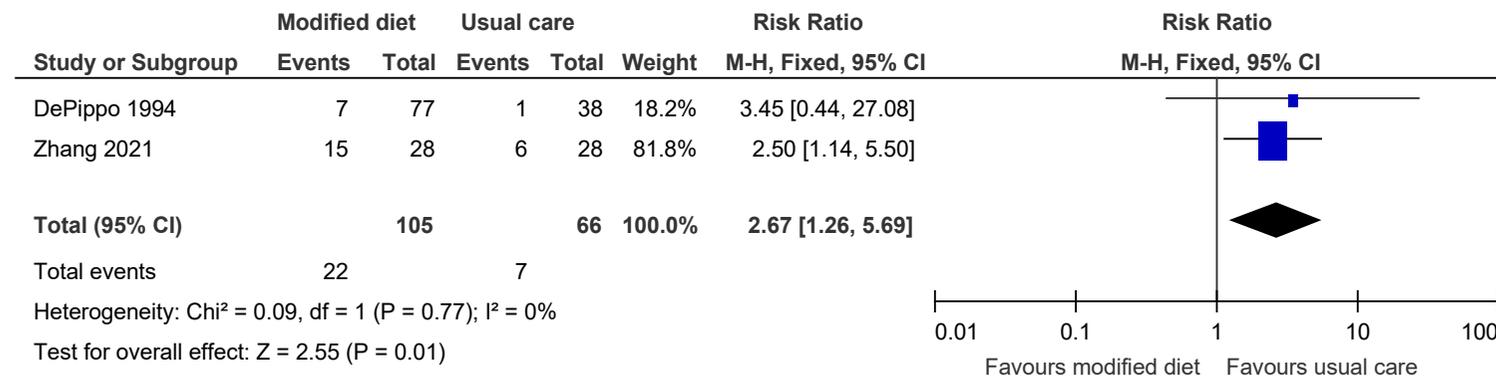


Figure 113: Nutrition (calorie-nitrogen deficit) at <3 months

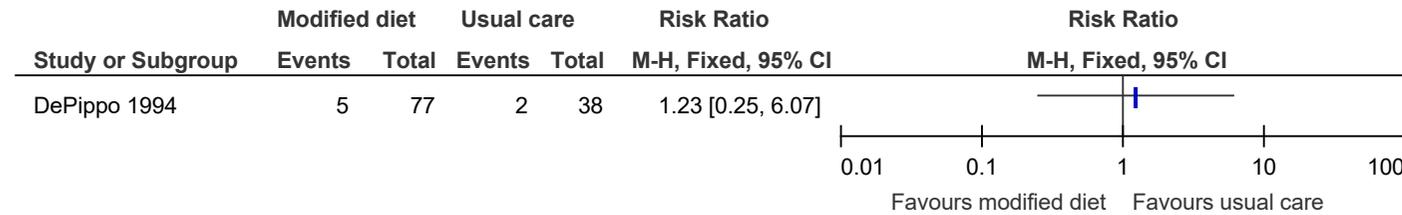
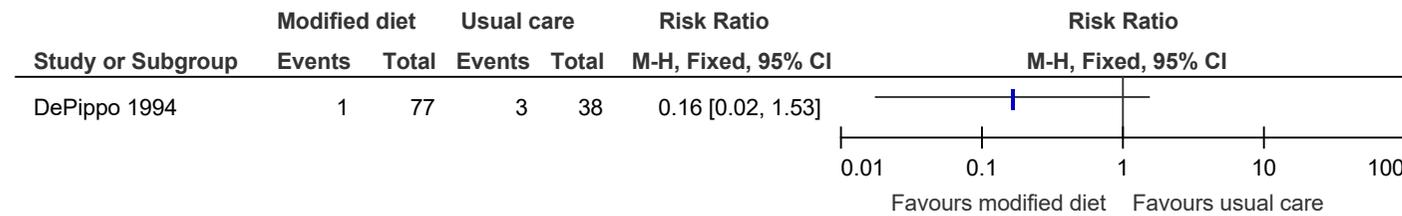


Figure 114: Hydration (dehydration) at <3 months



E.3.2 Free water protocol compared to usual care

Figure 115: Occurrence of chest infection at <3 months

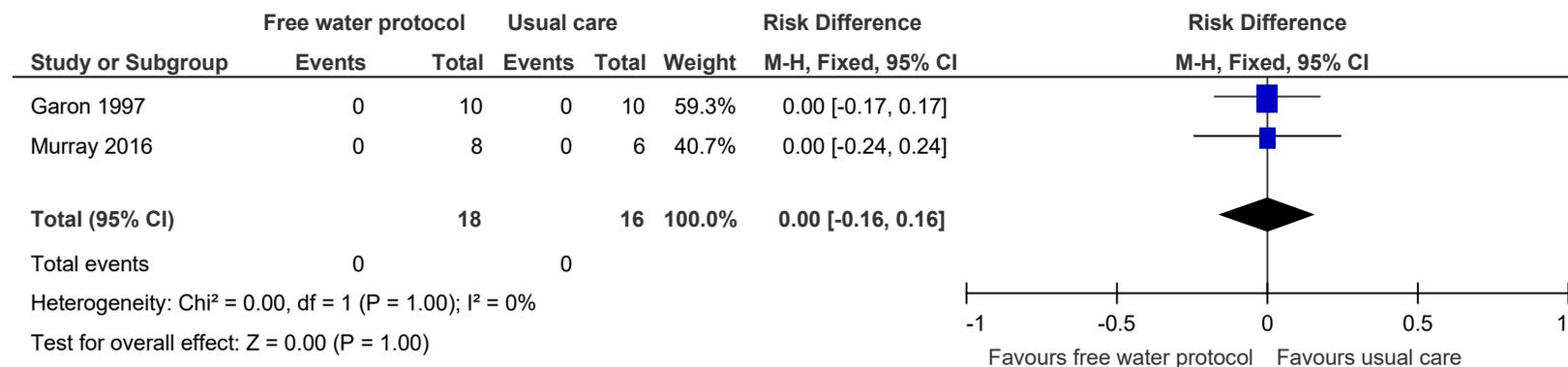


Figure 116: Hydration (dehydration) at <3 months

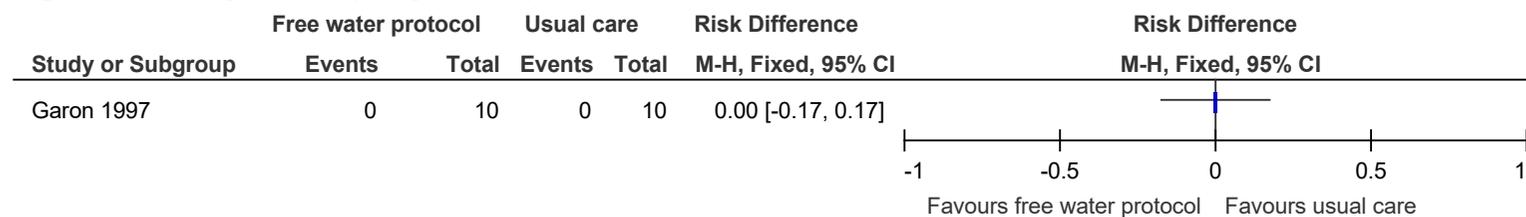
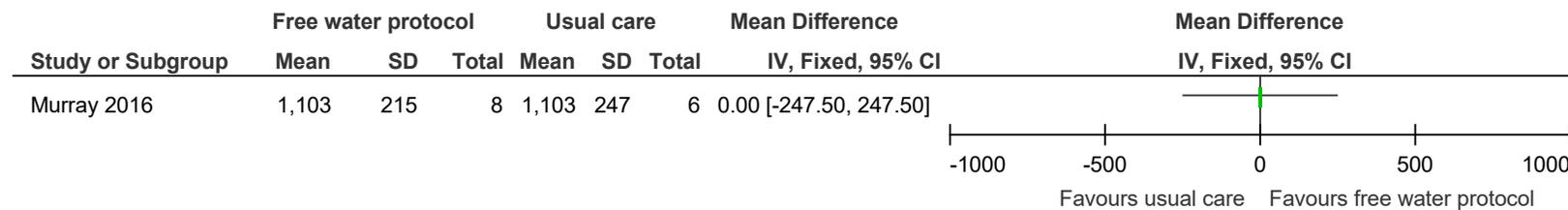


Figure 117: Hydration (fluid intake, mL, higher values are better, final value) at <3 months



E.3.3 Combinations (modified diet, positioning, modifying bolus volume/mode of delivery) compared to usual care

Figure 118: Mortality at ≥3 months

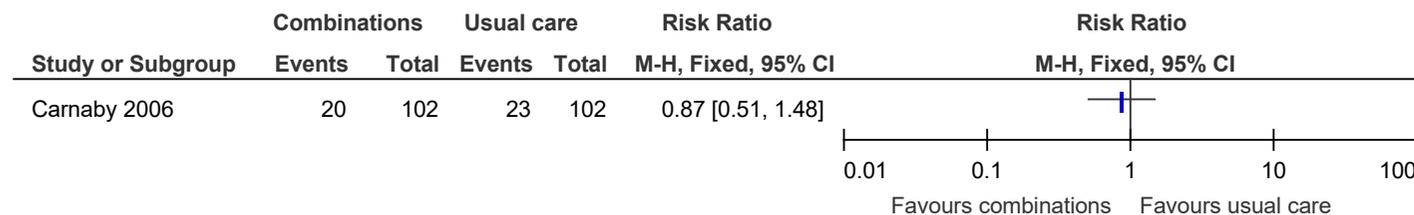


Figure 119: Occurrence of chest infections at ≥3 months

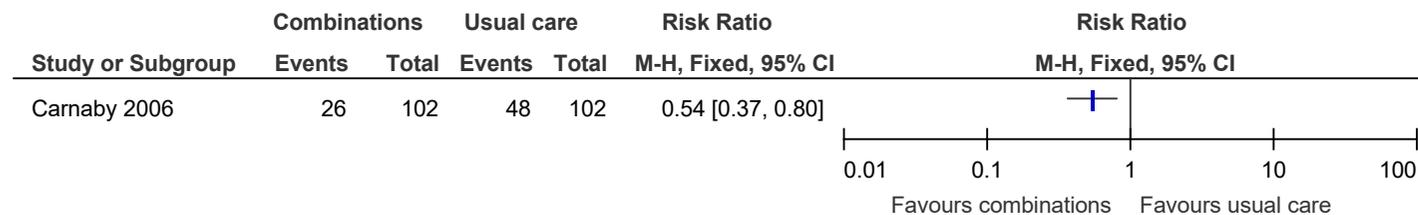


Figure 120: Dysphagia present/return to normal diet (return to normal diet) at ≥3 months

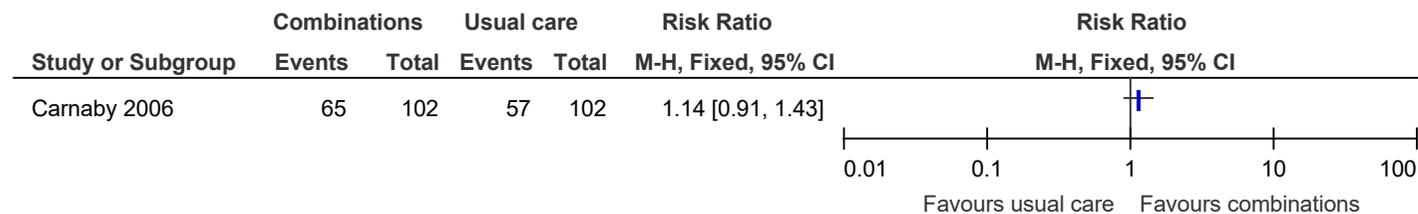


Figure 121: Discharge to residential service at ≥3 months

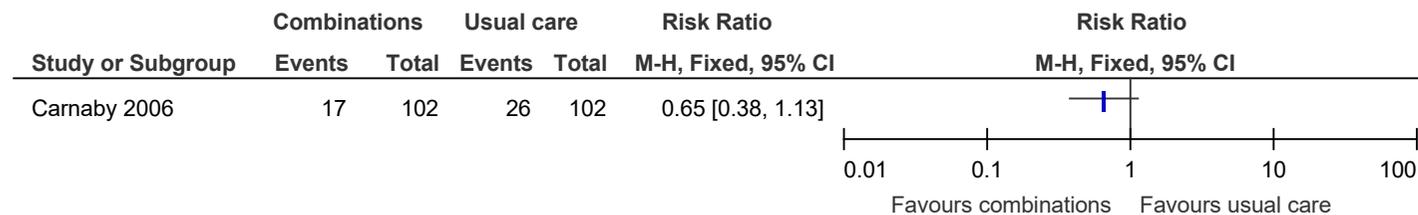
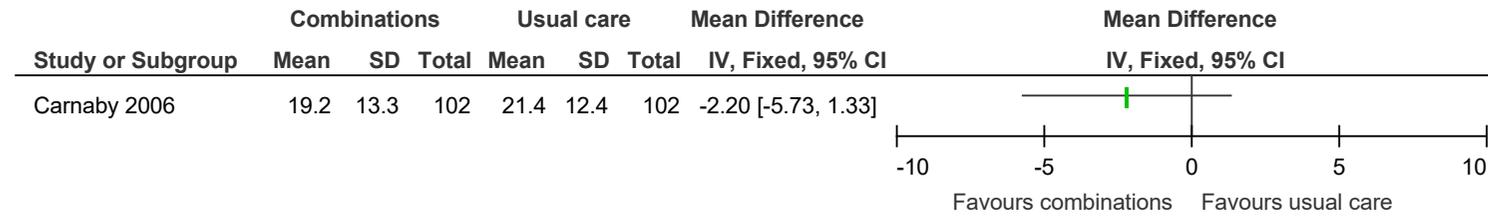


Figure 122: Length of hospital stay at ≥3 months



1 Appendix F GRADE tables

2 F.1 Interventions for oropharyngeal dysphagia

3 **Table 38: Clinical evidence profile: acupuncture/electroacupuncture compared to placebo/sham therapy**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	acupuncture/electroacupuncture	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 6 weeks)

1	randomised trials	serious ^a	not serious	not serious	not serious	none	22/60 (36.7%)	45/60 (75.0%)	RR 0.49 (0.34 to 0.70)	383 fewer per 1,000 (from 495 fewer to 225 fewer)		CRITICAL
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4 CI: confidence interval; RR: risk ratio

5 Explanations

6 a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)

7

8 **Table 39: Clinical evidence profile: acupuncture/electroacupuncture compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	acupuncture/electroacupuncture	usual care	Relative (95% CI)	Absolute (95% CI)		

Occurrence of chest infections at <3 months (follow-up: 30 days)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	acupuncture/electroacupuncture	usual care	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious ^a	not serious	not serious	very serious ^b	none	8/30 (26.7%)	10/30 (33.3%)	RR 0.80 (0.37 to 1.74)	67 fewer per 1,000 (from 210 fewer to 247 more)	⊕○○○ Very low	CRITICAL

Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: mean 4 weeks)

5	randomised trials	very serious ^c	not serious	not serious	serious ^b	none	103/184 (56.0%)	131/173 (75.7%)	RR 0.74 (0.65 to 0.85)	197 fewer per 1,000 (from 265 fewer to 114 fewer)	⊕○○○ Very low	CRITICAL
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Swallowing ability (videofluoroscopic swallowing study, 0-8, higher values are better, change score) at <3 months (follow-up: 30 days)

1	randomised trials	very serious ^d	not serious	not serious	serious ^b	none	30	30	-	MD 1.87 higher (0.53 higher to 3.21 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Standardised swallowing assessment, dysphagia outcome severity scale [different scale ranges], lower values are better, final values) at <3 months (follow-up: mean 6 weeks)

2	randomised trials	not serious	not serious ^a	not serious	not serious	none	110	111	-	SMD 1.22 SD lower (1.52 lower to 0.93 lower)	⊕⊕⊕⊕ High	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

- 3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)
- 4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 5 6 c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)
- 7 d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias in measurement of the outcome)

1 e. While statistical heterogeneity is present, all effect sizes are within the same MID and so this has been deemed to not be important heterogeneity

2

3 **Table 40: Clinical evidence profile: behavioural interventions compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	behavioural interventions	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score) at <3 months (follow-up: 4 weeks)												
1	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	13	13	-	MD 1 lower (1.76 lower to 0.24 lower)	⊕○○○ Very low	CRITICAL
Swallowing ability (videofluoroscopic dysphagia scale, 0-100, lower values are better, change score) at <3 months (follow-up: 4 weeks)												
1	randomised trials	very serious ^a	not serious	not serious	not serious	none	13	13	-	MD 10.42 lower (15.9 lower to 4.94 lower)	⊕⊕○○ Low	CRITICAL
Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months (follow-up: 4 weeks)												
1	randomised trials	serious ^c	not serious	not serious	serious ^b	none	14	13	-	MD 1.3 higher (0.19 higher to 2.41 higher)	⊕⊕○○ Low	CRITICAL

4 CI: confidence interval; MD: mean difference

5 **Explanations**

6 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)

7 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

8 c. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)

9

1 **Table 41: Clinical evidence profile: behavioural interventions compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	behavioural interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
Occurrence of chest infections at <3 months (follow-up: mean 5 weeks)												
6	randomised trials	very serious ^a	serious ^b	not serious	not serious ^c	none	10/144 (6.9%)	27/129 (20.9%)	RD -0.11 (-0.20 to -0.01)	110 fewer per 1,000 (from 200 fewer to 10 fewer) ^c	⊕○○○ Very low	CRITICAL
Occurrence of chest infections at ≥3 months (follow-up: 3 months)												
1	randomised trials	serious ^d	not serious	not serious	very serious ^e	none	2/16 (12.5%)	4/10 (40.0%)	RR 0.31 (0.07 to 1.40)	276 fewer per 1,000 (from 372 fewer to 160 more)	⊕○○○ Very low	CRITICAL
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final values) at <3 months (follow-up: mean 5 weeks)												
8	randomised trials	very serious ^f	not serious	not serious	serious ^g	none	106	105	-	MD 0.86 lower (1.15 lower to 0.58 lower)	⊕○○○ Very low	CRITICAL
Occurrence of aspiration at ≥3 months (follow-up: 3 months)												
1	randomised trials	very serious ^g	not serious	serious ^h	very serious ^e	none	4/16 (25.0%)	5/10 (50.0%)	RR 0.50 (0.17 to 1.43)	250 fewer per 1,000 (from 415 fewer to 215 more)	⊕○○○ Very low	CRITICAL
Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: mean 3 weeks)												
4	randomised trials	very serious ^a	serious ⁱ	not serious	serious ^e	none	72/141 (51.1%)	98/132 (74.2%)	RR 0.75 (0.57 to 0.97)	186 fewer per 1,000 (from 319 fewer to 22 fewer)	⊕○○○ Very low	CRITICAL

Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: mean 6 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	behavioural interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
3	randomised trials	very serious ^a	very serious ⁱ	not serious	very serious ^a	none	23/36 (63.9%)	10/36 (27.8%)	RR 2.14 (0.54 to 8.48)	317 more per 1,000 (from 128 fewer to 1,000 more)	⊕○○○ Very low	CRITICAL

Length of hospital stay (days, lower values are better, final values) at <3 months (follow-up: mean 3 weeks)

2	randomised trials	very serious ^a	serious ⁱ	not serious	very serious ^a	none	62	64	-	MD 1.91 lower (7.51 lower to 3.7 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale, Mann Assessment of Swallowing, ASHA-NOMS [different scale ranges], higher values are better, change scores) at <3 months (follow-up: mean 6 weeks)

6	randomised trials	very serious ⁱ	not serious	not serious	serious ^a	none	67	67	-	SMD 0.79 higher (0.43 higher to 1.14 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Videofluoroscopic Dysphagia Rating Scale, Water swallowing test [different scale ranges], higher values are better, final values) at <3 months (follow-up: mean 4 weeks)

4	randomised trials	very serious ⁱ	not serious	not serious	serious ^a	none	93	92	-	SMD 0.72 higher (0.42 higher to 1.02 higher)	⊕○○○ Very low	CRITICAL
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Nutrition (units unclear, final values) at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^a	not serious	not serious	very serious ^a	none	22	24	-	MD 0.2 higher (5.63 lower to 6.03 higher)	⊕○○○ Very low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias
4 in selection of the reported result)

- 1 b. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)
- 2 c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study
- 3 d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)
- 4 e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 5 f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)
- 6 g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)
- 7 h. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)
- 8 i. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
- 9

10 **Table 42: Clinical evidence profile: drug interventions (metoclopramide) compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (metoclopramide)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
Mortality at <3 months (follow-up: 3 weeks)												
1	randomised trials	not serious	not serious	not serious	very serious ^a	none	8/30 (26.7%)	12/30 (40.0%)	RR 0.67 (0.32 to 1.39)	132 fewer per 1,000 (from 272 fewer to 156 more)	⊕⊕○○ Low	CRITICAL
Occurrence of chest infections at <3 months (follow-up: 3 weeks)												
1	randomised trials	not serious	not serious	not serious	not serious	none	8/30 (26.7%)	26/30 (86.7%)	RR 0.31 (0.17 to 0.57)	598 fewer per 1,000 (from 719 fewer to 373 fewer)	⊕⊕⊕⊕ High	CRITICAL
Occurrence of aspiration (number of episodes of aspiration, lower values are better, final value) at <3 months (follow-up: 3 weeks)												
1	randomised trials	not serious	not serious	not serious	serious ^a	none	30	30	-	MD 0.7 lower (1.03 lower to 0.37 lower)	⊕⊕⊕○ Moderate	CRITICAL

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (metoclopramide)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 3 weeks)

1	randomised trials	not serious	not serious	not serious	serious ^a	none	23/30 (76.7%)	17/30 (56.7%)	RR 1.35 (0.93 to 1.96)	198 more per 1,000 (from 40 fewer to 544 more)	 Moderate	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio

2 Explanations

3 a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

4

5 **Table 43: Clinical evidence profile: drug interventions (domperidone) compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (domperidone)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months (follow-up: 11 days)

1	randomised trials	not serious	not serious	serious ^a	very serious ^b	none	2/76 (2.6%)	2/74 (2.7%)	RR 0.97 (0.14 to 6.73)	1 fewer per 1,000 (from 23 fewer to 155 more)	 Very low	CRITICAL
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Occurrence of aspiration at <3 months (follow-up: 11 days)

1	randomised trials	not serious	not serious	very serious ^a	not serious	none	9/76 (11.8%)	40/74 (54.1%)	RR 0.22 (0.11 to 0.42)	422 fewer per 1,000 (from 481 fewer to 314 fewer)	 Low	CRITICAL
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Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (domperidone)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 11 days)

1	randomised trials	not serious	not serious	serious ^a	very serious ^b	none	6/76 (7.9%)	5/74 (6.8%)	RR 1.17 (0.37 to 3.66)	11 more per 1,000 (from 43 fewer to 180 more)	 Very low	CRITICAL
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1 CI: confidence interval; RR: risk ratio

2 Explanations

3 a. Downgraded by 1 increment because of population indirectness (as the proportion of people with oropharyngeal dysphagia was unclear)

4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

5 c. Downgraded by 2 increments because of population and outcome indirectness (as the proportion of people with oropharyngeal dysphagia was unclear and as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)

7

8 **Table 44: Clinical evidence profile: drug interventions (lisinopril) compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (lisinopril)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at ≥3 months (follow-up: 26 weeks)

1	randomised trials	serious ^a	not serious	not serious	serious ^b	none	19/33 (57.6%)	10/38 (26.3%)	RR 2.19 (1.19 to 4.02)	313 more per 1,000 (from 50 more to 795 more)	 Low	CRITICAL
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Occurrence of chest infections at ≥3 months (follow-up: 26 weeks)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (lisinopril)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious ^a	not serious	not serious	serious ^b	none	19/33 (57.6%)	18/38 (47.4%)	RR 1.22 (0.78 to 1.90)	104 more per 1,000 (from 104 fewer to 426 more)	 Low	CRITICAL

Swallowing ability (Royal Brisbane Hospital Outcome Measure for Swallowing, scale range unclear, higher values are better, final value) at <3 months (follow-up: 12 weeks)

1	randomised trials	serious ^a	not serious	not serious	serious ^b	none	20	28	-	MD 0.7 higher (0.16 lower to 1.56 higher)	 Low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio

2 Explanations

- 3 a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)
- 4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

5

6 Table 45: Clinical evidence profile: drug interventions (nifedipine) compared to placebo/sham therapy

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (nifedipine)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
Mortality at <3 months (follow-up: 4 weeks)												
1	randomised trials	serious ^a	not serious	not serious	very serious ^b	none	1/8 (12.5%)	1/9 (11.1%)	RR 1.13 (0.08 to 15.19)	14 more per 1,000 (from 102 fewer to 1,000 more)	 Very low	CRITICAL

Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 4 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (nifedipine)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious ^a	not serious	not serious	very serious ^b	none	3/8 (37.5%)	5/9 (55.6%)	RR 0.68 (0.23 to 1.97)	178 fewer per 1,000 (from 428 fewer to 539 more)	Very low	CRITICAL

1 CI: confidence interval; RR: risk ratio

2 Explanations

3 a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)

4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

5

6 **Table 46: Clinical evidence profile: neuromuscular electrical stimulation (NMES) compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months

1	randomised trials	not serious	not serious	not serious	very serious ^a	none	3/17 (17.6%)	3/16 (18.8%)	RR 0.94 (0.22 to 4.00)	11 fewer per 1,000 (from 146 fewer to 563 more)	Low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change scores and final value) at <3 months (follow-up: mean 4 weeks)

3	randomised trials	very serious ^b	serious ^c	not serious	serious ^d	none	60	57	-	MD 0.66 lower (1.78 lower to 0.45 higher)	Very low	CRITICAL
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Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Occurrence of aspiration at <3 months (follow-up: 3 weeks)

1	randomised trials	not serious	not serious	serious ^a	very serious ^a	none	6/17 (35.3%)	4/15 (26.7%)	RR 1.32 (0.46 to 3.81)	85 more per 1,000 (from 144 fewer to 749 more)	⊕○○○ Very low	CRITICAL
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Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 3 weeks)

1	randomised trials	not serious	not serious	not serious	very serious ^a	none	10/17 (58.8%)	11/16 (68.8%)	RR 0.86 (0.51 to 1.43)	96 fewer per 1,000 (from 337 fewer to 296 more)	⊕⊕○○ Low	CRITICAL
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Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 1 weeks)

1	randomised trials	very serious ^f	not serious	not serious	very serious ^d	none	8/16 (50.0%)	6/17 (35.3%)	RR 1.42 (0.63 to 3.18)	148 more per 1,000 (from 131 fewer to 769 more)	⊕○○○ Very low	CRITICAL
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Length of hospital stay (days, lower values are better, final value) at <3 months (follow-up: 3 weeks)

1	randomised trials	not serious	not serious	not serious	very serious ^d	none	17	16	-	MD 0.04 higher (3.25 lower to 3.33 higher)	⊕⊕○○ Low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Videofluoroscopic Dysphagia Scale, Mann Assessment of Swallowing Ability [different scale ranges], higher values are better, change scores) at <3 months (follow-up: mean 4 weeks)

4	randomised trials	not serious	very serious ^c	not serious	serious ^a	none	126	104	-	SMD 0.69 SD higher (0.16 lower to 1.54 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at <3 months (follow-up: 1 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious ^a	not serious	not serious	very serious ^d	none	16	17	-	MD 0.26 higher (1.16 lower to 1.68 higher)	 Very low	CRITICAL

1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

3 a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

4 b. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

5 c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

6 d. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

7 e. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)

8 f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

9 g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

10

11 **Table 47: Clinical evidence profile: neuromuscular electrical stimulation (NMES) compared to usual care**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	usual care	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months (follow-up: mean 3 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	usual care	Relative (95% CI)	Absolute (95% CI)		
2	randomised trials	very serious ^a	serious ^b	not serious	very serious ^{c,d}	none	3/36 (8.3%)	1/35 (2.9%)	RD 0.05 (-0.06 to 0.17)	50 more per 1,000 (from 60 fewer to 170 more) ^d	⊕○○○ Very low	CRITICAL

Mortality at ≥3 months (follow-up: mean 36 weeks)

2	randomised trials	very serious ^a	serious ^b	not serious	very serious ^c	none	4/79 (5.1%)	1/48 (2.1%)	RD 0.02 (-0.05 to 0.09)	20 more per 1,000 (from 50 fewer to 90 more) ^d	⊕○○○ Very low	CRITICAL
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Person/participant generic health-related quality of life (EQ-VAS, 0-100, higher values are better, final value) at ≥3 months (follow-up: 1 years)

1	randomised trials	very serious ^a	not serious	not serious	serious ^e	none	51	26	-	MD 10.38 higher (0.69 lower to 21.45 higher)	⊕○○○ Very low	CRITICAL
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Occurrence of chest infections at <3 months (follow-up: mean 5 weeks)

4	randomised trials	very serious ^f	serious ^b	not serious	not serious	none	0/103 (0.0%)	6/91 (6.6%)	RD -0.05 (-0.13 to 0.04)	50 fewer per 1,000 (from 130 fewer to 40 more) ^d	⊕○○○ Very low	CRITICAL
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Occurrence of chest infections at ≥3 months (follow-up: mean 27 weeks)

3	randomised trials	very serious ^g	very serious ^h	not serious	not serious	none	4/96 (4.2%)	10/58 (17.2%)	RD -0.12 (-0.33 to 0.09)	120 fewer per 1,000 (from 330 fewer to 90 more) ^d	⊕○○○ Very low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months (follow-up: mean 4 weeks)

2	randomised trials	very serious ^g	serious ^h	not serious	serious ^e	none	37	37	-	MD 0.55 lower (1.76 lower to 0.67 higher)	⊕○○○ Very low	CRITICAL
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Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	usual care	Relative (95% CI)	Absolute (95% CI)		

Occurrence of aspiration at <3 months (follow-up: 3 weeks)

1	randomised trials	serious ⁱ	not serious	serious ⁱ	very serious ^o	none	6/17 (35.3%)	5/16 (31.3%)	RR 1.13 (0.43 to 2.98)	41 more per 1,000 (from 178 fewer to 619 more)	Very low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months (follow-up: 1 years)

1	randomised trials	very serious ^a	not serious	not serious	serious ^o	none	51	26	-	MD 0.67 lower (1.46 lower to 0.12 higher)	Very low	CRITICAL
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Occurrence of aspiration at ≥3 months (follow-up: 3 months)

1	randomised trials	very serious ⁱ	not serious	serious ⁱ	very serious ^o	none	6/17 (35.3%)	5/10 (50.0%)	RR 0.71 (0.29 to 1.73)	145 fewer per 1,000 (from 355 fewer to 365 more)	Very low	CRITICAL
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Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: mean 3 weeks)

4	randomised trials	serious ^k	not serious	not serious	serious ^o	none	42/79 (53.2%)	49/63 (77.8%)	RR 0.66 (0.52 to 0.85)	264 fewer per 1,000 (from 373 fewer to 117 fewer)	Low	CRITICAL
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Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 12 weeks)

1	randomised trials	serious ⁱ	not serious	not serious	very serious ^o	none	15/31 (48.4%)	10/26 (38.5%)	RR 1.26 (0.69 to 2.31)	100 more per 1,000 (from 119 fewer to 504 more)	Very low	CRITICAL
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Dysphagia present/return to normal diet (dysphagia present) at ≥3 months (follow-up: 1 years)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	neuromuscular electrical stimulation (NMES)	usual care	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious ^a	not serious	not serious	serious ^a	none	34/51 (66.7%)	22/26 (84.6%)	RR 0.79 (0.61 to 1.02)	178 fewer per 1,000 (from 330 fewer to 17 more)	⊕○○○ Very low	CRITICAL

Length of hospital stay (days, lower values are better, final values) at <3 months (follow-up: 3 weeks)

1	randomised trials	serious ⁱ	not serious	not serious	very serious ^a	none	17	16	-	MD 0.84 days lower (5.2 lower to 3.52 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months (follow-up: mean 6 weeks)

3	randomised trials	very serious ^f	not serious	not serious	not serious	none	68	62	-	SMD 0.91 SD higher (0.55 higher to 1.28 higher)	⊕⊕○○ Low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome and Severity Scale, Standardised swallowing assessment, Dysphagia severity [different scale ranges], higher values are better, final values) at <3 months (follow-up: mean 3 weeks)

5	randomised trials	very serious ^m	very serious ^h	not serious	serious ^a	none	113	99	-	SMD 1.07 SD higher (0.05 lower to 2.19 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, 1-7, higher values are better, final value) at ≥3 months (follow-up: 15 weeks)

1	randomised trials	very serious ^a	not serious	not serious	serious ^a	none	17	17	-	MD 0.2 higher (0.74 lower to 1.14 higher)	⊕○○○ Very low	CRITICAL
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Nutrition (Mini Nutritional Assessment-short form, 0-14, higher values are better, final value) at ≥3 months (follow-up: 1 years)

1	randomised trials	very serious ^a	not serious	not serious	serious ^a	none	51	26	-	MD 0.21 higher (1 lower to 1.42 higher)	⊕○○○ Very low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

- 3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)
- 4 b. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)
- 5 c. Downgraded by 1 to 2 increments for imprecision due to zero events and small sample size
- 6 d. Absolute effect calculated by risk difference due to zero events in at least one arm of one study
- 7 e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 8 f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)
- 9 g. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, and bias due to missing outcome data)
- 10 h. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
- 11 i. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to deviations from the intended interventions)
- 12 j. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)
- 13 k. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process, bias due to deviations from the intended intervention, bias due to missing outcome data and bias in measurement of the outcome)
- 14 l. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)
- 15 m. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias in measurement of the outcome)

17 **Table 48: Clinical evidence profile: pharyngeal electrical stimulation (PES) compared to placebo/sham therapy**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	pharyngeal electrical stimulation (PES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
Mortality at <3 months (follow-up: mean 2 weeks)												
3	randomised trials	very serious ^a	not serious	not serious	very serious ^b	none	4/138 (2.9%)	1/121 (0.8%)	RR 2.13 (0.42 to 10.75)	9 more per 1,000 (from 5 fewer to 81 more)	 Very low	CRITICAL

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	pharyngeal electrical stimulation (PES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at ≥3 months (follow-up: mean 3 months)

2	randomised trials	very serious ^c	not serious	not serious	very serious ^b	none	10/105 (9.5%)	10/93 (10.8%)	RR 0.87 (0.38 to 2.00)	14 fewer per 1,000 (from 67 fewer to 108 more)	 Very low	CRITICAL
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Person/participant generic health-related quality of life (EQ-5D, -0.11-1, higher values are better, change score) at ≥3 months (follow-up: 12 weeks)

1	randomised trials	very serious ^c	not serious	not serious	serious ^b	none	87	75	-	MD 0.12 higher (0 to 0.24 higher)	 Very low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final values) at <3 months (follow-up: mean 2 weeks)

3	randomised trials	very serious ^a	not serious	not serious	not serious	none	95	77	-	MD 0.2 lower (0.72 lower to 0.31 higher)	 Low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at ≥3 months (follow-up: mean 3 months)

2	randomised trials	very serious ^c	serious ^d	not serious	very serious ^b	none	76	63	-	MD 0.36 lower (2.18 lower to 1.46 higher)	 Very low	CRITICAL
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Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: mean 2 weeks)

2	randomised trials	very serious ^a	serious ^d	not serious	very serious ^b	none	64/86 (74.4%)	52/68 (76.5%)	RR 0.76 (0.30 to 1.94)	184 fewer per 1,000 (from 535 fewer to 719 more)	 Very low	CRITICAL
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Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 3 days)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	pharyngeal electrical stimulation (PES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious ^a	not serious	not serious	very serious ^b	none	12/20 (60.0%)	4/10 (40.0%)	RR 1.50 (0.65 to 3.47)	200 more per 1,000 (from 140 fewer to 988 more)	⊕○○○ Very low	CRITICAL

Dysphagia present/return to normal diet (dysphagia present) at ≥3 months (follow-up: 12 weeks)

1	randomised trials	very serious ^c	not serious	not serious	very serious ^b	none	36/70 (51.4%)	33/56 (58.9%)	RR 0.87 (0.64 to 1.20)	77 fewer per 1,000 (from 212 fewer to 118 more)	⊕○○○ Very low	CRITICAL
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Dysphagia present/return to normal diet (return to normal diet) at ≥3 months (follow-up: 3 months)

1	randomised trials	not serious	not serious	not serious	very serious ^b	none	8/14 (57.1%)	4/14 (28.6%)	RR 2.00 (0.78 to 5.14)	286 more per 1,000 (from 63 fewer to 1,000 more)	⊕⊕○○ Low	CRITICAL
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Discharge to residential service at ≥3 months (follow-up: 12 weeks)

1	randomised trials	very serious ^c	not serious	not serious	serious ^b	none	49/87 (56.3%)	44/75 (58.7%)	RR 0.96 (0.74 to 1.25)	23 fewer per 1,000 (from 153 fewer to 147 more)	⊕○○○ Very low	CRITICAL
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Length of hospital stay (hours, lower values are better, final values) at <3 months (follow-up: 12 weeks)

1	randomised trials	not serious	not serious	not serious	very serious ^b	none	20	10	-	MD 11 hours higher (343.25 lower to 365.25 higher)	⊕⊕○○ Low	CRITICAL
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Length of hospital stay (days, lower values are better, final values) at <3 months (follow-up: mean 9 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	pharyngeal electrical stimulation (PES)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
3	randomised trials	very serious ^a	not serious	not serious	not serious	none	117	101	-	MD 3.09 days lower (9.39 lower to 3.2 higher)	⊕⊕○○ Low	CRITICAL

Swallowing ability (Functional Oral Intake Scale, Dysphagia Severity Rating Scale [different scale ranges], higher values are better, final values) at <3 months (follow-up: mean 1 weeks)

3	randomised trials	very serious ^a	not serious	not serious	not serious	none	127	114	-	SMD 0.05 SD lower (0.3 lower to 0.21 higher)	⊕⊕○○ Low	CRITICAL
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Swallowing ability (Dysphagia Severity Rating Scale, 0-12, lower values are better, final values) at ≥3 months (follow-up: mean 3 months)

2	randomised trials	very serious ^c	not serious	not serious	not serious	none	105	92	-	MD 0.3 higher (1.08 lower to 1.68 higher)	⊕⊕○○ Low	CRITICAL
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Nutrition (albumin, g/L, higher values are better, final value) at <3 months (follow-up: 2 weeks)

1	randomised trials	very serious ^c	not serious	not serious	not serious	none	87	75	-	MD 0.4 higher (1.22 lower to 2.02 higher)	⊕⊕○○ Low	CRITICAL
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Nutrition (albumin, g/L, higher values are better, final value) at ≥3 months (follow-up: 12 weeks)

1	randomised trials	very serious ^c	not serious	not serious	not serious	none	87	75	-	MD 0.6 higher (1.07 lower to 2.27 higher)	⊕⊕○○ Low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

- 1 c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias due to deviations from the intended interventions and bias due to missing outcome data)
- 2 d. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
- 3 e. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias in selection of reported result)

5 **Table 49: Clinical evidence profile: physical stimulation compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	physical stimulation	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^a	not serious	not serious	very serious ^b	none	1/60 (1.7%)	1/60 (1.7%)	RR 1.00 (0.06 to 15.62)	0 fewer per 1,000 (from 16 fewer to 244 more)	⊕○○○ Very low	CRITICAL
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Swallowing ability (standardised swallowing assessment, scale range unclear, lower values are better, change score) at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	60	60	-	MD 1.43 lower (2.32 lower to 0.54 lower)	⊕○○○ Very low	CRITICAL
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6 CI: confidence interval; MD: mean difference; RR: risk ratio

7 **Explanations**

- 8 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)
- 9 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

10

1 **Table 50: Clinical evidence profile: physical stimulation compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	physical stimulation	usual care	Relative (95% CI)	Absolute (95% CI)		
Occurrence of chest infections at <3 months (follow-up: mean 3 weeks)												
2	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	4/78 (5.1%)	13/78 (16.7%)	RR 0.31 (0.11 to 0.90)	115 fewer per 1,000 (from 148 fewer to 17 fewer)	⊕○○○ Very low	CRITICAL
Occurrence of aspiration at <3 months (follow-up: 2 weeks)												
1	randomised trials	very serious ^a	not serious	serious ^c	serious ^b	none	6/48 (12.5%)	17/48 (35.4%)	RR 0.35 (0.15 to 0.82)	230 fewer per 1,000 (from 301 fewer to 64 fewer)	⊕○○○ Very low	CRITICAL
Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 3 weeks)												
1	randomised trials	very serious ^a	not serious	not serious	not serious	none	19/48 (39.6%)	37/48 (77.1%)	RR 0.51 (0.35 to 0.75)	378 fewer per 1,000 (from 501 fewer to 193 fewer)	⊕⊕○○ Low	CRITICAL
Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 3 weeks)												
1	randomised trials	serious ^d	not serious	not serious	not serious	none	27/30 (90.0%)	9/30 (30.0%)	RR 3.00 (1.71 to 5.25)	600 more per 1,000 (from 213 more to 1,000 more)	⊕⊕⊕○ Moderate	CRITICAL
Swallowing ability (Eat-10, 0-40, lower values are better, change score) at <3 months (follow-up: 3 weeks)												
1	randomised trials	serious ^d	not serious	not serious	serious ^b	none	30	30	-	MD 2.37 lower (3.7 lower to 1.04 lower)	⊕⊕○○ Low	CRITICAL
Nutrition (albumin, units unclear, higher values are better, final value) at <3 months (follow-up: 2 weeks)												

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	physical stimulation	usual care	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious ^a	not serious	not serious	not serious	none	48	48	-	MD 5.7 higher (4.41 higher to 6.99 higher)	 Low	CRITICAL

1 CI: confidence interval; MD: mean difference; RR: risk ratio

2 Explanations

- 3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)
- 4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 5 c. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specified it should be reported as a continuous outcome)
- 6 d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)

7

8 Table 51: Clinical evidence profile: transcranial direct current stimulation (TDCS) compared to placebo/sham therapy

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial direct current stimulation (TDCS)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months (follow-up: 1 months)

1	randomised trials	not serious	not serious	not serious	very serious ^a	none	2/27 (7.4%)	1/15 (6.7%)	RR 1.11 (0.11 to 11.26)	7 more per 1,000 (from 59 fewer to 684 more)	 Low	CRITICAL
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Occurrence of chest infection at <3 months (follow-up: 3 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial direct current stimulation (TDCS)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious ^b	not serious	not serious	very serious ^a	none	11/29 (37.9%)	16/30 (53.3%)	RR 0.71 (0.40 to 1.26)	155 fewer per 1,000 (from 320 fewer to 139 more)	⊕○○○ Very low	CRITICAL

Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score) at <3 months (follow-up: mean 3 weeks)

2	randomised trials	not serious	serious ^c	not serious	very serious ^a	none	47	25	-	MD 0.39 lower (1.65 lower to 0.88 higher)	⊕○○○ Very low	CRITICAL
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Occurrence of aspiration at <3 months (follow-up: 2 weeks)

1	randomised trials	very serious ^d	not serious	serious ^a	not serious	none	6/20 (30.0%)	17/20 (85.0%)	RR 0.35 (0.18 to 0.71)	553 fewer per 1,000 (from 697 fewer to 247 fewer)	⊕○○○ Very low	CRITICAL
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Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 1 months)

1	randomised trials	not serious	not serious	not serious	serious ^a	none	6/22 (27.3%)	15/22 (68.2%)	RR 0.40 (0.19 to 0.84)	409 fewer per 1,000 (from 552 fewer to 109 fewer)	⊕⊕⊕○ Moderate	CRITICAL
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Length of hospital stay (days, lower values are better, final value) at <3 months (follow-up: 3 weeks)

1	randomised trials	serious ^b	not serious	not serious	serious ^a	none	29	30	-	MD 2.8 days higher (0.28 lower to 5.88 higher)	⊕⊕○○ Low	CRITICAL
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Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, change scores) at <3 months (follow-up: mean 3 weeks)

5	randomised trials	serious ^f	not serious	not serious	serious ^a	none	93	74	-	SMD 0.51 SD higher (0.19 higher to 0.82 higher)	⊕⊕○○ Low	CRITICAL
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Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial direct current stimulation (TDCS)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Swallowing ability (Functional Oral Intake Scale, Dysphagia Outcome Severity Scale, Functional Dysphagia Scale [different scale ranges], higher values are better, final values) at <3 months (follow-up: mean 5 weeks)

4	randomised trials	serious ^f	very serious ^c	not serious	very serious ^a	none	55	53	-	SMD 0.34 SD higher (0.66 lower to 1.35 higher)	 Very low	CRITICAL
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Swallowing ability (Functional dysphagia scale, 0-100, lower values are better, change score) at ≥3 months (follow-up: 3 months)

1	randomised trials	serious ^b	not serious	not serious	not serious	none	9	7	-	MD 22.83 lower (32.35 lower to 13.31 lower)	 Moderate	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

- 3 a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 4 b. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)
- 5 c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
- 6 d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)
- 7 e. Downgraded by 1 increment because of outcome indirectness (as the outcome was reported in a dichotomous form when the protocol specifies it should be reported in a continuous form)
- 8 f. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process and bias in measurement of the outcome)

9

1 **Table 52: Clinical evidence profile: transcranial direct current stimulation (TDCS) compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial direct current stimulation (TDCS)	usual care	Relative (95% CI)	Absolute (95% CI)		

Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 6 days)

1	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	30/32 (93.8%)	28/32 (87.5%)	RR 1.07 (0.91 to 1.26)	61 more per 1,000 (from 79 fewer to 228 more)	⊕○○○ Very low	CRITICAL
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Swallowing ability (functional oral intake scale, 1-7, higher values are better, final value) at <3 months (follow-up: 6 days)

1	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	32	32	-	MD 0.9 higher (0.09 higher to 1.71 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (functional dysphagia scale, 0-100, lower values are better, final value) at ≥3 months (follow-up: 3 months)

1	randomised trials	very serious ^c	not serious	not serious	serious ^b	none	20	20	-	MD 10.6 lower (20.86 lower to 0.34 lower)	⊕○○○ Very low	CRITICAL
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Nutrition (albumin, units unclear, higher values are better, final value) at ≥3 months (follow-up: 3 months)

1	randomised trials	very serious ^c	not serious	not serious	not serious	none	20	20	-	MD 8.1 higher (6.73 higher to 9.47 higher)	⊕⊕○○ Low	CRITICAL
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2 CI: confidence interval; MD: mean difference; RR: risk ratio

3 **Explanations**

4 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data and bias in selection of the reported result)

5 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

6 c. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

7

1 **Table 53: Clinical evidence profile: transcranial magnetic stimulation (TMS) compared to placebo/sham therapy**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial magnetic stimulation (TMS)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months (follow-up: mean 2 weeks)

3	randomised trials	very serious ^a	not serious	not serious	very serious ^{b,c}	none	0/49 (0.0%)	3/50 (6.0%)	RD -0.06 (-0.15 to 0.03)	60 fewer per 1,000 (from 150 fewer to 30 more) ^b	⊕○○○ Very low	CRITICAL
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Occurrence of chest infections at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^d	not serious	not serious	very serious ^e	none	0/23 (0.0%)	0/26 (0.0%)	RD 0.00 (-0.08 to 0.08)	0 fewer per 1,000 (from 80 fewer to 80 more) ^b	⊕○○○ Very low	CRITICAL
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Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final values) at <3 months (follow-up: mean 3 weeks)

3	randomised trials	very serious ^d	not serious	not serious	serious ^e	none	45	50	-	MD 0.97 lower (1.67 lower to 0.28 lower)	⊕○○○ Very low	CRITICAL
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Dysphagia present/return to normal diet (removal of feeding tube) at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^d	not serious	not serious	very serious ^e	none	11/23 (47.8%)	10/26 (38.5%)	RR 1.24 (0.65 to 2.37)	92 more per 1,000 (from 135 fewer to 527 more)	⊕○○○ Very low	CRITICAL
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Swallowing ability (dysphagia outcome and severity scale, dysphagia grade, videofluoroscopic dysphagia scale, standardised swallow assessment, swallowing activity and participation profile scores [different scale ranges], lower values are better, final values) at <3 months (follow-up: mean 4 weeks)

5	randomised trials	very serious ^f	very serious ^g	not serious	very serious ^e	none	69	65	-	SMD 0.76 SD lower (1.98 lower to 0.45 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (standardised swallowing assessment, swallowing activity and participation scale [different scale ranges], lower values are better, final values) at ≥3 months (follow-up: mean 8 months)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial magnetic stimulation (TMS)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
2	randomised trials	serious ^b	very serious ^d	not serious	very serious ^e	none	37	16	-	SMD 1.35 SD lower (4.3 lower to 1.61 higher)	⊕○○○ Very low	CRITICAL

1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)

4 b. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

5 c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

6 d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)

7 e. Downgraded by 1 to 2 increments for imprecision due to zero events and small sample size

8 f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result)

10 g. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

11 h. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data and bias in measurement of the outcome)

13

1 **Table 54: Clinical evidence profile: transcranial magnetic stimulation (TMS) compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial magnetic stimulation (TMS)	usual care	Relative (95% CI)	Absolute (95% CI)		
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, change score and final value) at <3 months (follow-up: mean 5 weeks)												
2	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	35	33	-	MD 0.65 lower (1.35 lower to 0.05 higher)	⊕○○○ Very low	CRITICAL
Occurrence of aspiration (penetration aspiration scale, 1-8, lower values are better, final value) at ≥3 months (follow-up: 3 months)												
1	randomised trials	serious ^c	not serious	not serious	very serious ^b	none	15	13	-	MD 0.02 lower (2.29 lower to 2.25 higher)	⊕○○○ Very low	CRITICAL
Dysphagia present/return to normal diet (dysphagia present) at <3 months (follow-up: 2 weeks)												
1	randomised trials	very serious ^d	not serious	not serious	serious ^b	none	11/32 (34.4%)	20/29 (69.0%)	RR 0.50 (0.29 to 0.85)	345 fewer per 1,000 (from 490 fewer to 103 fewer)	⊕○○○ Very low	CRITICAL
Dysphagia present/return to normal diet (return to normal diet) at <3 months (follow-up: 1 months)												
1	randomised trials	serious ^c	not serious	not serious	very serious ^b	none	9/15 (60.0%)	9/15 (60.0%)	RR 1.00 (0.56 to 1.79)	0 fewer per 1,000 (from 264 fewer to 474 more)	⊕○○○ Very low	CRITICAL
Dysphagia present/return to normal diet (return to normal diet) at ≥3 months (follow-up: 3 months)												
1	randomised trials	serious ^c	not serious	not serious	very serious ^b	none	10/15 (66.7%)	9/15 (60.0%)	RR 1.11 (0.64 to 1.92)	66 more per 1,000 (from 216 fewer to 552 more)	⊕○○○ Very low	CRITICAL

Swallowing ability (water swallow test, swallowing ability and function evaluation [different scale ranges], higher values are better, final values) at <3 months (follow-up: mean 4 weeks)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	transcranial magnetic stimulation (TMS)	usual care	Relative (95% CI)	Absolute (95% CI)		
2	randomised trials	very serious ^a	serious ^d	not serious	serious ^b	none	47	42	-	SMD 0.37 SD higher (0.26 lower to 1 higher)	⊕○○○ Very low	CRITICAL

Swallowing ability (functional dysphagia scale, 0-100, lower values are better, change score) at <3 months (follow-up: 4 weeks)

1	randomised trials	very serious ^a	not serious	not serious	serious ^b	none	20	20	-	MD 4.6 lower (10.47 lower to 1.27 higher)	⊕○○○ Very low	CRITICAL
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Swallowing ability (swallowing ability and functional evaluation, scale range unclear, higher values are better, final value) at >3 months (follow-up: 3 months)

1	randomised trials	serious ^c	not serious	not serious	very serious ^b	none	15	13	-	MD 0.39 higher (1.03 lower to 1.81 higher)	⊕○○○ Very low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference

2 Explanations

- 3 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to missing outcome data)
- 4 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 5 c. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)
- 6 d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias in measurement of the outcome)
- 7 e. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to missing outcome data and bias in measurement of the outcome)
- 8 f. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

9

1 F.2 Interventions for oesophageal dysphagia

2 **Table 55: Clinical evidence profile: drug interventions (domperidone) compared to placebo/sham therapy**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	drug intervention (domperidone)	placebo/sham therapy	Relative (95% CI)	Absolute (95% CI)		
Mortality at <3 months (follow-up: 11 days)												
1	randomised trials	not serious	not serious	serious ^a	very serious ^b	none	2/76 (2.6%)	2/74 (2.7%)	RR 0.97 (0.14 to 6.73)	1 fewer per 1,000 (from 23 fewer to 155 more)	⊕○○○ Very low	CRITICAL
Occurrence of aspiration at <3 months (follow-up: 11 days)												
1	randomised trials	not serious	not serious	serious ^a	not serious	none	9/76 (11.8%)	40/74 (54.1%)	RR 0.22 (0.11 to 0.42)	422 fewer per 1,000 (from 481 fewer to 314 fewer)	⊕⊕⊕○ Moderate	CRITICAL
Dysphagia present/Return to normal diet (presence of nasogastric tube) at <3 months (follow-up: 11 days)												
1	randomised trials	not serious	not serious	very serious ^c	very serious ^b	none	6/76 (7.9%)	5/74 (6.8%)	RR 1.17 (0.37 to 3.66)	11 more per 1,000 (from 43 fewer to 180 more)	⊕○○○ Very low	CRITICAL

3 CI: confidence interval; RR: risk ratio

4 Explanations

- 5 a. Downgraded by 1 increment because of population indirectness (as it was unclear the proportion of people who had oesophageal dysphagia)
- 6 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 7 c. Downgraded by 2 increments because of population indirectness (as it was unclear the proportion of people who had oesophageal dysphagia) and outcome indirectness (due to the measure being a surrogate measure for the protocol outcome)

8

1 F.3 Adaptations to support people with dysphagia

2 **Table 56: Clinical evidence profile: modified diet compared to usual care**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adaptations for oral feeding - modified diet	usual care	Relative (95% CI)	Absolute (95% CI)		

Mortality at <3 months (follow-up: 8 weeks)

1	randomised trials	very serious ^a	not serious	not serious	serious ^{b,c}	none	0/77 (0.0%)	0/38 (0.0%)	RD 0.00 (-0.04 to 0.04)	0 fewer per 1,000 (from 40 fewer to 40 more) ^c	⊕○○○ Very low	CRITICAL
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Occurrence of chest infections at <3 months (follow-up: mean 7 weeks)

2	randomised trials	very serious ^d	not serious	not serious	not serious	none	22/105 (21.0%)	7/66 (10.6%)	RR 2.67 (1.26 to 5.69)	177 more per 1,000 (from 28 more to 497 more)	⊕⊕○○ Low	CRITICAL
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Nutrition (calorie-nitrogen deficit) at <3 months (follow-up: 8 weeks)

1	randomised trials	very serious ^a	not serious	not serious	very serious ^a	none	5/77 (6.5%)	2/38 (5.3%)	RR 1.23 (0.25 to 6.07)	12 more per 1,000 (from 39 fewer to 267 more)	⊕○○○ Very low	CRITICAL
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Hydration (dehydration) at <3 months (follow-up: 8 weeks)

1	randomised trials	very serious ^a	not serious	not serious	very serious ^a	none	1/77 (1.3%)	3/38 (7.9%)	RR 0.16 (0.02 to 1.53)	66 fewer per 1,000 (from 77 fewer to 42 more)	⊕○○○ Very low	CRITICAL
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3 CI: confidence interval; RR: risk ratio

4 Explanations

5 a. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

- 1 b. Downgraded by 1 to 2 increments for imprecision due to zero events and small sample size
- 2 c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study
- 3 d. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process, bias due to deviations from the intended interventions and bias due to missing outcome data)
- 4 e. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

5

6 **Table 57: Clinical evidence profile: free water protocol compared to usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adaptations for oral feeding - free water protocol	usual care	Relative (95% CI)	Absolute (95% CI)		
Occurrence of chest infection at <3 months (follow-up: mean 26 days)												
2	randomised trials	serious ^a	not serious	not serious	very serious ^{b,c}	none	0/18 (0.0%)	0/16 (0.0%)	RD 0.00 (-0.16 to 0.16)	0 fewer per 1,000 (from 160 fewer to 160 more) ^c	 Very low	CRITICAL
Hydration (dehydration) at <3 months (follow-up: 30 days)												
1	randomised trials	serious ^d	not serious	serious ^e	very serious ^{b,c}	none	0/10 (0.0%)	0/10 (0.0%)	RD 0.00 (-0.17 to 0.17)	0 fewer per 1,000 (from 170 fewer to 170 more) ^c	 Very low	CRITICAL
Hydration (fluid intake, mL, higher values are better, final value) at <3 months (follow-up: 21 days)												
1	randomised trials	very serious ^f	not serious	not serious	very serious ^b	none	8	6	-	MD 0 mL (247.5 lower to 247.5 higher)	 Very low	CRITICAL

7 CI: confidence interval; MD: mean difference

8 **Explanations**

9 a. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to a mixture of bias arising from the randomisation process and bias due to deviations from the intended interventions)

- 1 b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 2 c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study
- 3 d. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias arising from the randomisation process)
- 4 e. Downgraded by 1 or 2 increments because of outcome indirectness (as protocol outcome that is stated to be a continuous outcome is reported in the study as a dichotomous outcome)
- 5 f. Downgraded by 2 increments as the majority of the evidence was of very high risk of bias (due to bias arising from the randomisation process and bias due to deviations from the intended interventions)

7 **Table 58: Clinical evidence profile: combinations (modified diet, positioning, modifying bolus volume/mode of delivery) compared to**
 8 **usual care**

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adaptations for oral feeding - combinations (modified diet, positioning, modifying bolus volume/mode of delivery)	usual care	Relative (95% CI)	Absolute (95% CI)		

Mortality at ≥3 months (follow-up: 6 months)

1	randomised trials	not serious	not serious	not serious	very serious ^a	none	20/102 (19.6%)	23/102 (22.5%)	RR 0.87 (0.51 to 1.48)	29 fewer per 1,000 (from 110 fewer to 108 more)	 Low	CRITICAL
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Occurrence of chest infections at ≥3 months (follow-up: 6 months)

1	randomised trials	serious ^b	not serious	not serious	serious ^a	none	26/102 (25.5%)	48/102 (47.1%)	RR 0.54 (0.37 to 0.80)	216 fewer per 1,000 (from 296 fewer to 94 fewer)	 Low	CRITICAL
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Dysphagia present/return to normal diet (return to normal diet) at ≥3 months (follow-up: 6 months)

1	randomised trials	serious ^b	not serious	not serious	serious ^a	none	65/102 (63.7%)	57/102 (55.9%)	RR 1.14 (0.91 to 1.43)	78 more per 1,000 (from 50 fewer to 240 more)	 Low	CRITICAL
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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adaptations for oral feeding - combinations (modified diet, positioning, modifying bolus volume/mode of delivery)	usual care	Relative (95% CI)	Absolute (95% CI)		

Discharge to residential service at ≥3 months (follow-up: 6 months)

1	randomised trials	serious ^b	not serious	not serious	serious ^a	none	17/102 (16.7%)	26/102 (25.5%)	RR 0.65 (0.38 to 1.13)	89 fewer per 1,000 (from 158 fewer to 33 more)	 Low	CRITICAL
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Length of hospital stay at ≥3 months (follow-up: 6 months)

1	randomised trials	serious ^b	not serious	not serious	serious ^a	none	102	102	-	MD 2.2 days lower (5.73 lower to 1.33 higher)	 Low	CRITICAL
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1 CI: confidence interval; MD: mean difference; RR: risk ratio

2 Explanations

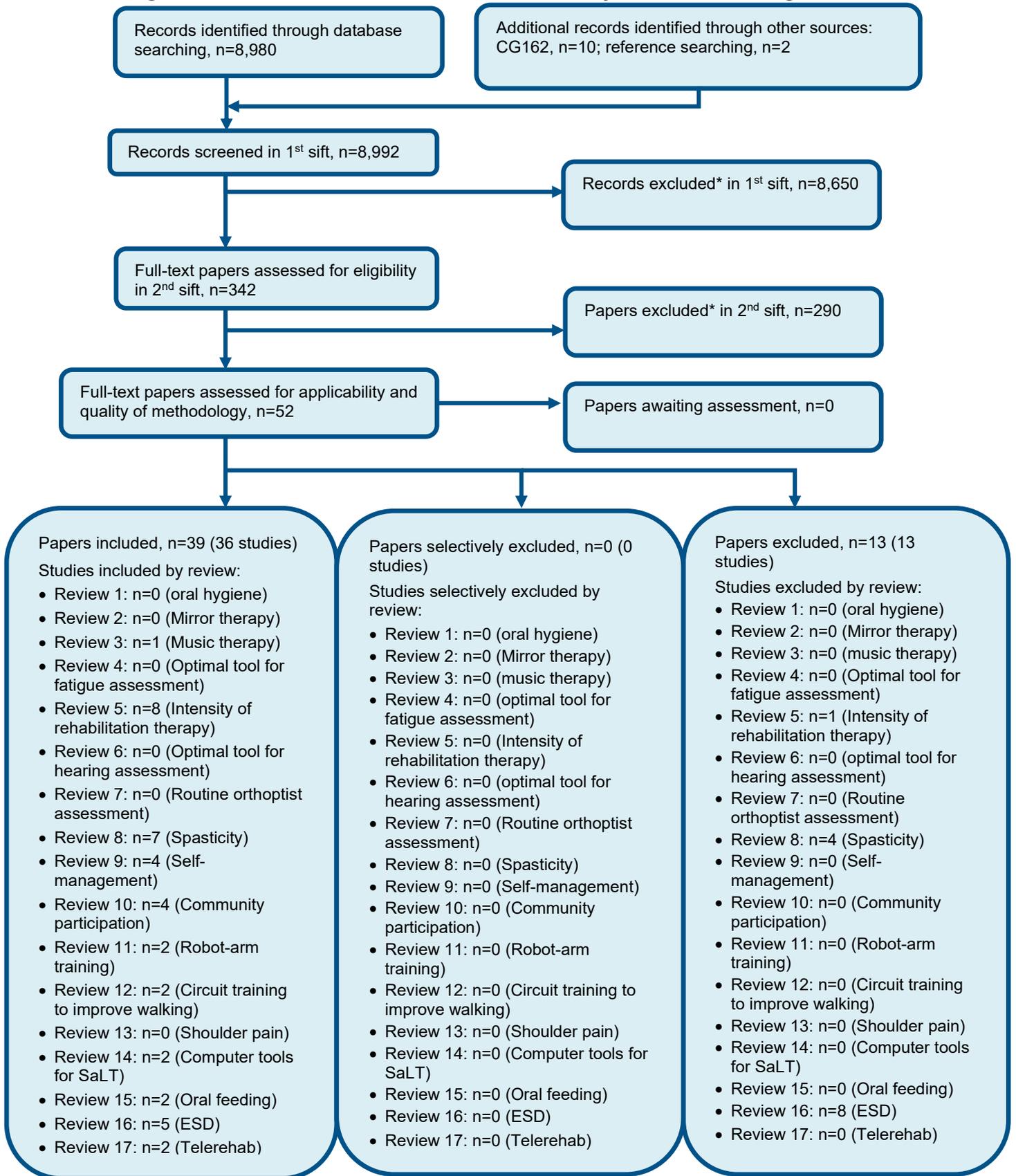
3 a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

4 b. Downgraded by 1 increment as the majority of the evidence was of high risk of bias (due to bias due to missing outcome data)

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1 **Appendix G Economic evidence study selection**
 2 **Figure 123: Flow chart of health economic study selection for the guideline**



* Non-relevant population, intervention, comparison, design or setting; non-English language

Appendix H Economic evidence tables

Study	Marsh 2010 ⁴⁸ (Page 15)			
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: Cost-consequence analysis (health outcomes included reduction in chest infections)</p> <p>Study design: Decision tree model.</p> <p>Approach to analysis: Patients received the intervention and could go on to develop a chest infection or not. Patients with a chest infection could be treated in either the community or hospital.</p> <p>Perspective: UK NHS</p> <p>Follow-up: 1 year Treatment effect duration:^(a) 1 year Discounting: NA</p>	<p>Population: Patients with stroke within the previous 7 days with a clinical diagnosis of swallowing difficulty and no history of swallowing treatment or surgery of the head or neck.</p> <p>Patient characteristics: N = 306 Mean age in years (SD), Intervention 1: 71.4 (12.7) Intervention 2: 72 (12.4) Male: 58%</p> <p>Intervention 1: Usual care - 4.8 sessions equivalent to 1.28 hours for one month. Intervention delivered by an NHS hospital day nurse (non-specialised staff).</p> <p>Intervention 2:</p>	<p>Intervention cost per patient: Intervention 1: £58 Intervention 2: £219 Incremental (2-1): £161</p> <p>Cost of chest infections: Intervention 1: £813 Intervention 2: £432 Incremental (2-1): saves £381</p> <p>Total costs (mean per patient): Intervention 1: £871 Intervention 2: £651 Incremental (2-1): saves £220 (95% CI: NR; p=NR)</p> <p>Currency & cost year: 2009 UK pounds (£)</p> <p>Cost components incorporated: Costs of staff time, costs of treating</p>	<p>QALYs (mean per patient): NR From clinical review (2-1)^{11;(b)} Occurrence of chest infection ≥ 3 months (RR): 0.54 (95% CI: 0.37, 0.80) Return to normal diet ≥ 3 months (RR): 1.14 (95% CI: 0.91, 1.43) Discharge to residential service ≥ 3 months (RR):^(c) 0.65 (95% CI: 0.38, 1.13) Length of hospital stay ≥ 3 months (MD): -2.2 (95% CI: -5.73, 1.33)</p>	<p>ICER (Intervention 2 versus Intervention 1): NR</p> <p>Results suggest that low swallowing therapy dominates usual care (lower costs and improved clinical outcomes), with an infection risk ratio of 0.54, which resulted in cost-savings of £381 per patient for the treatment of chest infections and total cost-savings of £220 per patient.</p> <p>Analysis of uncertainty:</p> <ul style="list-style-type: none"> The probability of developing a chest infection with standard therapy was varied between 25% and 40%. Standard low intensity swallowing therapy was cost saving as long as this probability was below 38%. The cost of chest infection requiring hospital admission was varied between £1,800 and £5,100. Standard low intensity swallowing therapy was cost saving as long as the costs were above £2,000.

	Standard 'low intensity' swallowing therapy - 7.8 sessions equivalent to 3.22 hours. Intervention delivered by a Band 7 hospital SLT.	chest infections in hospital and community.		
Data sources				
Health outcomes: Treatment effect (probability of developing a chest infection) was taken from Carnaby et al. 2006 ¹¹ (included in the review), while the probability of receiving either hospital or community treatment from Guest et al. 1997 ³² Cost sources: Staff time- PSSRU 2009, treatment of chest infection - Guest et al. 1997 (updated to 2009 prices).				
Comments				
Source of funding: Royal College of Speech and Language Therapists. Limitations: QALYs not reported as EQ5D not collected. 2009-unit costs may not reflect current UK NHS context. Primary clinical data inputs based on a single RCT. The probability of a chest infection requiring either hospital or community care was based on descriptive data not specific to dysphagia patients. Costs of treating a chest infection in a hospital or community setting were taken from Guest et al. 1997 and updated to 2009 prices. PSA not performed. Other: The authors labelled this study as a cost-benefit analysis; however, it is better described as a cost-consequence analysis taking into account costs and various disaggregated health outcomes.				
Overall applicability: ^(d) Partially applicable Overall quality: ^(e) Potentially serious limitations				

Abbreviations: 95% CI= 95% confidence interval; ICER= incremental cost-effectiveness ratio; MD= mean difference; NR= not reported; QALYs= quality-adjusted life years; PSA= probabilistic sensitivity analysis; RR= risk ratio; SLT= Speech and language therapist

- For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.
- Lower values are better. Study aim was to reduce the rate of institutionalisation following stroke (discharge to residential service).
- Between-group differences in clinical outcomes taken from figures 117-120 in the guideline clinical review.
- Directly applicable / Partially applicable / Not applicable
- Minor limitations / Potentially serious Limitations / Very serious limitations

Study	Pelczarska 2020 ³⁴			
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: Cost-utility analysis (health outcome: QALYs)	Population: Adults who have had a stroke with the aspiration level 10–14 on Gugging Swallowing Screen (GUSS) scale (patients who tolerate	Intervention cost per patient: Intervention 1: £0 Intervention 2: £224 Incremental (2-1): £224	QALYs (mean per patient): Intervention 1: 0.331 Intervention 2: 0.351 Incremental (2–1): 0.02 (95% CI: NR; p=NR)	ICER (Intervention 2 versus Intervention 1): £8,076 (95% CI: NR; p=NR) Probability Intervention 2 cost effective (£20K/30K threshold): NR/NR

<p>Study design: Probabilistic (dynamic) decision analytic model</p> <p>Approach to analysis: Markov model where utility values of hypothetical patient cohort depended on whether they experienced post-stroke dysphagia and/or consequent clinical events (for example: aspiration, aspiration pneumonia, death). Model assumed that Nutilis Clear® does not affect the dysphagia duration but reduces the risk of aspiration pneumonia (by preventing aspirations). Probability of being diagnosed with post-stroke dysphagia declined over time and approached zero at the 52nd week of follow-up.</p> <p>Perspective: Polish public healthcare perspective</p> <p>Time horizon: 1 year</p> <p>Treatment effect duration:^(a) Reduced</p>	<p>semisolid intake but not fluids).</p> <p>Cohort settings: Mean age: NR Male: NR</p> <p>Intervention 1: Routine clinical practice, including the use of behavioural compensations and manoeuvres (posture, sensory enhancement) as well as rehabilitation exercises aiming to alter swallowing physiology through strength and skill exercises.</p> <p>Intervention 2: Xanthan gum-based consistency modification therapy (Nutilis Clear®) plus routine clinical practice for an average of approximately 5 weeks.</p>	<p>Cost of aspiration pneumonia treatment: Intervention 1: £94 Intervention 2: £32 Incremental (2-1): saves £62</p> <p>Cost of monitoring: Intervention 1: £126 Intervention 2: £127 Incremental (2-1): £0.70</p> <p>Total costs (mean per patient): Intervention 1: £219 Intervention 2: £383 Incremental (2-1): £163 (95% CI: NR; p=NR)</p> <p>Currency & cost year: 2019 Polish złoty (PLN) converted to UK pounds (£)^(b)</p> <p>Cost components incorporated: direct costs of dysphagia treatment (including Nutilis Clear® costs), aspiration pneumonia treatment, and monitoring.</p>	<p>Aspiration pneumonia Intervention 1: 12.6% Intervention 2: 4.3%</p>	<p>Analysis of uncertainty: Results were robust to the following sensitivity analyses:</p> <ul style="list-style-type: none"> One-way sensitivity analyses performed on the risk of aspiration pneumonia in patients both with and without aspiration, the utility of aspiration and utility decrement caused by aspiration pneumonia. Various scenario analyses such as assuming a higher consumption (54g daily) of Nutilis Clear® (ICER of £12,768); lowering the cost of aspiration pneumonia treatment (ICER of £9,068); applying different mortality data (ICER of £8,431); removing monitoring costs (ICER of £5,512) and applying a lifetime horizon (ICER of £7,958). <p>The only scenario that produced an ICER >£20,000 per QALY gained was when the model assumed that the effectiveness of Nutilis Clear® stems only from the patients' years of life gained, as opposed to there being quality-of-life benefits. (ICER of £29,795)</p>
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rate of aspiration was associated with reduced rate of 2 weeks of aspiration pneumonia (14 days of utility decrements applied).

Discounting: NA

Data sources

Health outcomes: Weekly mortality rate taken from Polish annual mortality data.⁷⁸ An increased risk of death for patients with aspiration pneumonia was applied (RR=2.99; 95%CI: 2.44 to 3.66).⁵⁰ Rate of natural resolution of dysphagia taken from Barer 1989⁵ and Smithard 1997¹⁰⁵. Clinical effectiveness (odds ratio of aspiration) taken from Rofes 2014¹⁰¹ and Leonard 2014⁶³. Utility values for people with post-stroke dysphagia were taken from Dennis 2005.²⁰ Disutility for patients with dysphagia and aspiration was not identified in the literature, therefore, data from Dennis 2005 was used for approximation (where it was assumed those with delayed enteral nutrition would be the most comparable to population fed orally with the use of Nutilis Clear®). Disutility data from Mangen 2017⁷³ (>65 years old patients with community-acquired pneumonia) and Wildi 2004¹²⁵ (patients with head or neck cancer and dysphagia) were used in lieu of utility data identified for stroke patients with aspiration pneumonia and post-stroke dysphagia without aspirations, respectively. **Quality-of-life weights:** EQ-5D-3L was used (population tariff not reported). **Cost sources:** Cost year and references not stated. 175g tin of Nutilis Clear costs approximately £30 for Polish healthcare system. Daily consumption cost of Nutilis Clear® was calculated using a weighted average of the share of each available product consistency (Garcia 2005³⁰), and the average daily demand for fluids in post-stroke patients (National Stroke Foundation 2010⁸⁶). Monitoring and aspiration pneumonia treatment costs were calculated using Polish NFZ data.

Comments

Source of funding: The preparation of the cost-effectiveness models was sponsored by NUTRICIA Polska sp. z o.o., the manufacturer of Nutilis Clear®. The authors declare that they have no other competing interests. **Limitations:** Polish context may not reflect current UK NHS context. Population tariff for EQ-5D not reported. Utilities for a few health states were based on non-stroke population with dysphagia. Lack of references for unit costs and resource use estimates creates uncertainty for the results presented for UK context. Study only assesses one type of oral feeding intervention. Clinical effectiveness (reduced aspiration) data not based on stroke-specific population. Study was funded by manufacturer of intervention. Cost of Nutilis Clear® is lower in the UK (5-week consumption costs is £64 compared to £224)^(e). **Other:** None.

Overall applicability:^(c) Partially applicable **Overall quality:**^(d) Potentially serious limitations

Abbreviations: 95% CI= 95% confidence interval; ICER= incremental cost-effectiveness ratio; NR= not reported; NFZ= National Health Fund (Narodowy Fundusz Zdrowia); QALYs= quality-adjusted life years; PSA= Probabilistic sensitivity analysis; RR= risk ratio.

- For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.
- Converted using 2019 purchasing power parities.⁹⁰
- Directly applicable / Partially applicable / Not applicable
- Minor limitations / Potentially serious Limitations / Very serious limitations
- Calculated by the guideline development team. UK cost of Nutilis Clear® (£8.46 per 175g tin, reported in the BNF⁹) was applied to the total dose in the dynamic model (1324g, based on the total intervention cost (583 PLN or approximately £244)

- 1 **Appendix I Health economic model**
- 2 Original economic modelling was not conducted for this question.

1 Appendix J Excluded studies

2 J.1 Clinical studies

3 Table 59: Studies excluded from the clinical review

Study	Code [Reason]
(2009) Improvement of swallowing reflex after electrical stimulation to lower leg acupoints in patients after stroke. Journal - American Geriatrics Society 57(10): 1959-60	- Conference abstract
(2020) Effects of Head Lift Exercise on Oropharyngeal Swallowing Function and Dropout Rate According to Reclining Angle in Patients with Dysphagia after Stroke: a Randomized Trial. J korean dysphagia soc 10(2): 159-166	- Comparator in study does not match that specified in this review protocol <i>Compares the same exercise performed at different angles which was not stated as a comparison in the protocol for this review</i>
(2011) Cost and effectiveness analysis using nursing staff-prepared thickened liquids versus commercially thickened liquids in stroke patients with dysphagia...Kotecki S, Schmidt R Nurs Econom 2010;28:106-113. Dysphagia (0179051X) 26(1): 88-89	- Duplicate reference
Alamer, Abayneh; Melese, Haimanot; Nigussie, Fetene (2020) Effectiveness of Neuromuscular Electrical Stimulation on Post-Stroke Dysphagia: A Systematic Review of Randomized Controlled Trials. Clinical interventions in aging 15: 1521-1531	- Systematic review used as source of primary studies
Aoki, Yusuke, Kabuto, Shuntaro, Ozeki, Yasunori et al. (2015) The effect of tongue pressure strengthening exercise for dysphagic patients. Japanese Journal of Comprehensive Rehabilitation Science 6: 129-136	- Population not relevant to this review protocol <i>>20% of the population did not have a stroke</i>
Arreola, V., Alvarez-Berdugo, D., Rofes, L. et al. (2019) Clinical and biomechanical effects of transcutaneous electrical stimulation on chronic post-stroke oropharyngeal dysphagia: Results at one year follow up of a randomized controlled trial. European Stroke Journal 4(supplement1): 58-59	- Conference abstract
Arreola, V., Alvarez-Berdugo, D., Rofes, L. et al. (2018) Transcutaneous electrical stimulation improves the swallow safety and reduces the need of fluid thickening in patients with chronic post-stroke oropharyngeal dysphagia. European Stroke Journal 3(1supplement1): 51-52	- Conference abstract

Study	Code [Reason]
<p>Arreola, V., Rofes, L., Vilardell, N. et al. (2018) Therapeutic effect of transcutaneous electrical stimulation on chronic post-stroke oropharyngeal dysphagia: A randomized controlled trial with two stimulation intensities. <i>Dysphagia</i> 33(4): 519-520</p>	<p>- Conference abstract</p>
<p>Bakhtiyari, J, Sarraf, P, Nakhostin-Ansari, N et al. (2015) Effects of early intervention of swallowing therapy on recovery from dysphagia following stroke. <i>Iranian journal of neurology</i> 14(3): 119-124</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Randomised into groups based on the time after stroke, rather than to a different intervention</i></p>
<p>Bath, P. M. W.; Kerr, J.; Collins, M.; Factorial trial of swallowing versus conventional therapy, and PEG versus nasogastric tube feeding, in dysphagic patients with recent stroke; Unpublished; 1997</p>	<p>- Outcome data not available for this report</p>
<p>Bath, P M; Bath, F J; Smithard, D G (2000) Interventions for dysphagia in acute stroke. The Cochrane database of systematic reviews: cd000323</p>	<p>- More recent systematic review included that covers the same topic</p>
<p>Bath, P.M., Scutt, P., Love, J. et al. (2016) Swallowing treatment using electrical pharyngeal stimulation (STEPS) after stroke: A randomised controlled phase III trial. <i>Dysphagia</i> 31(2): 270-271</p>	<p>- Conference abstract</p>
<p>Bath, P.M., Woodhouse, L.J., Suntrup-Krueger, S. et al. (2020) Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain injury or other causes: Main results from the PHADER cohort study. <i>EClinicalMedicine</i> 28: 100608</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Split into groups by the need for ventilation and type of neurological difference. Does not compare the treatment to any other treatments.</i></p>
<p>Benard-Laribiere, A., Hucteau, E., Debette, S. et al. (2021) Risk of first ischemic stroke and use of antidopaminergic antiemetics: A case-time-control study in France. <i>Pharmacoepidemiology and Drug Safety</i> 30(suppl1): 328</p>	<p>- Conference abstract</p>
<p>Benard-Laribiere, Anne, Hucteau, Emilie, Debette, Stephanie et al. (2022) Risk of first ischaemic stroke and use of antidopaminergic antiemetics: nationwide case-time-control study. <i>BMJ (Clinical research ed.)</i> 376: e066192</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Case control study. Looking at risk of ischaemic stroke with using antidopaminergic antiemetics rather than the effect of these agents for people with dysphagia</i></p>

Study	Code [Reason]
<p>Benfield, J.K., Everton, L.F., Bath, P.M. et al. (2019) Dysphagia therapy with surface electromyographic biofeedback: A feasibility randomised controlled trial in acute stroke. <i>Dysphagia</i> 34(5): 747</p>	<p>- Conference abstract</p>
<p>Benfield, J.K., Everton, L.F., Bath, P.M. et al. (2017) A systematic review and meta-analysis of the effectiveness of biofeedback in dysphagia therapy. <i>International Journal of Stroke</i> 12(5supplement2): 13-14</p>	<p>- Conference abstract</p>
<p>Benfield, Jacqueline K, Everton, Lisa F, Bath, Philip M et al. (2019) Does Therapy With Biofeedback Improve Swallowing in Adults With Dysphagia? A Systematic Review and Meta-Analysis. <i>Archives of physical medicine and rehabilitation</i> 100(3): 551-561</p>	<p>- Systematic review used as source of primary studies</p>
<p>Benfield, J.; Everton, L.; Hedstrom, A.; Bath, P.; England, T.; Randomised controlled feasibility trial of swallow strength and skill training with surface electromyographic biofeedback in acute stroke patients with dysphagia; <i>European Stroke Journal</i>; 2021; vol. 6 (no. 1suppl); 168</p>	<p>- Outcome data not available for this report</p>
<p>Bogaardt, H C A; Grolman, W; Fokkens, W J (2009) The use of biofeedback in the treatment of chronic dysphagia in stroke patients. <i>Folia phoniatrica et logopaedica : official organ of the International Association of Logopedics and Phoniatrics (IALP)</i> 61(4): 200-5</p>	<p>- Study design not relevant to this review protocol <i>Single arm trial comparing before and after treatment</i></p>
<p>Bogaardt, H.; Hakkesteegt, M.; Speyer, R. (2013) The use of transcutaneous electrostimulation in the treatment of dysphagia: A systematic review. <i>Dysphagia</i> 28(2): 316</p>	<p>- Conference abstract</p>
<p>Bolivar-Prados, M., Rofes, L., Arreola, V. et al. (2019) Effect of a gum-based thickener on the safety of swallowing in patients with poststroke oropharyngeal dysphagia. <i>Neurogastroenterology and Motility</i> 31(11): e13695</p>	<p>- Study design not relevant to this review protocol <i>Single arm trial comparing before and after treatment</i></p>
<p>Bulow, Margareta, Speyer, Renee, Baijens, Laura et al. (2008) Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. <i>Dysphagia</i> 23(3): 302-9</p>	<p>- Data not reported in an extractable format or a format that can be analysed <i>Only reports median and interquartile range values</i></p>

Study	Code [Reason]
<p>Carnaby, G., LaGorio, L., Crary, M. et al. (2012) A randomized, double blind trial of neuromuscular electrical stimulation + mcnell dysphagia therapy (MDTP) after stroke (ANSRS). Dysphagia 27(4): 575</p>	<p>- Conference abstract</p>
<p>Chan, S. L., Or, K. H., Sun, W. Z. et al. (2012) Therapeutic effects of acupuncture for neurogenic dysphagia--a randomized controlled trial. J Tradit Chin Med 32(1): 25-30</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Relevant outcomes only reported in a graph where data cannot be extracted.</i></p>
<p>Chan, Y.T., Zhang, H.W., Sun, W.Z. et al. (2020) Acupuncture for Poststroke Dysphagia: A Pilot, Nonrandomized, Self-Controlled Trial. Evidence-based Complementary and Alternative Medicine 2020: 4689296</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Single arm trial comparing before and after treatment</i></p>
<p>Chan, YT, Zhang, HW, Guo, YQ et al. (2017) Effectiveness and safety of acupuncture for poststroke dysphagia: Study protocol for a pragmatic multicenter nonrandomized controlled trial. Evidence-Based Complementary and Alternative Medicine 2017: 2349794</p>	<p>- Protocol only</p> <p><i>Protocol for Chan 2020, excluded due to it being a single arm trial comparing before and after treatment</i></p>
<p>Chang, L, He, PL, Zhou, ZZ et al. (2014) Efficacy observation of dysphagia after acute stroke treated with acupuncture and functional electric stimulation. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 34(8): 737-740</p>	<p>- Study not reported in English</p>
<p>Chen, D and Guo, H (2018) Therapeutic effects of acupuncture combined with rehabilitation training on dysphagia in post-stroke pseudobulbar palsy. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 38(4): 364-368</p>	<p>- Study not reported in English</p>
<p>Chen, Lifang, Fang, Jianqiao, Ma, Ruijie et al. (2014) Acupuncture for acute stroke: study protocol for a multicenter, randomized, controlled trial. Trials 15: 214</p>	<p>- Protocol only</p>
<p>Chen, Lifang, Fang, Jianqiao, Ma, Ruijie et al. (2016) Additional effects of acupuncture on early comprehensive rehabilitation in patients with mild to moderate acute ischemic stroke: a multicenter randomized controlled trial. BMC complementary and alternative medicine 16: 226</p>	<p>- Population not relevant to this review protocol</p> <p><i>Only approximately 50% of the people had dysphagia and so does not fulfill the minimum number for the population requirement in the protocol.</i></p>

Study	Code [Reason]
<p>Chen, Q., Huang, H., Chen, G. et al. (2022) The Effect of Cerebellar Repetitive Transcranial Magnetic Stimulation on Dysphagia due to Posterior Circulation Stroke, a Randomized Controlled Trial Protocol. <i>Cerebrovascular Diseases</i></p>	<p>- Protocol only</p>
<p>Chen, R-Z and Fang, W-B (2005) Early intervention for impaired swallowing in patients with unilateral acute cerebral infarction. <i>Chinese journal of clinical rehabilitation</i> 9(17): 6-7</p>	<p>- Study not reported in English</p>
<p>Chen, Yi-Wen, Chang, Kwang-Hwa, Chen, Hung-Chou et al. (2016) The effects of surface neuromuscular electrical stimulation on post-stroke dysphagia: a systemic review and meta-analysis. <i>Clinical rehabilitation</i> 30(1): 24-35</p>	<p>- Systematic review used as source of primary studies</p>
<p>Cheng, FX and Chen, T (2014) Efficacy observation of post-stroke dysphagia treated with acupuncture at Lianquan (CV 23). <i>Zhongguo zhen jiu [Chinese acupuncture & moxibustion]</i> 34(7): 627-630</p>	<p>- Study not reported in English</p>
<p>Cheng, I.K.Y.; Yiu, E.M.L.; Chan, K.M.K. (2019) Inter-individual variability in the responses to rTMS as a treatment for chronic post-stroke dysphagia. <i>Dysphagia</i> 34(5): 748</p>	<p>- Conference abstract</p>
<p>Cheng, Ivy K Y, Chan, Karen M K, Wong, C S et al. (2015) Preliminary evidence of the effects of high-frequency repetitive transcranial magnetic stimulation (rTMS) on swallowing functions in post-stroke individuals with chronic dysphagia. <i>International journal of language & communication disorders</i> 50(3): 389-96</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Case series</i></p>
<p>Cheng, Ivy; Sasegbon, Ayodele; Hamdy, Shaheen (2022) Effects of pharmacological agents for neurogenic oropharyngeal dysphagia: A systematic review and meta-analysis. <i>Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society</i> 34(3): e14220</p>	<p>- Systematic review used as source of primary studies</p>
<p>Cheng, Ivy; Sasegbon, Ayodele; Hamdy, Shaheen (2021) Effects of Neurostimulation on Poststroke Dysphagia: A Synthesis of Current Evidence From Randomized Controlled Trials. <i>Neuromodulation : journal of the International Neuromodulation Society</i> 24(8): 1388-1401</p>	<p>- Systematic review used as source of primary studies</p>

Study	Code [Reason]
<p>Cheng, K.Y.I., Chan, M.K.K., Pu, D. et al. (2016) Effects of 5 Hz repetitive transcranial magnetic stimulation (RTMS) on swallowing functions of dysphagic individuals. Dysphagia 31(2): 266</p>	<p>- Conference abstract</p>
<p>Cheng, K.Y.I., Chan, M.K.K., Wong, C.S. et al. (2017) Short term effects of 5Hz repetitive transcranial magnetic stimulation (rTMS) on swallowing and speech functions in post-stroke individuals. Dysphagia 32(1): 192</p>	<p>- Conference abstract</p>
<p>Cheng, K.Y.I., Yiu, E., Wong, C.S. et al. (2017) The use of 5 Hz rTMS to improve swallowing functions in chronic poststroke dysphagia. Dysphagia 32(6): 806-807</p>	<p>- Conference abstract</p>
<p>Choi, Jong Bae; Jung, Young Jin; Park, Ji-Su (2020) Comparison of 2 types of therapeutic exercise: jaw opening exercise and head lift exercise for dysphagic stroke: A pilot study. Medicine 99(38): e22136</p>	<p>- Comparator in study does not match that specified in this review protocol <i>Compares two types of exercise</i></p>
<p>Choy, J., Pourkazemi, F., Anderson, C. et al. (2022) Dosages of swallowing exercises in stroke rehabilitation: a systematic review. European Archives of Oto-Rhino-Laryngology</p>	<p>- Systematic review used as source of primary studies</p>
<p>Chu, J, Liu, X, Chen, F et al. (2017) Effects of GAO's neck acupuncture on swallowing function and quality of life in patients with post-stroke pseudobulbar palsy: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 37(7): 691-695</p>	<p>- Study not reported in English</p>
<p>Chu, Q; Xu, Y; Lu, Y (2015) Post-stroke dysphagia treated with long needle technique at SJ17 (Yifeng). International Journal of Clinical Acupuncture 24(4): 264-5</p>	<p>- Commentary only</p>
<p>Cui, Feifei, Yin, Qingmei, Wu, Chao et al. (2020) Capsaicin combined with ice stimulation improves swallowing function in patients with dysphagia after stroke: A randomised controlled trial. Journal of oral rehabilitation 47(10): 1297-1303</p>	<p>- Comparator in study does not match that specified in this review protocol <i>Compares different physical stimuli to each other</i></p>
<p>De Fraga, B.F.; De Almeida, S.T.; Santana, M.G.; Cassol, M.; Effectiveness of myofunctional exercises associated with vocal exercises in the rehabilitation of neurogenic oropharyngeal dysphagia: A randomized double blind clinical</p>	<p>- Outcome data not available for this report</p>

Study	Code [Reason]
trial; International Archives of Otorhinolaryngology; 2015; vol. 19 (no. supplement2); 77	
Diniz, Patricia B, Vanin, Gabriela, Xavier, Rogerio et al. (2009) Reduced incidence of aspiration with spoon-thick consistency in stroke patients. Nutrition in clinical practice : official publication of the American Society for Parenteral and Enteral Nutrition 24(3): 414-8	<p>- Study design not relevant to this review protocol</p> <p><i>Crossover trial for people in the acute phase after stroke</i></p>
Dionisio, Ana, Duarte, Isabel Catarina, Patricio, Miguel et al. (2018) Transcranial Magnetic Stimulation as an Intervention Tool to Recover from Language, Swallowing and Attentional Deficits after Stroke: A Systematic Review. Cerebrovascular diseases (Basel, Switzerland) 46(34): 178-185	<p>- Systematic review used as source of primary studies</p>
Drulia, Teresa C and Ludlow, Christy L (2013) Relative Efficacy of Swallowing versus Non-swallowing Tasks in Dysphagia Rehabilitation: Current Evidence and Future Directions. Current physical medicine and rehabilitation reports 1(4): 242-256	<p>- Review article but not a systematic review</p>
Du, Yupeng, Wei, Li, Lu, Ying et al. (2022) The effects of different frequencies of repetitive transcranial magnetic stimulation (rTMS) on patients with swallowing disorders after cerebral infarction. NeuroRehabilitation 50(1): 115-122	<p>- Population not relevant to this review protocol</p> <p><i>Included people who did not have a stroke or swallowing disorders</i></p>
Duncan, Sallyanne, McAuley, Daniel F, Walshe, Margaret et al. (2020) Interventions for oropharyngeal dysphagia in acute and critical care: a systematic review and meta-analysis. Intensive care medicine 46(7): 1326-1338	<p>- Systematic review used as source of primary studies</p>
Dziewas, R., Stellato, R., Van Der Tweel, I. et al. (2018) Pharyngeal electrical stimulation for early decannulation in tracheotomised stroke patients with neurogenic dysphagia (phast-trac): A prospective randomised singleblinded interventional study -secondary outcomes. European Stroke Journal 3(1supplement1): 587	<p>- Conference abstract</p>
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, Psychiatry and Neurosurgery 52(3): 201-205	<p>- Reports no outcomes specified in the protocol</p> <p><i>Excluded in the Cochrane review for no usable outcomes</i></p>

Study	Code [Reason]
<p>Eltringham, Sabrina A, Kilner, Karen, Gee, Melanie et al. (2018) Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review. Cerebrovascular diseases (Basel, Switzerland) 46(34): 99-107</p>	<p>- Population not relevant to this review protocol</p> <p><i>Comparing people with dysphagia to people without dysphagia</i></p>
<p>Everton, Lisa F, Benfield, Jacqueline K, Michou, Emilia et al. (2021) Effects of Pharyngeal Electrical Stimulation on Swallow Timings, Clearance and Safety in Post-Stroke Dysphagia: Analysis from the Swallowing Treatment Using Electrical Pharyngeal Stimulation (STEPS) Trial. Stroke research and treatment 2021: 5520657</p>	<p>- Secondary publication of an included study that does not provide any additional relevant information</p> <p><i>Post-hoc analysis</i></p>
<p>Feng, S.; Cao, S.; Du, S.; Yin, T.; Mai, F.; Chen, X.; Su, X.; [Acupuncture combined with swallowing training for post-stroke dysphagia: a randomized controlled trial]; Zhongguo Zhen Jiu; 2016; vol. 36 (no. 4); 347-50</p>	<p>- Outcome data not available for this report</p>
<p>Field, Makaela, Wenke, Rachel, Sabet, Arman et al. (2018) Implementing Cough Reflex Testing in a Clinical Pathway for Acute Stroke: A Pragmatic Randomised Controlled Trial. Dysphagia 33(6): 827-839</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Cough reflex testing - not a stated intervention in the protocol for this review</i></p>
<p>Foley, Norine, Teasell, Robert, Salter, Katherine et al. (2008) Dysphagia treatment post stroke: a systematic review of randomised controlled trials. Age and ageing 37(3): 258-64</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Unclear interventions</i></p>
<p>Fraga, B. F., Almeida, S. T., Santana, M. G. et al. (2018) Efficacy of Myofunctional Therapy Associated with Voice Therapy in the Rehabilitation of Neurogenic Oropharyngeal Dysphagia: a pilot study. Int Arch Otorhinolaryngol 22(3): 225-230</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Reports medians and range only.</i></p>
<p>Frey, Kimberly L and Ramsberger, Gail (2011) Comparison of outcomes before and after implementation of a water protocol for patients with cerebrovascular accident and dysphagia. The Journal of neuroscience nursing : journal of the American Association of Neuroscience Nurses 43(3): 165-71</p>	<p>- Reports no outcomes specified in the protocol</p> <p><i>Reports activities of daily living which is not a specified outcome in the protocol</i></p>
<p>Gao, Jing and Zhang, Hui-Jun (2017) Effects of chin tuck against resistance exercise versus Shaker exercise on dysphagia and psychological state after cerebral infarction.</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares two different exercises for dysphagia</i></p>

Study	Code [Reason]
European journal of physical and rehabilitation medicine 53(3): 426-432	
Gao, JX and Zhou, HF (2020) Therapeutic effect of nape cluster acupuncture combined with swallowing function training on post-stroke dysphagia. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 40(6): 586-590	- Study not reported in English
Garcia, JM and Chambers IV, E (2010) Managing dysphagia through diet modifications: evidence-based help for patients with impaired swallowing. AJN American Journal of Nursing 110(11): 26-35	- Review article but not a systematic review
Geeganage, Chamila, Beavan, Jessica, Ellender, Sharon et al. (2012) Interventions for dysphagia and nutritional support in acute and subacute stroke. The Cochrane database of systematic reviews 10: cd000323	- More recent systematic review included that covers the same topic
Gillman, A.; Winkler, R.; Taylor, N.F. (2017) Implementing the Free Water Protocol does not Result in Aspiration Pneumonia in Carefully Selected Patients with Dysphagia: A Systematic Review. Dysphagia 32(3): 345-361	- Systematic review used as source of primary studies
Goulding, R and Bakheit, A M (2000) Evaluation of the benefits of monitoring fluid thickness in the dietary management of dysphagic stroke patients. Clinical rehabilitation 14(2): 119-24	- Comparator in study does not match that specified in this review protocol <i>Compares thickened fluids to other types of thickened fluids</i>
Grocott, J. (2019) Free water or thickened fluids for patients with dysphagia: A systematic review. International Journal of Stroke 14(4suppl): 55	- Conference abstract
Guillen-Sola, A., Messagi-Sartor, M., Barrera De Paz, C. et al. (2015) Effects of neuromuscular electrostimulation and respiratory muscle training in acute/subacute dysphagic stroke patients. Retornus: A randomized control trial. Dysphagia 30(2): 236-237	- Conference abstract
Guillen-Sola, A., Messagi-Sartor, M., Bofill, N. et al. (2016) Swallowing and respiratory muscle strength training in subacute dysphagic stroke patient: A prospective study. Dysphagia 31(2): 297	- Conference abstract
Guillen-Sola, A, Messaggi-Sartor, M, Ramirez-Fuentes, C et al. (2021) The Retornus-2 study:	- Protocol only

Study	Code [Reason]
impact of respiratory muscle training in subacute stroke patients with dysphagia, study protocol of a double-blind randomized controlled trial. <i>Trials</i> 22(1): 416	
Gulec, Ayse, Albayrak, Ilknur, Erdur, Omer et al. (2021) Effect of swallowing rehabilitation using traditional therapy, kinesiology taping and neuromuscular electrical stimulation on dysphagia in post-stroke patients: A randomized clinical trial. <i>Clinical neurology and neurosurgery</i> 211: 107020	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares combinations of active treatments (kinesio tape and NMES combined with training +/- each other)</i></p>
Hagglund, P., Hagg, M., Levring Jaghagen, E. et al. (2020) Oral neuromuscular training in patients with dysphagia after stroke: a prospective, randomized, open-label study with blinded evaluators. <i>BMC Neurology</i> 20(1): 405	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Excluded from Cochrane review for errors in outcome reporting table. Only reports range for Penetration Aspiration Scale which could not be converted for mean difference.</i></p>
Haggulund, P., Jaghagen, E.L., Hagg, M. et al. (2019) Effect of a new treatment compared with conventional therapy on swallowing function among older people with dysphagia-a cluster randomised controlled trial. <i>International Journal of Stroke</i> 14(4suppl): 47	<p>- Conference abstract</p>
Hamdy, S., Dziejwas, R., Van Der Tweel, I. et al. (2019) Pharyngeal electrical stimulation for early decannulation in tracheotomised stroke patients with dysphagia (phast-trac): A randomised, single-blind, pivotal, superiority trial. <i>Dysphagia</i> 34(3): 455	<p>- Conference abstract</p>
Hamdy, S, Jilani, S, Price, V et al. (2003) Modulation of human swallowing behaviour by thermal and chemical stimulation in health and after brain injury. <i>Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society</i> 15(1): 69-77	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Swallow testing which is not an intervention included in the protocol</i></p>
Hammad, A.B., Elhamrawy, E.A., Abdel-Tawab, H. et al. (2022) Transcranial magnetic stimulation versus transcutaneous neuromuscular electrical stimulation in post stroke dysphagia: A clinical randomized controlled trial. <i>Journal of Stroke and Cerebrovascular Diseases</i> 31(8): 106554	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Only reports outcomes for the two intervention groups (rather than for those groups and the control group).</i></p>
Hegland, Karen Wheeler, Davenport, Paul W, Brandimore, Alexandra E et al. (2016) Rehabilitation of Swallowing and Cough	<p>- Study design not relevant to this review protocol</p>

Study	Code [Reason]
Functions Following Stroke: An Expiratory Muscle Strength Training Trial . Archives of physical medicine and rehabilitation 97(8): 1345-51	<i>Pre-post single arm trial</i>
Heo, S. Y.; Kim, K. M.; Immediate effects of Kinesio Taping on the movement of the hyoid bone and epiglottis during swallowing by stroke patients with dysphagia; J Phys Ther Sci; 2015; vol. 27 (no. 11); 3355-7	- Outcome data not available for this report
Hong, Zhou; Yulin, Wang; Qin, Yu; Influence of diet nursing care on the prognosis of patients with poststroke dysphagia.; Chinese Nursing Research; 2011; vol. 25 (no. 1c); 211-213	- Outcome data not available for this report
Howard, M., Block, E., Mearns, D. et al. (2022) The Effect of Sensory Versus Motor Level Electrical Stimulation in Acute Stroke Patients With Dysphagia . Archives of Physical Medicine and Rehabilitation 103(12): e148	- Comparator in study does not match that specified in this review protocol
Hsiao, M.-Y., Choo, Y.J., Liu, I.-C. et al. (2022) Effect of Repetitive Transcranial Magnetic Stimulation on Post-stroke Dysphagia: A Meta-analysis of Stimulation Frequency, Stimulation Site, and Timing of Outcome Measurement . Dysphagia	- Protocol only
Huang, J., Shi, Y., Qin, X. et al. (2020) Clinical Effects and Safety of Electroacupuncture for the Treatment of Poststroke Dysphagia: A Comprehensive Systematic Review and Meta-Analysis . Evidence-based Complementary and Alternative Medicine 2020: 1560978	- Systematic review used as source of primary studies
Huang, Kun-Ling, Liu, Ting-Yuan, Huang, Yu-Chi et al. (2014) Functional outcome in acute stroke patients with oropharyngeal Dysphagia after swallowing therapy . Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association 23(10): 2547-2553	- Data not reported in an extractable format or a format that can be analysed <i>Reports median and interquartile range values only</i>
Huang, YL; Liang, FR; Chang, HS (2008) Effect of acupuncture on quality of life in post-ischemic stroke patients with dysphagia . Zhongguo zhong xi yi jie he za zhi zhongguo zhongxiyi jiehe zazhi = chinese journal of integrated traditional and western medicine 28(6): 505-508	- Study not reported in English

Study	Code [Reason]
<p>Huang, Z, Huang, F, Yan, HX et al. (2010) Dysphagia after stroke treated with acupuncture or electric stimulation: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 30(12): 969-973</p>	<p>- Study not reported in English</p>
<p>Hwang, Na-Kyoung, Kim, Hwan-Hee, Shim, Je-Myung et al. (2019) Tongue stretching exercises improve tongue motility and oromotor function in patients with dysphagia after stroke: A preliminary randomized controlled trial. Archives of oral biology 108: 104521</p>	<p>- Reports no outcomes specified in the protocol</p>
<p>Hyland, P (2003) Easy to chew means easy to swallow -- or does it? The place of diet modification in the management of dysphagia. Asia Pacific Journal of Speech, Language & Hearing 8(2): 131-145</p>	<p>- Review article but not a systematic review</p>
<p>IRCT2013072514161N1 (2013) The effect of onset time of swallowing therapy exercises on recovery from Dysphagia in stroke patients. IRCT [www.irct.ir]</p>	<p>- Trial registry</p>
<p>Jayasekeran, V., Michou, E., Singh, S. et al. (2009) Adjunctive pharyngeal electrical stimulation in the rehabilitation of dysphagia following stroke: A randomised control trial. Gastroenterology 136(5suppl1): a777</p>	<p>- Conference abstract</p>
<p>Jayasekeran, V., Michou, E., Singh, S. et al. (2009) Pharyngeal electrical stimulation as an adjunct to rehabilitation of dysphagia following stroke : A randomised control trial. Gut 58(suppl1): a29</p>	<p>- Conference abstract</p>
<p>Jayasekeran, V., Michou, E., Singh, S. et al. (2009) Adjunctive pharyngeal electrical stimulation in the rehabilitation of dysphagia following stroke: A randomized control trial. Neurogastroenterology and Motility 21(suppl1): 61-62</p>	<p>- Conference abstract</p>
<p>Jeon, Yung Hyun; Cho, Kyun Hee; Park, Shin Jun (2020) Effects of Neuromuscular Electrical Stimulation (NMES) Plus Upper Cervical Spine Mobilization on Forward Head Posture and Swallowing Function in Stroke Patients with Dysphagia. Brain sciences 10(8)</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Spinal mobilisation was not a protocol intervention and so comparing NMES and spinal mobilisation to NMES alone does not fulfill the criteria</i></p>

Study	Code [Reason]
<p>Ji-Su, Park, Na-Kyoung, Hwang, Hwan-Hee, Kim et al. (2019) Effect of neuromuscular electrical stimulation combined with effortful swallowing using electromyographic biofeedback on oropharyngeal swallowing function in stroke patients with dysphagia: A pilot study. Medicine 98(44): 1-6</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Single arm trial comparing before and after treatment</i></p>
<p>Jia, YB; Wang, JM; Liu, XF (2009) Clinical observation on acupuncture Combined with diagnosis and treatment of swallowing miriam speech therapy post-stroke dysphagia. Journal of liaoning traditional chinese medicine 36(10): 1776-1777</p>	<p>- Study not reported in English</p>
<p>Jiang, H., Zhang, Q., Zhao, Q. et al. (2022) Manual Acupuncture or Combination of Rehabilitation Therapy to Treat Poststroke Dysphagia: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Evidence-based Complementary and Alternative Medicine 2022: 8803507</p>	<p>- Review article but not a systematic review</p>
<p>Jiang, W., Tan, Botao, Zhou, Y. et al. (2014) Clinical study on treatment of patients with dysphagia after stroke by improved Vitalstim electroacupuncture. Journal of Shanghai Jiaotong University (Medical Science) 34: 1361-1364 and 1371</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compared NMES, electroacupuncture and routine treatment to each other. Electroacupuncture and routine treatment would likely be more intense than what usual care would be.</i></p>
<p>Jin, H. P., Li, X. L., Ye, Q. J. et al. (2020) Double side head needle stimulation on cortical swallowing disorder after stroke Swallowing imaging time to learn parameters and the influence of cortical excitability. Acupuncture Research, 45(6): 473-479</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares two types of acupuncture.</i></p>
<p>Jin-liang, Li; Acupuncture used to treat dysphagia induced by ischemic stroke; Journal of Beijing University of Traditional Chinese Medicine; 2008</p>	<p>- Outcome data not available for this report</p>
<p>Jin-Woo, P., Youngsun, K., Jong-Chi, O. et al. (2009) Effortful swallow combined with electrical stimulation in post-stroke dysphagic patients. Dysphagia 24(4): 462-463</p>	<p>- Conference abstract</p>
<p>Jung, SE, Han, MA, Park, J et al. (2015) Effects of Tongue-Holding Maneuver Compared with Mendelsohn Maneuver on Swallowing Function</p>	<p>- Study not reported in English</p>

Study	Code [Reason]
in Stroke Patients . Korean j health promot 15(2): 83-90	
Kiger, M, Brown, CS, Watkins, L et al. (2006) Dysphagia management: an analysis of patient outcomes using VitalStim therapy compared to traditional swallow therapy . Dysphagia (0179051X) 21(4): 243-253	- Population not relevant to this review protocol <i>>20% of the population did not have a stroke</i>
Kim, H; Park, J-W; 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	- Study design not relevant to this review protocol <i>Single arm trial</i>
Ko, S.-H., Kim, S.-Y., Park, M. et al. (2016) Effect of tanscranial direct current stimulation for swallowing function in the stroke patients . Archives of Physical Medicine and Rehabilitation 97(10): e104	- Conference abstract
Konecny, Petr and Elfmark, Milan (2018) Electrical stimulation of hyoid muscles in post-stroke dysphagia . Biomedical papers of the Medical Faculty of the University Palacky, Olomouc, Czechoslovakia 162(1): 40-42	- Reports no outcomes specified in the protocol <i>Reported oral and pharyngeal transit time only</i>
Kotecki, S and Schmidt, R (2010) Cost and effectiveness analysis using nursing staff-prepared thickened liquids vs. commercially thickened liquids in stroke patients with dysphagia . Nursing Economic\$ 28(2): 106-113	- Comparator in study does not match that specified in this review protocol <i>Nursing staff-prepared thickened liquids compared to commercially thickened liquids, which does not fulfill the protocol criteria</i>
Koyama, Yuji, Sugimoto, Ayaka, Hamano, Takahide et al. (2017) Proposal for a Modified Jaw Opening Exercise for Dysphagia: A Randomized, Controlled Trial . The Tokai journal of experimental and clinical medicine 42(2): 71-78	- Comparator in study does not match that specified in this review protocol <i>Compares different intensities of exercises</i>
Krajczyk, Edyta, Krajczyk, Marcin, Luniewski, Jacek et al. (2019) Assessment of the effects of dysphagia therapy in patients in the early post-stroke period: a randomised controlled trial . Neurologia i neurochirurgia polska 53(6): 428-434	- Reports no outcomes specified in the protocol
Kushner, David S, Peters, Kenneth, Eroglu, Stacy Thomashaw et al. (2013) Neuromuscular electrical stimulation efficacy in acute stroke feeding tube-dependent dysphagia during	- Study design not relevant to this review protocol <i>Case control study</i>

Study	Code [Reason]
<p>inpatient rehabilitation. American journal of physical medicine & rehabilitation 92(6): 486-95</p>	
<p>Lee, Kyeong Woo, Kim, Sang Beom, Lee, Jong Hwa et al. (2019) Effects of Neuromuscular Electrical Stimulation for Masseter Muscle on Oral Dysfunction After Stroke. Annals of rehabilitation medicine 43(1): 11-18</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares two different approaches to NMES</i></p>
<p>Li, Xian-zeng; Gu, Bo-lin; Zhou, Hong; Xue, Jianting; Zhou, Xiang-ming; Influence of nape acupuncture therapy on swallowing function of patients with cerebral infarction; Medical Journal of Chinese People's Liberation Army; 2019; vol. 44; 322-326</p>	<p>- Outcome data not available for this report</p>
<p>Li, B D, Bai, J, Cui, J J et al. (2016) Clinical observation of acupuncture plus rehabilitation in treating deglutition disorders due to cerebral stroke. Shanghai journal of acupuncture and moxibustion [shang hai zhen jiu za zhi] 35(10): 1166-1169</p>	<p>- Study not reported in English</p>
<p>Li, B. (2013) Effects of repetitive transcranial magnetic stimulation and neuromuscular electrical stimulation on dysphagia in patients of unilateral hemispheric stroke. Dysphagia 28(2): 300</p>	<p>- Conference abstract</p>
<p>Li, Hailong, Li, Lin, Zhang, Rui et al. (2022) Effectiveness of repetitive transcranial magnetic stimulation on poststroke dysphagia: a meta-analysis of randomized-controlled trials. International journal of rehabilitation research. Internationale Zeitschrift fur Rehabilitationsforschung. Revue internationale de recherches de readaptation 45(2): 109-117</p>	<p>- Systematic review used as source of primary studies</p>
<p>Li, L., Shi, J., Yin, J. et al. (2014) Study of transcutaneous neuromuscular electrical stimulation (VitalStim) therapy for post-stroke dysphagia. European Journal of Physical and Rehabilitation Medicine july(23)</p>	<p>- Retracted from journal</p>
<p>Li, L., Yin, J., Shen, Y. 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(13): 37-42</p>	<p>- Full text paper not available</p>

Study	Code [Reason]
<p>Li, L, Li, Y, Huang, R et al. (2015) The value of adding transcutaneous neuromuscular electrical stimulation (VitalStim) to traditional therapy for post-stroke dysphagia: a randomized controlled trial. European Journal of Physical & Rehabilitation Medicine 51(1): 71-78</p>	<p>- Retracted from journal</p> <p><i>Retracted due to being a 'redundant article'</i></p>
<p>Li, Ling Xin and Deng, Kai (2019) Acupuncture combined with swallowing training for poststroke dysphagia: a meta-analysis of randomised controlled trials. Acupuncture in Medicine 37(2): 81-90</p>	<p>- Systematic review used as source of primary studies</p>
<p>Li, Ling-Xin; Deng, Kai; Qu, Yun (2018) Acupuncture Treatment for Post-Stroke Dysphagia: An Update Meta-Analysis of Randomized Controlled Trials. Chinese journal of integrative medicine 24(9): 686-695</p>	<p>- More recent systematic review included that covers the same topic</p>
<p>Li, Xiangwei, Jin, Linna, Gu, Chengxiao et al. (2022) Effect of Cold Fluid Compensatory Swallowing Combined with Balloon Dilatation on the Treatment of Poststroke Cricopharyngeal Achalasia: A Pilot Randomized Controlled Trial. BioMed research international 2022: 4171561</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares ice water compensatory swallowing treatment with balloon dilatation with balloon dilatation and nebulisation with dexamethasone, chymotrypsin and gentamycin which was not stated to be available to the intervention group. This appears to be greater than usual care and is not specified as a comparison in the protocol and so is excluded.</i></p>
<p>Li, Yabin, Feng, Haixia, Li, Jiao et al. (2020) The effect of transcranial direct current stimulation of pharyngeal motor cortex on swallowing function in patients with chronic dysphagia after stroke: A retrospective cohort study. Medicine 99(10): e19121</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Non-randomised study when there is sufficient randomised evidence for this comparator</i></p>
<p>Li, Yanjie, Feng, Xiaodong, Yang, Zhongjie et al. (2020) Mechanism of deglutition stage acupuncture for treating deglutition disorder after stroke. Pakistan journal of pharmaceutical sciences 33(1suppl): 307-315</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares acupuncture to other types of acupuncture</i></p>
<p>Li, Yanjie, Ren, Kun, Xing, Ruoxing et al. (2016) Clinical research of the five needles combined with rehabilitation training treatment dysphagia after stroke. Pakistan journal of pharmaceutical sciences 29(5suppl): 1745-1748</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares five key groups acupuncture to conventional acupuncture which is not a comparison listed in the protocol</i></p>

Study	Code [Reason]
<p>Li, ZH; Li, HM; Ai, NN (2021) Clinical trials of Xingnao Kaiqiao needling combined with respiratory training for post-stroke dysphagia. Zhen Ci yan jiu = acupuncture research 46(10): 875-879</p>	<p>- Study not reported in English</p>
<p>Liang, XS, Yan, LD, Zhang, Y et al. (2022) Lateral needling at Lianquan (CV 23) for post-stroke dysphagia: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 42(7): 717-720</p>	<p>- Study not reported in English</p>
<p>Liao, Xiang, Xing, Guoqiang, Guo, Zhiwei et al. (2017) Repetitive transcranial magnetic stimulation as an alternative therapy for dysphagia after stroke: a systematic review and meta-analysis. Clinical rehabilitation 31(3): 289-298</p>	<p>- Systematic review used as source of primary studies</p>
<p>Liaw, Mei-Yun, Hsu, Chia-Hao, Leong, Chau-Peng et al. (2020) Respiratory muscle training in stroke patients with respiratory muscle weakness, dysphagia, and dysarthria - a prospective randomized trial. Medicine 99(10): e19337</p>	<p>- Population not relevant to this review protocol <i>Only 60-70% of people had dysphagia</i></p>
<p>Lin, Li-Chan, Wang, Shu-Chen, Chen, Seng Hwa et al. (2003) ISSUES AND INNOVATIONS IN NURSING PRACTICE Efficacy of swallowing training for residents following stroke. Journal of Advanced Nursing (Wiley-Blackwell) 44(5): 469-478</p>	<p>- Comparator in study does not match that specified in this review protocol <i>Includes a combination of behavioural and thermal stimulation compared to no treatment. Not included in the protocol.</i></p>
<p>Lin, Li-Chan, Wang, Shu-Chen, Chen, Seng Hwa et al. (2003) Efficacy of swallowing training for residents following stroke. Journal of advanced nursing 44(5): 469-78</p>	<p>- Study design not relevant to this review protocol <i>Non-randomised study when there is sufficient randomised evidence for the comparison</i></p>
<p>Lin, Q, Li, XY, Chen, LL et al. (2022) Effect of acupuncture for dysphagia after stroke based on fiberoptic endoscopic swallowing function evaluation. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 42(5): 486-490</p>	<p>- Study not reported in English</p>
<p>Lin, Qian, Lin, Shu-Fang, Ke, Xiao-Hua et al. (2022) A Systematic Review and Meta-analysis on the Effectiveness of Transcranial Direct Current Stimulation on Swallowing Function of Poststroke Patients. American journal of physical medicine & rehabilitation 101(5): 446-453</p>	<p>- Systematic review used as source of primary studies</p>

Study	Code [Reason]
<p>Lin, Shu-Chi, Lin, Kuan-Hung, Tsai, Yi-Chi et al. (2021) Effects of a food preparation program on dietary well-being for stroke patients with dysphagia: A pilot study. Medicine 100(25): e26479</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares multiple interventions (exercise, thickener usage and recognition, hands-on food preparation) to no treatment, which is not a comparator stated in the protocol</i></p>
<p>Liu, L. (2000) Acupuncture treatment of bulbar palsy--a report of 54 cases. J Tradit Chin Med 20(1): 30-2</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares people using acupuncture to people receiving a selection of different medicines that are not available to both study arms and therefore does not appear to reflect usual care.</i></p>
<p>Liu, L, Lü, TL, Nie, LM et al. (2022) Observation on the efficacy of post-stroke dysphagia treated with He's santong acupuncture therapy through surface electromyography: a randomized controlled trial. Zhen Ci yan jiu = acupuncture research 47(3): 256-261</p>	<p>- Study not reported in English</p>
<p>Liu, Y. (2004) Treatment of pseudobulbar paralysis by scalp acupuncture and sublingual needling. J Tradit Chin Med 24(1): 26-7</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares acupuncture (scalp acupuncture and sublingual needling) with other types of acupuncture (scalp acupuncture and control needling)</i></p>
<p>Liu, Y, Lu, YQ, Zhou, FX et al. (2015) Clinical study on acupuncture treatment of dysphagia after stroke dysphagia. Liaoning journal of traditional chinese medicine [liao ning zhong yi za zhi] 42(3): 590-592</p>	<p>- Study not reported in English</p>
<p>Lo, Yu-Kuan, Fu, Tieh-Cheng, Chen, Carl P et al. (2019) Involvement of swallowing therapy is associated with improved long-term survival in patients with post-stroke dysphagia. European journal of physical and rehabilitation medicine 55(6): 728-734</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares multiple interventions (swallowing exercise, safe swallowing, diet modification) to no treatment, which is not a comparison in the protocol.</i></p>
<p>Long, Yao-Bin and Wu, Xiao-Ping (2012) A meta-analysis of the efficacy of acupuncture in treating dysphagia in patients with a stroke. Acupuncture in medicine : journal of the British Medical Acupuncture Society 30(4): 291-7</p>	<p>- Systematic review used as source of primary studies</p>
<p>Lu, Yanyan, Chen, Ying, Huang, Dongting et al. (2021) Efficacy of acupuncture for dysphagia</p>	<p>- Systematic review used as source of primary studies</p>

Study	Code [Reason]
after stroke: a systematic review and meta-analysis. Annals of palliative medicine 10(3): 3410-3422	
Lu, Ying, Zhou, Wangyang, Lin, Yachen et al. (2021) The effects of traditional Chinese medicine sensory stimulation combined with transcranial direct current stimulation on deglutition and related complications in stroke patients with dysphagia: a randomized trial. Annals of palliative medicine 10(6): 6597-6605	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Traditional Chinese Medicine is not a protocol intervention</i></p>
Ma, FX; Cao, GP; Li, WL (2014) Post-stroke dysphagia treated with acupoint injection combined with neural electrical stimulation. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 34(12): 1169-1173	<p>- Study not reported in English</p>
Ma, FX, Chen, L, Cao, GP et al. (2022) Acupoint injection combined with Vitalstim electrical stimulation for post-stroke dysphagia: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 42(2): 133-136	<p>- Study not reported in English</p>
Ma, JN, Wang, ZL, Ning, LN et al. (2015) Observation on Therapeutic Effects of Acupuncture Combined with Cutaneous Electrical Stimulation for Dysphagia in Patients with Cerebral Infarction. Zhen Ci yan jiu = acupuncture research 40(3): 238-241	<p>- Study not reported in English</p>
Ma, P, Xu, S, Tian, W et al. (2016) Efficacy observation of post-stroke pseudo-bulbar palsy treated with quick needle insertion therapy at Aqiang point. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 36(10): 1027-1030	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares acupuncture to another type of acupuncture</i></p>
<p>Malik, Sumera; Khan, Muhammad; Ehsaan, Fazaila; Ain, Qurrat Ul; Effectiveness of swallow maneuvers, thermal stimulation and combination both in treatment of patients with dysphagia using functional outcome swallowing scale; Biomed Res- India; 2017; vol. 28; 1479-1482</p>	<p>- Outcome data not available for this report</p>
Mann, G., Hankey, G., Davis, B. et al. (1999) Swallowing therapy after acute stroke study (STAASS): where are we now?. Journal of clinical neuroscience 6(3): 281	<p>- Conference abstract</p>

Study	Code [Reason]
<p>Mao, Li-Ya, Li, Li-Li, Mao, Zhong-Nan et al. (2016) Therapeutic effect of acupuncture combining standard swallowing training for post-stroke dysphagia: A prospective cohort study. Chinese journal of integrative medicine 22(7): 525-31</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Prospective cohort study while there is sufficient randomised evidence for this comparison.</i></p>
<p>Marchina, Sarah, Piseгна, Jessica M, Massaro, Joseph M et al. (2021) Transcranial direct current stimulation for post-stroke dysphagia: a systematic review and meta-analysis of randomized controlled trials. Journal of neurology 268(1): 293-304</p>	<p>- Systematic review used as source of primary studies</p>
<p>Meisel, Andreas and Smith, Craig J. (2015) Stroke: Preventive antibiotics for stroke-associated pneumonia. Nature Reviews Neurology 11(12): 672-673</p>	<p>- Commentary only</p>
<p>Meng, Y, Wang, C, Shang, S et al. (2015) Effects of different acupuncture depths of Lianquan (CV 23) for dysphagia after stroke: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 35(10): 990-994</p>	<p>- Study not reported in English</p>
<p>Mepani, R., Antonik, S., Massey, B. et al. (2009) Augmentation of deglutitive thyrohyoid muscle shortening by the shaker exercise. Dysphagia 24(1): 26-31</p>	<p>- Population not relevant to this review protocol</p> <p><i>Includes people with cancer and people after stroke.</i></p>
<p>Michou, E., Mistry, S., Jefferson, S. et al. (2010) Addressing oropharyngeal dysphagia post stroke with neurostimulation interventions: A pilot study. International Journal of Stroke 5(suppl3): 61-62</p>	<p>- Conference abstract</p>
<p>Miller, Simone, Diers, Daniela, Jungheim, Michael et al. (2021) Studying effects of neuromuscular electrostimulation therapy in patients with dysphagia: which pitfalls may occur? A translational phase I study. German medical science : GMS e-journal 19: doc07</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Outcomes reported as individual investigator assessments that is not usable in the analysis</i></p>
<p>Miller, Simone; Peters, Katharina; Ptok, Martin (2022) Review of the effectiveness of neuromuscular electrical stimulation in the treatment of dysphagia - an update. German medical science : GMS e-journal 20: doc08</p>	<p>- Systematic review used as source of primary studies</p>

Study	Code [Reason]
<p>Momosaki, Ryo, Abo, Masahiro, Watanabe, Shu et al. (2014) Functional magnetic stimulation using a parabolic coil for dysphagia after stroke. <i>Neuromodulation : journal of the International Neuromodulation Society</i> 17(7): 637-641</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Functional magnetic stimulation (not transcranial magnetic stimulation)</i></p>
<p>Moon, J.-H.; Heo, S.-J.; Jung, J.-H. (2019) Effects of orofacial muscles exercise program on swallowing function and satisfaction in sub-acute stroke patients with dysphagia. <i>Medico-Legal Update</i> 19(1): 623-628</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Included in the Cochrane review. Compares orofacial exercises instructed from a video to the same exercises instructed by a leaflet. For the purposes of this protocol this is comparing the same intervention (both behavioural interventions).</i></p>
<p>Murray, J (2010) Managing swallowing in stroke patients - free water versus thickened fluids.</p>	<p>- Trial registry</p>
<p>Murray, J., Doeltgen, S., Miller, M. et al. (2015) Does access to water improve the hydration of patients with dysphagia post-stroke?. <i>International Journal of Stroke</i> 10(suppl3): 30-31</p>	<p>- Conference abstract</p>
<p>Oh, Dong-Hwan, Park, Ji-Su, Kim, Hee-Jeong et al. (2020) The effect of neuromuscular electrical stimulation with different electrode positions on swallowing in stroke patients with oropharyngeal dysphagia: A randomized trial. <i>Journal of back and musculoskeletal rehabilitation</i> 33(4): 637-644</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Comparisons of different NMES positions rather than different interventions</i></p>
<p>Park, E., Cho, J.Y., Kim, M.S. et al. (2016) Bilateral repetitive transcranial magnetic stimulation on dysphagia in patients with subacute stroke. <i>Cerebrovascular Diseases</i> 41(suppl1): 19</p>	<p>- Conference abstract</p>
<p>Park, Eunhee, Kim, Min Su, Chang, Won Hyuk et al. (2017) Effects of Bilateral Repetitive Transcranial Magnetic Stimulation on Post-Stroke Dysphagia. <i>Brain stimulation</i> 10(1): 75-82</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Data reported in graphs without clear indication of the relevant values.</i></p>
<p>Park, J.-W. (2013) The effect of 5 HZ high-frequency repetitive transcranial magnetic stimulation on contra-lesional swallowing motor cortex in post-stroke dysphagic patients: A randomized controlled study. <i>Dysphagia</i> 28(2): 299-300</p>	<p>- Conference abstract</p>

Study	Code [Reason]
<p>Park, Ji-Su, An, Duk-Hyun, Kam, Kyung-Yoon et al. (2020) Effects of resistive jaw opening exercise in stroke patients with dysphagia: A double-blind, randomized controlled study. Journal of back and musculoskeletal rehabilitation 33(3): 507-513</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Uses a device that is not stated in the protocol for this review</i></p>
<p>Park, Ji-Su and Hwang, Na-Kyoung (2021) Chin tuck against resistance exercise for dysphagia rehabilitation: A systematic review. Journal of oral rehabilitation 48(8): 968-977</p>	<p>- Systematic review used as source of primary studies</p>
<p>Park, Ji-Su; Lee, Gihyoun; Jung, Young-Jin (2019) Effects of game-based chin tuck against resistance exercise vs head-lift exercise in patients with dysphagia after stroke: An assessor-blind, randomized controlled trial. Journal of rehabilitation medicine 51(10): 749-754</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Comparing different types of exercise which is not specified as a comparison in the protocol</i></p>
<p>Pelczarska, Aleksandra; Jakubczyk, Michał; Niewada, Maciej (2020) The cost-effectiveness of food consistency modification with xanthan gum-based Nutilis Clear® in patients with post-stroke dysphagia in Poland. BMC Health Services Research 20(1): 1-9</p>	<p>- Cost-effectiveness evidence only</p> <p><i>Uses clinical effectiveness data from other studies that do not necessarily include people after stroke</i></p>
<p>Permsirivanich, Wutichai, Tipchatyotin, Suttipong, Wongchai, Manit 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 = Chotmaihet thangphaet 92(2): 259-65</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares a combination of therapies (physical stimulation, behavioural) to another active treatment (NMES), which is not a comparison included in the protocol</i></p>
<p>Pingue, Valeria, Priori, Alberto, Malovini, Alberto et al. (2018) Dual Transcranial Direct Current Stimulation for Poststroke Dysphagia: A Randomized Controlled Trial. Neurorehabilitation and neural repair 32(67): 635-644</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Medians and interquartile ranges or responder analyses</i></p>
<p>Pisegna, Jessica M, Kaneoka, Asako, Pearson, William G Jr et al. (2016) Effects of non-invasive brain stimulation on post-stroke dysphagia: A systematic review and meta-analysis of randomized controlled trials. Clinical neurophysiology : official journal of the International Federation of Clinical Neurophysiology 127(1): 956-968</p>	<p>- Systematic review used as source of primary studies</p>

Study	Code [Reason]
<p>Ploumis, Avraam; Papadopoulou, Soutana L; Theodorou, Stavroula J; Exarchakos, George; Givissis, Panagiotis; Beris, Alexander; Cervical isometric exercises improve dysphagia and cervical spine malalignment following stroke with hemiparesis: a randomized controlled trial.; European journal of physical and rehabilitation medicine; 2018; vol. 54 (no. 6); 845-852</p>	<p>- Outcome data not available for this report</p>
<p>Pooyania, S., Galimova, L., Buchel, C. et al. (2013) Effects of a free water protocol on inpatients in a neurological rehabilitation setting. Stroke 44(12): e220-e221</p>	<p>- Conference abstract</p>
<p>Power, Maxine L, Fraser, Christopher H, Hobson, Anthony et al. (2006) Evaluating oral stimulation as a treatment for dysphagia after stroke. Dysphagia 21(1): 49-55</p>	<p>- Study design not relevant to this review protocol <i>Before-after study</i></p>
<p>Pownall, Sue and Taylor, Carolyn (2017) Use of thickening agents and nutritional supplements for patients with dysphagia following stroke. British Journal of Neuroscience Nursing 13(6): 260-268</p>	<p>- Review article but not a systematic review</p>
<p>Qi, YJ, Pan, QY, Wang, WY et al. (2021) Effect of nape cluster acupuncture on swallowing function and respiratory function in patients with post-stroke dysphagia. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 41(12): 1303-1307</p>	<p>- Study not reported in English</p>
<p>Qian, Surong, Zhang, Xiaomin, Wang, Tong et al. (2022) Effects of Comprehensive Swallowing Intervention on Obstructive Sleep Apnea and Dysphagia After Stroke: A Randomized Controlled Trial. Journal of Stroke & Cerebrovascular Diseases 31(8): npag-npag</p>	<p>- Comparator in study does not match that specified in this review protocol <i>Compares a combination of NMES and behavioural techniques to usual care. Not included in the protocol.</i></p>
<p>Qin, L, Zhang, XP, Yang, XC et al. (2019) Deep acupuncture of Lianquan (CV23) and Yifeng (TE17) in combination with conventional acupuncture of other acupoints is superior to swallowing rehabilitation training in improving post-stroke dysphagia in apoplexy patients. Zhen CI yan jiu = acupuncture research 44(2): 144-147</p>	<p>- Study not reported in English</p>
<p>Rao, Jinzhu, Li, Fang, Zhong, Lida et al. (2022) Bilateral Cerebellar Intermittent Theta Burst Stimulation Combined With Swallowing Speech Therapy for Dysphagia After Stroke: A</p>	<p>- Study does not contain an intervention relevant to this review protocol</p>

Study	Code [Reason]
Randomized, Double-Blind, Sham-Controlled, Clinical Trial. Neurorehabilitation and neural repair: 15459683221092995	<i>Bilateral cerebellar intermittent theta burst stimulation</i>
Rofes, L., Arreola, V., Lopez, I. et al. (2013) Sensory transcutaneous electrical stimulation improves safety of swallow in post-stroke dysphagic patients. Dysphagia 28(4): 610	- Conference abstract
Roffe, C., Bath, P., Warusevitane, A. et al. (2021) The metoclopramide for avoiding pneumonia after stroke (MAPS-2) trial: A single-blind RCT of metoclopramide for the prevention of pneumonia in patients with dysphagia after stroke. International Journal of Stroke 16(3suppl): 31	- Conference abstract
Roffe, C, Jeans, A, Warusevitane, A et al. (2016) The Metoclopramide and selective oral decontamination for Avoiding Pneumonia after Stroke (MAPS-2) Trial: a 2x2 double-blind, randomized controlled trial of metoclopramide and selective oral decontamination for the prevention of pneumonia in patients with dysphagia after an acute stroke.	- Full text paper not available <i>Health technology assessment - statement about the project only</i>
Rosenbek, J C, Robbins, J, Fishback, B et al. (1991) Effects of thermal application on dysphagia after stroke. Journal of speech and hearing research 34(6): 1257-68	- Study design not relevant to this review protocol <i>Crossover trial for people in the acute/subacute phase after stroke</i>
Rosenbek, J.C., Roecker, E.B., Wood, J.L. et al. (1996) Thermal application reduces the duration of stage transition in dysphagia after stroke. Dysphagia 11(4): 225-233	- Study design not relevant to this review protocol <i>Crossover study including people after acute/subacute stroke and does not report the different treatment arms separately</i>
Salle, J.-Y., Tchalla, A., Thirion, R. et al. (2021) Efficacy of a Ready-to-Drink Gelled Water and of a Thickening Powder in Patients with Oropharyngeal Dysphagia: a Crossover Randomized Study. SN Comprehensive Clinical Medicine 3(11): 2244-2250	- Comparator in study does not match that specified in this review protocol <i>Compares two different types of thickened fluid solutions</i>
Scutt, P., Lee, H.S., Hamdy, S. et al. (2015) Pharyngeal Electrical Stimulation for Treatment of Poststroke Dysphagia: Individual Patient Data Meta-Analysis of Randomised Controlled Trials. Stroke Research and Treatment 2015: 429053	- Systematic review used as source of primary studies <i>IPD analysis including some but not all of the studies included in the review. Analysis not possible to unpick therefore, used as a source of reference checking instead.</i>

Study	Code [Reason]
Shao, WB; Wang, Y; Jiang, WW; Tian, L; Zhang, J; Clinical study of columnar balloon dilatation therapy for severe dysphagia caused by upper esophageal sphincter achalasia after stroke; Chinese journal of contemporary neurology and neurosurgery; 2017; vol. 17 (no. 3); 185-191	- Outcome data not available for this report
Shimazu, Sayuri, Yoshimura, Yoshihiro, Kudo, Mai et al. (2021) Frequent and personalized nutritional support leads to improved nutritional status, activities of daily living, and dysphagia after stroke. Nutrition (Burbank, Los Angeles County, Calif.) 83: 111091	- Comparator in study does not match that specified in this review protocol <i>Compares different intensities of diet prescribing</i>
Smaoui, Sana; Langridge, Amy; Steele, Catriona M. (2020) The Effect of Lingual Resistance Training Interventions on Adult Swallow Function: A Systematic Review. Dysphagia 35(5): 745-761	- Systematic review used as source of primary studies
Smithard, D.; Perez, I.; Kalra, L. (1997) Pharmacological Treatment of Dysphagia in Stroke. Age and Ageing 26(suppl1): P40-b	- Duplicate reference
Song, Manping; Liu, Lanlan; Wu, Weiwei; Xian, Donglian; Feng, B.; A comparative study on the clinical efficacy of swallowing function training with and without acupuncture in the treatment of dysphagia after cerebral infarction; 2020	- Outcome data not available for this report
Sproson, L., Pownall, S., Enderby, P. et al. (2015) Randomised control pilot trial evaluating the ampcare esp (effective swallowing programme) for treatment of persistent dysphagia post stroke. Dysphagia 30(5): 658	- Conference abstract
Sproson, L., Pownall, S., Enderby, P. et al. (2014) Pilot RCT evaluating a new approach to neuromuscular stimulation to treat dysphagia post stroke. International Journal of Stroke 9(suppl4): 22	- Conference abstract
Sproson, L., Pownall, S., Enderby, P. et al. (2015) Randomised control pilot trial evaluating the ampcare ESP (Effective swallowing programme) for treatment of dysphagia post stroke. Dysphagia 30(2): 263-264	- Conference abstract
Sproson, Lise; Pownall, Sue; Enderby, Pam; Freeman, Jenny; Combined electrical	- Outcome data not available for this report

Study	Code [Reason]
stimulation and exercise for swallow rehabilitation post-stroke: a pilot randomized control trial.; International journal of language & communication disorders; 2018; vol. 53 (no. 2); 405-417	
Steele, C.M., Alsanei, W.A., Ayanikalath, S. et al. (2015) The Influence of Food Texture and Liquid Consistency Modification on Swallowing Physiology and Function: A Systematic Review. <i>Dysphagia</i> 30(1): 2-26	- Population not relevant to this review protocol <i>Includes people who do not have stroke (including healthy people, people with other reasons for dysphagia)</i>
Sun, D, Xu, W, Chen, N et al. (2018) Clinical Effectiveness of Intradermal Needle-embedding Therapy for Swallowing Function in Stroke Patients with Dysphagia. <i>Zhen CI yan jiu = acupuncture research</i> 43(2): 118-122	- Study not reported in English
Sun, Shu-Fen, Hsu, Chien-Wei, Lin, Huey-Shyan et al. (2013) Combined neuromuscular electrical stimulation (NMES) with fiberoptic endoscopic evaluation of swallowing (FEES) and traditional swallowing rehabilitation in the treatment of stroke-related dysphagia. <i>Dysphagia</i> 28(4): 557-66	- Study design not relevant to this review protocol <i>Single arm study</i>
Suntrup, S., Marian, T., Schroder, J. et al. (2015) Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients. <i>Dysphagia</i> 30(5): 603	- Conference abstract
Suntrup, S., Marian, T., Schroder, J. et al. (2016) Enhancing dyphagia rehabilitation in tracheotomized stroke patients with electrical pharyngeal stimulation. <i>Dysphagia</i> 31(2): 267	- Conference abstract
Suntrup-Kruger, S., Ringmaier, C., Muhle, P. et al. (2017) Randomized controlled trial of TDCS for the treatment of poststroke dysphagia. <i>Dysphagia</i> 32(1): 170	- Conference abstract
Tai, S-H; Chang, Y-H; hang, L-C (2014) On the use of the chin-down posture for dysphagia in stroke patients. <i>Cerebrovascular diseases (Basel, Switzerland)</i> 38(suppl1): 105	- Conference abstract
Takahata, Hideaki, Tsutsumi, Keisuke, Baba, Hiroshi et al. (2011) Early intervention to promote oral feeding in patients with intracerebral hemorrhage: a retrospective cohort study. <i>BMC neurology</i> 11: 6	- Comparator in study does not match that specified in this review protocol <i>Comparing early intense intervention with less intense intervention that contain similar components</i>

Study	Code [Reason]
<p>Tan, Z., Wei, X., Tan, C. et al. (2022) Effect of neuromuscular electrical stimulation combined with swallowing rehabilitation training on the treatment efficacy and life quality of stroke patients with dysphagia. American Journal of Translational Research 14(2): 1258-1267</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Retrospective cohort study when there is sufficient randomised evidence for this comparison</i></p>
<p>Tang, Qiang, Liang, Biying, Liang, Runyu et al. (2021) Study on optimization and evaluation system of traditional Chinese medicine rehabilitation program for swallowing disorder after stroke. Medicine 100(19): e25731</p>	<p>- Protocol only</p>
<p>Tarameshlu, Maryam, Ansari, Nouredin N, Ghelichi, Leila et al. (2019) The effect of repetitive transcranial magnetic stimulation combined with traditional dysphagia therapy on poststroke dysphagia: a pilot double-blinded randomized-controlled trial. International journal of rehabilitation research. Internationale Zeitschrift fur Rehabilitationsforschung. Revue internationale de recherches de readaptation 42(2): 133-138</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Reports median and interquartile range values only</i></p>
<p>Terre, R and Mearin, F (2015) A randomized controlled study of neuromuscular electrical stimulation in oropharyngeal dysphagia secondary to acquired brain injury. European journal of neurology 22(4): 687-e44</p>	<p>- Population not relevant to this review protocol</p> <p><i>>20% of the population had a traumatic brain injury rather than a stroke.</i></p>
<p>Tiemi Mituuti, Cláudia, Alves da Silva Arone, Marcela Maria, Rodrigues Rosa, Raquel et al. (2018) Effects of Sensory Neuromuscular Electrical Stimulation on Swallowing in the Elderly Affected by Stroke: A Pilot Study. Topics in Geriatric Rehabilitation 34(1): 71-81</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Single arm trial comparing before and after treatment</i></p>
<p>Tomsen, N., Guanyabens Busca, N., Ortega, O. et al. (2022) A RANDOMIZED CLINICAL TRIAL ON THE EFFECT OF TWO WEEKS OF TREATMENT WITH CAPSAICIN IN OLDER PATIENTS WITH OROPHARYNGEAL DYSPHAGIA. United European Gastroenterology Journal 10(supplement8): 265</p>	<p>- Conference abstract</p>
<p>Unluer, Temucin, C., Demir, N. et al. (2018) The effects of 1Hz low frequency transcranial magnetic stimulation on swallowing function in post-stroke dysphagia. Dysphagia 33(4): 492</p>	<p>- Conference abstract</p>
<p>Vasant, D.H., Michou, E., Tyrrell, P. et al. (2014) Pharyngeal electrical stimulation (PES)</p>	<p>- Conference abstract</p>

Study	Code [Reason]
expedites swallowing recovery in dysphagia post-acute stroke: A phase II double-blinded randomised controlled trial. Gastroenterology 146(5suppl1): 77	
Vasant, Dipesh H, Michou, Emilia, O'Leary, Neil et al. (2016) Pharyngeal Electrical Stimulation in Dysphagia Poststroke: A Prospective, Randomized Single-Blinded Interventional Study. Neurorehabilitation and neural repair 30(9): 866-75	- Duplicate reference
Vilardell, N, Rofes, L, Arreola, V et al. (2016) A Comparative Study Between Modified Starch and Xanthan Gum Thickeners in Post-Stroke Oropharyngeal Dysphagia. Dysphagia 31(2): 169-79	- Comparator in study does not match that specified in this review protocol <i>Compares two different types of thickener to each other</i>
Wang, Li'na; Gu, Changwei; Jing, Xiao'na (2015) Application of remote nursing intervention for discharged stroke patients with dysphagia. Chinese Nursing Research 29(12c): 4509-4512	- Study not reported in English
Wang, Ling-shu; Zhao, Hui-yi; Zhang, Yu; Li李冠男, Guan-nan; Combination of acupuncture with rehabilitation training for pseudobulbar paralysis after stroke:A randomized controlled trial 吞咽五穴联合康复训练 治疗脑卒中后假性延髓麻痹：随机对照试验; World Journal of Acupuncture - Moxibustion; 2021; vol. 31 (no. 3); 202-206	- Outcome data not available for this report
Wang, Q; Clinical study on Tong Guan Li Qiao needling method for post-stroke deglutition disorders; Shanghai journal of acupuncture and moxibustion [shang hai zhen jiu za zhi]; 2015; vol. 34 (no. 8); 721-723	- Outcome data not available for this report
Wang, Tong, Dong, Linghui, Cong, Xiaomeng et al. (2021) Comparative efficacy of non-invasive neurostimulation therapies for poststroke dysphagia: A systematic review and meta-analysis. Neurophysiologie clinique = Clinical neurophysiology 51(6): 493-506	- Systematic review used as source of primary studies
Wang, W, Jia, Y, Cai, H et al. (2020) Functional patch combined with surface electromyographic biofeedback for post-stroke dysphagia. Chinese journal of tissue engineering research 24(29): 4697-4701	- Study not reported in English

Study	Code [Reason]
<p>Wang, Y., He, Y., Jiang, L. et al. (2022) Effect of transcutaneous auricular vagus nerve stimulation on post-stroke dysphagia. Journal of Neurology</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Vagus nerve stimulator which is not included in the protocol</i></p>
<p>Wang, Zhuo, Wang, Zhi, Fang, Qi et al. (2019) Effect of Expiratory Muscle Strength Training on Swallowing and Cough Functions in Patients With Neurological Diseases: A Meta-analysis. American Journal of Physical Medicine & Rehabilitation 98(12): 1060-1066</p>	<p>- Systematic review used as source of primary studies</p>
<p>Warusevitane, A (2014) Does metoclopramide reduce aspiration, pneumonia and hypoxia in acute stroke patients who are fed by nasogastric tubes.</p>	<p>- Trial registry</p>
<p>Warusevitane, A.B., Karunatilake, D.S., Lally, F. et al. (2012) Does metoclopramide reduce pneumonia in acute stroke patients on nasogastric feeds?. International Journal of Stroke 7(suppl2): 10</p>	<p>- Conference abstract</p>
<p>Warusevitane, A.B.; Karunatilake, D.S.; Roffe, C. (2013) Effect of metoclopramide on survival, aspiration, hypoxia and pneumonia in acute stroke patients fed via nasogastric tubes. Cerebrovascular Diseases 35(suppl3): 13-14</p>	<p>- Conference abstract</p>
<p>Wei, L-L (2005) Effect of Shuitu acupoint injection with stellate ganglion block on swallow dysfunction after stroke. Chinese journal of clinical rehabilitation 9(9): 106-107</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares acupuncture with usual care, which may include acupuncture.</i></p>
<p>Wen, X., Liu, Z., Zhong, L. et al. (2022) The Effectiveness of Repetitive Transcranial Magnetic Stimulation for Post-stroke Dysphagia: A Systematic Review and Meta-Analysis. Frontiers in Human Neuroscience 16: 841781</p>	<p>- Systematic review used as source of primary studies</p>
<p>Wenguang, Xia; Chanjuan, Zheng; Sui-qiang, Zhu; Combination of feeding-swallowing training and acupuncture: an effective rehabilitation method for dysphagia post stroke; Huazhong Journal of Huazhong University of Science and Technology,; 2010; vol. 39 (no. 5); 614-9</p>	<p>- Outcome data not available for this report</p>
<p>Wilkinson, G., Benfield, J. K., Everton, L. F. et al. (2022) Swallowing therapy for dysphagia in acute and subacute stroke.</p>	<p>- Unpublished material that was not included in the review.</p>

Study	Code [Reason]
<p>Woodhouse, L.J., England, T., Everton, L. et al. (2022) DOES PHARYNGEAL ELECTRICAL STIMULATION IMPROVE SWALLOWING IN ACUTE STROKE DYSPHAGIA? THE PHEAST TRIAL. European Stroke Journal 7(1suppl): 147</p>	<p>- Conference abstract</p>
<p>Woodhouse, Lisa J, Scutt, Polly, Hamdy, Shaheen et al. (2018) Route of Feeding as a Proxy for Dysphagia After Stroke and the Effect of Transdermal Glyceryl Trinitrate: Data from the Efficacy of Nitric Oxide in Stroke Randomised Controlled Trial. Translational stroke research 9(2): 120-129</p>	<p>- Comparator in study does not match that specified in this review protocol</p> <p><i>Compares people receiving oral feeding/fluids and non-oral feeding/fluids</i></p>
<p>WU, W.-B., FAN, D.-F., ZHENG, C. et al. (2019) Relieving throat and opening orifice acupuncture therapy for the post-stroke dysphagia. World Journal of Acupuncture - Moxibustion 29(1): 37-41</p>	<p>- Data not reported in an extractable format or a format that can be analysed</p> <p><i>Only reports responder criteria</i></p>
<p>Wu, WB, Fan, DF, Que, BF et al. (2020) Clinical effect of Liyan Tongqiao acupuncture in treatment of post-stroke dysphagia: an analysis based on diffusion tensor imaging. Zhen CI yan jiu = acupuncture research 45(12): 985-989</p>	<p>- Study not reported in English</p>
<p>Xia, W, Zheng, C, Xia, J et al. (2016) Post-stroke dysphagia treated with acupuncture of meridian differentiation: a randomized controlled trial. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 36(7): 673-678</p>	<p>- Study not reported in English</p>
<p>Xie, Y.-L., Wang, S., Jia, J.-M. et al. (2022) Transcranial Magnetic Stimulation for Improving Dysphagia After Stroke: A Meta-Analysis of Randomized Controlled Trials. Frontiers in Neuroscience 16: 854219</p>	<p>- Systematic review used as source of primary studies</p>
<p>Xie, Y; Liu, H; Zhou, W (2011) Effect of acupuncture on dysphagia of convalescent stroke patients. Zhongguo zhong xi yi jie he za zhi zhongguo zhongxiyi jiehe zazhi = chinese journal of integrated traditional and western medicine 31(6): 736-740</p>	<p>- Study not reported in English</p>
<p>Xie, Yue, Wang, Liping, He, Jinghua et al. (2008) Acupuncture for dysphagia in acute stroke. The Cochrane database of systematic reviews: cd006076</p>	<p>- More recent systematic review included that covers the same topic</p>

Study	Code [Reason]
Xing, BF; Zhou, X; Deng, XQ; Effect of "Tongdu Tiaoshen" needling combined with swallowing training on dysphagia, cerebral blood flow and serum BDNF and NGF levels in ischemic stroke patients; Zhen Ci yan jiu = acupuncture research; 2019; vol. 44 (no. 7); 506-511	- Outcome data not available for this report
Yang, Seung Nam, Pyun, Sung-Bom, Kim, Hyun Jung et al. (2015) Effectiveness of Non-invasive Brain Stimulation in Dysphagia Subsequent to Stroke: A Systemic Review and Meta-analysis. Dysphagia 30(4): 383-91	- Systematic review used as source of primary studies
Yang, W., Cao, X., Zhang, X. et al. (2021) The Effect of Repetitive Transcranial Magnetic Stimulation on Dysphagia After Stroke: A Systematic Review and Meta-Analysis. Frontiers in Neuroscience 15: 769848	- Systematic review used as source of primary studies
Ye, Q, Xie, Y, Shi, J et al. (2017) Systematic review on acupuncture for treatment of dysphagia after stroke. Evidence-Based Complementary and Alternative Medicine 2017: 6421852	- Systematic review used as source of primary studies
Yi, Wu; Wang, L.; Tuo, M.; Clinical study on acupuncture kinesitherapy treatment for dysphagia caused by pseudobulbar paralysis after stroke; Chinese Journal of Rehabilitation Medicine; 2013; vol. 28; 739-742+757	- Outcome data not available for this report
Yu-Lei, Xie, Shan, Wang, Ju, Yang et al. (2022) Theta burst stimulation versus high-frequency repetitive transcranial magnetic stimulation for poststroke dysphagia: A randomized, double-blind, controlled trial. Medicine 101(2): e28576	- Comparator in study does not match that specified in this review protocol <i>Comparing two types of transcranial magnetic stimulation</i>
Yuan, Y, Cai, XH, Chen, F et al. (2019) Clinical trials of acupuncture treatment of post-stroke dysphagia by deep acupuncture of Tiantu (CV22) in combination with swallowing rehabilitation training. Zhen Ci yan jiu = acupuncture research 44(1): 47-50	- Study not reported in English
Yue, G. R.; Liu, D. P.; Zhou, H. F. (2009) Clinical observations on acupuncture plus rehabilitation training for improving postapoplectic dysphagia. Shanghai journal of acupuncture and moxibustion 28(7): 388-389	- Study not reported in English

Study	Code [Reason]
<p>Zeng, Yanfang; Yip, James; Cui, Hongli; Guan, Longfei; Zhu, Haomeng; Zhang, Weidong; Du, Huishan; Geng, Xiaokun; Efficacy of neuromuscular electrical stimulation in improving the negative psychological state in patients with cerebral infarction and dysphagia.; Neurological research; 2018; vol. 40 (no. 6); 473-479</p>	<p>- Outcome data not available for this report</p>
<p>Zhang, CX; Huang, Y; Xie, XN; Zeng, KX; Wang, X; Zheng, FR; Analysis of Huoshe Liyan Decoction on treatment of 198 cases of stroke patients with dysphagia; Liaoning journal of traditional chinese medicine [liaoning zhong yi za zhi]; 2015; vol. 42 (no. 8); 1436-1438</p>	<p>- Outcome data not available for this report</p>
<p>Zhang, Ming; Tao, Tao; Zhang, Zhao-Bo; Zhu, Xiao; Fan, Wen-Guo; Pu, Li-Jun; Chu, Lei; Yue, Shou-Wei; Effectiveness of Neuromuscular Electrical Stimulation on Patients With Dysphagia With Medullary Infarction.; Archives of physical medicine and rehabilitation; 2016; vol. 97 (no. 3); 355-62</p>	<p>- Outcome data not available for this report</p>
<p>Zhang, C.-H., Bian, J.-L., Meng, Z.-H. et al. (2016) Tongguan Liqiao acupuncture therapy improves dysphagia after brainstem stroke. Neural Regeneration Research 11(2): 285-291</p>	<p>- Comparator in study does not match that specified in this review protocol <i>Compares people with stroke in different brain regions</i></p>
<p>Zhang, Chengliang, Zheng, Xiuqin, Lu, Rulan et al. (2019) Repetitive transcranial magnetic stimulation in combination with neuromuscular electrical stimulation for treatment of post-stroke dysphagia. The Journal of international medical research 47(2): 662-672</p>	<p>- Data not reported in an extractable format or a format that can be analysed <i>Outcomes reported as P values or F values only</i></p>
<p>Zhang, L, Xu, N, Li, R et al. (2018) Clinical study of electroacupuncture with different frequencies at Lianquan (CV 23) and Fengfu (GV 16) for stroke dysphagia. Zhongguo zhen jiu [Chinese acupuncture & moxibustion] 38(2): 115-119</p>	<p>- Study not reported in English</p>
<p>Zhang, R. and Ju, X.-M. (2018) Clinical improvement of nursing intervention in swallowing dysfunction of elderly stroke patients. Biomedical Research (India) 29(6): 1099-1102</p>	<p>- Study does not contain an intervention relevant to this review protocol <i>Intervention includes a combination of communication exercises, swallowing exercises, psychological advice, health education and a diet interventions. The combination of these is not applicable to the protocol for this review.</i></p>

Study	Code [Reason]
<p>Zhang, SY, Liu, SB, Wu, W et al. (2017) Clinical Trials for Treatment of Stroke Patients with Dysphagia by Vitalstim Electroacupuncture Combined with Swallowing Rehabilitation Training. Zhen Ci yan jiu = acupuncture research 42(2): 168-172</p>	<p>- Study not reported in English</p>
<p>Zhang, Yao-Wen, Dou, Zu-Lin, Zhao, Fei et al. (2022) Neuromuscular electrical stimulation improves swallowing initiation in patients with post-stroke dysphagia. Frontiers in neuroscience 16: 1011824</p>	<p>- Study design not relevant to this review protocol</p> <p><i>Crossover study while the population in the study was in the subacute period after a stroke</i></p>
<p>Zhao, Jingjing, Yuan, Fang, Song, Changgeng et al. (2022) Safety and efficacy of three enteral feeding strategies in patients with severe stroke in China (OPENS): a multicentre, prospective, randomised, open-label, blinded-endpoint trial. The Lancet. Neurology 21(4): 319-328</p>	<p>- Population not relevant to this review protocol</p> <p><i>People receiving enteral feeding rather than oral feeding</i></p>
<p>Zhao, Na, Sun, Weiming, Xiao, Zebu et al. (2022) Effects of Transcranial Direct Current Stimulation on Poststroke Dysphagia: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Archives of Physical Medicine & Rehabilitation 103(7): 1436-1447</p>	<p>- Systematic review used as source of primary studies</p>
<p>Zhao, W., Ju, C., Wang, D. et al. (2019) Clinical observation of effects of ultrashort wave therapy combined with acupuncture and rehabilitation training in the treatment of patients with dysphagia after stroke. Journal of Neurorestoratology 7(3): 136-142</p>	<p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Intervention including ultrashort wave therapy which was not an intervention stated in the protocol for the review</i></p>
<p>Zhi-zhong, Z. H. U.; Li-ling, C. U. I.; Miao-miao, Y. I. N.; Yang, Y. U.; Hong-tu, Wang; Effects of swallowing training combined with low-frequency electrical stimulation on dysphagia after ischemic stroke; Chinese Journal of Contemporary Neurology & Neurosurgery; 2015; vol. 15 (no. 4); 285-289</p>	<p>- Outcome data not available for this report</p>
<p>Zhong, C-M; Rong, G; He, F-Z; Jin, H-Y; Comparison of head and body acupuncture in the treatment of deglutition disorders in subacute period of stroke; Chinese journal of clinical rehabilitation; 2003; vol. 7 (no. 19); 2706-2707</p>	<p>- Outcome data not available for this report</p>
<p>Zhong, L., Rao, J., Wang, J. et al. (2021) Repetitive Transcranial Magnetic Stimulation at</p>	<p>- Study design not relevant to this review protocol</p>

Study	Code [Reason]
Different Sites for Dysphagia After Stroke: A Randomized, Observer-Blind Clinical Trial. <i>Frontiers in Neurology</i> 12: 625683	Control group was not randomised
Zhong, Lida, Wang, Jing, Li, Fang et al. (2021) The Effectiveness of Acupuncture for Dysphagia after Stroke: A Systematic Review and Meta-Analysis. <i>Evidence-based complementary and alternative medicine : eCAM</i> 2021: 8837625	- Systematic review used as source of primary studies
Zhu, Yixin and Gu, Lihua (2022) Noninvasive Brain Stimulation for Poststroke Dysphagia: A Meta-Analysis for Randomized Controlled Trials. <i>European neurology</i> 85(1): 31-38	- Systematic review used as source of primary studies
Zou, Fengjiao, Chen, Xiaoxu, Niu, Lingchuan et al. (2022) Effect of Repetitive Transcranial Magnetic Stimulation on Post-stroke Dysphagia in Acute Stage. <i>Dysphagia</i>	- Data not reported in an extractable format or a format that can be analysed <i>Only reports outcomes in a graphical form</i>
吴, 敏 (2021) 食品增稠剂预防卒中相关性肺炎 及改善吞咽困难的临床观察. <i>Chinese Journal of Integrative Nursing</i> 7(12): 142-144	- Study not reported in English
张有文, 杨, 凌, 白岫丹 et al. (2021) 励-协夫曼言语训练对脑梗死病人吞咽 功能、嗓音质量和日常生活能力的影响. <i>Chinese Nursing Research</i> 35(16): 2864-2868	- Study not reported in English
邵伟波, 王珧, 蒋惟伟 et al. (2017) 柱状球囊扩张术治疗脑卒中后食管上括约肌弛缓致重度吞咽障碍临床研究. <i>Chinese Journal of Contemporary Neurology & Neurosurgery</i> 17(3): 185-191	- Study not reported in English
배한솔 and 이은남 (2021) 연하장애를 가진 급성기 뇌졸중환자의 캡사이신을 이용한 구인두 감각 자극의 효과. <i>Journal of Korean Critical Care Nursing</i> 14(3): 73-86	- Study not reported in English

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2 J.2 Health Economic studies

3 Published health economic studies that met the inclusion criteria (relevant population,
4 comparators, economic study design, published 2006 or later and not from non-OECD

1 country or USA) but that were excluded following appraisal of applicability and
2 methodological quality are listed below. See the health economic protocol for more details.

3 **Table 60: Studies excluded from the health economic review**

Reference	Reason for exclusion
None.	

4

1 Appendix K Recommendation for research – full details

2 K.1 Recommendation for research

3 What is the clinical and cost-effectiveness of neurostimulation (pharyngeal electrical
4 stimulation, transcranial direct current stimulation, transcranial magnetic stimulation) to
5 improve swallowing in people with oropharyngeal dysphagia after stroke?

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7 K.1.1 Why this is important

8 Dysphagia is a common functional disorder after stroke where 11-50% of people can have
9 persistent dysphagia at six months. Dysphagia is associated with negative health and
10 psychosocial outcomes and can lead to malnutrition, dehydration, reduced quality of life, and
11 aspiration pneumonia. It is also linked to increases in mortality and length of hospital stay.
12 Management of post-stroke dysphagia involves a mixture of compensatory strategies and
13 adaptations along with various therapeutic interventions. This review has found several
14 therapies to be clinically effective, including behavioural exercises and physical stimulation.
15 The evidence base for the use of neurostimulation therapies including pharyngeal electrical
16 stimulation, transcranial magnetic stimulation and transcranial direct current stimulation was
17 limited and despite showing trends towards benefits for many outcomes, due to their poor
18 quality and small study populations the evidence was insufficient to inform clinical decision
19 making. High quality research with cost effectiveness data is required to fully examine their
20 efficacy in this population.

21

22 K.1.2 Rationale for the recommendation for research

Importance to 'patients' or the population	Dysphagia is a common functional disorder after stroke and can affect up to 80% of stroke survivors. It is closely linked to higher rates of mortality and morbidity and can adversely impact health related quality of life. Therefore, identifying effective treatments to manage this condition is of utmost importance to stroke survivors.
Relevance to NICE guidance	There is a growing body of evidence into the use electrotherapies for the treatment of post stroke dysphagia. However, the evidence for the neurostimulation therapies was insufficient to make a positive recommendation with the majority of trials being small, low quality and there being a lack of cost effectiveness data. Further high-quality evidence examining the clinical and cost effectiveness of transcranial magnetic stimulation, pharyngeal electrical stimulation and transcranial direct current stimulation would help to answer the original review question and inform future NICE guidance.
Relevance to the NHS	Dysphagia is common post stroke condition that is closely linked with increased mortality morbidity and increased length of hospital stays. Use of electrotherapies to manage this condition is currently not widely used in the NHS. Therefore, establishing new effective ways to

	manage post stroke dysphagia is highly important for the NHS and may lead to reduced burden on the NHS and improved patient outcomes.
National priorities	None identified.
Current evidence base	This review identified a number of effective treatment therapies for the management of dysphagia. The evidence for neurostimulation was limited to small trials with a limited number of outcomes and no cost effectiveness evidence. Research in this area is growing but high-quality research, investigating the effectiveness and cost effectiveness of each treatment is required.
Equality considerations	No specific equality considerations were identified. The committee noted that in general throughout the guideline, people with communication and cognitive difficulties, older people and people who have had a previous stroke or transient ischaemic attack were excluded from trials but are people that the guideline is for. Therefore, research should aim to include these people where possible.

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2 **K.1.3 Modified PICO table**

Population	<p>Inclusion:</p> <ul style="list-style-type: none"> Adults (age ≥ 16 years) who have had a first or recurrent stroke and have oropharyngeal dysphagia <p>Exclusion:</p> <ul style="list-style-type: none"> Children (age < 16 years) People who have had a transient ischaemic attack
Intervention	<ul style="list-style-type: none"> Pharyngeal electrical stimulation (PES) Transcranial direct current stimulation (tDCS) Transcranial magnetic stimulation (TMS)
Comparator	<ul style="list-style-type: none"> Usual care Placebo/sham Each other
Outcome	<ul style="list-style-type: none"> Mortality Person/participant generic health-related quality of life Carer generic health-related quality of life Occurrence of chest infections Occurrence of aspiration Dysphagia present/Return to normal diet Discharge to residential service Length of hospital stay Re-admission Swallowing ability Nutrition (measured using nutrition screening tools such as the Malnutrition universal

	screen tool or the Mini Nutritional Assessment) <ul style="list-style-type: none"> Hydration (measured using fluid balance charts/amount of fluid drank) Withdrawal due to adverse events
Study design	Randomised-controlled trial (RCT)
Timeframe	3 months
Additional information	Sub-group analyses: <ul style="list-style-type: none"> Severity of dysphagia (mild, moderate, severe, very severe) Chronicity (Acute/Subacute or Chronic) Type of stroke using the Bamford scale (TACS, PACS, LACS, POCS) People requiring enteral feeding support at baseline (people requiring enteral feeding support at baseline, people not requiring enteral feeding support at baseline, mixed)

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3 **K.2 Recommendation for research**

4 What is the clinical and cost-effectiveness of neuromuscular electrical stimulation (NMES) to
5 improve swallowing in people with oropharyngeal dysphagia after stroke?

6 **K.2.1 Why this is important**

7 Dysphagia is a common functional disorder after stroke where 11-50% of people can have
8 persistent dysphagia at six months. Dysphagia is associated with negative health and
9 psychosocial outcomes and can lead to malnutrition, dehydration, reduced quality of life, and
10 aspiration pneumonia. It is also linked to increases in mortality and length of hospital stay.
11 Management of post-stroke dysphagia involves a mixture of compensatory strategies and
12 adaptations along with various therapeutic interventions. This review has found several
13 therapies to be clinically effective, including behavioural exercises and physical stimulation.
14 There was some evidence to suggest that neuromuscular electrical stimulation was a
15 clinically effective treatment to improve quality of life, reduce dysphagia and chest infections
16 and help people to return to a normal diet. However, there was an unclear effect on mortality
17 and the effect on quality of life was not reported on a scale that could be used for health
18 economic analysis. There was no associated cost effectiveness analysis that could be used
19 to investigate the cost effectiveness of the treatment. Given these factors, the committee
20 could not recommend the treatment at this time. Therefore, a research recommendation was
21 made to investigate the clinical and cost-effectiveness of neuromuscular electrical stimulation
22 for the treatment of oropharyngeal dysphagia.

23

24 **K.2.2 Rationale for the recommendation for research**

Importance to 'patients' or the population	Dysphagia is a common functional disorder after stroke and can affect up to 80% of stroke survivors. It is closely linked to higher rates of mortality and morbidity and can adversely impact health related quality of life. Therefore,
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	identifying effective treatments to manage this condition is of utmost importance to stroke survivors. Neuromuscular electrical stimulation is sometimes used by people after stroke and so having more information about whether it is an effective treatment will help to give them more information to help them make an informed decision about their treatment options.
Relevance to NICE guidance	There is a growing body of evidence into the use electrotherapies for the treatment of post stroke dysphagia. Neuromuscular electrical stimulation was suggested to be effective for improving health related quality of life and reducing dysphagia and occurrence of chest infections. However, the evidence for mortality was unclear and there is a need for cost effectiveness evidence so a decision can be made about recommending this treatment. Neuromuscular electrical stimulation for swallowing has previously been examined in an interventional procedures guidance (IPG634) in 2018 which recommended that the evidence suggests a potential benefit but is limited in quality and quantity. This has not changed by the time of this guideline being published and so further evidence is required to change this.
Relevance to the NHS	Dysphagia is common post stroke condition that is closely linked with increased mortality morbidity and increased length of hospital stays. Neuromuscular electrical stimulation is sometimes used to manage dysphagia in the NHS, but practice is inconsistent. Establishing effective ways to manage post-stroke dysphagia is highly important for the NHS and may lead to reduced burden on the NHS and improved outcomes.
National priorities	None identified.
Current evidence base	Neuromuscular electrical stimulation was indicated to be effective. However, there was limited evidence discussing the cost effectiveness. Research in this area is growing but high-quality research, investigating the effectiveness and cost effectiveness is required.
Equality considerations	No specific equality considerations were identified. The committee noted that in general throughout the guideline, people with communication and cognitive difficulties, older people and people who have had a previous stroke or transient ischaemic attack were excluded from trials but are people that the guideline is for. Therefore, research should aim to include these people where possible.

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2 **K.2.3 Modified PICO table**

Population	Inclusion: <ul style="list-style-type: none"> Adults (age ≥16 years) who have had a first or recurrent stroke and have oropharyngeal dysphagia
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	<p>Exclusion:</p> <ul style="list-style-type: none"> • Children (age <16 years) • People who have had a transient ischaemic attack
Intervention	<ul style="list-style-type: none"> • Neuromuscular electrical stimulation (NMES)
Comparator	<ul style="list-style-type: none"> • Placebo/sham • Usual care
Outcome	<ul style="list-style-type: none"> • Mortality • Person/participant generic health-related quality of life • Carer generic health-related quality of life • Occurrence of chest infections • Occurrence of aspiration • Dysphagia present/Return to normal diet • Discharge to residential service • Length of hospital stay • Re-admission • Swallowing ability • Nutrition (measured using nutrition screening tools such as the Malnutrition universal screen tool or the Mini Nutritional Assessment) • Hydration (measured using fluid balance charts/amount of fluid drank) • Withdrawal due to adverse events
Study design	Randomised-controlled trial (RCT)
Timeframe	3 months
Additional information	<p>Sub-group analyses:</p> <ul style="list-style-type: none"> • Severity of dysphagia (mild, moderate, severe, very severe) • Chronicity (Acute/Subacute or Chronic) • Type of stroke using the Bamford scale (TACS, PACS, LACS, POCS) • People requiring enteral feeding support at baseline (people requiring enteral feeding support at baseline, people not requiring enteral feeding support at baseline, mixed)

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3 **K.3 Recommendation for research**

4 What is the clinical and cost-effectiveness of acupuncture to improve swallowing in people
5 with oropharyngeal dysphagia after stroke?

1 **K.3.1 Why this is important**

2 Dysphagia is a common functional disorder after stroke where 11-50% of people can have
3 persistent dysphagia at six months. Dysphagia is associated with negative health and
4 psychosocial outcomes and can lead to malnutrition, dehydration, reduced quality of life, and
5 aspiration pneumonia. It is also linked to increased mortality and length of hospital stay.

6 Management of post-stroke dysphagia involves a mixture of compensatory strategies and
7 adaptations along with various therapeutic interventions. This review has found several
8 therapies to be clinically effective including behavioural exercises and physical stimulation.
9 The use of acupuncture to treat dysphagia is not currently used in the NHS but there is
10 growing evidence base emerging for its use. Despite a number of clinically important benefits
11 identified in this review, there was an insufficient amount of evidence to indicate clinical and
12 cost effectiveness to recommend it at this time. Therefore, high-quality research with cost-
13 effectiveness evidence is required.

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15 **K.3.2 Rationale for the recommendation for research**

Importance to 'patients' or the population	Dysphagia is a common functional disorder after stroke and can affect up to 80% of stroke survivors. It is closely linked to higher rates of mortality and morbidity and can adversely impact health related quality of life. Evidence on the effectiveness of acupuncture is limited but there appears to be a growing body of evidence emerging for its effectiveness. Identifying effective treatments to manage this condition is of great importance to stroke survivors.
Relevance to NICE guidance	There is a growing body of evidence on the use of acupuncture to treat dysphagia after stroke. However, due to the limited evidence and lack of health economic data a recommendation could not be made. Further research will help to answer to original review question and inform future guidance.
Relevance to the NHS	Dysphagia is common post stroke condition that is closely linked with increased mortality morbidity and increased length of hospital stays. The evidence base for acupuncture in the treatment of dysphagia is growing. However, acupuncture is not currently used in the NHS so a recommendation for its use would have a cost implication. High quality evidence including cost effectiveness data is important to be able to understand the effects of implementing acupuncture in the NHS.
National priorities	None identified.
Current evidence base	This review included six studies comparing acupuncture to usual care and one study with a placebo comparison. Evidence identified clinically important benefits of acupuncture. However, the evidence was of low quality from small trials and there was a lack of any cost effectiveness. Therefore, further evidence, including cost effectiveness data is required.
Equality considerations	No specific equality considerations were identified. The committee noted that in general

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throughout the guideline, people with communication and cognitive difficulties, older people and people who have had a previous stroke or transient ischaemic attack were excluded from trials but are people that the guideline is for. Therefore, research should aim to include these people where possible.

2 **K.3.3 Modified PICO table**

Population	<p>Inclusion:</p> <ul style="list-style-type: none"> Adults (age ≥ 16 years) who have had a first or recurrent stroke and have dysphagia. <p>Exclusion:</p> <ul style="list-style-type: none"> Children (age < 16 years) People who have had a transient ischaemic attack
Intervention	<ul style="list-style-type: none"> Acupuncture
Comparator	<ul style="list-style-type: none"> Sham acupuncture Usual care (equivalent time spent with a healthcare professional receiving swallowing therapy)
Outcome	<ul style="list-style-type: none"> Mortality Person/participant generic health-related quality of life Carer generic health-related quality of life Occurrence of chest infections Occurrence of aspiration Dysphagia present/Return to normal diet Discharge to residential service Length of hospital stay Re-admission Swallowing ability Nutrition (measured using nutrition screening tools such as the Malnutrition universal screen tool or the Mini Nutritional Assessment) Hydration (measured using fluid balance charts/amount of fluid drank) Withdrawal due to adverse events
Study design	Randomised controlled trial (RCT)
Timeframe	6 months
Additional information	<p>Sub-group analyses:</p> <ul style="list-style-type: none"> Severity of dysphagia (mild, moderate, severe, very severe) Chronicity (Acute/Subacute or Chronic) Type of stroke using the Bamford scale (TACS, PACS, LACS, POCS) People requiring enteral feeding support at baseline (people requiring enteral feeding

	support at baseline, people not requiring enteral feeding support at baseline, mixed)
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