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A Systematic Review of Randomized Controlled Trials in the Field of Dysphagia Rehabilitation

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Abstract We carried out a systematic review of randomized controlled trials (RCT) of oropharyngeal swallowing interventions conducted between years 2010 and 2013. A systematic literature search of RCTs was conducted using databases MEDLINE (PubMed), PsychInfo, Google Scholar, EBSCO, PROQUEST, Web of Science, and grey literature. Data were abstracted from all eligible studies by the first author and independently assessed by two raters using the Van Tulder scale. A total of 15 RCTs of behavioral swallowing therapy were included for evaluation. Significant heterogeneity between experimental studies was noted. Only 33 % (5) of studies included met the quality criterion identified by the van Tulder scale for high study rigor. Data supporting swallowing rehabilitation methods with adult dysphagic patients is advancing. Although studies intervention approaches remain diverse, the use of RCT designs is increasing with noted improvements in control methods. More research is needed to ascertain the most optimal intervention methodology for dysphagia rehabilitation.

Keywords Deglutition · Swallowing · Dysphagia randomized controlled trial · Rehabilitation · Systematic review

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Introduction

Health care decisions are frequently directed by the best available evidence from research studies. As both diagnostic and treatment options multiply rapidly in health care, increases in available research bring with it challenges in identifying which studies are of the highest quality. This challenge is made more difficult when different studies provide results that support different conclusions or lead a field erroneously through bias in reporting.

To answer these challenges, researchers have developed methods to synthesize and evaluate research from multiple studies. Systematic reviews represent one method to rigorously compile scientific evidence to answer questions regarding the state of science in an area. They can help clinicians make decisions when similar studies present apparently confusing or conflicting results [1].

Different research designs shed different amounts of light on how treatments work under controlled conditions. Some designs provide information on the association between treatments and their outcomes, but do not control for the myriad of intervening or confounding issues surrounding treatment applications, e.g., age, gender, disease severity, co-interventions, enthusiasm, etc. One design that provides definitive evidence of intervention efficacy is the randomized controlled trial (RCT) [2].

The RCT is one of the simplest, but most powerful research designs available to a researcher to evaluate the efficacy of an intervention. The key feature of this design is that, after an assessment of eligibility, subjects in the study are randomly and independently assigned to receive one or other treatments under investigation. Once randomized the groups are followed in exactly the same way and only differences in response to the treatment they receive are

compared. The power of the design lies in its ability to minimize bias in treatment allocation and balance prognostic factors between the groups. Well-conducted RCTs minimize bias by controlling known and unknown factors (confounders) that may distort treatment effects. Unfortunately, it is estimated that fewer than 10 % of all literature published are well-conducted RCTs, with <5 % reported from the area of rehabilitation [3, 4]. Despite the strength and benefits of RCTs, poorly conducted or poorly reported trials can yield misleading data and misdirect knowledge and development of a field.

Like other areas of health care, dysphagia intervention methods are diverse and rapidly advancing within the literature. Common categories of dysphagia rehabilitation methods include; behavioral maneuvers, behavioral compensations, exercise interventions, dietary interventions (including modified diets and enteral feeding methods), pharmaceutical applications, electro-physical applications, and sensory-motor applications to mention but a few. To date, evaluations of the strength of data supporting swallowing interventions have been equivocal. Some reviews identifying an increase in the quality of supportive data whilst others have admonished the field for a lack of supportive evidence and suggested the need for more rigorous study designs [5, 6] (Fig. 1).

Recently, a published review of abstracts presented to an international dysphagia meeting (Dysphagia Research Society) over the last decade (2001–2011) suggested that there has been a surge in the use of more rigorous research designs to evaluate swallowing. In fact, they reported that the use of RCT methodologies in that group had tripled since 2001, and that at present RCTs constituted 3.3 % of all abstracts presented at this meeting [7]. However, data for this review were generated from study abstracts only and the authors did not evaluate the individual study rigor of each trial using a validated qualitative analysis system.

To further evaluate the use of rigor in recent RCT studies in the field of dysphagia rehabilitation, we proposed to undertake a systematic review of all RCTs of behavioral intervention for oro-pharyngeal dysphagia during the period from January 2010 to June 2013.

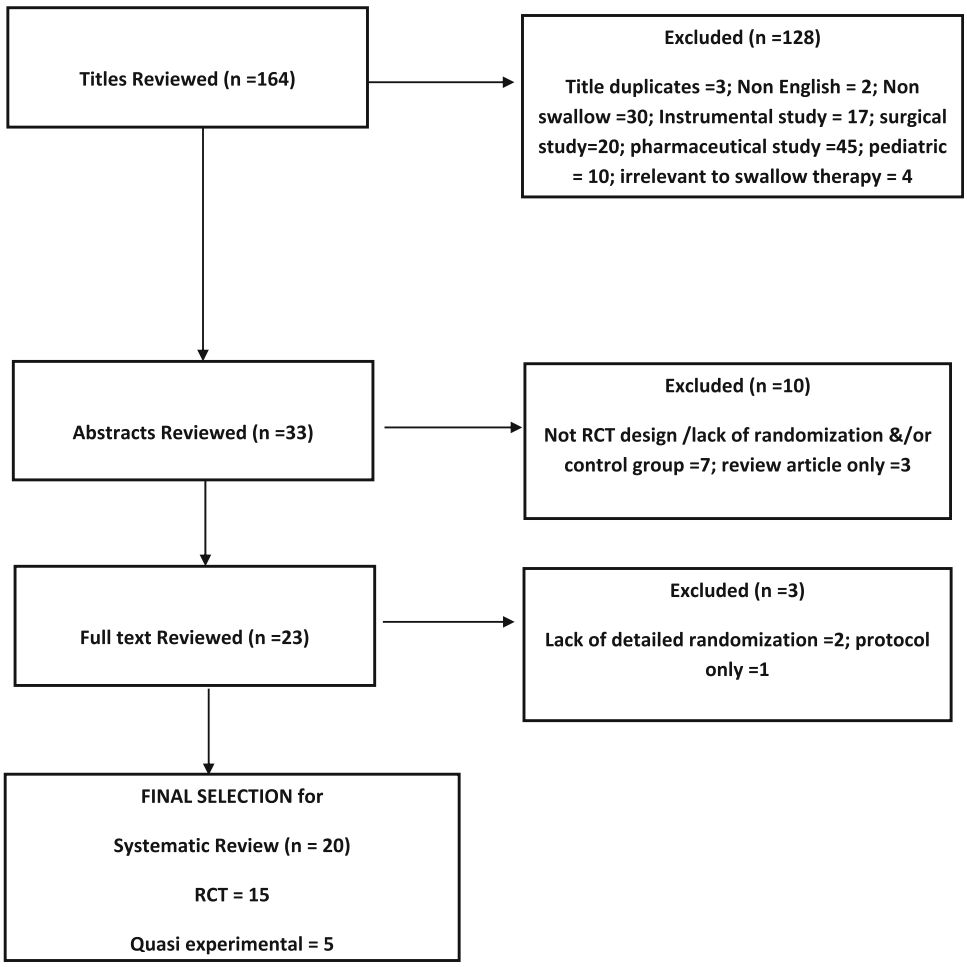

Fig. 1 Flow chart of study selection process

Methods

Study Identification

Studies were identified using searches on MEDLINE (PubMed), PsychInfo, Google Scholar, EBSCO, PROQUEST Web of Science, and grey literature. In addition, meeting abstracts and Cochrane Reviews and reviews of reference lists of related book chapters and journal articles from January 2010 to June 2013 were screened. A comprehensive list of search terms included; "swallowing intervention," "swallowing treatment trial," "randomized clinical trial", "RCT", "randomized controlled clinical trial", "and swallowing rehabilitation trial", "dysphagia rehabilitation". MESH terms (PubMed) used included, "humans", "dysphagia", "swallowing trial", "treatment". For databases allowing advanced search techniques, articles were restricted to RCTs. Potentially eligible articles were first screened for relevance by the first author, using article titles and then abstracts. Articles that appeared to meet eligibility criteria after this initial review were then reviewed independently by the first and second authors, using the measures described below.

Inclusion Criteria

The current review included RCTs that assessed the impact of behavioral interventions to reduce or ameliorate oropharyngeal dysphagia. Due to the differences in intervention format and treatment goals for programs involving children and adolescents, the current review was restricted to studies investigating adults (age $\geq$18) only. To be eligible for inclusion, the following inclusion/exclusion criteria were used: (1) must include a randomized control trial design; (2) published in English or capable of being translated; (3) accessible in full text; (4) evaluated an oropharyngeal swallowing intervention; (5) assessed a measurable swallowing outcome; (6) did not evaluate a surgical interventions; (7) did not evaluate a pharmaceutical intervention; and (8) was not a device trial.

RCT

For the purposes of this systematic review, an RCT was defined a priori as a study in which subjects are randomly allocated (by chance alone) to receive one of several clinical swallowing interventions. One of these interventions must be a standard of comparison or control. This control group should be receiving either no treatment or receive the current standard treatment. The use of a placebo comparison only without a standard control comparison will be considered a quasi-experimental trial, as the placebo effect alone cannot be adequately identified. Furthermore, for the purposes of qualitative grading, reviewers were advised that an acceptable randomization procedure should include either use of computer generated random numbers or random numbers tables. In addition, concealed allocation should be described as either use of a centralized or independently controlled randomization procedure, serially-numbered identical containers, or randomization sequences not readable until allocation.

Data Extraction

The first author (G.C.) systematically abstracted data from all articles reviewed in full text including authors, year in which the study was published, country in which the study was conducted, characteristics of the sample (e.g., sample size, gender, age range, diagnostic group, and treatment type), the intervention and control group's methodology, length of intervention, length of follow-up, and all relevant dysphagia outcome measures. For studies employing more than one treatment arm (or those using factorial designs), only data related to the current review were used. To calculate intervention effect sizes, mean differences between an intervention and a control group and associated standard deviations (if available) or next through the use of either pre- and post-test means and standard deviations, group *n*, and *F* ratio were abstracted. If more than one intervention arm met criteria for inclusion, data were combined to create pooled estimates. Following this, effect data were standardized using accepted methods to single comparable effect metric, Cohen's d.

Quality Assessment

Two independent reviewers, blinded to the study's' authors, author's affiliations, and journal, independently used the van Tulder scale to determine the quality of the trials. Where a selected study included an author of this paper, it was re-directed to a third independent reviewer. The van Tulder scale is a qualitative assessment tool designed to make assessments on 11 components of RCT study design including randomization method, allocation concealment, baseline characteristics, patient blinding, therapist blinding, observer blinding, co-intervention control, compliance, drop-out rate, end-point assessment time point, and intention-to-treat analysis (see Table 3 in Appendix). The reviewer is required to select 'yes', 'no', or 'don't know' for each item. A rating of '1' is allocated for any affirmative response, or '0' for 'no', or 'don't know. When $\geq$5 items are satisfied ($\geq$5 points), the quality of the report is deemed high [8]. The van Tulder scale has previously been evaluated for interrater reliability, face, content, and concurrent validity [8]. In the present study, only 'high quality' rated studies were included in the analysis of

primary effect within the systematic review (see Table 4 in Appendix).

Reliability

Two independent raters utilized a standardized rating sheet to record study details for the van Tulder qualitative grading (Table 1). The inter-class correlation coefficient for van Tulder scores between the reviewers was $\alpha = 0.976$ (95 % CI 0.938–0.991).To further explore areas of concordance in ratings across studies a fixed marginal kappa analysis [9] was conducted and revealed 94 % agreement in coding across studies. Kappa values of 0.75 or higher reflect excellent agreement between raters [10]. Overall rater agreement was strong across categories of the scale, ranging from 86 to 100 % agreement. The item demonstrating the greatest discrepancy between raters was item H; "were co-interventions avoided or controlled". This item was often not explicitly stated by authors and overall agreement for this item was 86 %. Inconsistencies identified between raters were later discussed and resolved by consensus.

Results

Initial queries using the search terms listed yielded a total of 164 articles of which the titles were screened. Following this, 128 studies did not meet the inclusion criteria and were excluded (Table 1). Thirty-three studies were evaluated by abstract review, of which ten were deemed ineligible for the reasons; failure to use of RCT design ($n = 2$) lack of control arm ($n = 2$), lack of randomization ($n = 3$), review article only ($n = 3$).After reviewing the full text studies a further three studies were eliminated due to failure to provide randomization details ($n = 2$) and providing a protocol only ($n = 1$). In total, 20 studies met all eligibility criteria and were included in the systematic review. While all the studies included self-identified as RCTs, only 15 met the RCT criteria by including a true comparison (control) arm [11–26]. A further 5 studies utilized sham/placebo comparators only (without a standard control comparison) or non-randomized controls and were deemed quasi-randomized trials [26–30].

Quality Ratings

The 15 studies identified as RCTs averaged a quality rating score of a 4.46 (SD 2.6), with scores ranging from 1 [21] to a score of 9 [24]. The modal score for the group was 4 (range 1–9). Of the 15 included RCTs, five studies were conducted in Asia with an average quality rating of 2.6 (SD 0.89), four trials were conducted in the USA and scored an average quality rating of 7 (SD 2.1), two in Europe with an average quality rating of 3 (SD 1.4), and two from Australia rating 6 (SD 2.8) and a single trial from the UK scoring 7.

Only 5 RCTs met the van Tulder criteria (>5) indicating high quality trials [11, 14, 19, 22, 24]. Only 46 % (7) of studies provided adequate detail regarding the randomization and concealment procedures, while 86 % (13) studies identified and confirmed similarity of baseline group comparability (item C) and 93 % (14) defined similar timing of evaluation points between the groups (item J). 26 % (4) of studies reported post-intervention data with <20 % attrition [13, 14, 16, 23] and only 20 % reported the compliance of subjects to the treatment provided [11, 22, 24]. Limited blinding was demonstrated across studies with only 13 % (2) of studies blinding subjects and 6 % (1) blinding therapists. Further, only 53 % (8) studies [11, 13, 14, 17, 19, 22, 24, 25] reported that assessors who measured the main outcome were blinded to treatment allocation. Lastly, 46 % (7) of studies were conducted with intent-to-treat analysis [11, 14, 17, 19, 22, 24] (Table 1).

Study Characteristics

Ten studies were two-arm RCTs (intervention and control), while 5 were three-arm trials were either intervention, placebo, and control [19, 24] or intervention, intervention, and control [12, 22, 23]. Only one study was a cluster trial of 19 centers [14]. The average size of study recruitment was 64.5 (SD 37.4), with the range from 16 [21] to 130 [22] subjects. The mean ages of patients enrolled across the RCTs ranged from 25.4 [18] to 80 [13]. The proportion of subjects recruited were 1.5 times more likely to be male (1,190) versus female (793).

The most frequent intervention group diagnosis was head and neck cancer (40 %), followed by stroke (27 %). Two studies were conducted using acute care patients [11, 14], four with sub-acute rehabilitation patients [12, 13, 21, 24] and eight with either chronic conditions [23] or patients presenting for outpatient-based medical interventions [15–17, 19, 20, 22, 25]. An additional study utilized healthy normal volunteers only [18].

In four studies, confirmation of dysphagia status was made on the basis of a non-validated clinical examination [13, 14, 23] or patient history [20]. Seven studies utilized a validated clinical exam only [11], videofluoroscopic examination only [21], or both methods [12, 18, 19, 25]. Additionally, two studies utilized patient report or a quality of life survey [15, 17] and only one study did not specifically report the process for dysphagia status confirmation at study onset [16].

Table 1 Van Tulder [8] quality assessment ratings

Study	Randomization detailed	Allocation concealed	Similar groups at baseline	Subject blind	Therapist blind	Assessor blind	Co-intervention controlled	Acceptable compliance	Acceptable withdrawal rate	Timing of outcome	ITT	Total
Bevan et al. [11][a]	√	√	√			√		√		√	√	7
Xia et al. [12]			√							√		2
Karagiannis et al. [13]		√				√			√	√		4
Middleton et al. [14][a]	√	√	√	√		√			√	√	√	8
Tang et al. [15][a]			√							√		2
Van der Molen et al. [16]			√						√	√	√	4
Kotz et al. [17]			√			√				√	√	4
Oh et al. [18]			√							√		2
Carnaby-Mann [19][a]	√	√	√			√	√			√	√	7
Chen et al. [20]	√		√							√		3
Carlaw et al. [21]			√									1
Carnaby et al. [22][a]	√	√	√			√	√	√		√	√	8
Heijnen et al. [23]									√	√		2
Carnaby ANSRS [24][a]	√	√	√	√	√	√		√		√	√	9
Long et al. [25]	√		√			√				√		4
Quasi experimental trials-sham control only												
Troche et al. [26]			√	√	√	√			√	√	√	7
Terre et al. [27]										√		1
Yang et al. [28]			√		√	√		√	√	√	√	7
Feng et al. [29]	√	√	√						√	√		5
Chan et al. [30]		√		√		√				√		4

[a] Denotes high-grade RCT

Nature of the Interventions

The 15 RCTs included a diverse range of swallowing intervention methodologies (Table 2; Table 5 in Appendix) including: dietary [11, 13, 21], electrotherapeutic [12, 23–25], preventative behavioral exercise [16, 17, 19, 22], behavioral maneuvers and compensations [15, 18], program effectiveness [14], and behavioral exercise alone [20]. Within the quasi-experimental trials, three studies evaluated alternative medicine approaches [28–30], one evaluated a postural adjustment [27], and another evaluated respiratory strength training [26].

Recruitment into the studies was variable across the groups. Three studies reported consecutive recruitment from admission to medical care [11, 14, 24], while a further six studies reported consecutive recruitment from outpatient admission [16, 17, 19, 22, 25], five studies did not report time to recruitment [12, 13, 20, 21, 23], one study reported recruitment on average 4.7 years post-medical treatment [15], and one utilized volunteers [18] (Table 2).

Intervention Timing

The duration of intervention was highly variable, ranging from 3 days to 4 months. The average number of days treatment was provided across all studies was >5 weeks (mean days: 40.47, SD 36.0).The total amount of intervention prescribed within a treatment period was also variable ranging from 1.5 to 189 h, with the average for all studies equal to 55.7 (SD 61) h. The frequency of treatment provided (sessions/day) was on average 1.7 (SD 0.9) with seven studies providing daily treatment [11–14, 21, 23, 24], three studies providing treatment twice daily [19, 20, 22], and four studies providing intervention three times a day [15–17, 25]. One study also provided intervention on alternating days [18]. In general, studies evaluating dietary interventions provided care on a daily basis. Studies evaluating electrotherapeutic interventions provided care for 30–60 min daily, while prophylactic exercise interventions were more often provided 2–3 times daily for 15–45 min. Behavioral interventions only [15, 18, 20] were highly variable, ranging from 1 to 3 times a day.

Outcome Assessment

The assessments of outcomes in 15 RCTs were evaluated at mixed time points. Nine studies evaluated pre- and post-intervention only [11–16, 18, 21, 25], three studies completed pre- and post-intervention measures and followed patients out to 3 months [22–24], and three followed patients for ≥6 months [17, 19, 20]. The outcome evaluated by the majority of studies (7) was swallowing function measured by a clinical swallowing evaluation [12, 15, 17, 20, 23, 25]. Two studies evaluated swallowing physiology as the primary target using videofluoroscopic analysis [16, 18]. Two studies evaluated swallowing muscle composition using T2-weighted MRI [19, 22]. Two studies evaluated the larger functional outcomes of lung infection from clinical report, and death/dependency using the modified Rankin Scale [13, 14]. Lastly, two studies evaluated fluid and enteral intake [11, 13]. In total, six trials utilized non-validated primary outcome tools [12, 13, 16, 18, 20, 23], and of these four were non-validated clinical assessment measures and two were non-validated instrumental approaches. Nine studies utilized validated clinical and instrumental outcome assessment tools [11, 14, 15, 17, 19, 22, 24, 25].

Secondary outcomes were evaluated in 93 % of trials. Only one study utilized a single primary outcome [18]. The range of secondary outcomes reviewed included: need for additional medical intervention [11, 17, 21], weight change [11, 16, 19], occurrence of dysphagia-related adverse events [11, 14, 19–21, 24], change in core temperature [13, 14], dietary/fluid intake [13, 16, 19, 22–24], quality of life [12, 13, 21–23], swallow physiology/biomechanics [12, 24, 25], chemosensory function [19], clinical swallowing ability [14, 19, 22], mouth opening [15, 16, 19], mouth/neck pain [16, 19, 20, 22], psycho-social measures (fatigue, depression, mood, anxiety, fear) [19, 22], and length of stay [14] .

Statistical Approach

Of the total 15 RCTs, four studies provided descriptive and uni-variate analyses only [12, 13, 15, 25], four provided descriptive and non-parametric analyses [16–18, 23] and four trials [11, 14, 19, 22] provided descriptive, uni-variate, and multivariate results. Eight studies conducted appropriate statistical analyses for their reported sample size and statistical plan [11, 12, 14–16, 19, 22, 24]. Of this group, five studies, however, did not meet statistical reporting standards by failing to provide specific parametric and non-parametric details beyond providing a p value for results [31]. A further seven studies did not conduct appropriate statistical analyses including: inappropriate analysis for stratification reported [13], inadequate sample size for RCT to ensure randomization [17, 18], incorrect application of parametric analyses [21], and failure to adjust for multiple testwise error [17, 20, 25]. Lastly, a single study's results could not be confidently evaluated as the numbers reported in the text and tables conflicted [23].

Reported Outcomes

Eleven (73 %) of the RCTs reported a positive outcome from the intervention used to remediate dysphagia [11–15,

Table 2 Study demographics

Study	Country of origin	Sample size	Gender (M:F)	Sample age (Mean, SD)	Diagnostic group	Severity of dysphagia (baseline)	Treatment type	Primary outcome measures	Secondary outcome measures
Intervention type = dietary									
Bevan et al. [11] Does looped nasogastric tube feeding improve nutritional delivery for patients with dysphagia after acute stroke? A randomized controlled trial	UK	$n = 104$ Experimental (Exp) = 51 Control = 53	43:61	Experimental (Exp) = 79 (10) Control = 80 (10)	Stroke	Not reported	Enteral nutrition	Proportion of prescribed nutrition delivered through NG tube over 2 weeks	Mean volume of feed and fluids Proportion of participants not receiving any feeds Supplemental parenteral feeds # of NG insertions # chest X-rays to check NG insertion Change in weight Treatment failure (defined as PEG insertion within two weeks or abandoned NG feeds) Adverse events (included—nasal trauma, chest infection, diarrhea, vomiting, GI bleed, electrolyte abnormalities, and tolerability)
Karagiannis et al. [13] Effects of oral intake of water in patients with oropharyngeal dysphagia	Australia	$n = 76$ Exp = 42 Control = 34	39:37	Exp = 80 (7) Control = 79 (11)	Stroke, Dementia, Alzheimer's disease, Parkinson's disease, cancer, motor neuron disease, Huntington's disease, motor vehicle accident	Persons with Dysphagia who had been prescribed a modified diet	Thickened diet modification + Free water	Presence of lung complications measured by physician review	Core body temperature Daily fluid intake Quality of life
Carlaw et al. [21] Outcomes of a pilot water protocol project in a rehabilitation setting	Canada	$n = 16$ Exp = 9 Control = 7[a] Control crossed over to experimental following a 14-day control phase[a]	10:06	Males = 53.7, females = 44.1	Stroke, spinal cord injury, traumatic brain injury	"Thin liquid dysphagia"	Behavioral + free water	Fluid intake	Quality of life Adverse events—aspiration pneumonia Initiation of intravenous fluids Re-initiate tube—feeding Acute care hospitalization

Table 2 continued

Study	Country of origin	Sample size	Gender (M:F)	Sample age(Mean, SD)	Diagnostic group	Severity of dysphagia (baseline)	Treatment type	Primary outcome measures	Secondary outcome measures
Intervention type = electrotherapy									
Xia et al. [12] Treatment of post-stroke dysphagia by vitalstim therapy coupled with conventional swallowing training	China	$n = 120$ Exp (1) = 40 Exp (2) = 40 Control = 40	76:44	Exp (1) = 66.4 (15.6) Exp (2) = 65.85 (14.6) Control = 65.3 (14.3)	Stroke	Standardized swallowing assessment score (Mean, SD) Conventional swallowing therapy = 37.9 (6.4) VitalStim therapy = 38 (6.9) VitalStim plus conventional swallowing therapy = 39.5 (7.1)	Behavioral + NMES	Swallowing ability measured by bedside swallowing assessment on standardized swallowing assessment	Surface electromyography Videofluoroscopic swallowing study Swallowing related quality of life measured on SWAL-QOL
Heijnen et al. [23] Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life	The Netherlands	$n = 85$ Exp (1) sensory = 30 Exp (2) motor = 27 Control = 28	Numbers in table and text do not match. Not calculable	Median age Exp (1) = 66 Exp (2) = 65 Control = 69	Parkinson's disease	Dysphagia severity scale (DSS) (median scores) NMES-S = 74 NMES-M = 72 Control = 59	Behavioral and NMES	Change in DSS score	SWAL-QOL score FOIS score MDADI score
Long et al. [25] A randomized controlled trial of combination therapy of neuromuscular electrical stimulation and balloon dilatation in the treatment of radiation-induced dysphagia in nasopharyngeal carcinoma patients	China	$n = 60$ Experimental = 31 Control = 29	29:31	Exp = 56.5 (8.7) Control = 55.8 (7.97)	Nasopharyngeal carcinoma with radiation induced strictures	Not reported	Behavioral exercise + NMES	Water swallow test (WST)	Oral transit time, swallow reaction time, pharyngeal transit time, laryngeal closure duration as measured on videofluoroscopic swallow study
Carnaby et al. [22] A randomized trial of NMES vs. traditional dysphagia therapy after stroke: ANSRS	USA	$n = 53$ Exp (1) = 18 Sham (2) = 18 Control = 17	25:28	Exp (1) = 62.7 (12.2) Exp (2) = 70.6 (11.8) Control = 64.3 (14.7)	Sub-acute dysphagic stroke	Mann Assessment of Swallowing (MASA) scores (Mean) – Exp NMES = 157.2 Sham NMES = 154.6 Usual care = 158.4	Behavioral exercises + NMES	Improvement in clinical swallowing ability (MASA) Improvement in oral intake level (functional oral intake scale—FOIS) Improvement in body weight	Improvement in VFSS biomechanically measured physiology of swallowing Return to pre-stroke diet Occurrence of dysphagia related medical complications

Table 2 continued

Study	Country of origin	Sample size	Gender (M:F)	Sample age(Mean, SD)	Diagnostic group	Severity of dysphagia (baseline)	Treatment type	Primary outcome measures	Secondary outcome measures
Intervention type = preventative behavioral exercise									
Carnaby-Mann et al. [19] "Pharyngocise": A randomized controlled trial of preventative exercises to maintain muscle structure and swallowing function during head and neck chemoradiotherapy	USA	$n = 58$ Exp = 20 Sham = 18 Control = 20	44:14	Exp = 59 (10.4) Sham = 60 (12.2) Control = 54 (11.3)	Head and neck cancer	MASA score ≥178 indicating no dysphagia	Behavioral exercise	Muscle size and composition measured by MRI	Functional swallowing ability Mouth opening Chemosensory function Salivation Nutritional status Occurrence of dysphagia-related complications
Van der Molen et al. [16] A randomized preventive rehabilitation trial in advanced head and neck cancer patients treated with chemoraditherapy: feasibility, compliance, and short-term effects	The Netherlands	$n = 55$ Exp = 27 Control = 28	39:10	Exp = 57 Control = 56	Head and neck cancer	Not reported	Behavioral exercise and maneuvers	Swallowing function measured with videofluoroscopy Using penetration–aspiration scale	Mouth opening—maximum interincisor Weight changes Body mass index Oral Intake—measured using the functional oral intake scale (FOIS) Pain—using a visual analog scale for pain assessment
Kotz et al. [17] Prophylactic Swallowing exercises in patients with head and neck cancer undergoing chemoradiation	USA	$n = 26$ Exp = 13 Control = 13	20:06	Exp = 57 (10) Control = 62 (11)	Head and neck cancer	No dysphagia at baseline (Functional oral intake scale (FOIS) score—7, Performance status scale for head and neck cancer patients (PSS) score—100)	Behavioral exercises	FOIS, PSS scale	PEG tube insertion
Carnaby et al. [22] Dysphagia prevention exercises in head neck cancer: pharyngocise: dose response study	USA	$n = 130$ Exp (1) = 50 Exp (2) = 52 Control = 28	101:29	Exp (1) = 58.3 (9.2) Exp (2) = 57.8 (9.8) Control = 57.2 (9.8)	Head and neck cancer	MASA score (≥178) indicating no dysphagia	Behavioral exercises	Maintenance of muscle composition measured on T_2MRI	Functional swallowing ability (measured on MASA and FOIS) Patient perception of swallowing function and quality of life (measured on psychological scales for health related QOL)

Table 2 continued

Study	Country of origin	Sample size	Gender (M:F)	Sample age (Mean, SD)	Diagnostic group	Severity of dysphagia (baseline)	Treatment type	Primary outcome measures	Secondary outcome measures
Intervention type = behavioral maneuvers/compensations plus alternative medicine									
Feng et al. [29] Clinical study on Tongyan spray for post-stroke dysphagia patients: a randomized controlled trial	China	$n = 120$ Exp = 60 Sham = 60	79:41	Exp = 70.6, (10.5) Sham = 71.2 (10.3)	Stroke (patients referred with dysphagia)	The standard swallowing assessment scale (SSA)—score >30	Behavioral maneuvers + alternative medicine	Change in SSA score	N/A
Chan et al. [30] Therapeutic effects of acupuncture for neurogenic dysphagia—a randomized controlled trial	China	$n = 87$ Exp = 20 Control 1 = 19 Control 2 = 48 [non-randomized]	43:44	Exp = 74.05 (11) Control 1 = 80 (9.4) Control 2 = 75.4 (12.8)	Stroke, Parkinson's disease or vascular dementia	Royal Brisbane hospital outcome measure for swallowing score (RBHOMS) between 5 and 5.5 for all three groups	Behavioral maneuvers and alternative medicine	Change in RBHOMS score	Food and fluid consistencies
Yang et al. [28] Effects of transcranial direct current stimulation (tDCS) on post stroke dysphagia	South Korea	$n = 16$ Exp = 9 Sham = 7	10:06	Whole group reported only 71 (10.8)	Stroke (acute post stroke dysphagia)	"History of indirect aspiration symptoms"	Behavioral modifications and maneuvers + electro stimulation Instrument	Swallowing function measured on videofluoroscopic study using functional dysphagia scale (FDS)	Measured on videofluoroscopic study Oral transit time [0TT] Pharyngeal transit time[PTT] Total transit time [TTT]
Intervention type = program effectiveness									
Middleton et al. [14] Implementation of evidence-based treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction in acute stroke (QASC): a cluster randomized trial	Australia	$n = 19$ centers ($n = 1{,}126$ patients) Exp = 10 (626 patients) Control = 9 (500 patients) [cluster trial across 19 centers]	674:452	None reported	Acute stroke	Not reported	Medical and behavioral management protocols	Death or dependency (Modified Rankin scale ≥ 2) Functional dependency (Barthel index) Mean SF—36 mental component Mean SF—36 physical component	Mean temperature for first 72 h Blood glucose for first 72 h Proportion of swallowing screening undertaken within the first 24 h of admission Discharge diagnosis of aspiration pneumonia Length of hospital stay
Intervention type = behavioral maneuvers/compensations									
Tang et al. [15] A randomized prospective study of rehabilitation therapy in the treatment of radiation-induced dysphagia and trismus	China	$n = 43$ Exp = 22 Control = 21	32:11	Whole group reported only 49.3 (11)	Nasopharyngeal carcinoma	Score on water swallow test at baseline (Mean, SD) Exp group = 3.6 (1) Control group = 3.8 (1)	Behavioral	Severity of dysphagia (water swallow test)	Trismus (LENT/SOMA score Mean interincisor distance)

Table 2 continued

Study	Country of origin	Sample size	Gender (M:F)	Sample age(Mean, SD)	Diagnostic group	Severity of dysphagia (baseline)	Treatment type	Primary outcome measures	Secondary outcome measures
Oh et al. [18] Exercise using tongue-holding swallow does not improve swallowing function in normal subjects	South Korea	$n = 20$ Exp = 10 Control = 10	7:13	Exp = 27.4 (3.98) Control = 25.4 (2.5)	Healthy	Non-dysphagic	Behavioral maneuvers	Hyolaryngeal movement, pharyngeal constriction, posterior pharyngeal wall movement using videofluoroscopy	N/A
Terre et al. [27] Effectiveness of chin-down posture to prevent tracheal aspiration in dysphagia secondary to acquired brain injury. A videofluoroscopy study	Spain	$n = 72$ Exp (aspirating) = 47 Control (not aspirating) = 25 (NB: groups not randomized only presentation of chin down maneuver alternating/cross over/randomized)	50:22	Exp = 43 Control = 51	Neurogenic dysphagia Stroke = 45 TBI = 27	+/− Aspiration on videofluoroscopy prior to study	Postural adjustment	Aspiration (+/−)	Oral transit time Pharyngeal transit time Pharyngeal delay time
Intervention type = behavioral exercises									
Troche et al. [26] Aspiration and swallowing in Parkinson disease and rehabilitation with EMST	USA	$n = 60$ Exp = 30 Sham = 30	47:13	Exp = 66.7 (8.9) Sham = 68.5 (10.3)	Parkinson's disease	"Some degree of swallowing disturbance" reported	Devise based airway exercise	Swallow safety [penetration–aspiration score] on videofluoroscopy	Videofluoroscopic swallow measures Swallowing quality of life [SWAL-QOL]
Chen et al. [20] Tracheal traction exercise reduces the occurrence of postoperative dysphagia after anterior cervical spine surgery	China	$n = 102$ Exp = 52 Control = 50	51:51	Exp = 54.5 (9.3) Control = 54.5 (9.2)	Cervical spine radiculopathy or myelopathy	No reported dysphagia prior to surgery	Behavioral exercises	Bazaz dysphagia scores	Neck disability index Pain VAS-arm Pain VAS-neck

17, 19–22, 25]. Positive outcomes included improved nutritional intake [11, 24], increased fluid intake [13, 21] improved swallowing ability [12, 15, 19, 20, 22, 24], improved quality of life [22], improved swallow physiology [25], reduced death or disability [14], increased mouth opening [19, 22], maintenance of chemo-sensory function [19], and maintenance of swallowing muscle composition [19, 22].

Two studies reported negative outcomes for their primary variable [13, 24]. Three studies reported no change in outcome from intervention [16, 18, 23]. In reviewing the design quality rating and statistical conduct of each study, five studies reporting positive outcomes could not be justified due to methodological and statistical issues [13, 17, 20, 21, 25]. An additional two studies with low methodological rigor and identified statistical issues did not report improved outcomes for their sample and remained inconclusive [18, 23].

Discussion

Systematic reviews are conducted to appraise the volume and strength of a body of research surrounding a topic. As the name implies, they are systematic, organized, comprehensive, and structured investigations. A thorough systematic review can assist researchers and clinicians in outlining the benefits of available treatments, and provide direction for future work.

We conducted a systematic review of dysphagia rehabilitation and evaluated the quality of RCTs meeting recommended methodological rigor. Our review identified 15 studies meeting the a priori inclusion criteria for a randomized trial of oro-pharyngeal dysphagia in adults over the years 2010–2013. Of those studies, only five met the criteria for high quality using a validated evaluation scale [8]. Specific weaknesses of the lower rated studies included: incomplete details regarding randomization procedures, lack of information on allocation concealment, limited blinding of subjects and therapists to the provision of the intervention, control of co-intervention contamination, and management/reporting of sample attrition. Importantly, an additional five studies were designated as quasi-experimental trials as they did not include a standard control comparator in the trial design. If a study provides only comparison between an active arm and a placebo, critical information about the true and placebo effect of an intervention cannot be fully obtained. For example, where the natural progression of a disease is variable or unknown, we would not be able to identify the true responders, as some patients will garner benefit by any intervention alone (enthusiasm bias). Without a true "control", the impact of the placebo strategy cannot be determined and may lead to exaggerated treatment effect estimation.

Another potential problem identified from the current review is the continuing publication of trials with limited sample sizes. Small clinical trials ($n < 80$) using conventional simple randomization methods may result in imbalanced covariate distributions between treatment and control groups. Similarly, smaller trials are often hampered by power limitations in analysis resulting from their size. The use of alternate methods of randomization that support balance in smaller trials, including blocked, stratified, and covariate adaptive designs, however, remain limited within the dysphagia rehabilitation literature.

No matter how well designed an RCT, it is only as good as its outcome assessment. In this review, we identified only 60 % of studies utilizing validated outcome assessment tools. The majority of studies used clinical dysphagia assessment methods, with only 26 % utilizing both validated clinical and instrumental methods. Accuracy of assessment using proven methods reduces investigator bias and improves the ability for findings to be translated across studies. Clearly, dysphagia researchers must continue to strive to use outcome metrics that improve the accuracy and clarity of measurement within trials to advance science in this area.

This review has identified a diverse range of dysphagia interventions and applications. Without accepted and utilized standards, comparisons of outcomes or treatment effects is not possible. The current RCTs reviewed demonstrate little concordance in either timing of interventions, duration of interventions, or frequency of application. The only intervention area demonstrating any concordance was the application of neuromuscular electrical stimulation (NMES). This treatment method, although controversial in outcome, was applied daily in all four studies reviewed. Unfortunately, the exact timing, duration, and configuration of this application were haphazard, underscoring the lack of accepted standards in treatment approaches. Consequently, RCTs in dysphagia rehabilitation would benefit greatly from procedures to reduce variability of investigation and promote comparisons across studies.

The majority of RCTs in this review presented data from pre- to post-evaluation comparisons. Only 20 % of trials provided any outcome data beyond the post-intervention time point. Moreover, only one study evaluated outcome

out to 12 months. Lack of follow-up and the inclusion of methods to manage attrition of study samples is another area that needs to be addressed in future research. Likewise, the use and application of statistical methods that match the trial design and recruited sample sizes needs further consideration. Many researchers did not conform to statistical reporting standards for publication, providing only p values without specific details of direction or variability of effect. The continued use of inadequate statistical reporting within trials limits the ability to synthesize data across swallowing studies (meta-analysis) or to inform effect size calculation for future research protocols.

In this review, we sought to identify both published and unpublished trials of dysphagia rehabilitation to evaluate the scope and quality of recently completed research. Our final study sample included 13 published RCTs and two grey (unpublished) papers. The literature search included here was comprehensive, including academic search premier, and conference proceedings and abstracts; as such, we believe it reflects the current knowledge base in this area. Despite this, it is possible that not all studies were captured. Our review differs from previously published systematic reviews [5–7] in that we included grey literature within our sample. The addition of grey data is important as they may be the only source of important up-to-date information. Further, it may offer insight into unique directions for a burgeoning field.

Although our study is distinct from previous systematic reviews that have sought to evaluate dysphagia interventions, our results are consistent with their findings that the rigor of swallowing intervention trials remains lacking. It is important to note, however, that the number of RCTs on swallowing rehabilitation published over the last 2.5 years has increased steadily. Previous reviews have identified a publication rate of 0.36 trials/year, which has now risen to an average of 6 per year [5, 6]. Moreover, the use methodological control strategies within current trials is continuing to advance.

Conclusion

Emerging evidence demonstrates that the breadth of dysphagia rehabilitation intervention methods is rapidly advancing. The use of more advanced study designs has also increased and the publication rate for RCTs appears to be growing. Despite this, newly published RCTs continue to demonstrate significant weaknesses in design and heterogeneity in treatment methods, limiting current comparisons and data to support the efficacy of dysphagia rehabilitation approaches.

Compliance with Ethics Guidelines

Conflict of Interest Both authors are free of professional areas of conflict of interest such as financial remuneration as employee, consultant, or subcontractor with companies. G. Carnaby and A. Madhavan declare no conflicts of interest

Human and Animal Rights and Informed Consent This article is not a specific study with human or animal subjects research performed by any of the authors. Note however, that all studies referenced in which the author GC participated, received local Institutional Review Board approval for human subjects research.

Appendix

See Tables 3, 4, and 5.

Table 3 van Tulder scale [8]

Item	Yes	No/Dk
A. Was there a method of randomization using an adequate procedure?		
B. Was the treatment allocation concealed?		
C. Were the groups similar at baseline regarding the most important prognostic indicators?		
D. Was the patient blinded to the intervention?		
E. Was the care provider blinded to the intervention?		
F. Was the outcome assessor blinded to the intervention?		
G. Were co-interventions avoided or similar? Was there control for co-interventions?		
H. Was the compliance acceptable in all groups?		
I. Was the withdrawal/drop-out rate described & acceptable? (i.e. <20 % short term and <30 % long term with no substantial bias)		
J. Was the timing of outcome assessment in all groups similar?		
K. Did the analysis include an intention-to-treat analysis?		
Total items scored yes (0–11)	/11	

Table 4 Study characteristics and relevant findings (cont)

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Intervention type = dietary					
Bevan et al. [11][b]	Looped NGT insertion	Standard NGT insertion	(i) Proportion of feed/fluids delivered after 2 weeks[a] (ii) Tolerability likert scale (i) Direct costs [*Measurement* post 2 weeks]	Looped NGT resulted in 17 % increase in volume delivered, fewer NGT. Lower electrolyte abnormalities, but higher cost	Binary proportion comparison[a] Cohen's $d = 0.45$ (95 % CI −0.01 to 0.9)
Karagiannis et al. [13]	Thickened fluid diet + free H_2O [30 min after meals for 5 days]	Thickened fluid diets	(i) Chest status/infection[a] (ii) Core body temperature (iii) Total fluid intake (iv) QOL survey [non validated] [*Measurement* baseline and day 5]	Total fluid intake and QOL increased in free water group. Lung complications increased in free water group	
Carlaw et al. [21]	Immediate implementation of H_2O protocol [Day 4–14 days]	Delayed implementation of H_2O protocol for 14 days [Cross-over after day 14]	(i) Fluid intake (ii) SWALQOL [*Measurement* baseline and day 14]	Fluid intake greater in the experimental group compared to the "no access" measure in the control group. Improved QOL scores at post trial measure	
Intervention type = electrotherapy					
Xia et al. [12]	(a) Vital stim + conventional therapy (b) Vital stim therapy alone [30 min/day × 5 days a week for 4 weeks]	Conventional swallow therapy = diet intake, posture, environment control	(i) SSA (ii) sEMG (iii) VFSS (vi) SWAL-QOL [*Measurement* baseline and post treatment]	All scores post 4-weeks treatment significantly higher in vital stim + conventional therapy group	
Heijnen et al. [23]	(a) NMES motor + usual swallowing treatment (b) NMES-sensory + usual swallowing treatment [30 mins/day × 5 consecutive days for 13–15 sessions] NB: reported variable amounts provided	Usual swallowing treatment = oromotor exercise's, airway-protection maneuvers, postural compensations	(i) SWAL-QOL (ii) MD Anderson dysphagia inventory (iii) FOIS (iv) Dysphagia severity scale [non validated] [*Measurement* baseline, post treatment and 3 months following treatment]	No significant difference in swallowing or QOL outcomes between groups	
Long et al. [25]	Combination therapy + NMES + UES balloon dilation [3 × day/45 cycles for 4 months]	Routine swallow rehab therapy = tongue, pharynx, larynx exercises [3 × day/45 cycles/4 months]	(i) Water sallow test [WST] (ii) VFSS-biomechanics [OTT, SRT, PTT, LCD] [*Measurement* baseline and post treatment]	Significant improvement in post treatment WST score and all biomechanic values in the intervention group	

Table 4 continued

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Carnaby ANSRS [24] [grey][b]	(a) Swallowing behavioral therapy—McNeill dysphagia therapy [MDTP] + NMES (b) MDTP + sham NMES	Usual care = swallowing maneuvers, compensations, diet modification [1 h/day/3 weeks]	(i) Clinical swallowing ability [MASA][a] (ii) Oral intake [FOIS] (iii) Body weight (iv) Dysphagia-related complication (v) Return to pre-stroke diet (vi) Patient perception of swallow [*Measurement* baseline, post treatment and 3 months following treatment]	MASA score[a], FOIS score post treatment and proportion of treatment responders[a] (return to pre-stroke diet) significantly improved for the sham arm than experimental or control. No difference in patient perception of swallow between intervention and sham groups	Mean standardized difference) MASA score)[a] Cohen's $d = 0.25$ (95 % CI −0.4 to 0.94) Binary proportion comparison(response) Cohen's $d = 1.7$ (95 % CI 0.4–3)
Intervention type = preventative behavioral exercise					
Carnaby-Mann et al. [19][b]	(a) Prophylactic swallowing exercise during CRT = pharyngocise (b) Sham swallowing exercise during CRT [Pharyngocise = effortful swallow, tongue press, falsetto, jaw strengthening (Therabite)] (45 m ins/2 × day/5 days/6 weeks)	No preventative exercise	(i) T2 weighted MRI[a] (ii) Functional swallowing (MASA +FOIS) (iii) Taste scores (iv) Smell (v) Salivation (vi) Body weight (vii) Mouth opening [*Measurement* baseline, CRT completion, 6 months after CRT]	Prophylactic exercise Intervention group demonstrated superior preservation in T2 MRI scores, functional swallowing, mouth opening taste and salivation	Mean standardized difference (t2 value mylohyoid)[a] Cohen's $d = -0.36$ (95 % CI −0.098 to 0.26)
van der Molen et al. [16]	Prophylactic swallowing exercise = swallowing with Therabite in place + swallowing with tongue elevated [8–12 reps, 3 × daily for 10 weeks]	Standard therapy = gargle task, oral stretching, masako, supr-supraglottic, forceful biting maneuvers [8–12 reps, 3 × daily for 10 weeks]	(i) Penetration–aspiration scale [non validated] (ii) Maximum incisor distance (iii) Body mass index (iv) FOIS score (v) QOL survey [*Measurement* baseline and post treatment]	No significant differences between groups Only pre- to post-intervention (whole group) results presented Patients in intervention arm practiced less often but obtained comparable results	No quantitative result comparison available between groups (for any outcome) insufficient statistics
Kotz et al. [17]	Prophylactic swallowing exercise during CRT = effortful swallow, tongue base retraction, Masako, super-spuraglottic, mendelsohns maneuvers [30 mins/3 × daily for 7 weeks at home on own]	Usual care = no exercises	(i) Performance status scale HN [PSSH&N eating in public scale][a] (ii) FOIS scale [*Measurement* baseline, 7 weeks post treatment, 3, 6, 9, 12 months]	No significant difference between scores post treatment. Scores on both scales demonstrated significant differences at 3 and 6 months but not at later time points	No quantitative result comparison available between groups (for any outcome)—insufficient statistics

Table 4 continued

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Carnaby et al. [22][b]	(a)Prophylactic swallowing exercise-therapist directed = Pharyngocise (b)Prophylactic swallowing exercise-patient directed [45 mins/2 × day/5 days/ 6 weeks]	Usual care = no exercises	(i) T_2 MRI (ii) MASA-C (iii) FOIS (iv) SWALQOL (v) Body weight (vi) Psycho-social measures (vii) Compliance with exercise [*Measurement* baseline, post treatment, 3-months following treatment]	Less swallow muscle deterioration, less functional swallow change and greater compliance identified in the therapist directed arm compared to patient directed or control	Mean standardized difference (length mylohyoid) Cohen's $d = 0.51$ (95 % CI 0.03–0.99)

[a] Denotes primary outcome for effect size calculation

[b] Denotes high-grade RCT

Table 5 Study characteristics and relevant findings (cont)

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Intervention type = behavioral maneuvers/compensations plus alternative medicine					
Feng et al. [29]	Tongyan spray + mixed swallow therapy = ROM, modified diets, ice stimulation [3× day/28 days]	Placebo Tongyan spray + mixed swallow therapy = ROM, modified diets, ice stimulation [3× day/28 days]	(i) Standard swallowing assessment scale [Non-valid scale] [*Measurement* baseline, post 28 days]	Intervention group showed significantly more improvement on SSA scale than control post treatment	
Chan et al. [30]	Acupuncture + swallow therapy = oromotor exercises + maneuvers + diet modification + positioning + compensations [1.5 months of 20 sessions]	(1) Sham acupuncture + swallow therapy [1.5 months of 20 sessions] (2) Routine care (non-randomized group)	(i) Royal Brisbane Hospital outcome measure score (ii) Food /fluids consumed [*Measurement* baseline, week 2, week 4, 3 months post treatment]	Experimental group demonstrated significantly higher RBHOM scores after 18 weeks than control group 2 Sham showed significantly higher RBHOM scores after 18 weeks than control group 2 Experimental group demonstrated significantly greater food fluid consistencies consumed	

Table 5 continued

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Yang et al. [28]	Anodal transcranial direct current (tDCS) [1 mA for 20 min/daily for 10 days] + conventional swallow training (no details provided)	Sham tDCS [1 mA for 30 s/daily for 10 days] + conventional swallow training (no details provided)	(i) VFSS-biomechanics [OTT, PTT, TTT] (ii) Functional dysphagia scale [FDS] [*Measurement* baseline, post treatment and 3 months post treatment]	No difference in FDS scores post treatment. At 3-months post intervention demonstrated improved FDS scores compared to sham	
Intervention type = program effectiveness					
Middleton et al. [14][b]	Multidisciplinary treatment protocol for fever, hyperglycemia and swallowing management [Protocols provided 3 months prior to data collection]	Abridged current guidelines only	(i) Modified rank in score (mRS)[a] (ii) Barthel index (iii) SF-36pysical component (iv) SF-36 mental component [*Measurement* pre and post 90 days from admission]	Patients treated in intervention ASU less likely to be dead or dependent (mRS score) and better SF-36 physical scores than control group	Binary proportion comparison[a] Cohen's $d = -0.35$ (95 % CI -0.49 to 0.21)
Intervention type = behavioral maneuvers/compensations					
Tang et al. [15]	Rehabilitation therapy-tongue, pharynx,larynx exercise + ROM trismus (Therabite) [3× day/45 cycles for 3 months]	Routine treatment = no exercise + anti-inflammatory treatment	(i) Water swallow test score (ii) Incisor distance (lent soma score) [*Measurement* baseline and post treatment]	Significant improvement in swallow score in rehab group, significant decreased in incisor distance in control group	
Oh et al. [18]	Repetitive swallow with tongue hold maneuver [20 min × 20 sessions over 4 weeks]	Swallowing without tongue restriction [20 sessions over 4 weeks]	(i) Biomechanics from VFSS-pharyngeal constriction ratio, maximum hyo-laryngeal movement,, posterior pharyngeal wall movement [*Measurement* baseline and post treatment]	No significant difference in effect between groups	No quantitative result comparison available between groups (for any outcome)—insufficient statistics
Terre et al. [27]	Chin down position under videofluoroscopy	Anatomic position under videofluoroscopy	(i) Aspiration (+/−) from VFSS (ii) Biomechanics from VFSS [OTT, PTT, PDT] [*Measurement* pre-post alternating VFSS measures]	In aspirating subjects only 50 % avoided aspiration using chin down position (pre-swallow or during swallow) No control comparison could be reported	
Intervention type = behavioral exercises					
Troche et al. [26]	Expiratory muscle strength training [EMST] [75 % maximum for 5 sets/5 repetitions/ 5 days for 4 weeks]	Sham EMST [5 sets/5 repetitions/5 days for 4 weeks]	(i) Penetration–aspiration score [Non-validated scale] (ii) SWALQOL scores (ii) Hyoid, UES movement [*Measurement* baseline and post treatment]	Intervention group showed improved penetration scores, SWALQOL scores hyoid movement and UES opening diameter compared to sham	

Table 5 continued

Author	Intervention methodology	Control methodology	Evaluation measures	Main findings	Primary effect calculation
Chen et al. [20]	Pre-operative trachea/esophageal traction [2× day at 15 counts for 3 consecutive days before surgery]	No preoperative traction	(i) Bazaz dysphagia scores [Non valid scale] (ii) Neck disability index (iii) VAS for arm and neck pain [*Measurement* week 1, week 3, week 6, month 3, month 6 post-surgery]	No difference in neck disability or pain. Bazaz scores in experimental group significantly higher than control group at both time points	

[a] Denotes primary outcome for effect size calculation

[b] Denotes high-grade RCT

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