

SYSTEMATIC REVIEW



Interventions for oropharyngeal dysphagia in acute and critical care: a systematic review and meta-analysis

Sallyanne Duncan^{1*} , Daniel F. McAuley¹, Margaret Walshe², Jennifer McGaughey³, Rohan Anand¹, Richard Fallis⁴ and Bronagh Blackwood¹

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Abstract

Purpose: To determine the effectiveness of dysphagia interventions compared to standard care in improving oral intake and reducing aspiration for adults in acute and critical care.

Methods: We searched electronic literature for randomised and quasi-randomised trials and bibliography lists of included studies to March 2020. Study screening, data extraction, risk of bias and quality assessments were conducted independently by two reviewers. Meta-analysis used fixed effects modelling. The systematic review protocol is registered and published.

Results: We identified 22 studies (19 stroke, 2 intensive care stroke and 1 general intensive care) testing 9 interventions and representing 1700 patients. Swallowing treatment showed no evidence of a difference in the time to return to oral intake ($n = 33$, MD (days) $- 4.5$, 95% CI $- 10.6$ to 1.6 , 1 study, $P = 0.15$) (very low certainty) or in aspiration following treatment ($n = 113$, RR 0.79 , 95% CI 0.44 to 1.45 , 4 studies, $I^2 = 0\%$, $P = 0.45$) (low certainty). Swallowing treatment showed evidence of a reduced risk of pneumonia ($n = 719$, RR 0.71 , 95% CI 0.56 to 0.89 , 8 studies, $I^2 = 15\%$, $P = 0.004$) (low certainty) but no evidence of a difference in swallowing quality of life scores ($n = 239$, MD $- 11.38$, 95% CI $- 23.83$ to 1.08 , $I^2 = 78\%$, $P = 0.07$) (very low certainty).

Conclusion: There is limited evidence for the effectiveness of swallowing treatments in the acute and critical care setting. Clinical trials consistently measuring patient-centred outcomes are needed.

Keywords: Dysphagia, Deglutition disorders, Intensive care, Critical care, Swallowing therapy, Dysphagia rehabilitation

Introduction

Dysphagia in patients who are acutely and critically ill is often multi-factorial. Following acute stroke, dysphagia is in part caused by a loss of functional connectivity within the neural swallowing network. However, neuroplasticity results in the undamaged hemisphere compensating for lost functions from lesions in the affected hemisphere, with more than half of patients recovering swallow function in the first 3 weeks post-stroke [1]. In critical care, the pathogenesis of dysphagia may involve

*Correspondence: sduncan10@qub.ac.uk

¹ Wellcome-Wolfson Institute for Experimental Medicine, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, UK

Full author information is available at the end of the article

direct laryngeal trauma caused by endotracheal/tracheostomy tubes resulting in impairments in laryngeal closure, neuromyopathy resulting in weakness of oral, pharyngeal and laryngeal muscles and diminished laryngeal sensation secondary to prolonged endotracheal intubation [2, 3]. Up to 67% of patients intubated for prolonged periods can be affected [4, 5]. Studies using videofluoroscopy or endoscopy over clinical assessment report higher dysphagia incidence. This is because impaired physiology, resulting in symptoms such as silent aspiration (no cough response when food/fluids enter airway) and poor oropharyngeal secretion management can be visualised [6].

Consequences of dysphagia include delayed return to oral intake [7, 8], pneumonia, poor quality of life, longer intensive care and hospital stays [8–12] and is an independent predictor for 90-day mortality [13]. It remains an under-recognised but highly relevant clinical challenge with symptoms found to persist beyond hospital discharge for > 6 months in 23% of patients in a multicentre 5-year longitudinal study [14–17]. Sensory stimulation and muscle strengthening treatments may improve swallow function for such populations. The objective of this review was to determine the effectiveness of dysphagia interventions compared to standard care in improving oral intake and reducing aspiration for adults in acute and critical care settings.

Methods

We registered the protocol with the International Prospective Register of Systematic Reviews (PROSPERO CRD 42018116849) and published the review protocol in 2019 [18]. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines [19].

Study selection

We included randomised controlled trials (RCT) or quasi-RCT testing dysphagia interventions in adult patients in acute care or critical care settings. Cluster RCTs were excluded as we were not considering the group effect of a dysphagia intervention. We will consider their inclusion in future updates. Adult participants, 18 years or older of any sex, ethnicity and stage of illness were included. Acute care was defined as any acute hospital ward or unit (i.e. medical, respiratory, surgical, neurological or stroke units). Critical care was defined as intensive care units, with no limitation regarding intubation/ventilation times or the presence of tracheostomy in study participants. Studies conducted in rehabilitation, long-term care or outpatient settings were excluded.

We considered any dysphagia intervention delivered alone or in combination with traditional swallowing rehabilitation versus traditional swallowing rehabilitation,

Take-home message

There is limited research on dysphagia interventions in acute and critical care settings and limited evidence to guide clinical practice in this area. Clinical trials consistently measuring patient-centred outcomes are needed.

usual care or placebo (i.e. studies using a sham intervention). The primary outcomes were time taken to return to oral intake and aspiration incidence post-treatment (defined as score > 5 on the Penetration Aspiration Score [20]). Secondary outcomes included: incidence of pneumonia; quality of life (measured by Swallowing Quality of Life Scale [21]); length of hospital stay; change in secretion severity; change in pharyngeal residue severity; nutritional status; and intervention-related adverse events. Where studies report outcomes at different time-points, we will accept and report both.

Search strategy and data extraction

We searched Medline, CENTRAL, CINAHL, EMBASE, Web of Science, Clinicaltrials.gov, and the WHO International Clinical Trials Registry Platform from inception to March 2020 and included all languages. (Electronic Supplemental Material (ESM) Appendix A). Citations were imported to an online platform (www.covidence.org), and two reviewers (SD, JMcG) independently screened titles and abstracts for full-text review. Bibliography lists of included studies were searched in March 2020. We extracted information regarding setting, participant characteristics, intervention types and outcomes (ESM Appendix B). Intervention details were extracted using the Template for Intervention Description and Replication (TIDieR) checklist [22] (ESM Appendix C) and outcomes information gathered as per SPIRIT 2013 (i.e. specific measurement, analysis metric, method of aggregation and timepoint) [23] (ESM Appendix D). Two reviewers (SD, JMcG) independently extracted outcome data and assessed risk of bias using the Cochrane Collaboration Risk of Bias tool [24]. Disagreements were settled by consensus. Overall risk of bias for each study was then assigned low (all domains low); unclear (one or more domains unclear); high (one or more domains high) as per PROSPERO. We assigned an 'unclear' rating when the study did not report a specific domain in the published paper or protocol. We did not contact study authors for verbal clarification.

Data analysis and grading the evidence

We used RevMan software (Review Manager, version 5.3) for data analysis [25]. The following measures of treatment effect were used: risk ratio (RR) and 95% confidence

intervals (CI) for the analysis of dichotomous outcomes, mean difference and standard mean difference and 95% CI for continuous outcomes. Studies reporting median/interquartile ranges were not converted to mean/standard deviation values for meta-analysis, as it was assumed the underlying data were skewed and such conversions are ill-advised by Cochrane [24]. Where different scales were used to measure an outcome, we ensured directionality of scales was uniform in meta-analysis. The number of participants analysed rather than number recruited per study was used.

Meta-analyses were performed if outcomes from two or more studies with similar interventions were available, and we used fixed effects models to calculate pooled estimates. By choosing a fixed effects model, we assumed that the true effect of dysphagia interventions (in size and direction) would be the same in every study and that observed differences among studies would be due to chance. Statistical heterogeneity was evaluated using the Chi-square test and the I^2 statistic ($I^2 > 50\%$, substantial heterogeneity). If substantial heterogeneity existed, we repeated the meta-analysis using a random-effects model [24]. Subgroup analyses were planned for the following groups: acute versus critical care; younger age groups (<65 years) versus older age groups (i.e. >65 years) and types of interventions.

Applying Cochrane guidance, in three arm trials evaluating similar interventions, we statistically pooled the interventions rather than splitting control groups [24]. In three arm trials evaluating dissimilar interventions, control groups were split and compared to each intervention arm individually to avoid unit of analysis error [24]. Where additional unpublished outcome data were required, the review team contacted authors by email correspondence. If no author response was received, we contacted authors a second time, 4 weeks after initial correspondence.

We used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to classify the certainty of evidence into high, moderate, low or very low for each outcome [26] and included a summary of findings table for the main outcomes (Table 1). As planned, publication bias will be evaluated using funnel plot asymmetry testing if a sufficient number of studies are identified ($n > 10$).

Results

We identified 4893 studies. After removing duplicates and excluding irrelevant records, we assessed 99 full-text studies. We excluded a further 77 studies and included 22 trials (22 RCT, no quasi-RCT, and although not included, we found no cluster-RCTs). The trial populations included 19 stroke in acute care ($n = 1568$); 2

tracheostomised stroke in intensive care ($n = 99$); and 1 general intensive care ($n = 33$) [27–48] (Fig. 1) (ESM Appendix E and F). Twenty-three data sets were analysed in this review as one three-arm study compared two different interventions [32]. The majority of trials which were included were conducted in a single-centre setting ($n = 19$) with three multi-centre trials (Table 2). Twenty-one studies were published in English, and one study was published in Chinese and translated by a native Chinese researcher [46]

The overall mean age of participants in both groups in all studies was 70 years. Disease severity for stroke was reported using National Institute of Health Stroke Scale [49], with average scores across experimental (11) and control (11.5) groups indicating moderate stroke disability. No studies included frailty assessments. Baseline dysphagia severity was measured using fourteen different assessment tools. Eight clinical assessments evaluated function based on bedside clinical signs and symptoms and clinicians recommended altering oral diet/fluid consistencies and feeding supervision. Six validated rating scales were used during videofluoroscopy/endoscopy assessments, to grade swallow physiology at oral, pharyngeal and upper oesophageal stages. Average baseline scores for experimental and control groups across all studies indicated moderate to severe dysphagia.

Seven trials involved three intervention arms [28, 30, 32, 33, 37, 46, 47]. In five trials, data from both intervention arms (same intervention delivered at different intensities) were combined and compared to the control group for both dichotomous and continuous outcomes. One trial tested two different interventions, and so the control group was split in half and compared to each intervention arm [32]. One trial descriptively reported on adverse events so no numerical data was available for meta-analysis [37].

At present, seven trials are ongoing in acute care [50–56], four of these in intensive care, testing swallowing exercises post-extubation [50] or sensory electrical stimulation during intubation or post-extubation [51–53]. Ten trials are unclassified testing interventions in stroke [57–66]. The review team were unable to obtain trial results or sufficient data from authors to confirm inclusion. (ESM Appendix G). An expert advisory group in the field of dysphagia and critical care research was consulted in June 2019 and confirmed that to the best of their knowledge there were no other completed or ongoing trials in intensive care at that time (ESM Appendix H).

Risk of bias in included studies

Twenty-two trials (23 data sets) were assessed for risk of bias (17 high risk; 6 unclear risk of bias). Low risk was assigned to the following domains: selection bias

Table 1 Summary of findings

Swallowing therapy compared to standard care for oropharyngeal dysphagia in acute and critical care						
Patient or population: adults with oropharyngeal dysphagia						
Setting: Acute hospital wards and intensive care units						
Intervention: swallowing therapy						
Comparison: standard care						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard care	Risk with swallowing therapy				
Time (days) to return to oral intake	The mean time in days to return to oral intake was 11.9 days	MD 4.5 days lower (10.63 lower to 1.63 higher)	–	33 (1 RCT)	⊕○○○ Very low ^{a,b}	Oral intake was not defined (i.e. whether modified diet or pre-admission diet)
Aspiration incidence post-treatment assessed with: Penetration Aspiration Score rating 5 or greater on a 0–8 scale	318 per 1000	251 per 1000 (140 to 461)	RR 0.79 (0.44 to 1.45)	113 (4 RCTs)	⊕⊕○○ Low ^c	Variable time points: 3-months (32, 48); 2 weeks (40); not defined (33)
Incidence of pneumonia	311 per 1000	221 per 1000 (174 to 276)	RR 0.71 (0.56 to 0.89)	719 (8 RCTs)	⊕⊕○○ Low ^c	Variable time points used: during hospital admission (35, 44); post-randomisation (27); day 30 and hospital discharge (31); 2 months (45); 3 months (32); 6 month (28); and not defined (34)
Length of hospital stay (days)		MD 0.4 lower (3.6 lower to 2.8 higher)	–	536 (4 RCTs)	⊕○○○ Very low ^{c,d}	Defined as time from treatment to discharge (43); time from admission to discharge (27, 44) and not defined. (28)
Quality of life post-treatment assessed with: Swallowing Quality of Life Scale: 0 to 200		MD 11.38 SD lower (23.83 lower to 1.08 lower)	–	239 (2 RCTs)	⊕○○○ Very low ^{c,e}	Lower score indicates improved quality of life. Post-treatment timepoints not defined [39, 46]
Intervention-related adverse events	87 per 1000	151 per 1000 (50 to 458)	RR 1.74 (0.57 to 5.27)	109 (2 RCTs)	⊕⊕○○ Low ^c	Following treatment, timepoints not defined [30, 31]
Change in pharyngeal residue severity assessed with: functional dysphagia scale; video fluoroscopy scoring scale; video fluoroscopic dysphagia scale	–	SMD 0.78 SD lower (1.3 lower to 0.26 lower)	–	64 (3 RCTs)	⊕○○○ Very low ^{c,f}	Lower scores indicates improvement in pharyngeal residue severity. Timepoint: following 4-week treatment period [38, 41, 42]
Nutritional status assessed with: (Albumin level g/L)		MD 0.9 higher (0.99 lower to 2.79 higher)	–	141 (1 RCT)	⊕⊕○○ Low ^c	Higher scores indicates improved nutritional status

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)

CI confidence interval, MD mean difference, RR risk ratio, SMD standardised mean difference

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Table 1 (continued)

^a Downgraded one point due to serious inconsistency from wide CIs

^b Downgraded two points due to very serious imprecision as number of participants did not reach optimal information size and only one study reported this outcome

^c Downgraded two points due to very serious imprecision as number of participants did not reach optimal information size

^d Downgraded one point due to serious inconsistency as a result of substantial heterogeneity (52%)

^e Downgraded one point due to serious inconsistency as a result of substantial heterogeneity (78%)

^f Downgraded one point due to serious risk of bias in both studies: allocation concealment and blinding were not clearly stated

(random sequence generation: 18/23; 78%; allocation concealment: 14/23; 61%), detection bias (blinded outcome assessment) (19/23; 83%), attrition bias (20/23; 87%) and reporting bias (22/23; 96%). No studies clearly reported that personnel delivering the intervention were blinded and only 43% (10/23) of studies clearly reported that participants were blinded to the intervention. (ESM Appendix I).

Intervention reporting and replication

We assessed each study for the inclusion of twelve components involved in delivering an intervention as per TIDieR [22]. All studies reported rationale for treatment, materials and procedures used and the number, frequency, timing and intensity of treatment sessions. Thirteen studies reported who delivered the intervention [28, 29, 32–34, 37–39, 41, 42, 45, 47, 48] and seven detailed the training and/or experience of such personnel [27, 29, 33, 39, 41, 42, 45]. Thirteen studies provided information on whether treatments were tailored [27, 28, 30, 31, 33, 35, 37–40, 43, 45, 48], and no studies reported if an intervention was modified or whether intervention adherence assessment was completed. Actual adherence was calculated from the number of participants who completed an intervention. This was reported in all studies (ESM Appendix C).

Assessment of quality of the evidence

We present our assessment of the certainty of evidence for each outcome according to the GRADE approach in the summary of findings table (Table 1). We used a simple measure to assess publication bias based on the balance of published trials that showed an effect or not, as there was insufficient number of trials for funnel plot testing. Publication bias was not detected.

Subgroup analysis

Data were available to complete subgroup analysis of acute versus critical care for one outcome: pneumonia incidence and subgroup analysis of different interventions for five outcomes: aspiration incidence, quality of

life, length of stay, change in pharyngeal residue severity and intervention-related adverse events.

Sensitivity analysis

We planned to investigate the influence of bias on results by undertaking a sensitivity analysis of primary outcomes excluding studies with a high risk of bias. This was not undertaken as relevant studies were assessed as having a high risk of bias.

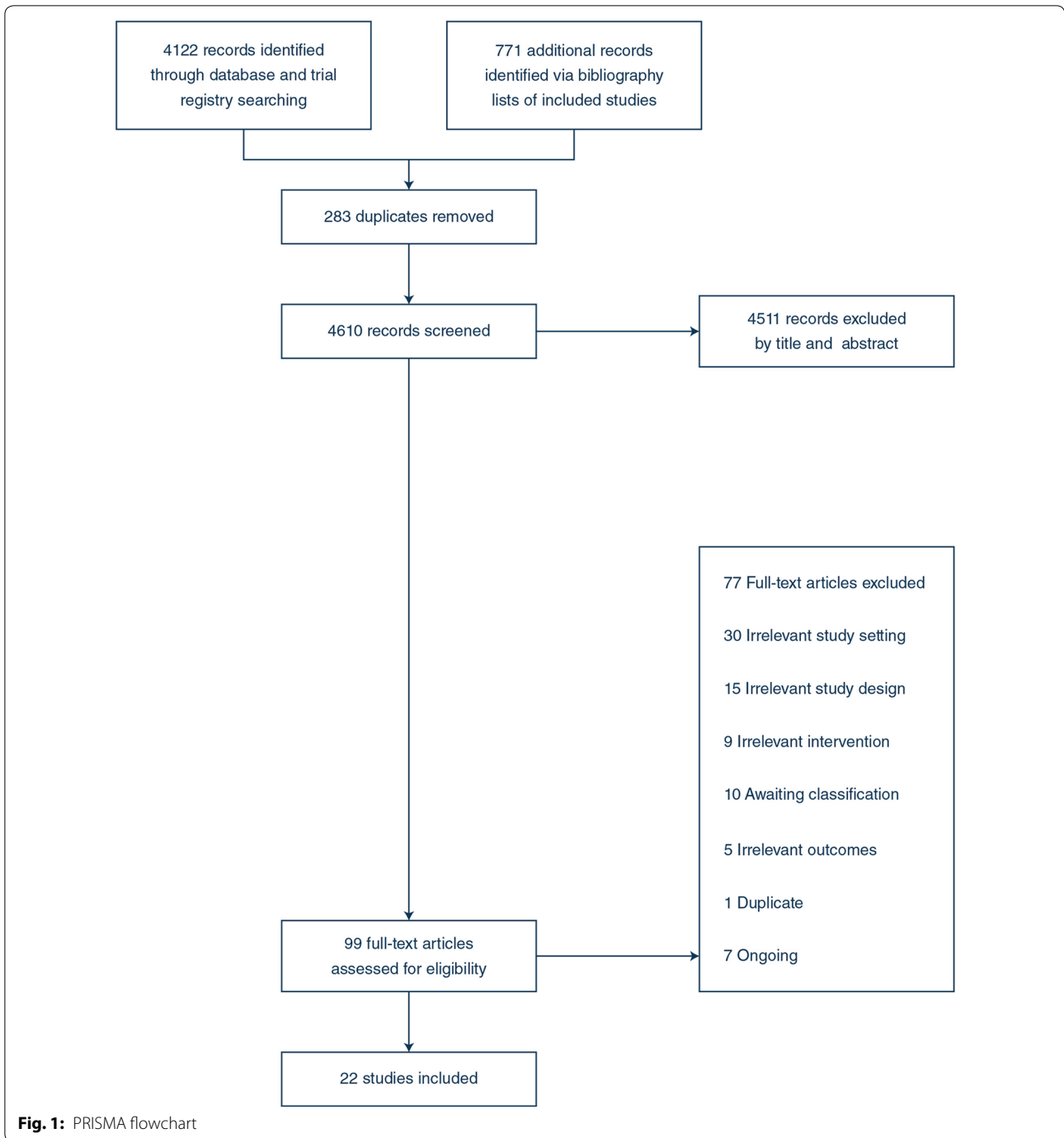
Main outcomes

Time taken in days to return to oral intake

One trial [34] reported this outcome and compared a behavioural intervention (i.e. swallowing exercises and oral stimulation) to standard care (no swallowing related exercises) in an intensive care setting. Swallowing therapy showed no evidence of a difference in the time to return to oral intake ($n=33$, MD (days) – 4.5, 95% CI – 10.6 to 1.6, 1 study, $P=0.15$) (very low certainty).

Aspiration incidence post-intervention

Four trials (5 data sets) reported this outcome for swallowing therapy versus standard care [32, 33, 40, 48]. Two studies provided unpublished data on request [33, 48]. Swallowing therapy showed no evidence of a difference in reducing aspiration post-intervention ($n=113$, RR 0.79; 95% CI 0.44 to 1.45, $I^2=0%$, $P=0.45$) (low certainty). Subgroup analysis of intervention types showed no significant effects for transcranial magnetic stimulation; transcranial direct current stimulation (tDCS); neuromuscular electrical stimulation (NMES); or respiratory muscle strength training (RMST), with no significant subgroup interaction ($P=0.59$, $I^2=0%$) (Fig. 2). Data on the number of patients aspirating per group were requested from authors of eleven studies. Penetration aspiration scores (PAS) were reported as mean and SD per group but did not report data on number of patients aspirating ($PAS>5$) versus not aspirating ($PAS<5$). Two authors provided unpublished data [33, 48], three authors reported data were unavailable [40, 43, 44] and six authors provided no response [27, 29, 35, 37, 38, 45].



Incidence of pneumonia

Eight trials (9 data sets) [27, 28, 31, 32, 34, 35, 44, 45] reported this outcome. The pooled results showed a beneficial effect for swallowing therapy ($n=719$, RR 0.71, 95% CI 0.56 to 0.89, $I^2=15\%$, $P=0.004$) (low certainty). Subgroup analysis of acute versus critical care showed a significant effect for acute care (7 datasets,

617 participants, RR 0.72, 95% CI 0.57 to 0.91, $I^2=33\%$, $P=0.007$) and no evidence of a difference for critical care (2 trials, 102 participants, RR 0.58, 95% CI 0.22 to 1.55, $I^2=0\%$, $P=0.28$) with no significant subgroup interaction ($P=0.68$, $I^2=0\%$) (Fig. 3).

Table 2 Details of included studies

Study and country	Clinical setting/population/sample size	Intervention	Comparator
Du et al. [30] China	Neurology unit Stroke N=40	Transcranial magnetic stimulation	Sham stimulation
Park et al. [40] Korea	Stroke unit N=18	Transcranial magnetic stimulation	Sham stimulation
Kumar et al. [36] USA	Stroke unit N=14	Transcranial direct current stimulation	Sham stimulation and swallowing exercises/oral stimulation
Suntrup-Kreuger et al. [44] Germany	Stroke unit N=60	Transcranial direct current stimulation	Sham stimulation and swallowing exercises/oral stimulation
Yang et al. [48] Korea	Neurology unit Stroke N=16	Transcranial direct current stimulation	Sham stimulation and swallowing exercises
Moon et al. [39] Korea	Hospital ward Stroke N=16	Tongue palate resistance training	Swallowing exercises
Moon et al. [38] Korea	Stroke unit N=18	Respiratory muscle strength training	Swallowing exercises/thermal stimulation
Guillan-Sola et al. [32] Spain	Hospital ward Stroke N=31	Respiratory muscle strength training	Swallowing exercises
Bath et al. [27] Multi-national	Stroke unit N=162	Pharyngeal electrical stimulation	Sham stimulation
Dziewas et al. [31] Multi-national	Neuro intensive care stroke N=69	Pharyngeal electrical stimulation	Sham stimulation
Jayakeren et al. [35] UK	Stroke unit N=28	Pharyngeal electrical stimulation	Sham stimulation
Suntrup et al. [43] Germany	Neuro intensive care stroke N=30	Pharyngeal electrical stimulation	Sham stimulation
Vasant et al. [45] UK	Stroke unit N=36	Pharyngeal electrical stimulation	Sham stimulation and swallowing exercises
Guillan-Sola et al. [32] Spain	Hospital ward Stroke N=31	Neuromuscular electrical stimulation	Swallowing exercises
Huang et al. [33] Taiwan	Hospital ward Stroke N=29	Neuromuscular electrical stimulation	Swallowing exercises/head postures
Li et al. [37] China	Stroke unit N=118	Neuromuscular electrical stimulation	Swallowing exercises with oral trials
Xia et al. [47] China	Neurology unit Stroke N=120	Neuromuscular electrical stimulation	Swallowing exercises
Park et al. [41] Korea	Hospital ward Stroke N=22	Chin tuck against resistance	Swallowing exercises/thermal stimulation
Chen et al. [29] China	Stroke unit N=250	Acupuncture	Swallowing exercises
Wu et al. [46] China	Stroke unit N=229	Acupuncture	Swallowing exercises/thermal stimulation
Carnaby et al. [28] Multi-national	Stroke unit N=306	Behavioural Intervention	Mealtime supervision/safe feeding practices
Hwang et al. [34] Korea	General intensive care population N=33	Behavioural Intervention	No therapy, oral hygiene
Park et al. [42] Korea	Stroke unit N=24	Effortful swallow training and traditional swallowing exercises	Traditional swallowing exercises

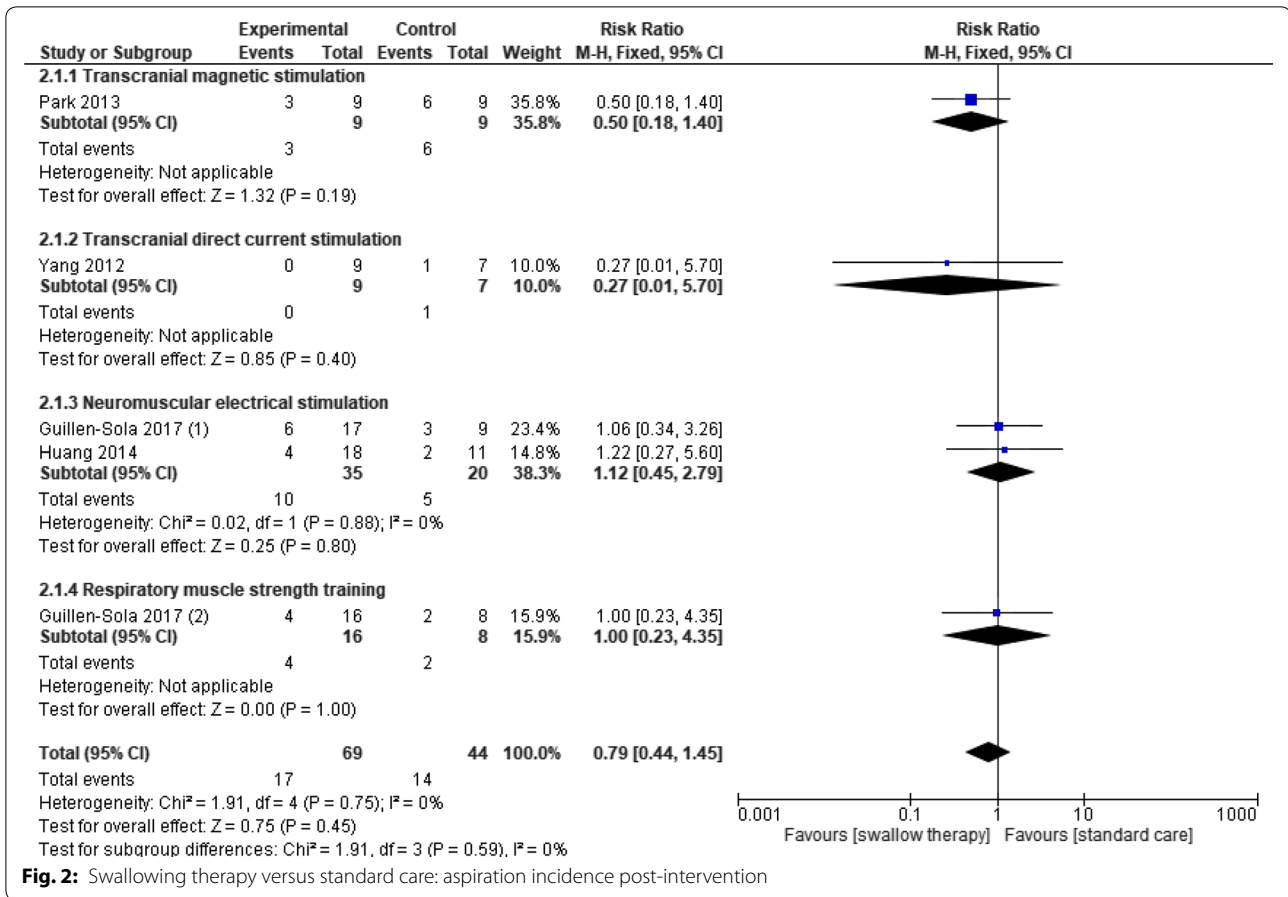
Quality of life post-intervention

Three trials reported this outcome [36, 42, 47]. Meta-analysis of data from two studies showed no evidence of a difference from swallowing therapy versus standard care ($n=239$, MD = 11.38, 95% CI = 23.83 to 1.08, $I^2=78%$, $P=0.07$) (very low certainty). Subgroup analysis of intervention types found effect sizes were statistically significant for acupuncture but not for tongue-palate resistance training, with a significant subgroup interaction ($P=0.03$, $I^2=77.9%$) (ESM Appendix J: Fig. 1). A third study testing NMES [47] reported using the same scale but the direction of scoring was opposite to the other two studies, and scores were very different so it is

reported individually. Swallowing therapy showed evidence of a difference ($n=120$, MD = 166.00, 95% CI = 180.66, = 151.34, $P<0.00001$).

Length of hospital stay

Five trials reported this outcome [27, 28, 43–45]. Meta-analysis of data from four studies showed no evidence of a difference from swallowing therapy versus standard care ($n=536$, MD (days) = 0.4, 95% CI = 3.6 to 2.8, $I^2=52%$, $P=0.81$) (very low certainty). Subgroup analysis of interventions showed no evidence of a difference for pharyngeal electrical stimulation, tDCS or behavioural interventions and a significant subgroup interaction



($P=0.04$, $I^2=67.9\%$) (ESM Appendix J: Fig. 2). A fifth trial, testing pharyngeal electrical stimulation [45], reported median length of stay was 39 days and 52 days in the active and sham groups with no significant difference between arms observed by a stratified log-rank test ($P=0.62$). Interquartile ranges were not reported.

Change in pharyngeal residue severity

Four studies reported this outcome [38, 40–42], using the Functional Dysphagia Scale (FDS) [67]; Videofluoroscopy Scoring Scale (VFSS) [68] and Videofluoroscopic Dysphagia Scale [69]. Meta-analysis of three studies reporting continuous outcomes found a beneficial effect from swallowing therapy ($n=64$, SMD (FDS, VFSS, VDS scores) – 0.78, 95% CI – 1.3 to – 0.26, $I^2=39\%$, $P=0.003$) (very low certainty). Subgroup analysis of interventions showed an individual effect for both RMST and chin tuck against resistance but no statistically significant difference for effortful swallowing training and no significant subgroup interaction

($P=0.19$, $I^2=39.5\%$) (ESM Appendix J: Fig. 3). The fourth trial, testing transcranial magnetic stimulation, reported changes in residue severity as a dichotomous outcome but effect size was not statistically significant ($n=18$, RR 0.5, 95% CI 0.18 to 1.40, $P=0.19$ [40]. Residue scores were sometimes subsumed within overall swallowing assessment scores reported in studies. Authors of two trials included in this review were contacted for relevant raw data on this outcome, but this information was not provided [33, 48].

Nutritional status

One trial comparing pharyngeal electrical stimulation to standard care reported on nutritional status (measuring blood albumin g/L), but the effect size was not statistically significant ($n=141$, MD 0.9, 95% CI – 0.99 to 2.79, $P=0.35$ [27] (low certainty).

Change in oral-pharyngeal secretion severity

This outcome was not reported in any included studies in this review.

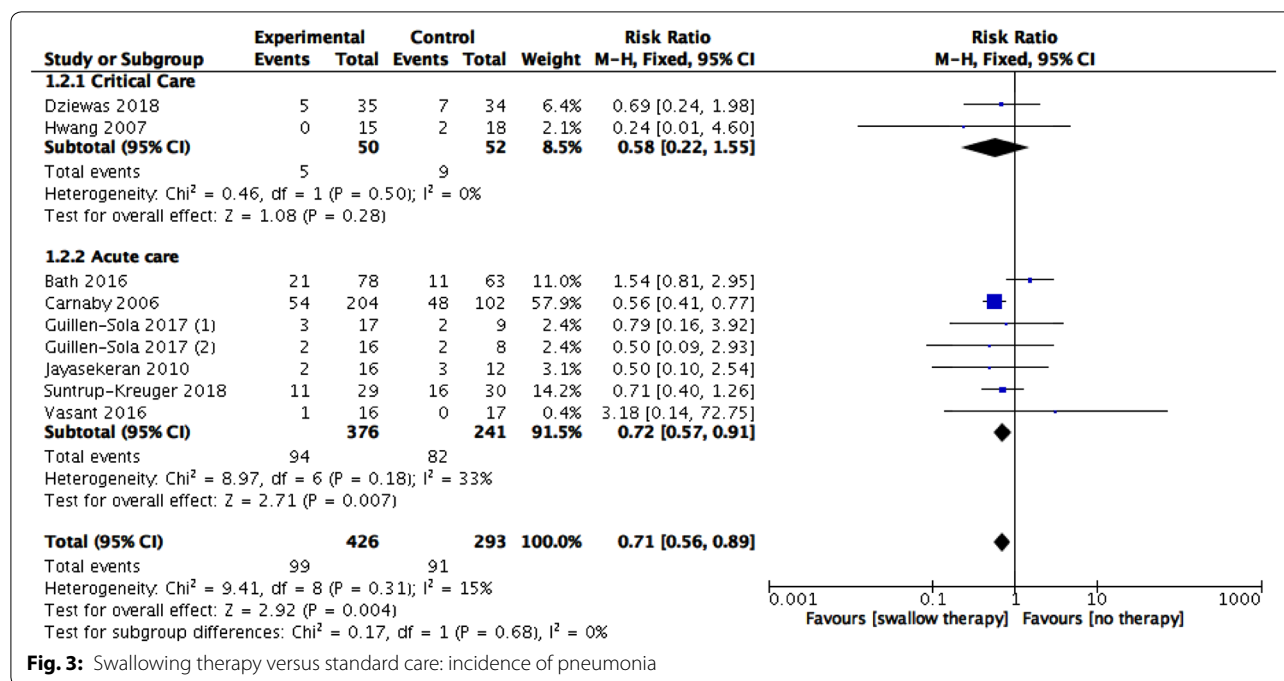


Fig. 3: Swallowing therapy versus standard care: incidence of pneumonia

Intervention-related adverse events

Twelve studies reported on intervention-related adverse events [27, 29–32, 36, 37, 43–46, 48]. Ten studies testing pharyngeal electrical stimulation [27, 43, 45]; transcranial direct current stimulation [36, 44, 48]; neuromuscular electrical stimulation [32, 37]; and acupuncture [29, 46] descriptively reported no adverse events. Meta-analysis of data from two studies [30, 31] showed no significant difference between number of adverse events reported during swallowing therapy or standard care ($n = 109$, RR 1.74, 95% CI 0.57 to 5.27, $I^2 = 0\%$, $P = 0.33$ (low certainty). Subgroup analysis showed no significant difference for number of adverse events (ESM Appendix J: Fig. 4).

Discussion

Of the 22 studies included in this review, 19 were acute stroke patients ($n = 1568$), two tracheostomised stroke patients in intensive care ($n = 99$) and one general intensive care population ($n = 33$). Nine interventions, including electrical and magnetic neurostimulation approaches and muscle strengthening treatments were identified. Days taken to return to oral intake were considered an important patient-relevant outcome in this review but were reported in only one trial, and effect sizes were not statistically significant. Swallowing treatment was found to have a beneficial effect on another patient relevant outcome, pneumonia. A beneficial effect on pharyngeal residue severity was also found. While adverse event reporting was most common in studies testing electrical or magnetic stimulation, overall event rates were low

(i.e. 9/63 vs 4/46 in experimental and control groups respectively) and not found to be statistically higher than controls. Effect sizes were not statistically significant for aspiration incidence post-treatment, quality of life, length of hospital stay or nutritional status. One review outcome, change in oral and pharyngeal secretion severity were not reported in any study.

Seven acute ($n = 617$) and two critical care studies ($n = 102$) reported on pneumonia incidence post-treatment (Fig. 2). A subgroup analysis of critical care studies revealed small sample sizes and wide confidence intervals, and therefore, we cannot be confident in finding a treatment effect. At present, it is unknown whether future, adequately powered trials will improve these findings.

As the populations included in this review were predominantly acute stroke with a very small number from intensive care; the resulting dysphagia in these populations will have different underlying mechanisms of impairment limiting generalisability of findings. Stroke patients present with neurogenic dysphagia resulting from cortical and/or sub-cortical damage to the swallowing network. Intensive care patients, however, present with dysphagia for a myriad of different reasons: mechanical injury due to pharyngeal and laryngeal trauma at intubation site; atrophy of skeletal muscle due to disuse during intubation; sensory deficits in swallowing due to disruption of sensory receptors during intubation and the sedating effects of medications in intensive care; and finally the presence and/or prolonged use of a

tracheostomy tube [3]. Therefore, the tracheostomised, acute stroke patients in this review will have a complex dysphagia presentation. Their central swallowing network is disrupted due to the brain lesion, but the presence of a tracheostomy will also affect laryngeal sensory receptors necessary for safe swallowing, in the context of likely continuing skeletal muscle atrophy during their intensive care stay.

These tracheostomised, acute stroke patients were treated using pharyngeal electrical stimulation (PES) in two studies [31, 43]. Significant group differences were found in primary outcome: time to tracheostomy decannulation but no significant differences in length of stay, tube-feeding cessation or return to oral intake. Electrotherapies such as PES or neuromuscular electrical stimulation (NMES) provide sensory feedback via bulbar cranial nerves that innervate the pharynx. This increased sensory input has been shown to drive long-term changes in the cortical control of swallowing [70]. One could argue such sensory treatments tested in stroke populations could be used to target sensory deficits often observed among critically ill patients with dysphagia. The third completed study with a general ICU population involved swallowing exercises/oral stimulation delivered during intubation and found significant improvements in swallowing efficiency but no group differences in aspiration/pneumonia incidence or length of stay [34].

Four ongoing ICU studies were also identified. Apart from one [50], all studies are testing sensory electrical stimulation either during intubation or post-extubation [51–53]. As these studies are testing treatments at different timepoints during a patient's ICU stay; they may provide valuable information on optimal treatment timing and its impact on patient relevant outcomes.

An expert advisory panel were consulted on the other interventions identified in this review and their use with intensive care patients. They questioned both the scientific rationale for using non-invasive brain stimulation treatments and the feasibility of using acupuncture for patients in intensive care. However, they suggested tongue-palate resistance training, chin tuck against resistance (CTAR) and respiratory muscle strength training (RMST) are all biologically plausible interventions that could target skeletal muscle atrophy of the swallowing mechanism commonly reported across both post-extubation and tracheostomised intensive care populations.

To date, no systematic review has evaluated dysphagia interventions conducted in intensive care. Our review's findings were compared with a recent Cochrane review of interventions in acute care (stroke) [71]. Both reviews highlight wide variability in reported outcomes and their timepoints across studies; various subjective and

objective assessment tools were used to measure swallow-related outcomes and moderate to very low study quality. The variability in outcome reporting in this review emphasises the need for a core outcome set for dysphagia intervention studies in intensive care.

In the interim, outcomes proposed in completed and ongoing ICU studies and recommended by an expert advisory group may be considered. They include: physiological outcomes (laryngeal closure times; pharyngolaryngeal sensation; swallow biomechanics); functional outcomes (tracheostomy decannulation time; time to tube-feeding cessation; return to oral intake); psychological outcomes (patient comfort, pain and anxiety levels during intervention delivery). The strengths of our review are the high-quality systematic review Cochrane methodology used to screen, extract data and assess study quality independently by two reviewers. A comprehensive search strategy, including studies in all languages was developed with an independent medical librarian. A limitation of this review is that trial authors were not contacted directly to clarify unclear risk of bias ratings which may have resulted in trials being rated differently. A further limitation is the small number of underpowered studies available to provide reliable subgroup analyses. With such limited data, we have low certainty in subgroup findings and cannot confidently recommend specific interventions for acute and critical care populations at this time.

Conclusion

This review highlights the limited research on dysphagia interventions in the acute and critical care setting and the limited evidence to guide clinical practice in this area. Future studies testing interventions in this setting should consider patient relevant outcomes using similar, validated measurement tools.

Deviations from protocol

Nutritional status was not included as an outcome in original PROSPERO registration (28/11/18) but was added to updated version (8/01/19). PROSPERO registration outlined the following subgroup analyses: acute versus critical care and types of dysphagia interventions. The published protocol included an additional subgroup: younger age groups (<65) versus older age groups (>65). In the final review, data were only available and reported for subgroup analyses: acute versus critical care and types of dysphagia interventions. PROSPERO registration contained one primary outcome (time to oral intake). However, the published protocol and this review include a second primary outcome (aspiration incidence

post-treatment) which we believe is important to consider in a critical care setting.

Electronic supplementary material

The online version of this article (<https://doi.org/10.1007/s00134-020-06126-y>) contains supplementary material, which is available to authorized users.

Author details

¹ Wellcome-Wolfson Institute for Experimental Medicine, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, UK. ² Department of Clinical Speech and Language Studies, Trinity College Dublin, Leinster St. South, Dublin 2 D02 KF66, Ireland. ³ School of Nursing and Midwifery, Medical Biology Centre, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, UK. ⁴ Queen's University Belfast Medical Library, Mullhouse Building, Mullhouse Road, Belfast BT12 6DP, UK.

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Author contributions

All authors contributed to this SR. As information specialist, RF led on developing a search strategy with SD and completing all database and clinical trial registry searches. All search terms were agreed with supervision team: BB, MW, DM. J McG and SD completed study screening, abstract and full-text viewing and data extraction and reviewed bibliography lists from included trials. SD entered and analysed data into RevMan, RA checked data entry and BB checked analysis. SD wrote review and all authors contributed. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflicts of interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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