# Post-Stroke Dysphagia: Clinical and radiological outcomes and efficacy

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Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy

# Abstract

Upwards of 50% of stroke survivors show symptoms of swallowing impairment (dysphagia) post-stroke. Dysphagia is clinically important as it results in poorer outcomes and affects quality of life. Despite this, there are few proven treatments. In addition, the act of swallowing is intricate and complex and may be best measured using multiple outcomes.

This thesis had three principal aims: firstly, to evaluate the current evidence base for swallowing therapy by updating the Cochrane review into swallowing therapy in acute and subacute stroke. Secondly, to evaluate the use of multiple measures of swallowing (timing and clearance measures) to detect change following a swallowing treatment (Pharyngeal Electrical Stimulation - PES) as opposed to only using a single measure of safety, the Penetration Aspiration Scale (PAS). This was done using retrospective data analysis of videofluoroscopic data from the Swallowing Treatment using Electrical Pharyngeal Stimulation Trial (STEPS) which had already been evaluated for safety using only the PAS. And thirdly, to expand the range of outcome measures available for measuring dysphagia by validating the dysphagia severity rating scale (DSRS), a clinical outcome measure currently in use but not yet validated.

The results of this thesis have confirmed three main findings with regards to clinical and radiological outcomes post-stroke. Firstly, the Cochrane review has highlighted that currently, swallowing therapy does show some positive benefits but this is based on evidence of variable quality. Recommendations for conducting more robust trials in the future are discussed. Secondly, with regards to using multiple measures, videofluoroscopic data analysis revealed that additional measures of

timing and clearance did not result in the identification of any improvements that may have gone undetected using safety measures alone (PAS). However, final numbers were reduced due to data quality and lower frame rate acquisition and hence it would be premature to conclude that using the PAS alone is sufficient when measuring swallowing outcomes post-stroke. Finally, with regards to measuring dysphagia severity post-stroke, the DSRS was validated. The results showed that it appears to be a valid tool for grading the severity of swallowing impairment in patients with post-stroke dysphagia and is appropriate for use in clinical research and clinical service delivery.

# Acknowledgements

I would like to express my gratitude to my supervisor, Professor Philip Bath, firstly for allowing me to do this PhD thesis as a secondment, thus giving me the opportunity to complete a thesis without compromising my career and future research prospects. Secondly, I wish to say thank-you to Professor Bath for all of his excellent advice, help and support throughout my thesis. I also wish to thank Professor Shaheen Hamdy, who also provided support, superb advice and encouragement throughout my time completing this project. I am grateful for all the learning opportunities that were given to me and indeed, I have learnt so much from both Professor Bath and Professor Hamdy, it has been a privilege to complete this PhD thesis in dysphagia under their guidance.

Special thanks also go to my PhD peers in room B56 who travelled this journey with me: in the early days - Dr Jason Appleton, Dr Zhe-Kang Law and Andrew Belcher and in the mid and latter days - Gwen Wilkinson, Rais Reiskewan and Mansour Alwjwaj. I would also like to say a special thank-you to Lee Haywood who provided invaluable advice, friendship, support and practical help to me. Thanks are also due to my clinical managers, Sally Knapp and Sara Dibben, who have always supported me in my research endeavours and who allowed me to take a secondment from the NHS to do this PhD. Thanks also go to my work colleagues, especially Becca and Caroline for providing advice, encouragement and a listening ear.

Thank-you also goes to Dr Han Sean Lee for his help and support with the Cochrane Review, Lisa Woodhouse and Polly Scutt for their advice and assistance, Dr Emilia Michou for her expert advice and guidance and Professor Nikki Sprigg for her support. I would also like to thank Phagenesis® for providing the data from the STEPS trial, that the bulk of this thesis is based upon, and each and every patient and family member who gave their consent to take part in the original trial and who have thus enabled this current work to be conducted.

Thanks to Jacqui Benfield for being my PhD buddy, always ready to listen, provide great advice, discuss at length, motivate, encourage, problem solve and inspire. I have valued her friendship and support throughout this journey immensely.

A special thank-you goes to my dear friend Jo, for the mentorship, kindness, help and constant encouragement she provided to me during this thesis. Jo began this journey with me, but she is not here at the end. The memory of her encouragement and love has spurred me on in the challenging times, motivated and inspired me and I hope this thesis would make her proud.

Lastly and most importantly, I would like to thank my Dad, and my children, Julia and Michael for their love and support. But most of all I would like to thank my husband, Michael who provided me with never-ending support as well as immense amounts of practical help and lots of patience all of which enabled me to devote the time I needed to complete this thesis. Thank-you!

# Contributors

The work presented in this thesis was done by the author with advice and guidance from Professor Philip Bath and Professor Shaheen Hamdy. Other contributors were:

Chapter two: Jacqueline Benfield and Emilia Michou were consulted in the development of the methods.

Chapter three: Jacqueline Benfield assisted with inter-rater reliability.

Chapter five: Dr Han Sean Lee assisted the author with selecting studies, data extraction and analysis and reviewing bias. LE refined and carried out the searches alongside the Cochrane Stroke Group, interpreted the data, completed the summary of findings table, assigned GRADE ratings to the quality of evidence and wrote the manuscript. Prof Bath assisted with agreeing criteria for inclusion studies and resolving disagreements regarding inclusion.

Chapter six: The author researched the literature, conceived and designed the research with assistance from Professor Bath and Professor Hamdy. The author analysed and interpreted the data. Jacqueline Benfield and Amanda Hedstrom assisted with collection of data for inter-rater reliability and performed statistical analyses for inter-rater reliability. Lisa Woodhouse provided data for anchor based and statistical distribution methods. Professor Bath provided data from the PHAST-TRAC trial.

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# 1. Introduction and background

## 1.1 Introduction

Throughout the world, stroke remains one of the main causes of long-term disability, causing 11% of all deaths. [1] Every year, 80 000 people are admitted to hospital with an acute stroke. [1] Stroke has an abrupt onset, which can result in numerous persistent focal neurological deficit(s). [2] The three main types of stroke are cerebral infarction (85%), primary haemorrhage (10%) and subarachnoid haemorrhage (5%). [1] The main treatment for ischemic stroke is recombinant tissue plasminogen (tr-PA) and mechanical thrombectomy. [2]

Treatment for haemorrhagic stroke includes controlling blood pressure (BP) and surgery. [2] Risk factors for stroke include hypertension, increased age, heart disease, smoking, alcohol abuse and hypercholesterolemia among others. [3] Stroke can cause a plethora of deficits, such as speech and language disturbances, reduced mobility, impaired cognition and visual perceptual deficits, emotional and psychological difficulties, incontinence and loss of independence to carry out social, occupational and societal roles. Another common deficit following stroke, is the occurrence of swallowing difficulties (also referred to as dysphagia) which presents in upwards of 40-50% of patients.

Dysphagia is a serious condition causing impairment to the swallowing mechanism, which can result in food, fluids or saliva entering the lungs rather than the stomach during swallowing. This is known clinically as aspiration and can lead to choking and/ or pneumonia.

## 1.2 Neurophysiology of swallowing

### 1.2.1 Neural control of swallowing

Swallowing is a truly remarkable act, a complex sensorimotor function. Daniels and Huckabee (2014) [3] provide a comprehensive discussion on current thinking around models of swallowing. These authors state that sensory information collated from the oral cavity during swallowing (from the sensory branches of the trigeminal; facial; glossopharyngeal and vagus nerves), pass into the Nucleus Tractus Solitarii (NTS) in the dorsal region of the brainstem. From there, some inputs then ascend through the sub-cortex and cortex for higher order processing. Once processed, this newly 'mediated' information descends and enters into the Nucleus Tractus Solitarii (NTS) together with sensory information from the aforementioned cranial nerves that entered the NTS directly from the oral cavity. The result is a motor plan being sent to the Nucleus Ambiguus in the ventral region of the brainstem, which triggers the motor branches of the appropriate cranial nerves (spinal accessory, vagus, glossopharyngeal, hypoglossal and trigeminal nerves) resulting in the pharyngeal swallow.

In essence, swallowing incorporates the cortex and sub-cortex primarily for the voluntary part of the swallow and the brainstem primarily for the reflexive pharyngeal swallow. In addition, the cerebellum has also been shown to be active during swallowing. [4, 5]

### 1.2.2 Stages of swallowing

Swallowing is divided into four stages. Only the first three stages, which cover oropharyngeal dysphagia will be discussed as this is the topic being studied in this research project. All 3 stages of swallowing are frequently impaired following stroke. Many cranial nerves are involved in each stage of swallowing, encompassing both sensory and motor components. The table below details the main events taking place during each stage of normal swallowing and common examples of how these are impaired when dysphagia is present.

**Table 1-1** The stages of swallowing

| **Pre-Oral Stage** | **Oral Stage** | **Pharyngeal Stage** |
|---|---|---|
| Occurs before the bolus has entered the mouth.<br>Includes anticipatory aspects, such as:<br>- salivation,<br>- visual perception of food,<br>- eye-hand coordination. | Begins as the bolus enters the mouth.<br>Jaw and lips open to receive the bolus.<br>Bolus is initially contained in the oral cavity:<br>- anteriorly by the lips forming an adequate seal, laterally by the buccinator muscles and posteriorly by the tongue lifting upwards to seal against the palate.<br><br>Tongue tip then elevates towards the hard palate and propels the bolus backwards in a stripping motion against the hard palate, moving it through the oral cavity.<br>When the propelled bolus reaches the ramus at the angle of the mandible, the oral stage is considered to be complete. [6]<br><br>For a solid bolus:<br>- lateral-rotatory chewing movements are seen as the bolus is masticated into a paste ready to be swallowed. | Begins when the bolus passes the ramus at the angle of the mandible. [6]<br>As the pharyngeal response is triggered:<br>- the soft palate lifts superiorly and posteriorly to form a seal against the posterior pharyngeal wall,<br>- tongue base retracts against posterior pharyngeal wall.<br><br>Airway closure is achieved by:<br>- adduction of the true vocal cords,<br>- adduction of false vocal cords<br>- adduction of arytenoids which then move anteriorly and superiorly to approximate the base of the epiglottis which has started to invert.<br><br>The epiglottis continues to move downwards until it is fully inverted.<br>Simultaneously, anterior-superior excursion of hyoid bone takes place, followed very closely by opening of the Upper Oesophageal Sphincter (UOS).<br>Bolus is propelled through the pharynx aided by pharyngeal contraction [3] |
| **Impairment at pre-oral stage** | **Impairment at oral stage** | **Impairment at pharyngeal stage** |
| Impaired eye-hand coordination.<br>Impaired vision to see food/ fluid.<br>Poor positioning.<br>Lack of smell. | Impaired lip seal.<br>Reduced buccal tone.<br>Reduced sensory awareness in the mouth.<br>Reduced tongue control.<br>Reduced tongue strength.<br>Weak mastication and reduced coordination for mastication. | Delayed signal to trigger swallow.<br>Slower closure of airway.<br>Incomplete closure of airway and/ or reduced laryngeal elevation.<br>Reduced anterior-superior hyoid movement.<br>Reduced pharyngeal contraction and tongue base retraction.<br>Reduced opening of UOS. |

## 1.3 Incidence of dysphagia

Dysphagia is common post-stroke, although the method used to identify dysphagia will yield different estimates, with instrumental assessments yielding the highest estimates. Martino et al. (2005) conducted a systematic review and reported an incidence of 37% to 45% for screening assessments, 51% to 55% for clinical bedside assessments and 64% to 78% for instrumental assessments. [7]

## 1.4 Clinical course/ recovery

Recovery of swallowing function can take place in days, weeks and months following a first ever cortical stroke. This is because swallowing is bilaterally represented in the brain, although there is one 'swallowing dominant' hemisphere where representation is greatest. Using Transcranial Magnetic Stimulation (TMS) in a series of landmark studies, researchers demonstrated that when this hemisphere suffers a lesion, the hemisphere without a lesion assumes responsibility for swallowing function over time. [8, 9] Whilst recovery occurs for most patients, some patients do not show this recovery. [9] Many studies present percentages of acute stroke patients who have recovered swallowing function. However, these estimates can vary due to differences in methods between studies. Readers should be aware of how and when the study was conducted as this may affect interpretation of the results. These include the method of identification of swallowing deficit (for example, screening versus bedside assessment), experience of assessors (for example, screeners versus specialist practitioners), time post-onset when the study was conducted and whether only first-ever strokes were included. Another important factor affecting

reporting of recovery is selection criteria for entry into studies, for example, one study reported on swallowing recovery in mild patients (as patients who could not swallow tablets were excluded) and therefore these results are not applicable to patients with moderate and severe dysphagia. [10]

## 1.5 Identification and assessment of dysphagia

### 1.5.1 Water screening

Screening for dysphagia is the first tier in identifying the problem. In the UK context, screening is carried out by appropriately trained personnel (usually a nurse) within 4 hours of admission or at least within 24 hours of admission. [11] Instituting water screening protocols (ensuring appropriate training) has been shown to reduce the prevalence of pneumonia. [12, 13] In addition, a recent large-scale study involving 63 650 patients found a modest association with delays in screening and the risk of Stroke Associated Pneumonia (SAP) [14] which was further confirmed in a follow-up study. [15]

### 1.5.2 Bedside assessment (BSA)

This assessment is conducted by a professional with expertise in dysphagia, most commonly a Speech and Language Therapist (SLT), although other professions may assume this role depending on the country, they are working in. Delays in swallowing assessment by SLTs have also been found to be associated with a higher risk of SAP [14] as did a further follow-up study. [15]

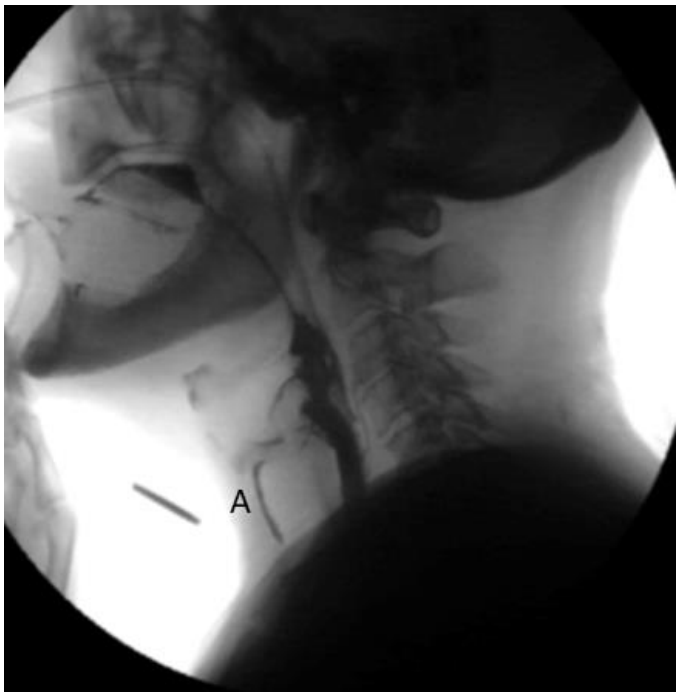
### 1.5.3 Instrumental assessment

There are two principal forms of instrumental assessment used in dysphagia assessment and rehabilitation, namely Videoflouroscopy Swallow Study (VFSS) and Fibreoptic Endoscopic Evaluation of Swallowing (FEES). If dysfunction of the UOS is suspected, manometry should also be considered, although this may not be widely available. A VFSS involves obtaining lateral and anterior-posterior views of the oro-pharynx using fluoroscopy, whilst a patient swallows a variety of consistencies. The result is a dynamic series of images depicting the whole swallowing process.

FEES involves passing a flexible endoscope through the nasal cavity to the level of the laryngo-pharynx and provides a direct view of the larynx and pharynx during swallowing and as such allows for more direct assessment of sensation and secretion management. Food dye is usually added to oral intake to enhance visualisation of the bolus, especially in detecting aspiration.

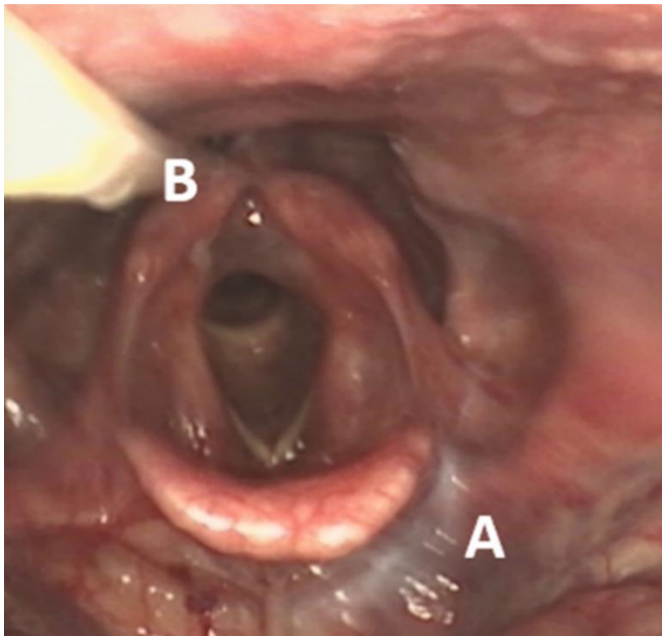
Both methods have advantages and disadvantages. Clinicians should evaluate which procedure is most suited to their individual patient needs. Figures 1.1 and 1.2 below provide an example of images obtained during each procedure.

**Figure 1-1** Image of Videofluoroscopy Swallow Study




Note aspiration of material into airway (A). Image taken from STEPS Trial.

**Figure 1-2** Image of Fibreoptic Endoscopic Evaluation of Swallowing




Note trace amount of residue (yoghurt) on left side of valleculae (A). Also note Nasogastric (NG) Tube (B). Image from clinical practice, with consent from patient. (Appendix 5).

## 1.6 Impact of dysphagia

### 1.6.1 Poorer outcomes

Dysphagia is clinically important as there is clear evidence that the presence of dysphagia in acute stroke is associated with poorer outcomes.

Firstly, dysphagia is associated with an increased risk of *mortality*, [16, 17, 18, 19, 20] with estimates falling between 27% and 37% [18] and some studies reporting a higher risk of mortality in the first three months' post-stroke. [19, 21, 22] Some stroke patients with Percutaneous Endoscopic Gastrostomies (PEG) or Radiological Inserted Gastrostomies (RIG) can have poorer outcomes. Two recent studies (N=174; N = 156) reported a median survival time of 245 days respectively and a 66% mortality rate at 2 years, [23, 24] whilst a third study (N=124) reported up to >80% 6-month mortality after PEG insertion for patients >80 years, with a Total Anterior Circulating Stroke (TACS) diagnosis, raised Charleston Co-Morbidity Index, lower serum albumin and lower BMI. [25]

Secondly, those patients that do survive are more likely to be *institutionalised* on discharge [16, 19] and disabled. [16, 17, 19]

Thirdly, patients with dysphagia develop *pneumonia* more frequently, [7, 15, 16, 19 20, 26] with cerebral haemorrhagic stroke having the highest risk in one study. [20] In a review article, the increased risk of aspiration pneumonia in stroke patients was calculated to be between three- to seven-fold [18] with increasingly severe aspiration seen on VFSS, associated with a higher relative risk of pneumonia reported in one study. [27] It is important to note that a 100% correlation between

dysphagia and chest infections is not possible, due to other factors, such as immune status and respiratory comorbidity. [18] Not all patients who aspirate will develop aspiration pneumonia. There is an increasing appreciation that the impaired physiological processes causing aspiration pneumonia or the more recently used term, stroke associated pneumonia (SAP) are multifactorial. [22] However, dysphagic stroke patients are considered at greater risk as they may suffer from other co-morbidities, such as those mentioned above, as well as other factors such as dependency for mouth care and oral feeding [28] making them more susceptible to developing pneumonia. Recent research points to acute stroke patients with reduced mobility and lower immunodepression being at increased risk but that currently the evidence for the effect of NG Tubes on pneumonia is ambivalent. [22] Nevertheless, dysphagia is considered to be the main risk factor for SAP. [14] Data from a systematic review shows the relative risk of pneumonia has been found to be 11-fold higher in patients who show aspiration, [7] although only two studies were included in this review. Due to the death rate associated with pneumonia, dysphagia is therefore, an independent predictor of mortality after stroke. [18]

### 1.6.2 Increased length of stay (LOS) and cost burden

Dysphagia is also associated with an extended hospital stay [16, 21] even when patients are cared for on dedicated stroke units. [19] Expenses incurred during the in-patient stay are often high due to the need for interventions such as chest x-rays and antibiotics.[19] A recent UK based study also confirmed significantly higher acute care costs for patients with stroke associated pneumonia. [26]

### 1.6.3 Reduced Quality of Life (QOL)

Dysphagia can severely impact on QOL. Where swallowing impairment is very severe, patients may be made nil-by-mouth (NBM) and fed with a NG Tube. In addition, one of the main compensatory strategies in dysphagia management in stroke is thickening fluids and modifying diets. Although modifying fluids has been shown to reduce the likelihood of aspiration in a recent systematic review that included stroke patients, [29] it can significantly impact on QOL and result in reduced fluid intake. [30] A recent systematic review examining quality of life and dysphagia reported that modifying oral intake was associated with a worse quality of life (food more than fluids), although the authors caution against firm conclusions being drawn, due to small numbers, heterogeneity of results and lack of standardised terminology. [31]

## 1.7 Treatment

Despite the deleterious effects described above, there are currently few, if any stand-alone *proven* treatments for post-stroke dysphagia (PSD). The research base into swallowing is lacking. This could be due to various factors. Deglutition as a separate field of research is relatively young. Although papers aimed at understanding the neurophysiology of swallowing and causes of swallowing had been published earlier (including in animals), it was only in the early 1980s that research into human swallowing began in earnest. In addition, swallowing is considered to be one of the most complex motor activities to study. [32] As research in the area grew, randomised control trials (RCTs) started to emerge, however study populations were often mixed in terms of aetiology and numbers were modest. However, despite the slow start, a variety of interventions have

since been proposed for the management and treatment of dysphagia and the methodology of studies is improving.

Interventions for dysphagia can broadly be divided into two areas:

1. Existing interventions comprising compensatory approaches; rehabilitative approaches; peripheral sensory stimulation methods and more recently, acupuncture (detailed in Table 1.2 below).
2. Emerging interventions comprising one of two types of stimulation. Firstly, *peripheral stimulation* at the level of the pharyngeal muscles, either to the muscles of the neck, using electrodes or internally to the muscles of the pharynx using a catheter tube. Secondly, *central stimulation* to the pharyngeal cortex with the aim of stimulating sensory drive to the brain and causing increased activity in the motor swallowing areas (detailed in Table 1.3 below). [33]

**Table 1-2** Existing interventions

| Approach | Intervention | Advantage | Disadvantage |
|---|---|---|---|
| Compensatory | Bolus modification (thickening fluids and modifying diets).<br>Postural changes such as a chin tuck or a head turn.<br>Swallow strategies such as breath-hold. | Can be instituted immediately and is cost effective.<br>Found to reduce aspiration. [29]<br>Allows some form of oral intake as opposed to being NBM which may worsen outcome through atrophy of neural swallowing mechanisms. [34]<br>Xanthan gum thickeners has been found not to leave more residue than thin fluids in stroke patients [35] and a mixed cohort (majority stroke). [36] | Manages the risk imposed by dysphagia but does not rehabilitate the problem.<br>Can result in a poorer quality of life.<br>There is a pressing need for evidence to demonstrate that thickening fluids does or does not reduce the incidence of pneumonia.<br>May result in reduced hydration and/ or malnutrition.<br>Patients may not always be able to do postures or strategies. |

| Approach | Intervention | Advantage | Disadvantage |
|---|---|---|---|
| Rehabilitation | Involves muscle training and strengthening, using well known exercises such as tongue exercises, the effortful swallow, the Mendelsohn's Manoeuvre, and the Shaker exercise.<br>More recently, Inspiratory and Expiratory Muscle Strength Training (I/EMST), the Iowa Oral Performance Instrument (IOPI), chin tuck against resistance (CTAR) and the McNeill Dysphagia Therapy Programme (MDTP) have been explored for stroke patients, as well as using biofeedback in dysphagia therapy. | Aims to remediate the cause of dysphagia and promote change/ true treatment approach.<br>SLT behavioural interventions (where swallowing exercises were included among other interventions) were found to reduce dysphagia. [37] | Often patients with communication and cognitive impairments or reduced stamina cannot carry out these techniques and are precluded from treatment.<br>Studies on optimal dosage of exercises to facilitate carry over of function are lacking.<br>More robust evidence is required even though some positive effects have been found. [37] |
| Peripheral sensory stimulation | Involves stimulation to the oral cavity with the aim of enhancing sensory input and the urge to swallow.<br>Common stimuli include chemical stimulation: Capsaicin, black pepper oil, sour; thermal stimulation: cold mirrors/ boluses; physical/ tactile stimulation: air pulse therapy, direct stimulation of faucial arches, carbonation. [38] | Some individual studies show some benefit.<br>May be easier to do and can include patients with communication and cognitive deficits more easily than exercise-based approaches. | High level evidence in acute stroke patients is lacking.<br>Studies have been done in chronic patients and not explored long- term effects. [38] |
| Acupuncture | Widely used in China. | May be beneficial [39, 40] and found to reduce dysphagia.[37] | Due to concerns regarding methodology/ quality, further high quality RCTs are needed. [39, 40]<br>Not used to treat dysphagia in many countries/ may have training issues. |

**Table 1-3** Emerging interventions

| Approach | Intervention | Advantage | Disadvantage |
|---|---|---|---|
| Peripheral stimulation: Pharyngeal Electrical Stimulation (PES) | Electrical stimulation applied internally to pharyngeal muscles via adapted Nasogastric Tube. | Improved swallowing in acute stroke patients [41] [42] and in meta-analysis. [43]<br>Reduced pharyngeal transit time. [37]<br>Requires short treatment time: 10 minutes per day over 3 days.<br>Dosage has been evaluated and standardised in treatment studies. | Mixed evidence: A recent large multi-centre RCT in acute dysphagic stroke patients (N=126) resulted in a neutral outcome. [44]<br>Requires some ability to follow instructions and tolerance of NG Tubes.<br>Not routinely available, limited number of hospitals offer currently in UK. |
| Peripheral stimulation: Neuromuscular electrical stimulation (NMES) | Electrodes placed externally on infra- and suprahyoid muscles. | A recent systematic review examined eight studies and concluded that in the short-term, standard swallow treatment combined with NMES appeared to be more effective than standard swallow treatment alone [45] but no evidence to show it is better than swallow treatment.<br>Becoming more routinely available. | More evidence required in acute stroke.[46, 47]<br>Requires some ability to follow instructions and generate a swallow to take part in exercises.[46, 47] |
| Central stimulation: Transcranial Direct Current Stimulation (tDCS) | Application of direct current through the scalp. | Two recent systematic reviews concluded that positive effects for tDCS was found. [46, 47] | Larger RCTs are needed to provide more evidence.<br>Not routinely available, limited to research trials. |

| Approach | Intervention | Advantage | Disadvantage |
|---|---|---|---|
| Central stimulation: Transcranial Magnetic Stimulation (TMS) and repetitive TMS (TMS/rTMS) | A brief pulse of current is produced in a copper coil which is positioned over swallowing muscle regions of the motor cortex to induce a magnetic field. [46] rTMS is when TMS is repeatedly applied. [46] | Two systematic reviews concluded that positive effects for rTMS were found. [46, 47] | Larger RCTs are needed to provide more evidence.<br>Not routinely available, limited to research trials. |
| Combined approach: Paired Associative Stimulation (PAS) | Combination of PES and rTMS | Increased pharyngeal excitability and improved swallowing function was reported in 6 of 18 patients. [48] | Further studies are required.<br>Not routinely available. Limited to research trials. |

The Cochrane review published in 2012 concluded that there was not enough data on the effectiveness of swallowing therapy, although some benefits for behavioural interventions and acupuncture were reported. [37] There is an urgent need to update the evidence in this expanding area.

## 1.8 Oral Hygiene

Poor oral hygiene may be *associated* with SAP [14] and although this association exists, currently, the evidence in stroke research, to demonstrate that improving oral hygiene reduces pneumonia or mortality is weak.[49] However, researchers and clinicians alike would all agree that poor oral hygiene reduces QOL in patients with dysphagia. It is not considered an intervention for dysphagia per se, although it is an important part of stroke care and patients with dysphagia are at risk of poor oral hygiene.

**To recap**, dysphagia is prevalent, is clinically important (being linked to poorer outcomes) but lacks a robust evidence base. Fortunately, the number of studies evaluating interventions aimed at treating post-stroke dysphagia (PSD) are ever increasing. As these numbers have increased, so has the amount of *outcome measures* used to evaluate potential changes in swallowing impairment following these interventions.

## 1.9 Outcome measurement in dysphagia

The purpose of outcome measurement in dysphagia is to evaluate whether interventions have lessened the impact and/ or severity of dysphagia and/ or had a positive outcome for a patient. The information used to make these

decisions is principally obtained from clinician- and patient rated scales and instrumental assessments.

### 1.9.1 Outcome data from clinician rated dysphagia scales

These scales are usually rated by SLTs (or other dysphagia trained professionals) involved in the care of the patient and are based on a patient's current oral intake or lack thereof. Table 1.4 details frequently used scales.

**Table 1-4** Clinician rated scales

| **Scale** | **Components** |
|---|---|
| Functional Oral Intake Scale (FOIS) [50] | Scale with 7 levels, levels 4-7 only score diet, includes measures of compensations/ strategies. |
| Dysphagia Severity Rating Scale (DSRS) [42] | Scale derived from Dysphagia Outcome Severity Scale, 3 levels (fluids/ diet/ supervision) totalling 12 points. |
| Therapy Outcome Measures for Rehabilitation Professionals (TOMS) [51] | Updated version of original TOMS, 4 domains: impairment, activity, participation, well-being. |
| Royal Brisbane Hospital Outcome Measure for Swallowing (RBHOMS) [52] | Measure of swallowing disability, 4 stages of oral intake with 10 levels at each stage. |
| ASHA-NOMS Scale [53] | Measure with 7 levels, includes measures of compensation/ strategies, requires registration and training. |
| AusTOMS Swallowing Scale [54] | Based on original TOMS, developed in Australian healthcare context 4 domains: structure/ function; activity limitation; participation restriction; well-being/ distress. |
| IDDSI Functional Diet Scale [55] | Based on IDDSI, 7 levels, measures food/ fluids. |

A drawback in dysphagia rehabilitation is that scales have different amounts of published information on reliability and validity and there are many different scales in use. The 2012 Cochrane Review stated that a 'lack of uniformity in outcome measures' (p. 15) led to significant amounts of trials being excluded. [37] Further, these authors recommend that studies into dysphagia must use standardised outcome measures so different trials can be compared more easily.

It is also important to remember that outcome measures directly influence decisions about what treatments are effective and what treatments should be invested in. It is therefore of vital importance that they are robust and validated so they can be trusted to accurately quantify swallowing and reliably detect change in swallowing impairment. This is even more important in the acute phase of stroke, where carrying out new intervention studies can be complex (sometimes leading to under recruitment), expensive and time consuming. Using validated outcome measures provides reassurance to patients, clinicians, researchers and healthcare funders alike that they are fit for purpose.

A second notable drawback is that although scales of swallowing outcomes can show statistically significant changes, it is unknown if these changes are also clinically meaningful. [56] The concept of the minimal clinically important difference (MCID) score aims to address this. The MCID is the smallest change to a score that a patient would consider represents a meaningful change to them and which leads to a change in their management. [57] Some authors argue that establishing the MCID should be a prerequisite when developing new therapies, is important in determining sample sizes for clinical trials and informs funding decisions. [58] In the context of swallowing rehabilitation there is very little in the way of MCID, apart from work by Hutcheson et al. (2016) with regards to the MD Anderson

Dysphagia Inventory in patients with head and neck cancer. [56] Given how much dysphagia impacts on QOL, the impact of meaningful changes (or lack thereof) on a person's life following an intervention is vital to capture. Research ascertaining the MCID of dysphagia rating scales should be included in validation studies.

### 1.9.2 Outcome data from patient reported scales/ (QOL) measures

Health Related QOL reflects the impact of disease (in this case, dysphagia) and its treatment on a person's wellbeing [59] and is reported by the patient not a professional. The 2012 Cochrane review found that QOL outcome measures were not frequently included in interventions for dysphagia in acute and sub-acute stroke. [37] These authors highlight the importance of including QOL measures to help weigh up the advantages and disadvantages of interventions in patients who have severe disability post-stroke. And of course, investigating QOL issues in patients with dysphagia is very important given the negative health sequelae of dysphagia. Indeed, 'functional recovery may be equally important as physiologic recovery in acute and protracted stroke' (p. 354). [60]

Patient reported outcome measures can assess both the functional health status of the disease (i.e. of dysphagia) on specific functional aspects, as well as health-related quality of life measures, i.e. dysphagic patients' views of their health, when considering social, functional, and psychological issues. [61] Ideally these two aspects should be evaluated separately (as they measures difference concepts), although in practise most scales combine both these aspects. [61] Table 1.5 overpage details well known patient reported outcomes measures which

focus mainly on health-related quality of life measures. This is opposed to patient reported measures such as the Eating Assessment Tool (EAT-10),[62] which focus mainly on functional health status. [61]

**Table 1-5** Patient rated quality of life scales

| **Scale** | **Components** |
|---|---|
| Dysphagia Handicap Index (DHI) [63] | Questionnaire plus visual analogue scale, 25 items |
| SWAL-QOL [64] | Questionnaire, includes general health indicators, 44 items plus extra questions |
| MD Anderson Dysphagia Inventory (MDADI) [65] | Questionnaire, 20 items, with subscales, emotional, physical and functional and 1 question assessing global impact |

### 1.9.3 Outcome data from instrumental assessments (FEES/ VFS)

These measures are derived from information obtained carrying out instrumental assessments in swallowing, most commonly VFSS and FEES, as detailed in Table 1.6 Outcomes have also been derived from other instrumental measures, such as electromyography and increasingly from manometry.

**Table 1-6** Outcome measures based on instrumental assessments

| Method | Type of measure |
|---|---|
| Penetration-Aspiration Scale (PAS) [66] | Visuoperceptual scale measuring penetration and aspiration, 8 levels. |
| Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) [67] | Visuoperceptual scale measuring safety (aspiration) and efficiency (residue) |
| Videofluoroscopic Dysphagia Scale (VDS) [68] | Visuoperceptual scale measuring multiple components of swallowing, 14 levels. |
| Dysphagia Outcome Severity Scale (DOSS) [69] | Visuoperceptual scale for rating functional severity and making recommendations for oral intake, 7 levels, includes supervision/ dependency for feeding. |
| Modified Barium Swallowing Impairment Profile (MBSImP) [70] | Visuoperceptual scale measuring 17 components of swallowing, requires registration and training to at least 80% accuracy. |
| Dejaeger [71] | Visuoperceptual scale measuring residue |
| Hind [72] | Visuoperceptual scale measuring residue |
| Oropharyngeal swallow efficiency (OPSE) [73] | Quantitative and visuoperceptual measure of swallowing |
| Functional Dysphagia Scale [74] | Visuoperceptual scale incorporating 11 components of swallowing |
| Eisenhuber [75] | Visuoperceptual scale measuring residue |
| Vallecular Residue Scale [76] | Quantitative computer-based measure of residue |
| Normalised Residue Rating Scale [77] | Quantitative computer-based measure of residue |
| Bolus Residue Scale [78] | Visuoperceptual scale measuring residue |
| Frame-by-frame analysis | Quantitative (ratio) measurements of swallow using timing (ms/ s) and displacement measures (mm) |

Some may feel that information collected from instrumental assessments may be more objective than information obtained from patient and clinician rated

scales. However, instrumental assessments frequently still rely on visuo-perceptual rating scales, which can lead to variation as the levels rely on subjective judgements and appear to be less reliable than quantitative measurements obtained using frame-by-frame analysis. [79] In addition, scales such as the MBSImP may well demonstrate improvement but may not be sensitive enough to detect small differences or precise enough to provide accurate measurements of swallows, for example, timings within fractions of seconds. [80] Using both quantitative measures as well as rating scales for VFSS interpretation, may improve identification of swallowing deficits over the PAS alone. [81]

Quantitative measures are an alternate way to analyse information obtained from VFSS and focus on two main areas. Displacement measures quantify how *far structures move* during swallowing (such as maximal hyoid movement) and timing measures calculate the *speed of bolus flow* during swallowing intervals (such as oral transit time) and the *duration of specific swallow events* (such as laryngeal closure duration). These techniques typically use frame-by-frame slow motion analysis of VFSS images to measure key swallowing events, which are then converted to provide a spatial measure in millimetres or a temporal measure in milliseconds or seconds.

Alongside frame-by-frame methods, computerised software has also been developed, for example, using image analysis to quantify digital images of residue by counting pixels. [77]

It is clear there are a variety of outcome measures used to assess swallowing impairment, ranging from visuo-perceptual scales through to quantitative

computer-based software. One of the most frequently used- and perhaps most influential of these outcome measures is the Penetration Aspiration Scale.

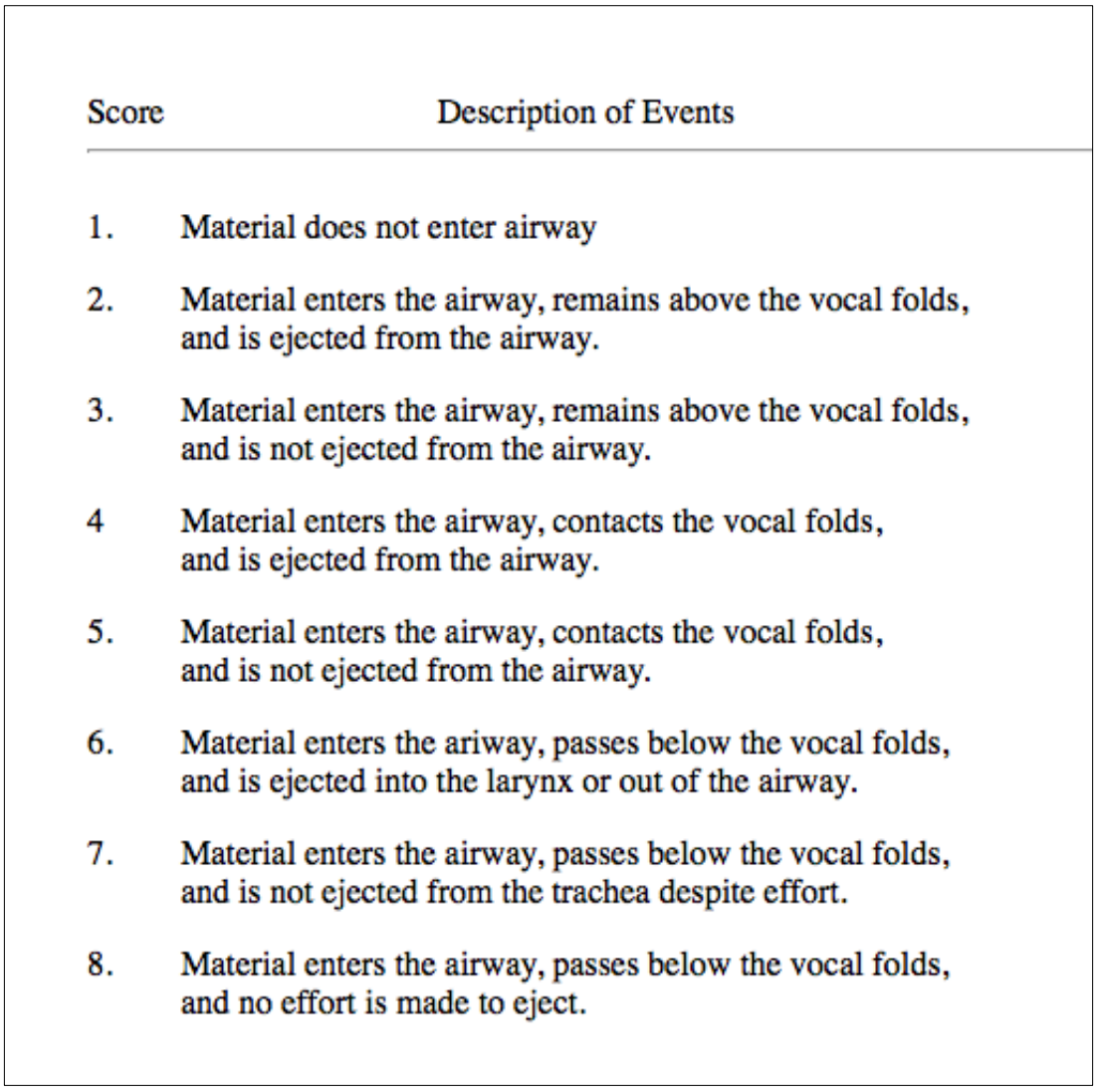
## 1.10 The Penetration-Aspiration Scale (PAS)

### 1.10.1 Background

The PAS is a standardised, eight-point scale developed by Rosenbek et al. in 1996. [66] In this landmark paper, Rosenbek et al. (1996) describe the scale, how it was developed and define essential terms. The most important of these terms being the distinction between penetration and aspiration. Penetration is defined as "passage of material into the larynx that does not pass below the vocal folds." (p.93) and aspiration as "passage of material below the vocal folds." (p.93).

The response to penetration or aspiration is also described, i.e., whether it is sensed and coughed out of the airway or whether there is no attempt to clear the material. A score of 1 indicates no penetration into the airway, whilst scores of 2-5 refer to penetration of material into the laryngeal vestibule above or on the vocal cords (which may or may not be expelled) and scores of 6-8 refer to aspiration of material, i.e., material that has moved below the true vocal cords (which may or may not be expelled). This scale is reproduced in the Figure 1.3 overpage.

**Figure 1-3** Penetration aspiration scale



| Score | Description of Events |
|---|---|
| 1. | Material does not enter airway |
| 2. | Material enters the airway, remains above the vocal folds, and is ejected from the airway. |
| 3. | Material enters the airway, remains above the vocal folds, and is not ejected from the airway. |
| 4 | Material enters the airway, contacts the vocal folds, and is ejected from the airway. |
| 5. | Material enters the airway, contacts the vocal folds, and is not ejected from the airway. |
| 6. | Material enters the ariway, passes below the vocal folds, and is ejected into the larynx or out of the airway. |
| 7. | Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort. |
| 8. | Material enters the airway, passes below the vocal folds, and no effort is made to eject. |

Taken from Rosenbek J, Robbins J, Roecker E, et al. A penetration-aspiration scale. Dysphagia 1996; 11: 93-98

### 1.10.2 Evidence base

The PAS has been shown to differentiate normal and abnormal swallowing, in many published studies. The first study using the PAS to demonstrate this examined swallowing function in healthy participants, stroke patients and patients with head and neck cancer. [82] The evidence from this formative study and subsequent research demonstrates that in most studies, healthy participants either all score a PAS of 1 or 2 [83-86] or mostly score a PAS of 1 or 2, with a small

number scoring a PAS of 3 [87] or infrequently a higher score.[35, 60, 82, 88, 89] Aspiration (PAS ≥6) is rare [89] even in the oldest old (>85 years) [90] or absent [35, 91] and not a normal phenomenon. Researchers have also found that older participants are more likely to more frequently score a PAS of 2 and 3 [82, 83, 91] including when undertaking sequential swallowing. [92] This latter occurrence could be due to a number of reasons: deviations in the swallowing mechanism or neural control as individuals age, [82] a reduction in the amount of reserve available for neuromuscular control [91] or later onset of apnoea (temporary cessation of breathing as airway closes during swallowing) in older adults, although this notion needs to be researched further. [88]

Studies using the PAS in patients with dysphagia have been reported by many researchers as it is such a frequently used measure. Various aspects have been reported on. McCullough et al. (2005) studied a cohort of 165 acute stroke patients (<6 weeks post-onset) and reported a 26% incidence of aspiration, with 51% silent aspiration. [93] In contrast, Power et al. (2007) found that in an acute stroke cohort (<2 weeks post-onset), 53% of patients aspirated (N= 90). [94] The higher aspiration rates in the latter study may be because these patients were more acute than in the former study, where more spontaneous recovery may have occurred. Both studies found that the highest number of aspirators were in older patients. Several other researchers have also demonstrated this. [83, 84, 95]

Some studies looking at the PAS in stroke patients have also demonstrated that more penetration occurs more often on a liquid bolus [89, 96] and on larger volumes. [97]

In terms of stroke sub-type, one study found that subcortical stroke patients showed more penetration and aspiration (76.9%) than cortical stroke patients (40%) as well as more silent aspiration, although subject numbers were modest (N=30). [98] Another study focusing only on subcortical stroke reported highest PAS scores for lesions in the caudate nucleus, but again subject numbers were small (N=21). [99] Perlman et al. (1994) also reported (in a cohort of mixed stroke patients), that the greatest aspiration occurred in sub-cortical stroke (75%), although an explicit measurement of aspiration was not specified in this study and the consistency of fluid and volumes were not provided. [100] Bingjie et al. (2010) reported that more haemorrhagic patients aspirated in their study, [84] whilst a further study looking at infra- and supratentorial strokes reported higher PAS scores for infratentorial stroke. [101]

In longitudinal studies, recovery of swallow function has been demonstrated by a reduction in PAS scores [60, 102] which have been found to show the most change over time compared to other measures [60] although this was reported on a small number of patients (N=9). Terre et al. (2009) also reported a reduction in silent aspiration, although this study did not use the PAS to quantify aspiration, rather precise definitions were provided. [102]

Robbins et al. (1999) reported that silent aspiration was much more common in stroke patients than head and neck cancer, suggesting more impairment of sensory pathways in stroke patients, although this was based on small numbers. [82]

In summary, in healthy subjects, the evidence suggests that penetration, although infrequent can occur but that aspiration is rare. In stroke patients,

older, subcortical patients are more likely to aspirate and silent aspiration is prevalent.

The PAS is an extremely important, if not the most important scale in the field of dysphagia rehabilitation. Many clinicians and researchers consider it to be the current 'gold standard'. It is one of the only stand-alone scale measuring penetration and aspiration that has been standardised. It measures arguably, the most important consequence of impaired swallowing, i.e., the presence of aspiration, the depth of penetrated material and the patient's response to it.

Severe aspiration which cannot be ameliorated with the use of strategies or modifying oral intake can result in decisions to tube feed. Furthermore, it is important to recall that aspiration is linked to an increased risk of pneumonia (relative risk 11-fold higher) [7] and that dysphagia is an independent predictor of mortality following stroke due to the death rate associated with pneumonia. [18] Given this clinical context, it is not surprising that the principal aim of most interventions for dysphagia in stroke is to lessen the risk of aspiration and in theory, lower the chance of developing aspiration pneumonia. Frequently the effectiveness of these interventions is assessed using the PAS as the primary outcome measure, both in stroke and across many aetiologies causing dysphagia.

Considering the importance of this scale, there are some issues to be aware of when using this scale as an outcome measure in PSD.

### 1.10.3 Intra-subject variability and statistical analysis

Although intra-subject variability and statistical analysis are two separate entities, they are also linked as variability of swallowing influences and complicates how the data is scored and analysed. These points are therefore considered together.

PAS scores for patients can be variable across trials, resulting in high intra-subject variability, such as has been reported in the literature. [44, 66, 94, 103] Scores can be variable for each bolus (tsp or sip) swallowed, but also *within* a bolus as dysphagic stroke patients frequently swallow more than once to clear a bolus. Depending on the swallow pattern, some patients may show a worse or better pattern of swallows across the same bolus. [103] Robbins et al. (1999) were the first group to use the PAS to examine this aspect, in 3 groups i.e. stroke patients (N= 15), head and neck cancer patients (N=16) and normal subjects (N=98). [82] Despite the small numbers of patients, the results indicated that the patient groups showed significantly greater intra-subject variability than the normal subjects and larger intervals between scores. Only 47% of the stroke patients (and 63% of head and neck cancer patients) received the same PA score for both 1$^{st}$ and 2$^{nd}$ swallows and were more likely than the normal group to have differences of 2 or more points on the PAS. In contrast 82% of normal subjects received the same score on both trials and the remaining 18% only differed by 1 point. A similar finding was reported in a study examining the sequence of temporal swallow events in healthy participants. [104] In this study, subjects' performance was consistent between two trials, with no intrasubject variability in onset of swallow events relative to UES opening. In keeping with Robbins et al.'s

(1999) finding with regards to stroke patients, other researchers have also subsequently reported on the variation in PAS scores of stroke patients. [44, 94]

The issue of variability makes the prediction of aspiration challenging [105] and it complicates how to score the PAS, i.e. deciding what swallow(s) to choose that best represent each patient's level of severity of dysphagia. If a single patient obtains a spread of scores, researchers need to decide how they will capture these scores and which scores will be included for analysis.

In addition, researchers need to consider what statistical approach to use. This is an ongoing area of debate within the literature. The PAS scale was originally described as ordinal. [66] However, a follow-up study showed that although the scale is neither strictly ordinal nor interval, [106] it is treated by many researchers as being continuous in nature. [103] In this vein, some researchers take the worst PAS score from each bolus to obtain an average (mean) PA score over several trials. [105] This approach treats the scale as interval rather than a scale with discrete values and it has been suggested that this risks bias towards impairment. [103]

Another method employed by some researchers is a cumulative PAS scoring method. [42, 107] This approach sums the PAS scores across a specific number of swallows, resulting in a cumulative score (where a higher score indicates more severe impairment). A difficulty with this approach is that if studies are terminated early due to patients displaying excessive aspiration, not all patients would have the same number of trials to sum. [103]

An alternate way forward, considering the variation within subjects, is to take the worst swallow as well as the mode in order to get the best representation of a patient's swallowing, for clinical purposes. [103]

In summary, there is still debate over how to both score and analyse the PAS in order to most accurately capture the degree of dysphagia a patient presents with, or as aptly described by Steele et al., [103] 'the patient's pattern of airway protection.' (p.6). It is important to be aware of these issues when using the PAS for research and interpreting research results.

### 1.10.4 Lack of operational rules and reliability

Another aspect which complicates scoring the PAS is a lack of operational detail on how to score it, especially subtle, atypical and complex scenarios. Few studies have been published that specifically focus on reliability of the PAS in the stroke population involving different research groups [66, 108] and the index publication only included 75 swallows from 15 patients. [66] Although many studies report high reliability in individual studies, different research groups likely employ their own scoring and subtle interpretation of PAS rules. There is consequently a need to standardise procedures with regards to the PAS which may result in better reliability of ratings. [103] This has been reported in the literature. An early study examining reliability of the PAS in stroke patients using VFSS concluded that attaining acceptable reliability required training to a criterion [108] and a more recent large-scale study using the PAS in dementia patients, with raters with different levels of experience, also made similar recommendations. [109]

### 1.10.5 Correlation with dysphagia severity

When considering correlation of airway invasion (as measured by the PAS) with dysphagic symptoms, one study reported that most patients who had moderate and even severe oral and pharyngeal impairments did not aspirate, scoring PAS scores of 1-2. [70] These authors suggested that the PAS scores were 'skewed towards more severe swallowing impairments.' (p.13), although in this study of 300 patients, only 16% of the sample had neurological impairment. A further small study with stroke patients (N=9) reported that not all patients with abnormal oral and/ or pharyngeal impairments aspirated. [60]

However, the picture may be more complex than that when comparing, for example different stroke types, such as infra- and supratentorial strokes. In a later study by the same author as above, the results suggested that the PAS may be a more sensitive measure to use with patients with mild stroke and mild dysphagia who have infratentorial strokes. [101] In this study infratentorial strokes did not predict oral and pharyngeal MBSImP component scores but were associated with higher PAS scores. It is evident that more research needs to be conducted in this area with greater numbers.

Aside from aspects around severity, there are considerations around what the PAS measures and what it does not measure.

### 1.10.6 Uni-dimensional measure

A notable drawback of the PAS is that it captures only one aspect of swallowing, i.e., direction of bolus flow. This could lead to an over-reliance on this

method of measurement of the swallow, resulting in an under-appreciation of the many other components of swallowing that may be disordered. In a similar vein, it is possible that patients may improve on one measure of swallowing and not another one, or they may show some degree of recovery. For example, a patient may progress from being NBM to swallowing thicker consistencies but remain dysphagic for thin fluids. If the PAS scale only assesses for recovery on thin fluids, as is often standard research practice, the extent of these improvements may be less apparent or even missed.

Daniels et al. (2006) used a range of measures, i.e. bolus direction (PAS), bolus timing (Oral Transit Time, Pharyngeal Transit Time and Stage Transition Duration) and bolus clearance (residue scale) in their study of stroke patients and healthy controls. [60] They concluded from their results that the most comprehensive measure of swallowing impairment for 'acute and protracted dysphagia' (p. 354) should be based on combined measures. Similarly, the Oropharyngeal Swallow Efficiency (OPSE) measure was developed in order to obtain a representative measure of swallowing function. [110] The authors of this measure state that a comprehensive assessment of swallowing requires transit times, residue measures and aspiration measures. As mentioned earlier, combining rating scales (such as the PAS) with quantitative measures has also been recommended by other authors. [81]

**In summary**, the importance of the PAS in dysphagia rehabilitation is undisputed. However, the complexities associated with measuring and analysing intra-subject variability in PSD when using the PAS need to be acknowledged and carefully considered when designing interventions. Importantly, the PAS, being a unidimensional measure, only measures direction of bolus flow per se.

Given these points, the argument is made that there is a good reason to consider *combining* the PAS *with multiple measures* when evaluating the complex act of deglutition in acute stroke patients.

## 1.11 Multiple Measures of swallowing

### 1.11.1 Background

Composite measures of swallowing (most frequently, timing and clearance measures) have been in use for several years. Most published studies incorporating these measures in stroke patients have been used to examine and define the characteristics of swallowing impairment in a group either at baseline or over time [102, 111] or to examine or predict the risk of aspiration. [105, 112, 113, 114] However, these measures are also starting to be used to measure change in swallowing function following an intervention. [41, 42, 48, 94]

In the literature review that follows, key measures were identified that were felt to be important to be considered as multiple measures in PSD, given the pathophysiology of dysphagia post-stroke. Current evidence regarding their use in dysphagia rehabilitation in stroke is discussed, with broad reference to what each parameter measures. These studies only refer to those conducted either on healthy participants or stroke patients, as well as studies that separately report results for swallowing thin (level 0) fluids. The table below provides a summary of the measures that were identified as being important to include, followed by a detailed discussion.

**Table 1-7** Outline of timing and clearance measures

| **Component** | **Measure** |
|---|---|
| Oral Phase Measures | Oral Transit Time (OTT) |
| | Bolus Transport (BT) |
| Pharyngeal Phase Measures | Stage Transition Duration (STD) |
| | Initiation of pharyngeal swallow (IPS) |
| | Initiation of Laryngeal Closure (ILC) |
| | Laryngeal vestibule closure-reaction time (LVCrt) |
| | Laryngeal Closure Duration (LCD) |
| | Pharyngeal Response Time (PRT) |
| | Pharyngeal Transit Time (PTT) |
| | Upper Oesophageal Sphincter Duration (UOSD) |
| Clearance Measures | Oral Residue |
| | Pharyngeal Residue |
| | Number of swallows to clear |
| | Swallow pattern to clear |

### 1.11.2 Oral phase measures

#### 1.11.2.1 Oral transit time (OTT)

OTT focuses on measuring the time it takes for the bolus to move through the oral cavity [60] and has been reported in VFSS studies of both normal participants and stroke patients with dysphagia.

Healthy population: Logemann (1993) originally reported OTT to usually be less than 1 second. [6] A systematic review subsequently reported values in the region of 0.42s and 0.97s for 5ml, including preparatory behaviours and 0.47s excluding preparatory behaviours. [115] OTT has been noted to reduce as bolus size increases in a study of 50 healthy participants. [94] This may be due to the fact that larger boluses are held in a more posterior position in the mouth and if the head of the bolus is taken as the point of measurement, OTT will be shorter. [6] OTT increases slightly with age, i.e. >60 years. [6]

Stroke population: In studies of stroke patients, results have been conflicting. Some studies have reported normal OTT times when comparing aspirating (mean 0.36s) and non-aspirating stroke patients (mean 0.31s and 0.32s). [94, 105] Another study noted that OTT times for aspirating and non-aspirating patients were comparable, but prolonged in comparison with control subjects, although mean values were not given. [84] One of the earliest comprehensive studies (N= 128 patients) using VFSS to examine recovery of swallow function in stroke reported that delayed oral transit was, at 6 months, the single most important predictor of non-return to a normal diet. [116] Although this study did not define how they measured oral transit, it is feasible that prolonged oral transit impacts

on a patient's ability to manage normal textures. Another study examining recovery of dysphagia following stroke reported abnormal OTT scores at baseline, which improved to within normal limits at 1 month post-stroke, [102] although this was based on timing measures on nectar liquids not thin liquids. As also observed in healthy participants, one study reported increasing bolus volume also shortened OTT in a group of stroke patients.[94]

#### 1.11.2.2 Bolus Transport

This aspect measures how efficiently the tongue transports the bolus posteriorly in the mouth once the bolus has started moving purposefully in a continuous posterior manner.

Healthy population: As healthy participants typically do not exhibit difficulties with this aspect of swallowing, there are no studies examining this aspect that the author is aware of.

Stroke population: Martin-Harris et al. (2008) have formalised a method to measure this aspect, on the MBSImP. [70] In the author's opinion, despite impaired bolus transport being a relatively common phenomenon post-stroke, it has not been studied widely and is important to consider in PSD. One study reported a high incidence (65%) of impaired tongue control in stroke patients at baseline, [102] although the definition given in this study is broader than the definition provided by the MBSImP and therefore may have included more patients or referred to how well the tongue held the bolus in the oral cavity not just bolus transport.

### 1.11.3 Pharyngeal phase measures

#### 1.11.3.1 Pharyngeal Transit Time (PTT)

This feature refers to the time taken for the bolus to travel through the pharynx, from the time the bolus leaves the oral cavity and fully enters the UOS.

Healthy population: A meta-analysis conducted on healthy individuals reported an aggregate mean range of 0.84s with a wide range (0.35s to 1.19s) and variation in Confidence Intervals (CIs) for PTT, based on 14 studies. [117] The authors concluded that there appeared to be no clear evidence that bolus volume had an impact on PTT, with conflicting reports from studies. However, these authors published a follow-up paper suggesting there was a volume effect. [85] These authors suggest that it stands to reason that as PTT includes UOS closure as one of its measures and this latter measure does show a volume effect, that PTT would be longer for larger volumes. A possible effect of age is also suggested, with longer PTTs occurring as one gets older, however, this was only based on one published study. [117] Another reported finding is longer PTT measures co-occurring with longer laryngeal closure duration (LCD), but again this was only one study with 50 participants. [94]

Stroke population: PTT is one of the most frequently reported measures. Studies examining PTT are often reported in conjunction with Stage Transition Duration (STD)/ Swallow Response Time (SRT), as both these parameters have overlapping frames of reference (both take the head of the bolus past the ramus at the angle of the mandible as first frame). A common finding is increased PTT occurring as STD increases. [84, 94, 95, 105] Taken together, prolonged STD and PTT

have been found to predict aspiration risk. [84, 95, 102, 105] Bolus volume effects were not found in one study of stroke patients, i.e., increasing bolus volume did not result in longer PTT. [94] A further study reported improvement in PTT timings for some but not all acute stroke patients at two time points (baseline and month one). [60] A final study reported that abnormal PTT timings in posterior lesions were less likely to recover at 1 year than abnormal PTT timings in anterior lesions. [102]

PTT has also been used to measure the effect of PES with no change shown in two studies [42, 48] and significantly reduced timings in one study. [41]

#### 1.11.3.2 Stage Transition Duration (STD) reported by timing

Various definitions have been used by researchers to describe this measure. It is important to bear this in mind when comparing studies.

This parameter measures the time taken for the pharyngeal swallow reflex to trigger in response to a bolus entering the pharynx from the oral cavity. It is one of the most commonly reported measures in VFSS studies and one of the measures to show the most disturbance post-stroke. It is usually measured as the interval from the first frame showing the head of the bolus passing the ramus at the angle of the mandible, to the first frame showing initiation of hyoid movement (referred to as STD) or alternatively, first frame showing initiation of laryngeal movement (referred to as swallow response time (SRT)).

Healthy Population: Molfenter and Steele et al. (2101) examined this measure in their 2012 meta-analysis, using the terminology Stage Transition Duration. [117] The mean range of values reported for this measure were derived from 14

studies and ranged from -0.22s to 0.54s, with an aggregate mean range of 0.76s. As with PTT, large mean ranges and wide CIs were reported.

The negative score refers to first hyoid (or laryngeal movement) being seen *prior* to the bolus reaching the ramus at the angle of the mandible, with increasingly positive scores indicating longer delays. There is considerable debate in the literature regarding what is considered within normal limits for this measure. Different studies have yielded conflicting results. As can be seen from this review, there are a range of times that are considered normal.

With regards to interaction of bolus volume on STD, this was not clear from the studies reported. The size of the bolus reaching the posterior angle of the ramus, is not thought to influence STD, i.e. the speed at which the pharyngeal response triggers. [85] In contrast to bolus volume, increasing age was shown to have a consistent effect on STD, i.e., as participants get older, STD gets longer.

Stroke population: Delays in STD have been shown to be the most common and disabling feature causing aspiration in cortical and brainstem strokes. [84, 94, 102, 105, 111, 113, 114, 118-120] One study found that that aspirating patients had longer STDs and the longer the delay, the more severe the aspiration. [94] These authors report this to the 'primary swallow abnormality in stroke' (p.145). Similarly, Kim and McCullough (2007) were able to predict aspiration in 75% of patients (and absence of aspiration in 93%) based on STD. [113] In attempting to quantify how much of a delay is too much, these authors propose a delay of 0.9s-1.0s increases the risk of aspiration before and during the swallow. In intervention studies, an immediate reduction (VFSS conducted one hour after treatment) in SRT following one dose of PES was reported. [41] In contrast, when looking at

subacute effects, no change in SRT timings at two weeks following three doses of PES were seen. [42]

#### 1.11.3.3 Initiation of the pharyngeal swallow (IPS)

Measuring the onset of swallowing can also be reported by location, i.e., where the bolus head is when first onset of the hyoid or larynx is seen. This has immediate clinical relevance and meaning to clinicians. The term 'initiation of the pharyngeal swallow' as used in this thesis, was proposed and labelled into five categories by Martin-Harris et al. (2008) [88] Other researchers have previously used similar measures, most commonly using the valleculae as the reference point. In one study, bolus location was labelled as superior, level or inferior to the valleculae. [92] In another, the severity of delay was judged by counting (in seconds) how long swallow initiation took once barium had entered the valleculae. [100]

Healthy population: Martin-Harris et al. (2008) evaluated swallowing in a group of healthy subjects (N=82) using IPS. [88] The results showed variability in location of bolus head at swallow onset, with 80% of participants showing at least one swallow past the angle of the ramus before swallow initiation. Older participants were more likely to have a later onset of swallow. The majority of younger participants showed onset at the ramus, with some showing onset more distally, except for the pyriform fossae. Other studies have focused on bolus location at swallow onset in cued and non-cued conditions, although numbers are relatively small in both studies. Both studies (one study included younger participants and one study included older participants) reported a more distal bolus location at swallow onset for non-cued swallows. [87, 121]

Stroke population: To date, no studies in acute stroke have published separate baseline data on IPS that the author is aware of, although studies in acute stroke using the MBSImP are starting to emerge. [101, 122] Similarly, one study has been conducted on stroke patients with a mild dysphagia, using terminology focusing on the bolus relative to the valleculae, i.e. superior, level or inferior to the valleculae. [123] In the context of a delay in STD, it has been suggested that if this is the only deficit seen, with no co-existing disorders, then this does not necessarily indicate a dysphagia. [88] However, a full assessment should always be undertaken in patients with a diagnosis of stroke where concern is suspected. This is important given the variability seen in stroke and particularly in older participants, where a higher frequency of airway penetration can result when the swallow is triggered at a deeper bolus location compared to younger participants. [92]

#### 1.11.3.4 Initiation of laryngeal closure (ILC)

This refers to the interval between how quickly laryngeal elevation (leading to airway closure) is initiated after the bolus has passed the ramus at the angle of the mandible.

Healthy population: Few studies have reported on this measure. One study reported a mean ILC for 10 healthy subjects, of 0.19s for a 5ml bolus, compared to much longer ILCs for aspirating and non-aspirating patients (1.71s and 0.99s respectively) in the same study. [119]

Stroke population: Park et al. (2010) demonstrated that aspirating stroke patients had longer ILC timings than non-aspirating patients and controls,

although study numbers were modest (N=30). [119] In a follow-up study, these authors reported, for 28 stroke patients, that sub-cortical patients showed longer ILC timings than cortical patients, suggesting that the subcortex may play an important role in initiating vestibule closure. [98] A recent systematic review investigating physiological factors related to risk of aspiration, proposed the term 'bolus dwell time' (p.302) which has a very similar definition to that of ILC used here. [124] In this review, bolus dwell time was found to be a laryngeal factor associated with aspiration, although this review did not just include stroke patients.

#### 1.11.3.5 Laryngeal vestibular closure – reaction time (LVCrt)

LVCrt measures how quickly the laryngeal vestibule closes once the swallow is initiated (as determined by onset of hyoid movement). This contrasts with how long the airway is closed for (as measured by LCD). LVCrt is a relatively new measure.

Healthy population: LVCrt was first described by Macrae et al. (2014) although initially termed dtLVC – duration to laryngeal vestibule closure. [125] In two subsequent papers, examining training of laryngeal vestibule manoeuvres [126] and kinematic swallow differences, the term was changed to LVCrt. [127] These authors report that LVCrt is very short, averaging roughly 0.198s-0.363s for 5ml thin liquids and is thought to assist airway protection in the initial stages of the swallow. [126] A further study reported LVCrt to be quicker with moderately and extremely thick fluids compared to thin fluids. [128]

Stroke population: LVCrt is a relatively new measure and there are few published studies in acute stroke. One study including acute stroke patients, although not explicitly defining LVCrt, makes reference to the interval between onset of laryngeal elevation and laryngeal closure, noting that there was no difference between patients with PSD and healthy subjects. [94] Another earlier study with neurogenic patients (majority stroke) reported a correlation between both delayed onset of laryngeal closure *and delay to closure* with penetration and aspiration on 5ml boluses. [112] It is felt that LVCrt may provide important insights into the speed of airway closure in stroke patients, especially in patients who still show airway invasion even though they have a timely swallow.

#### 1.11.3.6 Pharyngeal Response Time (PRT)

PRT measures how quickly the bolus passes into the UOS once the swallow reflex has triggered, measured either by the first frame of laryngeal elevation onset, [110] or hyoid onset. [129]

Healthy population: Two studies have explored PRT in healthy participants. Numbers for these studies are small (N=8 and N=25) and report PRT average times (for pooled bolus sizes 1ml – 10ml) of 0.9s [110] and 0.93s (5ml) respectively. [129]

Stroke population: There are only a few studies in stroke patients reporting on this measure, involving a small number of patients, with reported scores of 0.9s (1ml-10ml pooled scores) and 0.83s respectively. [110, 129] In an intervention study evaluating the effect of PAS (single TMS combined with PES as well as PES and rTMS delivered separately), PRT was the only timing measurement to show

improved times. [48] Interventions that target pharyngeal dysphagia (such as PES) should consider incorporating this measure into their studies.

#### 1.11.3.7 Laryngeal Closure Duration (LCD)

This measures how long the airway is closed for, based on the duration of full contact between the arytenoids and base of the epiglottis.

Healthy population: In Molfenter and Steele's (2012) review, fourteen studies examining LCD were included. [117] They reported a large range of mean values (0.31s to 1.07s), an aggregate mean range of 0.76s and wide CIs which suggests that this measure shows a large variation in normal subjects. In this section, 8 of 10 studies confirmed a finding of longer LCD as bolus size increased and 3 of 10 studies suggested a trend towards longer LCD in older subjects. Since this review was published, Molfenter and Steele (2013) published results on a further study (N=20) which also demonstrated increasing LCD according to increasing bolus size. [85]

Stroke population: Studies in stroke patients have yielded a variety of results. In some studies, LCD did not increase as bolus volume did. [94] In others, shorter LCDs for both aspirating and non-aspirating stroke patients were reported [119] whilst other studies reported no difference in LCD in either aspirators, non-aspirators or controls [114] or between LCD durations in cortical and subcortical strokes.[98] More research is required into this aspect, but shorter LCDs could place stroke patients at risk on larger volumes. It is possible that not only prolonged STD can cause aspiration but other factors, one of which may be linked to LCD. Power et al. (2009) noted that adding LCD to their model (along

with PTT and SRT) increased predictive power of swallowing performance. [105] It has been suggested that there is a need for both measurements of LCD and SRT to be considered and that if LCD is poor, patients may still aspirate even if the SRT is timely [113, 119] or was delayed but has since recovered. [111]

#### 1.11.3.8 Upper Oesophageal Sphincter Duration (UOSD)

This aspect looks at how long the UOS is open for, to allow the bolus to pass into the oesophagus. Once the bolus passes fully into the oesophagus, the oesophageal stage of swallowing has commenced.

Healthy population: Molfenter and Steele's (2012) review of healthy participants (N =20 studies), demonstrated that UOS opening showed an aggregate mean range of 0.76s and a range of values (0.21s-0.67s) with narrow CI's i.e. little spread of data. [117] The review also demonstrated that the duration of UOS opening showed a consistent increase as bolus volume increased with a trend for longer durations in older subjects. Recent studies hypothesize that longer UOSD in older participants could be due compensatory behaviour for slowed bolus transit. [130]

Stroke population: A recent systematic review into factors associated with aspiration risk did not find duration of UOS opening a risk for aspiration, which the authors suggest is surprising, [124] although this review was not just based on stroke patients. Interestingly, in a previous study, using only stroke patients, the only factor to differentiate aspirators from non-aspirators was UOSD. [131] However, this latter retrospective study has methodological issues, such as having incomplete patient data available regarding aetiology and exact boluses

given. In contrast, another study examining UOS duration in stroke patients reported prolonged UOS duration for aspirating stroke patients, possibly as a compensation. [132] UOSD has also been used as an outcome measure to evaluate the effects of PES, whereby no significant changes were reported. [48]

### 1.11.4 Clearance Measures

#### 1.11.4.1 Oral residue

This is a measure of the amount of material that remains in the oral cavity after the first swallow. If patients show no awareness of residue in the oral cavity post-swallow, this is felt to be an indirect measure of the integrity of sensory awareness in the mouth.

Healthy population: Following ingestion of a bolus, complete clearance or trace residue are considered normal phenomena according to the MBSImP manual. [133] This is borne out in studies of healthy subjects where any amount more than trace residue does not seem to be a normal occurrence, although more studies report on pharyngeal residue than oral residue. Notwithstanding, some studies have reported on oral residue. McCullough et al. (2007) examined residue in the oral cavity from 79 healthy participants from 21 to 103 years, with a variety of consistencies, including thin fluids, on a scale of no residue (0), trace residue (1) and coating (2). [97] They reported that most participants received a score of trace coating and no-one, even the oldest group, received a score of 2, although they also reported that young participants were twice as likely to receive a score of 0.

In a number of smaller studies, in one study of 24 healthy participants, only 2 participants were reported as having mild oral residue, although different volumes up to 20ml were given and it is unknown which volume the residue occurred on. [36] Rademaker et al. (1994) reported that oral residue was minor or absent but this was in a very small number of participants (N=8). [110] Another study examining healthy younger and older participants reported that the older participants (N=13) exhibited more oral residue than the younger participants (N=4), although precise definitions for residue or a range were not provided and the numbers of subjects was small (N=19). [91] In one final study, Kim et al. (2005) examined 40 subjects (two groups of 21-51 years and 70-87 years) swallowing 2 x 5ml thin liquid boluses and 2 x 10ml thin liquid boluses, and found no issue with residue other than trace coating. [134] However, in this study, the authors do not explicitly state if they are referring to oral or pharyngeal residue.

Stroke population: Rademaker et al. (1994) [110] also examined oral residue in 8 stroke patients and reported that residue was not a marked concern, although the group of patients was small, and all consisted of a left basal ganglion infarct. As with healthy participants, there are more studies reporting on pharyngeal residue in patients, compared to oral residue.

#### 1.11.4.2 Pharyngeal residue

This is a measure of the amount and location of material in the pharynx post-swallow. It is important to measure post-swallow residue as it can present a risk of aspiration after the swallow and provides information regarding sensory awareness of residue in the pharynx. In healthy subjects, residue post-swallow

activates glossopharyngeal nerve fibres which in turn sends information to the NTS which causes a clearing swallow to be initiated. [3]

Healthy population: The study above in the oral residue section by Kim et al. (2005) also presumably relates to studies of pharyngeal residue. Other studies that specifically do mention pharyngeal residue reported that healthy subjects demonstrated mild, trace or no pharyngeal residue, [36, 60, 86, 110] irrespective of bolus consistency (i.e. even with slightly, mildly, moderately and extremely thick fluids) [128] but did show more pharyngeal residue in older participants (N=8) than younger ones (N=0). [91] Although in this latter study, numbers were small (N=19) and precise details of how residue was scored were not provided. The McCullough et al. (2007) study (N=79) in the above section also investigated pharyngeal residue, reporting the results as above.

Stroke population: Rademaker et al.'s (1994) study [60] reported mild to no pharyngeal residue in 5 of 6 stroke subjects, as did an earlier study of 8 stroke patients. [110] A more recent study of primarily stroke patients, demonstrated that residue present post-swallow markedly impaired safety and surprisingly, this only reached significance for residue in the valleculae. [135] In terms of prevalence, one study reported pyriform sinus residue in 20% of the patients examined. [136]

#### 1.11.4.3 Number of swallows to clear

Recording the pattern and number of swallows required to clear swallow 5ml and 50ml amounts will help to inform how efficient the swallow is and may help to inform the debate over the risk of aspiration from post-swallow residue.

Healthy Participants: Logemann (1993) stated that small boluses typically given during a VFSS, should be cleared in one but that large amounts such as 15ml may require more than one swallow. [6] One study, using 2 x 5ml (thin) liquid boluses reported that all healthy subjects (N=76, i.e. 152 swallows) completed swallowing in 'one swallow' [88] (p.588). Similarly, in another study involving 180 swallows from 20 subjects of larger boluses (5,10, and 20ml), secondary swallows remained low (3.8%), i.e., seven occasions of a piecemeal swallow – one occurring with a 5ml bolus and six instances with a 20ml bolus. In a further study, McCullough et al. (2007) reported that over 90% of boluses (5ml, 10ml, 20ml) were ingested with 1 or 2 swallows, but did note as age increased, so did the number of swallows to clear the material. [97] However, this study reports on both thin and thicker consistencies, so whether the results are applicable to thin fluids is not clear. The authors reported that the number of swallows also increased as bolus size increased, which correlates with Logemann's (1993) earlier statement. Finally, a more recent study reported that sips (average 12ml) of thin fluids for 38 younger participants were cleared in a single swallow and that even thicker consistencies did not usually result in multiple swallows. [128]

Stroke participants: Few studies appear to have explicitly studied the number of swallows needed to clear a single bolus, although with an emerging interest in the efficiency and efficacy of the swallow, this is likely to change. Perlman et al. (1994) did count all swallows in their study which contained a subset of 101 stroke patients (30.6%). [100] They reported that piecemeal swallowing (requiring secondary swallows) was reported to be statistically significant ($p<0.049$) with aspiration (among other oral stage impairments). Terre et al. (2006) reported a

20% occurrence of piecemeal swallowing in their sample of 64 acute stroke patients and that this occurred most frequently in posterior lesions. [136]

#### 1.11.4.4 Type of swallows

There is very little literature on types of swallows occurring during ingestion of *single/ separate* 5ml 'teaspoon' amounts. However, types of swallows that occur during *continuous* drinking of 50ml have been studied. There is a small amount of literature on this.

Healthy population: During continuous drinking (using straws) with young and older adults, most individuals exhibit one of two patterns. The first pattern comprises lowering of the hyoid and larynx (the hyolaryngeal complex (HLC)) with the epiglottis returning to an upright position between swallows. [92, 123] The second pattern is seen when there is partial lowering of the HLC between swallows, with the epiglottis still inverted between swallows. [92, 123] Some participants exhibit a combination of these two patterns. [92] In addition, location of the head of the bolus when initiation of the swallow occurs has shown to be more inferior with partial lowering of the HLC, [92, 123] which results in longer STDs and PTTs.

Stroke population: Not many acute stroke studies have reported on continuous drinking possibly due to safety concerns. One study reported that continuous drinking resulted in more instances of aspiration, both in normal participants and patients with mild dysphagia. [123]

### 1.11.5 Displacement measures

These aspects measure how far the hyoid bone or larynx move during swallowing (anteriorly and superiorly). Evidence suggests that for cortical and subcortical stroke, significant changes in displacement measures are not frequently seen [95, 100, 111, 137] and hence not a key feature of PSD. Displacement measures were therefore not included in this study.

**In conclusion**, this chapter has provided an overview of the importance and size of the problem of dysphagia and an overview of outcome measures has been presented, with a focus on the PAS scale. Given this background, three key issues have emerged. Firstly, the lack of a robust evidence base for interventions in acute stroke has been highlighted, underscoring the pressing need for an updated review on the effectiveness of swallowing therapy in acute stroke. Secondly, the case for including timing and clearance measures in addition to using the PAS scale when evaluating the complex act of swallowing function has been presented. As part of this, current research that has been conducted into relevant multiple measures in healthy participants and stroke patients has been reviewed. And finally, the importance of using validated outcome measures with incorporation of meaningful clinical measures has been highlighted.

## 1.12 Aims and hypotheses of thesis

In addressing these issues, the aims of this thesis are:

1. To update the Cochrane review for swallowing therapy in acute and subacute stroke,

2. To evaluate the effectiveness of using multiple measures of timing and clearance compared to a single measure of safety, in detecting change following a swallowing treatment (Pharyngeal Electrical Stimulation) from the STEPS Trial and,

3. To validate an existing clinical dysphagia measure – the dysphagia severity rating scale.

The specific research **questions** which underpin these aims are:

1. Does swallowing therapy improve swallowing outcomes in acute and subacute stroke?

2. Are multiple measures of timing and clearance more likely to detect change in swallowing function following a swallowing treatment, Pharyngeal Electrical Stimulation, compared to only using a single measure of safety?

3. Is the dysphagia severity rating scale a valid scale for measuring dysphagia severity in stroke patients?

Given the research questions posed above, the following **hypotheses** will be explored:

1. Swallowing therapy improves swallowing outcomes in acute and subacute stroke.

2. Multiple measures of timing and clearance will detect changes in swallowing function, following treatment with Pharyngeal Electrical Stimulation, that are not identified using only a single measure of safety.

3. The dysphagia severity rating scale is a valid scale for measuring dysphagia severity in stroke patients.

## 1.13 Organisation of the thesis

In answering the research questions and exploring these hypotheses, the organisation of the thesis is as follows:

**Chapter one** has already presented an overview of dysphagia to provide a context of the size and importance of the problem. This chapter highlighted the lack of definitive interventions for dysphagia in acute stroke, the importance of considering multiple measures to detect change in swallowing function and the need for validated outcome measures.

**Chapter two** explores the current evidence base for swallowing therapy in acute and subacute stroke by updating the 2012 Cochrane systematic review, in order to answer the first research question.

The second research question is addressed in the next three chapters.

Specifically, **chapter three** details the methodology that was developed in order to process and organise the data for subsequent analysis.

**Chapter four** describes the process of establishing intra- and inter-rater reliability for the methods developed in chapter three.

Having established reliability for these methods, **chapter five** presents the results of the comparison of multiple measures of timing and clearance compared to a single measure of safety following treatment with Pharyngeal Electrical Stimulation, using videofluoroscopic data.

**Chapter six** presents the results of validation of the dysphagia severity rating scale in stroke patients using retrospective and prospective data.

**Chapter seven** summarises how this thesis has met the aims outlined above and discusses implications for future work in the field of post-stroke dysphagia.

# 2. Swallowing therapy for dysphagia in acute and subacute stroke: Cochrane systematic review and meta-analysis

# Publications arising from this chapter:

Bath PM, Lee HS and Everton LF. Swallowing therapy for dysphagia in acute and subacute stroke. Cochrane Database of Systematic Reviews 2018, Issue 10. Art. No.: CD000323. DOI: 10.1002/14651858.CD000323.pub3.

Bath PM, Lee HS and Everton LF. Swallowing therapy for dysphagia in acute and subacute stroke. Cochrane Corner, Stroke. 2019;50:e46-e47.

# Presentations arising from this chapter:

Everton LF, Lee HS and Bath, P. Swallowing therapy for dysphagia in acute and subacute stroke: Review – Cochrane Collaboration. 13th UK Stroke Forum Conference, Telford, 4 – 6 Dec 2018 [platform presentation, awarded AHP Stroke Abstract Prize for highest AHP oral abstract].

Invited speaker: Everton LF, Lee SH and Bath PB. Swallowing therapy for dysphagia in acute and subacute stroke: Review – Cochrane collaboration. 18th Welsh Stroke Forum, Cardiff, July 3-4th, 2019.

# ABSTRACT

## Background

As highlighted in Chapter One, dysphagia is associated with poorer outcomes but lacks a proven evidence base. Treatments provided to improve dysphagia are aimed at accelerating recovery of swallowing function and reducing these risks. This chapter presents an update of the review first published in 1999 and updated in 2012.

## Objectives

To assess the effects of swallowing therapy on death or dependency among stroke survivors with dysphagia within six months of stroke onset.

## Search methods

Searches were undertaken in The Cochrane Stroke Group trials register, databases and review articles, for randomised controlled trials of interventions for dysphagia (≤ 6 months). Odds ratio, mean difference and standardised mean difference were calculated using random effects models. Two review authors independently applied the inclusion criteria, extracted data, assessed risk of bias and used the GRADE approach to assess the quality of evidence.

# Results

Swallowing therapy had no effect on the primary outcome (death or dependency/disability at the end of the trial) based on data from one trial (two data sets) (OR 1.05, 95% CI 0.63 to 1.75; 306 participants; 2 studies; $I^2$ = 0%; P = 0.86; moderate-quality evidence). Swallowing therapy had no effect on case fatality at the end of the trial (OR 1.00, 95% CI 0.66 to 1.52; 766 participants; 14 studies; $I^2$ = 6%; P = 0.99; moderate-quality evidence). Swallowing therapy probably reduced length of inpatient stay (MD -2.9, 95% CI -5.65 to -0.15; 577 participants; 8 studies; $I^2$ = 11%; P = 0.04; moderate-quality evidence). No evidence of a subgroup effect based on testing for subgroup differences was found (P = 0.54).

Swallowing therapy may have reduced the proportion of participants with dysphagia at the end of the trial (OR 0.42, 95% CI 0.32 to 0.55; 1487 participants; 23 studies; $I^2$ = 0%; P = 0.00001; low-quality evidence). Trial results show no evidence of a subgroup effect based on testing for subgroup differences (P = 0.91). Swallowing therapy may improve swallowing ability (SMD -0.66, 95% CI -1.01 to -0.32; 1173 participants; 26 studies; $I^2$ = 86%; P = 0.0002; very low-quality evidence). No evidence of a subgroup effect based on testing for subgroup differences was found (P = 0.09). Moderate to substantial heterogeneity between trials for these interventions was observed. Swallowing therapy did not reduce the penetration aspiration score (i.e., it did not reduce radiological aspiration) (SMD -0.37, 95% CI -0.74 to -0.00; 303 participants; 11 studies; $I^2$ = 46%; P = 0.05; low-quality evidence). Swallowing therapy may reduce the incidence of chest infection or pneumonia (OR 0.36, 95% CI 0.16 to

0.78; 618 participants; 9 studies; $I^2$ = 59%; P = 0.009; very low-quality evidence).

# Conclusions

Moderate- and low-quality evidence suggests that swallowing therapy did not have a significant effect on the outcomes of death or dependency/disability, case fatality at the end of the trial, or penetration aspiration score. However, swallowing therapy may have reduced length of hospital stay, dysphagia, and chest infections, and may have improved swallowing ability. However, these results are based on evidence of variable quality, involving a variety of interventions. Further high-quality trials are needed to test whether specific interventions are effective.

## 2.1 Introduction

The negative consequences and poorer outcomes associated with dysphagia post-stroke have already been discussed in Chapter One, along with an overview on current interventions for stroke. The aim of these interventions is to promote recovery of swallowing function thereby reducing the risks and poor outcomes associated with dysphagia. Two previous versions of this review in 2000 and 2012 concluded that, overall, the current evidence for interventions was insufficient and no definitive treatments for dysphagia were identified. [138, 37]

There is hence a clear need for an updated version to appraise recent evidence regarding the effectiveness of interventions. This information will provide support for clinical practice; will inform stroke survivors, clinicians, and healthcare funders regarding which interventions are most effective and may help guide policy and funding decisions.

### 2.1.1 Objectives

To assess the effects of swallowing therapy on death or dependency among stroke survivors with dysphagia within six months of stroke onset.

## 2.2 Methods

### 2.2.1 Types of studies

Randomised controlled trials (RCTs) of swallowing therapy for stroke survivors with acute or subacute stroke and dysphagia were included.

Trials were excluded if they compared two or more active treatments (i.e., treatment was confounded), recruited participants after six months of stroke onset, involved a large proportion of participants with non-stroke causes of dysphagia, or used a cross-over design, where data could not just be used from the first treatment phase.

For this third version of the review, most trials examining postural studies were removed, and all trials examining modified fluids because of a lack of a true control group. Trials of free water protocols, oral hygiene, cough reflex testing, and swallow screening were also excluded as these were not considered to be interventions for dysphagia per se. Trials involving the use of antibiotics were also excluded.

### 2.2.2 Participant types

Participants were included if their stroke occurred with 6 months of onset (i.e., acute and subacute), were diagnosed with either an ischaemic or haemorrhagic stroke and diagnosed with dysphagia (by bedside assessment or instrumental assessment).

### 2.2.3 Types of interventions

Eight groups of intervention types were pre-defined, namely:

•Acupuncture versus no acupuncture or routine acupuncture or sham acupuncture

•Behavioural interventions such as swallowing exercises, or positioning versus limited, usual, or no treatment

•Drug intervention versus none or placebo

•Neuromuscular electrical stimulation (NMES) versus none or sham stimulation

•Pharyngeal electrical stimulation (PES) versus none or sham stimulation

•Physical stimulation such as thermal or tactile versus limited, usual or no treatment

•Transcranial direct current stimulation (tDCS) versus none or sham stimulation

•Transcranial magnetic stimulation (TMS) versus none or sham stimulation

These interventions were combined (collectively referred to as 'swallowing therapy') and assessed for an effect on several pre-defined outcomes. Given that the science of intervention development for dysphagia is at an early stage, it is reasonable to ask the question whether any intervention is better than no intervention. This means firstly establishing where the most positive effects for swallowing therapy as a whole on any of the main outcomes are seen and where more research is needed.

### 2.2.4 Primary outcome

The primary outcome was functional outcome which was defined in this review as death or dependency (modified Rankin Scale: mRS > 2), or death or disability (Barthel Index: BI < 60), at the end of the trial.

Functional outcome (i.e., death or dependency/disability) was chosen as the primary outcome because dysphagia is associated with increased risk of death or dependency in acute and subacute stroke. Whilst swallowing therapy aims to reduce dysphagia, it was necessary to assess whether evidence shows that people receiving swallowing therapy are less likely to die or remain dependent. However, other important outcomes relevant to swallowing function as secondary outcomes were included.

### 2.2.5 Secondary outcomes

•Case fatality at the end of the trial.

•Length of inpatient stay.

•Proportion of patients with dysphagia at the end of the trial.

•Swallowing ability using assessments of dysphagia impairment using the dysphagia severity rating scale (DSRS), functional oral intake scale (FOIS) or dysphagia outcome and severity scale (DOSS); or water swallowing tests.

•Aspiration determined by VFSS and FEES and quantified using a scale such as the Penetration Aspiration Scale (PAS).

•Swallowing timings from VFSS measurements, e.g., pharyngeal transit time (PTT).

•Chest infection or pneumonia determined either clinically or radiologically.

•Nutritional measure, using blood albumin.

•Institutionalisation with discharge to a residential, care or nursing home, or extended care facility.

•Neurological impairment within four weeks, e.g., using National Institutes of Health Stroke Scale (NIHSS) or Scandinavian Stroke Scale.

•Quality of life, e.g., using Short Form-36 (SF-36) or EuroQoL.

### 2.2.6 Search methods for identification of studies

Trials in all languages were searched and outstanding publications requiring translation were listed in the Characteristics of studies awaiting classification section. Electronic searches were conducted in the: Cochrane Stroke Group Trials Register (last searched on 26 June 2018); Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 6) (Appendix 1) in the Cochrane Library (searched 26 June 2018); MEDLINE Ovid (1946 to 26 June 2018) (Appendix 1); Embase (1974 to 26 June 2018) (Appendix 1); CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to 26 June 2018) (Appendix 1); Science Citation Index Expanded, Social Sciences Citation Index, Conference Proceedings Citation Index- Science (Web of Science Core Collection; 1900 to 26 June 2018) (Appendix 1); and SpeechBITE (searched 28 June 2018) (Appendix 1).

In addition, to further identify published, unpublished, and ongoing trials, the following websites were searched: the US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 26 June 2018; Appendix 1); the World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 26 June 2018; Appendix 1); and Google Scholar (searched 7 June 2018; Appendix 1). Lastly, the reference lists

of relevant trials, review articles, and the authors' own reference lists were searched. The author refined and carried out all searches alongside the Cochrane Stroke Group.

### 2.2.7 Data collection and analysis

#### 2.2.7.1 Selection of studies

HSL and LE scanned the titles and abstracts of the identified records and excluded obviously irrelevant articles. The full text of the remaining studies was independently reviewed, and relevant trials were selected according to the listed inclusion criteria. Disagreements were resolved through discussion with the third review author (PB).

#### 2.2.7.2 Data extraction and management

HSL and LE entered the data into RevMan 5 (RevMan 2014); disagreements were resolved through discussion and consultation with the third review author (PB). Information was assessed on randomisation, blinding, the number of participants randomized, time of treatment from stroke, type of dysphagia therapy, participant withdrawals and losses to follow-up, and relevant outcomes. Outcome data from dose escalation or dose comparison trials was aggregated into one active treatment group.

#### 2.2.7.3 Assessment of risk of bias in included studies

The potential for bias was assessed using the 'Risk of bias' tool as recommended in the Cochrane Handbook for Systematic Reviews of Interventions. [139] The

assessment includes sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other issues.

#### 2.2.7.4 Measures of treatment effect

The weighted estimate of the typical treatment effect across trials was assessed using odds ratio (OR) and 95% confidence intervals (CIs) for binary data, mean difference (MD) and 95% CIs for continuous data, or standardized mean difference (SMD) and 95% CIs for continuous data based on different scales. The analyses were performed using RevMan 5 (RevMan 2014). OR was calculated using the Mantel-Haenszel method and MDs using the inverse variance method.

#### 2.2.7.5 Unit of analysis issues

Where outcome measures included different scores, these were converted to grades in the same direction of mild-to-severe and analysed using MD. Where studies compared graduations of therapy (high-medium-low intensity) the middle intensity group was divided in two and study data was analysed by comparing high intensity with medium intensity, and medium intensity with low intensity or no treatment. Similarly, if a trial compared high versus low frequency stimulation or unilateral versus bilateral stimulation the control group participants were equally divided between treatment groups to prevent control participants being counted more than once and thereby artificially narrowing the CIs. Each set of data was entered as a separate trial.

#### 2.2.7.6 Dealing with missing data

If a trial publication did not provide relevant data or data were missing but it was felt to appropriate otherwise, the studies were placed into Characteristics of studies awaiting classification.

#### 2.2.7.7 Assessment of heterogeneity

The random-effects model was used to assess heterogeneity by looking at forest plots to see how CIs overlapped (non-overlapping studies are exhibiting statistical heterogeneity) and by the $I^2$ statistic. [140] Thresholds for interpreting heterogeneity were defined according to the Cochrane Handbook for Systematic Reviews of Interventions, where 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity, and 75% to 100% represents considerable heterogeneity. [140]

#### 2.2.7.8 Assessment of reporting biases

Selective outcome reporting was assessed as reported in the 'Risk of bias' table.

#### 2.2.7.9 Data synthesis

Meta-analysis was performed using the functionality within RevMan 5 (RevMan 2014): random-effects models (Mantel-Haenszel method) was used and presented data as number (%) or mean (standard deviation) with OR, MD, or SMD. Random-effects models were used since it was expected that the trials

would be heterogeneous in design and delivery, such as different types of participants and interventions.

#### 2.2.7.10 Grade and 'Summary of findings' table

The quality of the evidence was assessed using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) as described in the Cochrane Handbook for Systematic Reviews of Interventions, [140] for the following main outcomes of analysis: (maximum of seven allowed)

•death or dependency/disability at the end of the trial;
•case fatality at end of trial;
•length of inpatient stay;
•proportion of participants with dysphagia at the end of the trial;
•swallowing ability;
•penetration aspiration score;
•adverse event: chest infection or pneumonia.

#### 2.2.7.11 Subgroup analysis and investigation of heterogeneity

Subgroup analyses was performed on the eight different types of swallowing therapy in order to provide more specific information pertaining to the different interventions. Significant subgroup interactions were assessed using the test for subgroup differences for each main outcome.

#### 2.2.7.12 Sensitivity analysis

Sensitivity analyses was not performed because of the small number of trials.

## 2.3 Results

### 2.3.1 Description of studies

Twenty-seven new randomized controlled trials involving a total of 1777 acute or subacute stroke survivors with dysphagia were identified.

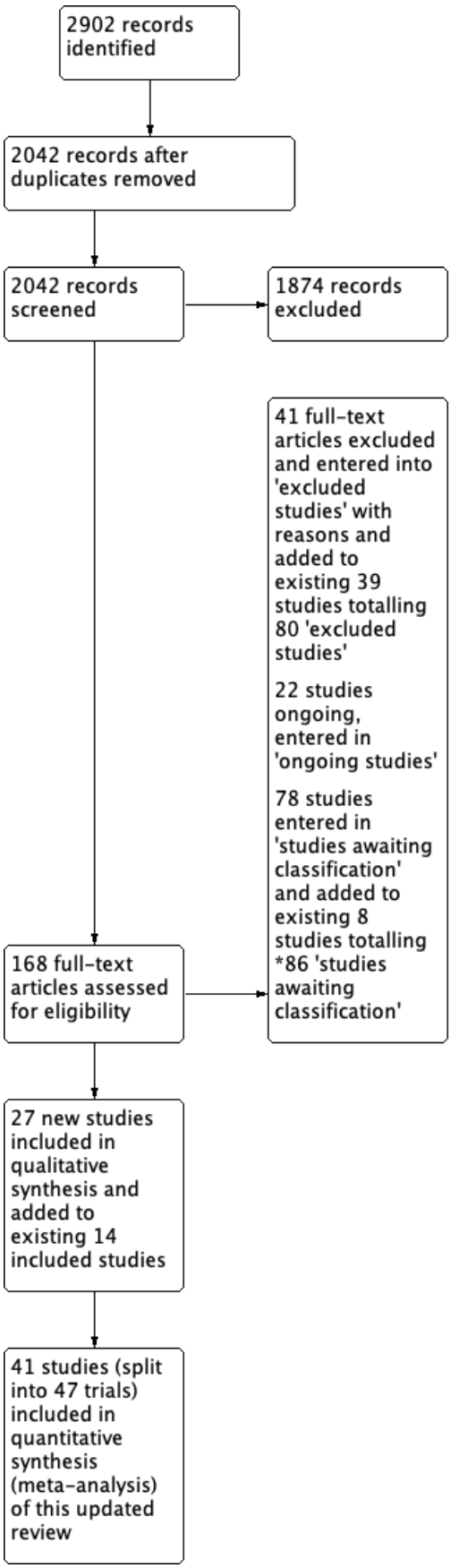
### 2.3.2 Results of the search

In total, 2902 references were identified, 860 duplicates removed and 2042 records screened. A further 1874 records were excluded, leaving a total of 168 records. After full text review, 41 studies were also excluded (please see website for details of excluded studies DOI: 10.1002/14651858.CD000323.pub3). These newly excluded studies were added to the existing list of 39 excluded studies, giving a total of 80. Twenty-two studies were added to the ongoing studies section (please see website for details of ongoing studies DOI: 10.1002/14651858.CD000323.pub3), whilst 78 new studies were added to the eight existing studies awaiting classification (please see website for details of studies awaiting classification DOI: 10.1002/14651858.CD000323.pub3.), giving a total of 86. These studies are either completed and awaiting publication, are awaiting translation, or a full-text article is being sought.

During external assessment of this review, a further update to the searches was requested and conducted; this revealed further potentially relevant studies, and these have been added to the awaiting classification section; these will be assessed as part of the next update of this review. Finally, 27 new studies were added to the existing 14 studies, giving a total of 41 studies (47 data sets). This

resulted in the addition of 1777 participants to the existing 883, giving a total of 2660 participants. The PRISMA study flow diagram is shown in Figure 2.1.

**Figure 2-1** Prisma flow diagram



### 2.3.3 Included studies

A total of 41 trials were included in this updated review (mean age 67.8 years). The trials looked at various forms of swallowing therapy after stroke. Details of included studies are detailed in Table 2.1.

Where outcome measures included different scores, these were converted to grades in the same direction of mild-to-severe and analysed using MD. Two studies compared graduations of therapy (high-medium-low intensity) [141, 142-144] here, the middle intensity group was divided in two, and the study data analysed by comparing high intensity with medium intensity, and medium intensity with low intensity or no treatment. Similarly, one trial of TMS compared high versus low frequency stimulation or unilateral versus bilateral stimulation [145, 146, 147] here, the control group participants were divided equally between treatment groups to prevent control participants being counted more than once and thereby artificially narrowing the CIs. Each set of data was entered as a separate trial, hence, although the total number of included studies was 41, the total number of data sets entered for analysis was 47.

**Table 2-1** Table of included studies

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| Bai 2007i [148] | Random numbers table<br>Outcomes not blinded (medium-intensity vs low-intensity data set) | 1 centre in China:111 participants within 2 weeks of stroke | A1: shallow needling (control) (n = 35) = low intensity. A2: single deep needling (n = 18) = medium intensity B: deep multi-needling | Watian drinking test grade<br>Return to normal diet |
| Bai 2007ii [148] | High vs medium data set | As data set 1 | A1: shallow needling (control)A2: single deep needling (n = 17) = medium intensity B: deep multi-needling (n = 40) = high intensity | As data set 1 |
| Bath 1997 [149] | Computerised randomisation by minimisation. Unblinded outcome assessment.<br>Analysis by ITT | 1 centre in UK 19 participants with stroke, within 2 weeks of onset | Factorial trial: PEG vs NGT; intensive vs conservative swallowing therapy. PEG: NGT: up to 3 NGTs | Primary outcomes: resumption of safe feeding (12 weeks), weight loss < 5% (6 weeks), discharge (6 weeks), secondary outcomes also |
| Carnaby 2006i [142] | Computerised randomisation. Blinded outcome assessments by SLT. ITT (Control vs low-intensity data set) | 1 centre in Australia<br>306 participants<br>Enrolment within 2 weeks of stroke onset | Rx 1: standardised high intensity swallowing therapy (n = 102). Rx 2: standardised low intensity swallowing therapy (n = 102); split into (n = 51) for each data set. C: usual care (n = 102). | Outcomes: time to return to normal diet; aspiration pneumonia; dysphagia (PHAD score < 85) |
| Carnaby 2006ii [142] | High-intensity vs low-intensity data set | As data set 1 | High intensity (n = 102). Low intensity (n = 51) | As data set 1 |
| Chan 2012 [150] | Randomisation by random sequences on black paper<br>Single-blind (participants blinded): outcome assessors blinded | 1 centre in Hong Kong<br>87 participants with neurogenic dysphagia (69%) participants with dysphagia due to cerebral infarct < 6 months | All groups given routine swallowing therapy<br>Rx 1: true acupuncture (n = 20)<br>Rx 2: sham acupuncture that did not puncture true acupoints lying on a meridian (n = 19)<br>C: routine swallowing therapy only (n = 48) | Outcomes: Royal Brisbane Hospital Outcome Measure Scale (RBHOMS), swallow function by consistencies of ingested food and fluid |
| Chen 2016a [151] | Computer-generated random numbers by independent research staff<br>Assessors blinded | Multi-centre trial in China<br>250 participants;<br>S troke within 2 to 7 days | Rx: acupuncture and conventional stroke rehabilitation care<br>C: conventional stroke rehabilitation care only | Primary outcome: NIHSS index<br>Secondary outcomes: FMA for motor function, recovery based on BSA, VFSS, MMSE, and MoCA |
| Du 2016i [145] | Randomisation by sequentially numbered sealed envelopes<br>Blinded outcome assessments by trained neurologist | 1 centre in China<br>40 participants<br>Enrolment within 2 months of stroke onset | Rx 1: 1 Hz rTMS to unaffected hemisphere (n = 13). Rx 2: 3 Hz rTMS to affected hemisphere (n = 13). C: sham rTMS (n = 12), split into n = 6 for each data set | Outcomes: swallow score using Standardised Swallow Assessment (SSA), BI, mRS, and measures of mylohyoid MEPs |

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| Du 2016ii [145] | High-frequency vs sham data set | As data set 1 | High = 102 (high intensity)<br>Sham = 51 (low intensity) | As data set 1 |
| Feng 2012 [152] | Randomisation by random numbers table<br>Blinding unclear | 1 centre in China; 122 participants; baseline characteristics similar<br>Enrolment within 2 weeks to 6 months of stroke onset | Rx: tongyan spray (n = 60)<br>C: placebo (n = 60) | Outcomes: swallow safety and function using the SSA |
| Han 2004 [153] | Randomisation by sealed opaque envelope. Assessors blinded | People with acute stroke,<br>1 centre in China<br>66 participants<br>within 30 days of onset | Rx: scalp and neck acupuncture with electroacupuncture with standard Western medical treatment<br>C: standard Western medical treatment only | Dysphagia at end of trial after 3 treatment sessions |
| Heo 2015 [154] | Participants were randomly allocated by drawing lots | 1 centre in Republic of Korea<br>44 participants with stroke within 3 months of diagnosis | Rx: kinesio-taping<br>C: no kinesio-taping | Kinematic analysis of movement of the hyoid bone; angular variation of the epiglottis; swallow score: FDS |
| Huang 2010 [155] | Method of randomisation and blinding unknown<br>Only data for groups 2 and 3 | 1 centre in China<br>97 participants with post-stroke dysphagia | Group 1: electrical stimulation (n = 35)<br>Group 2: rehabilitation training (n = 30)<br>Group 3: acupuncture (n = 32) | Swallowing function |
| Jayasekeran 2010a [42] | Dose comparison protocol (only data from stimulation once a day over 3 days included)<br>Computerised randomisation by minimisation<br>Blinded outcome measures | 1 centre in UK<br>10 participants with acute cerebral infarct (< 3 weeks) | Rx: bedside pharyngeal electrical stimulation<br>C: sham stimulation | Airway aspiration at 2 weeks' post intervention |
| Jayasekeran 2010b [42] | Parallel-group design protocol<br>Computerised randomisation by minimisation<br>Blinded outcome measures | 2 centres in UK<br>28 participants with acute cerebral infarct or haemorrhage (< 3 weeks) | Rx: bedside pharyngeal electrical stimulation<br>C: sham stimulation | Airway aspiration at 2 weeks post intervention |
| Jia 2006 [156] | Randomisation: participants randomised in visiting sequence<br>Blinding and ITT unclear | 1 centre in China<br>72 stroke confirmed by CT/ MRI scan but unclear patient inclusion criteria | Group 1: acupuncture + rehabilitation training<br>Group 2: rehabilitation training only | Primary outcomes: therapeutic assessment of swallowing function using 1 to 10 point scale |
| Kang 2012 [157] | Method of randomisation unclear | 1 centre in Korea<br>25 participants | Rx: additional exercise programme for dysphagia with thermal-tactile stimulation<br>C: thermal-tactile stimulation only | Videofluoroscopy, Functional Oral Intake Scale, transition |

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| | | Enrolment within 6 weeks of stroke onset | | from tube to oral feeding, aspiration pneumonia incidence |
| Khedr 2009 [158] | Method of randomisation unclear:<br>Blinded outcome assessment | 1 centre in Egypt<br>26 participants between 5th and 10th days post stroke | Rx: repetitive transcranial magnetic stimulation of the affected motor cortex (n = 14)<br>C: sham stimulation (n = 12) | Primary outcome: score on the dysphagia rating scale and secondary outcomes |
| Khedr 2010 [159] | Method of randomisation unclear<br>Blinded primary outcome assessment | 1 centre in Egypt<br>22 participants with hemispheric stroke: lateral medullary infarction or another brainstem infarction | Rx: repetitive transcranial magnetic stimulation of the affected motor cortex (n = 11)<br>C: sham stimulation (n = 11) | Primary outcome: score on the dysphagia rating scale<br>Secondary outcomes: motor power of hand grip, BI, NIHSS |
| Kim 2012i [146] | Method of randomisation unclear<br>Blinding unclear | 1 centre in Korea<br>30 participants with acute brain injury | Rx 1: high frequency (5 Hz) rTMS (n = 10)<br>Rx 2: low frequency (1 Hz) rTMS (n = 10)<br>(Using high frequency data set)<br>C: sham stimulation. (n = 10); control = 5 | Functional Dysphagia Scale and Penetration Aspiration Scale |
| Kim 2012ii [146] | Low-frequency data set vs control | As data set 1 | Low frequency rTMS = 10<br>Control (sham stimulation) = 5 | As data set 1 |
| Kumar 2011 [160] | Randomisation via simple randomisation<br>Double-blind<br>Analysis by ITT unclear | 1 centre in USA<br>14 participants with subacute (24 to 168 hours) unilateral infarction | Rx: anodal transcranial direct current stimulation<br>C: sham stimulation | Swallowing impairment using dysphagia outcome and severity scale |
| Lee 2014 [161] | Randomisation via computer-generated block randomisation<br>Blinding and ITT unclear | 1 centre in Korea<br>57 participants with dysphagic stroke within 10 days of onset | Rx: NMES combined with traditional dysphagia therapy (n = 31)<br>C: traditional dysphagia therapy only (n = 26)<br>5 days per week for 3 weeks | Swallowing function, Functional Oral Intake Scale |
| Lee 2015 [162] | Randomisation by computer-generated random sequence<br>Outcome assessors blinded | Multi-centre trial: Hong Kong<br>93 participants with stroke disease; onset unclear but recent hospitalisation in previous 3 months | Rx: lisinopril 2.5 mg once daily at bedtime<br>C: placebo | Incidence of pneumonia, mortality, and Royal Brisbane Hospital Outcome Measure Scale score |
| Li 2014 [163] | Randomisation via minimisation software<br>Single-blind - assessors blinded | Recruitment through newspaper advertisements in China<br>118 participants with hemispheric stroke | Rx 1: neuromuscular electrical stimulation (VitalStim)<br>Rx 2: combined NMES and traditional swallowing therapy<br>C: traditional swallowing therapy<br>(Data from Rx 2 vs control used in this review) | Swallow score, oral transit time, pharyngeal transit time, laryngeal closure duration, PAS |

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| Lim 2009 [164] | Method of randomisation unclear:<br>Blinding of outcomes unclear<br>Analysis by ITT unclear | 1 centre in Korea<br>22 participants with CT or MRI confirmed stroke < 6 months from onset | Rx: neuromuscular electrical stimulation + thermal-tactile stimulation (n = 13)<br>C: thermal-tactile stimulation (n = 9) | Swallow function scoring system, PAS and PTT |
| Liu 2000 [165] | Method of randomisation, blinding of outcomes and ITT unclear | 1 centre in China,<br>84 participants with stroke, within 2 months onset | Rx: acupuncture - Tiantu (CV 22), Lieque (LU 7), Zhaohai (KI 6) - once daily for 10 days (n = 54)<br>C: (n = 30) | Outcome: bulbar function (phonation, swallowing, cough reflex) |
| Liu 2004 [166] | RCT | 1 centre in China<br>82 participants with stroke: within 6 months of stroke onset | Rx: scalp acupuncture + sublingual needling (n = 44)<br>C: scalp acupuncture + control needling (n = 38) | Recovery of function (swallowing food and water, movement of the tongue, disappearance of dyslalia and hoarseness |
| Park 2012 [167] | Computer-generated randomisation sequence<br>Outcomes and participants blinded | Study in Korea<br>20 participants with stroke > 1 month | Rx: effortful swallow with infrahyoid motor electrical stimulation<br>C: effortful swallow with infrahyoid sensory electrical stimulation (placebo stimulation | Vertical laryngeal and hyoid movements, maximum width of UOS opening, PAS |
| Park 2013 [168] | Computer-generated randomisation sequence<br>Outcomes and participants blinded | Study in Korea<br>18 participants with stroke > 1 month | Rx: active high frequency rTMS (5 Hz) at the contralesional intact cortex<br>C: sham rTMS | VDS, PAS |
| Park 2016a(i) [147] | Randomisation unclear<br>Outcome assessor blinded | 1 centre in Korea<br>35 participants with subacute stroke with onset < 3 months | Rx 1: unilateral stimulation group with (10 Hz) rTMS on ipsilesional cortex and sham on contralesional cortex (n = 11)<br>Rx 2: bilateral stimulation group with (10 Hz) rTMS on ipsilesional and contralesional cortex (n = 11)<br>C: sham rTMS over bilateral hemispheres (n = 11) | Clinical Dysphagia Scale, Dysphagia Outcome and Severity Scale, PAS, VDS |
| Park 2016a (ii) [147] | As per Park 2016a | As data set 1 | Bilateral stimulation (n = 11) vs sham stimulation (n = 6) | As data set 1 |
| Park 2016b [169] | Randomisation by randomly selected envelopes with code<br>Outcomes partially blinded | 1 centre in Korea<br>33 participants with stroke onset within 6 months | Rx: EMST with a 70% threshold value of maximal expiratory pressure, using an EMST device<br>C: training with sham device | Swallow function using VFSS, PAS, Functional Oral Intake Scale |
| Perez 1997 [170] | Computerised randomisation<br>Triple-blind trial<br>Outcomes blinded | 1 centre in UK<br>17 participants with stroke within 2 weeks | Rx: nifedipine (30 mg orally daily, Bayer, UK) (n = 8) | Primary outcome: clinical improvement in swallowing |

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| | Analysis by ITT | | Pl: matching tablet; treatment for 4 weeks (n = 9) | Other outcomes also such as incidence of silent aspiration/PTT |
| Power 2006 [107] | Method of randomisation unclear<br>Blinded outcomes | 1 centre in UK<br>16 participants | Rx: actual electrical stimulation to faucial pillars<br>C: single episode of sham electrical stimulation | Changes on videofluoroscopy 60 minutes post intervention |
| Shigematsu 2013 [171] | Participants randomised using code numbers<br>Outcomes blinded | 1 centre in Japan<br>20 participants with stroke > 4 weeks | Rx: 1-mA anodal tDCS<br>C: sham tDCS (n = 10)<br>Treatment for 10 days | Dysphagia Outcome and Severity Scale, PAS, VFSS, FEES |
| Song 2004 [172] | Method of randomisation: random numbers table<br>Allocation method and concealment unclear | 1 centre in China<br>53 participants; 46 men | Rx: nurse-led swallowing exercises, oral stimulation and oral care (n = 29)<br>C (n = 24) | Primary and secondary outcomes not defined<br>Resolution of dysphagia by water swallow test and dietary ability, pneumonia rates |
| STEPS 2016 [44] | Computerised randomisation<br>Single-blind; outcome assessor blinded<br>Analysis by ITT | International trial<br>162 participants, acute stroke | Rx: active pharyngeal electrical stimulation<br>C: sham pharyngeal electrical stimulation | Primary: change in PAS at 2 weeks from baseline<br>Various secondary outcomes |
| Terre 2015 [173] | Computerised randomisation<br>Double-blinded study<br>Outcome assessors blinded | Study in Spain<br>20 participants (14 stroke) within 5 months of diagnosis | Rx: active NMES with conventional therapy<br>C: sham NMES with conventional therapy | Clinical, videofluoroscopic, and oesophageal manometric analyses of swallow; Functional Oral Intake Scale |
| Vasant 2016 [174] | Computerised randomisation<br>Single-blind trial<br>Outcomes blinded Analysis by ITT | 3 centres in UK<br>36 participants; acute stroke | Rx: pharyngeal electrical stimulation n = 18<br>C: sham n = 18 | Death, swallow function, dysphagia |
| Warusevitane 2015 [175] | Randomisation via a random numbers list independently generated<br>Double-blind | 1 centre in UK<br>60 participants within 7 days of acute ischaemic or haemorrhagic stroke | Rx: 10 mg metoclopramide (10 mL)<br>C: 10 mL normal saline | Swallowing impairment using dysphagia outcome and severity scale |
| Wei 2005 [176] | Method of randomisation unclear<br>Outcomes blinded | 1 centre in China<br>68 participants; timing post stroke unclear but suggests acute | Rx: Shuiti acupoint injection with stellate ganglion block for 40 days of treatment (n = 32)<br>C: standard medical care, which included some acupuncture (n = 33) | Resolution of dysphagia: water swallow test score<br>BI<br>Chinese Neurological Score<br>Fugl-Meyer Assessment |
| Xia 2011 [177] | Method of randomisation unclear<br>Outcomes blinded | 1 centre in China | Rx 1: combined VitalStim therapy + conventional swallowing training (n = 40)<br>Rx 2: VitalStim therapy (n = 40) | VFSS, Standardised Swallowing Assessment (SSA), surface EMG, |

| Trial | Methods | Participants | Interventions | Outcomes |
|---|---|---|---|---|
| | | | | |
| | | 120 participants, timing post stroke unclear but suggests acute | C: conventional swallowing training (n = 40)<br>For the purpose of this review, treatment group Rx 1 used as the treatment arm only | Swallowing Quality of Life (SWAL-QOL) |
| Xia 2016 [178] | Randomisation by random numbered tables<br>Outcomes blinded | 1 centre in China<br>124 participants, timing post stroke unclear but suggests acute | Rx: combined acupuncture with standard swallowing training (n = 62)<br>C: standard swallowing training only (n = 62) | Primary: Standardized Swallowing Assessment, Dysphagia Outcome Severity Scale plus secondary outcomes |
| Yuan 2003i [141] | Method of randomisation unclear<br>Blinding unclear | 1 centre in China<br>64 participants; timing unclear | R1: enteral nutrition agent with thickener and swallowing therapy (n = 18)<br>R2: traditional liquid diet and swallowing therapy (n = 22). This data set was split (n= 11) *<br>C: liquid diet only and no swallowing therapy (n = 24)<br>(R1 and R2 had NGTs for an uncertain amount of time)<br>*Compared in data set 1 | Length of stay, pneumonia rates, nutritional measures, resolution of dysphagia (swallow test grade) |
| Yuan 2003ii [141] | As data set 1 | As data set 1 | R1: enteral nutrition agent with thickener and swallowing therapy (n = 18)<br>R2: traditional liquid diet and swallowing therapy (n = 22). This data set was split (n = 11) | As data set 1 |
| Zheng 2014 [179] | Randomisation unclear<br>Blinding unclear | 1 centre in China<br>88 participants; onset of stroke within 2 weeks | Rx: individualised multi-disciplinary rehabilitation programme (n = 44)<br>C: conventional rehabilitation programme (n = 44) | Swallowing function by the water swallow test |

### 2.3.4 Excluded studies

Eighty studies were excluded in this updated review, most commonly because two active treatments were compared (confounded) or the trials were not RCTs. Ten studies were excluded as the reported outcomes were not relevant to this review. Eleven studies were excluded due to a lack of outcome data; some of these might be relevant to this review if outcome data were to become available. Details of characteristics of excluded studies can be viewed at: DOI: 10.1002/14651858.CD000323.pub3.

### 2.3.5 Risk of bias in included studies

Risk of bias for the included studies is presented below and summarised in Figure 2.2.

#### 2.3.5.1 Allocation (selection bias)

**Random sequence generation**

•Randomisation by computer occurred in 15 studies (low risk of bias) [149] [170, 180] [142-144, 42, 181, 167, 168, 161, 163, 162, 173, 151, 44, 174]

•Randomisation using random number tables occurred in 10 studies (low risk of bias) [172, 148, 150, 152, 171, 145, 175, 178]

•Simple randomisation occurred in 4 studies (low risk of bias) [153, 160, 154, 169]

•Method of randomisation was unclear in 16 studies (unclear risk of bias) [165, 141, 166, 107, 176, 158, 155, 159, 146, 157, 177, 179, 147]

•Non-randomised methods were used in 2 studies (high risk of bias) [156, 164]

**Allocation concealment**

•Allocation concealment was ensured in 17 studies (low risk of bias) [153, 142, 158, 150, 152, 167, 168, 171, 163, 162, 175, 151, 145, 169, 174]

•Allocation concealment unclear in 28 studies (unclear risk of bias) [149, 170, 180, 165, 141, 166, 172, 176, 107, 148, 155, 42, 159, 160, 177, 157, 146, 161, 179, 154, 173, 147, 44, 178]

•Allocation concealment was not ensured in two studies (high risk of bias) [156, 164]

**Baseline prognostic factors matching between intervention and control groups**

•Baseline factors similar in 34 studies (low risk of bias) [170, 180, 172, 142-144, 148, 158, 42, 159, 150, 177, 152, 157, 146, 167, 168, 161, 171, 154, 162, 163, 179, 173, 175, 145, 151, 147, 169, 44, 174, 178]

•Baseline factor matching unclear in 13 studies (unclear risk of bias) [149, 141, 153, 166, 176, 156, 107, 164, 155, 42, 160]

### 2.3.5.2 Blinding (performance bias and detection bias)

**Performance bias**

•Both participants and investigators blinded in three studies (low risk of bias) [170, 160, 180, 175]

•Participants blinded in nine studies (low risk of bias) [158, 150, 167, 168, 173, 145, 44, 174]

•Both participants and investigators unblinded in five studies (high risk of bias) [142, 151, 147,]

•Blinding of participants and investigators uncertain in 14 studies (unclear risk of bias) [149, 153, 148, 164, 42, 159, 177, 171, 163, 162, 169, 178]

**Detection bias**

•Outcomes blinded in 28 studies (low risk of bias) [170, 180, 153, 176, 142, 158, 164, 42, 159, 177, 150, 167, 168, 163, 171, 162, 173, 175, 151, 145, 147, 169, 44, 174, 178]

•Outcomes not blinded in three studies (high risk of bias) [149, 148]

- Overall, 16 studies did not report on any blinding procedures, i.e. participants, investigator or outcome assessment (unclear risk of bias) [165, 141, 166, 172, 176, 156, 107, 155, 152, 157, 146, 161, 179, 154]

### 2.3.5.3 Incomplete outcome data (attrition bias)

•Ten studies reported no loss of participants during follow-up (low risk of bias) [153, 42, 150, 157, 146, 168, 171, 161, 175]

•Twelve studies reported loss of participants during follow-up but were judged to be at low risk of bias [170, 180, 142, 158, 159, 152, 167, 145, 147, 174]

•Seven studies were judged to be at high risk of bias due to incomplete outcome data [164, 42, 163, 162, 151, 169, 44]

•Loss of participants during follow-up was unclear in 18 studies (unclear risk of bias) [141, 148, 149, 165, 166, 172, 176, 156, 107, 155, 160, 42, 179, 154, 177, 173, 178]

#### 2.3.5.4 Selective reporting (reporting bias)

•Thirty four were judged to be at low risk of reporting bias [170, 180, 142-144, 107, 158, 42, 159, 160, 177, 150, 152, 157, 146, 167, 168, 171, 161, 163, 179, 154, 162, 155, 173, 175, 151, 145, 147, 169, 44, 174, 178]

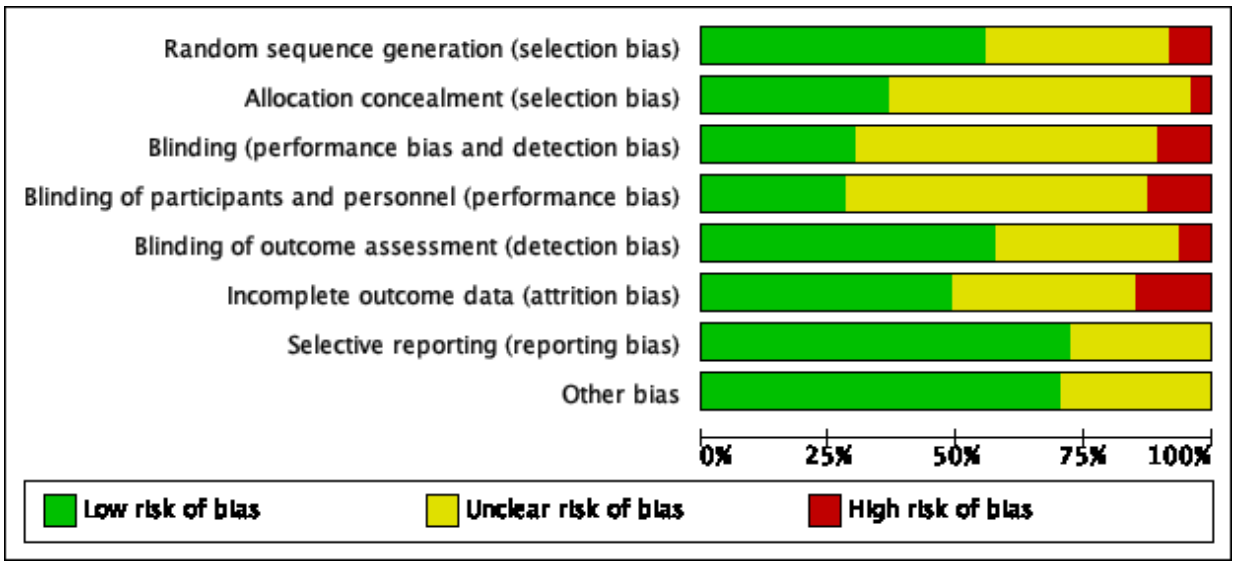
•In the remaining 13 studies, it was unclear if the reported data were complete (unclear risk of bias) [149, 165, 141, 166, 153, 172, 176, 156, 148, 164, 155]

#### 2.3.5.5 Other potential sources of bias

Seven studies were assessed based on translations of the original text [141, 172, 176, 148, 155] Translations from Chinese to English were performed by native Chinese speakers.

Outcome data was aggregated from dose escalation or comparison trials to form one active treatment group in one trial. [42]

**Figure 2-2** Risk of bias table



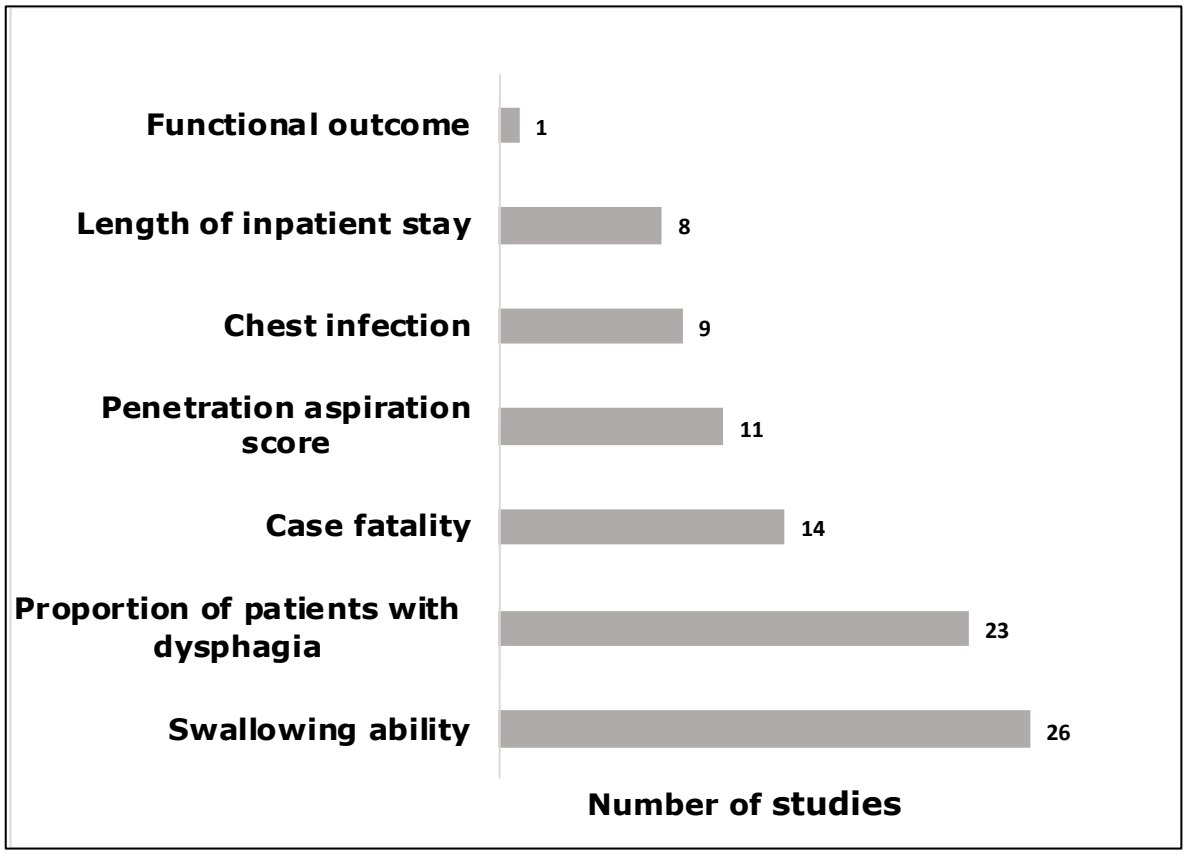

## 2.3.6 Effects of interventions

### 2.3.6.1 Summary of findings for main outcomes of swallowing therapy in general

The important outcomes in this review were entered into the Summary of findings table which are reported for 'swallowing therapy' versus 'no swallowing therapy'. This means that overall, for each outcome (e.g., length of inpatient stay), a number of different interventions were combined to test for efficacy. The result, therefore, provides information on the effectiveness of swallowing therapy as a whole on each outcome. Subgroup analysis for each different type of intervention was also performed.

The number of outcomes reported varied considerably between the studies and are detailed in Figure 2.3 below.

**Figure 2-3** Number of outcomes measured across studies




### 2.3.6.2 Main results

The main results of swallowing therapy compared to placebo are displayed in the summary of findings table (Table 2.2) on the next page.

**Table 2-2** Summary of findings table

| **Swallowing therapy compared to placebo for dysphagia in acute and subacute stroke** | | | | | | |
|---|---|---|---|---|---|---|
| **Patient or population:** dysphagia in acute and subacute stroke **Setting:** in hospital **Intervention:** swallowing therapy **Comparison:** placebo | | | | | | |
| **Outcomes** | **Anticipated absolute effects* (95% CI)** | | **Relative effect (95 % CI)** | **No. of participants ( studies)** | **Certainty of the evidence ( GRADE)** | **Comments** |
| | **Risk with placebo** | **Risk with swallowing therapy** | | | | |
| Death or dependency at end of trial | Study population | | OR 1.05 (0.63 to 1.75) | 306 (2 RCTs) | ⊕⊕⊕⊖ Moderate | a |
| | 693 per 1000 | 703 per 1000 (587 to 798) | | | | |
| Case fatality at end of trial | Study population | | OR 1.00 (0.66 to 1.52) | 766 (14 RCTs) | ⊕⊕⊕⊖ Moderate | b |
| | 197 per 1000 | 197 per 1000 (140 to 272) | | | | |
| Length of inpatient stay (days) | Mean length of inpatient stay (days) ranged from 19 to 119 | MD 2.9 lower (5.65 lower to 0.15 lower) | - | 577 (8 RCTs) | ⊕⊕⊕⊖ Moderate | c |
| Proportion of participants with dysphagia at end of trial | Study population | | OR 0.42 (0.32 to 0.55) | 1487 (23 RCTs) | ⊕⊕⊖⊖ Low | d |
| | 570 per 1000 | 357 per 1000 (298 to 421) | | | | |
| Swallowing ability | Mean swallowing ability was 0 | SMD 0.66 lower (1.01 lower to 0.32 lower) | - | 1173 (26 RCTs) | ⊕⊖⊖⊖ Very low | e |

| | | | | | | |
|---|---|---|---|---|---|---|
| Penetration aspiration score | Mean penetration aspiration score was 0 | SMD 0.37 lower (0.74 lower to 0 ) | - | 303 (11 RCTs) | ⨁⨁⨀⨀ Low | f |
| Adverse event: chest infection or pneumonia | Study population | | OR 0.34 (0.17 to 0.71) | 676 (10 RCTs) | ⨁⨀⨀⨀ Very low | g |
| | 343 per 1000 | 151 per 100 (82 to 271) | | | | |

*__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; OR: odds ratio; RCT: randomised controlled trial.

**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.

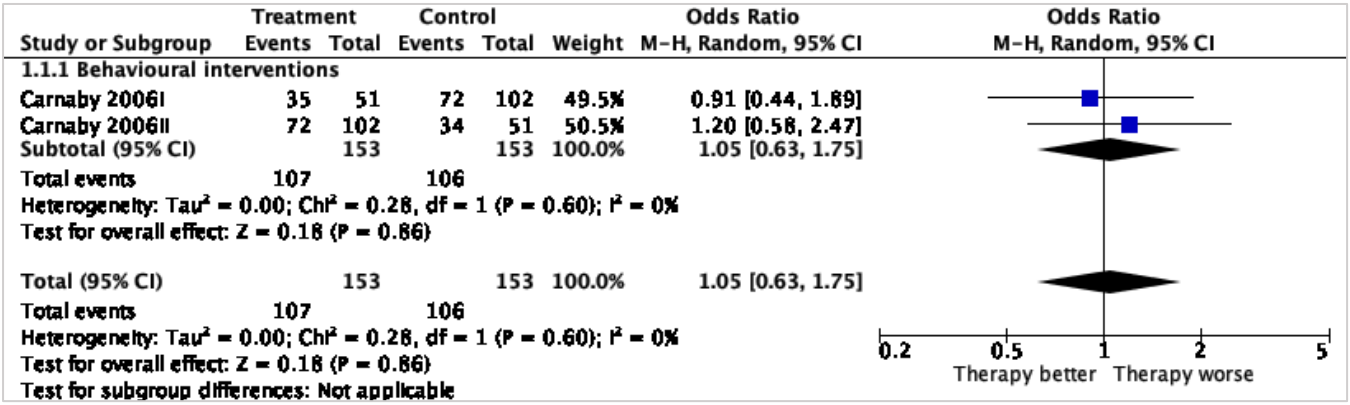
a Downgraded by one level due to lack of precision (one study split into two trials).
b Downgraded by one level for indirectness of the evidence (i.e. multiple different interventions).
c Downgraded by one level due to indirectness of the evidence (i.e. multiple different interventions). Note also that two studies had unclear blinding.
d Downgraded by two levels due to indirectness of the evidence and blinding - a large number of studies did not clarify blinding status.
e Downgraded by three levels due to indirectness of the evidence (i.e. multiple different interventions), considerable heterogeneity, and fair number of studies did not clarify blinding status.
f Downgraded by two levels due to indirectness of the evidence (i.e. multiple different interventions) and moderate heterogeneity.
g Downgraded by three levels due to indirectness of the evidence (i.e. multiple different interventions), substantial heterogeneity, and fair number of studies did not clarify blinding status.

### 2.3.6.3 Primary outcome

**Functional outcome: Death or dependency or death or disability, at end of trial**

Swallowing therapy had no effect on death or dependency, or death or disability, at end of trial (OR 1.05, 95% CI 0.63 to 1.75; 306 participants; two studies; I2 = 0%; P = 0.86: moderate-quality evidence; Analysis 1.1). One trial (two data sets) of behavioural interventions reported on this outcome.

**Figure 2-4** Forest plot of primary outcome, death or dependency or disability

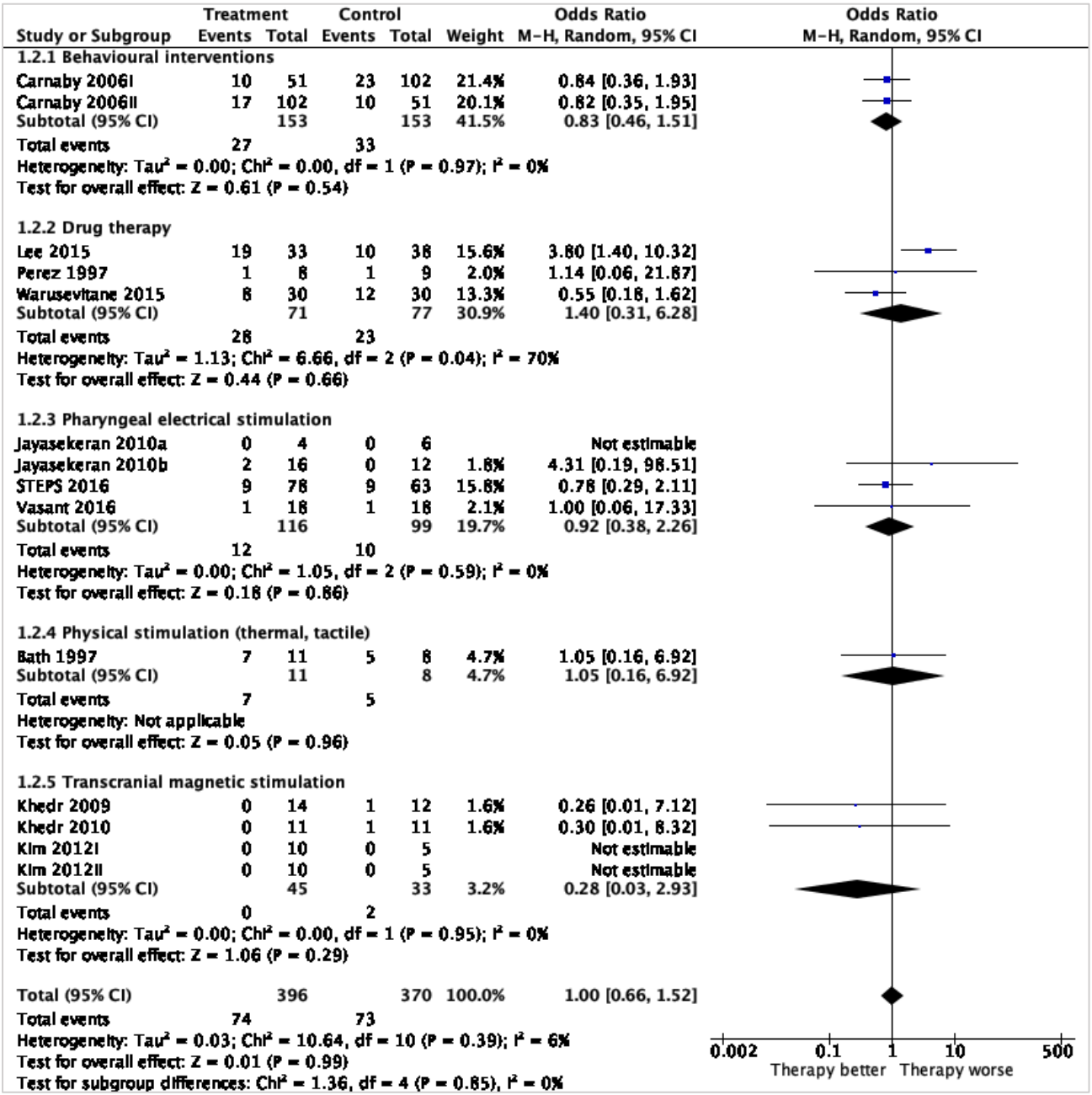



### 2.3.6.4 Secondary outcomes

**Case fatality at end of trial**

Swallowing therapy had no effect on case fatality at end of trial (OR 1.00, 95% CI 0.66 to 1.52; 766 participants; 14 studies; I2 = 6%; P = 0.99: moderate-quality evidence; Analysis 1.2). Trials of behavioural interventions, drug therapy, pharyngeal electrical stimulation, physical stimulation, and transcranial magnetic stimulation reported on this outcome.

**Figure 2-5** Forest plot of case fatality

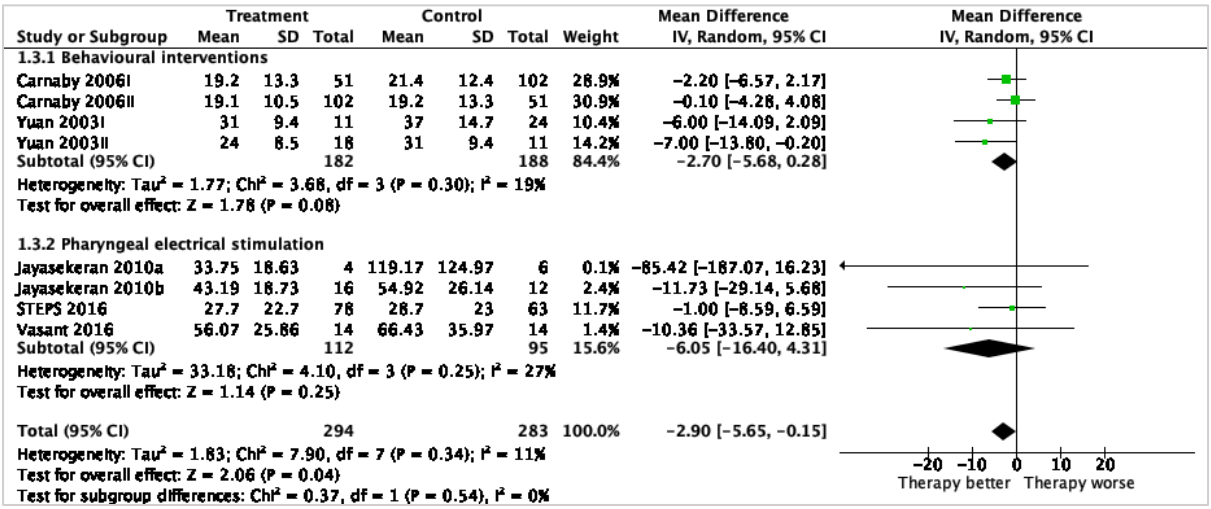



## Length of inpatient stay

Swallowing therapy probably reduced length of inpatient stay (MD -2.90, 95% CI -5.65 to -0.15; 577 participants; eight studies; I2 = 11%; P = 0.04: moderate-quality evidence; Analysis 1.3). Trials of behavioural interventions and PES

reported on this outcome. Subgroup analysis showed that the interventions did not differ (Analysis 1.3).

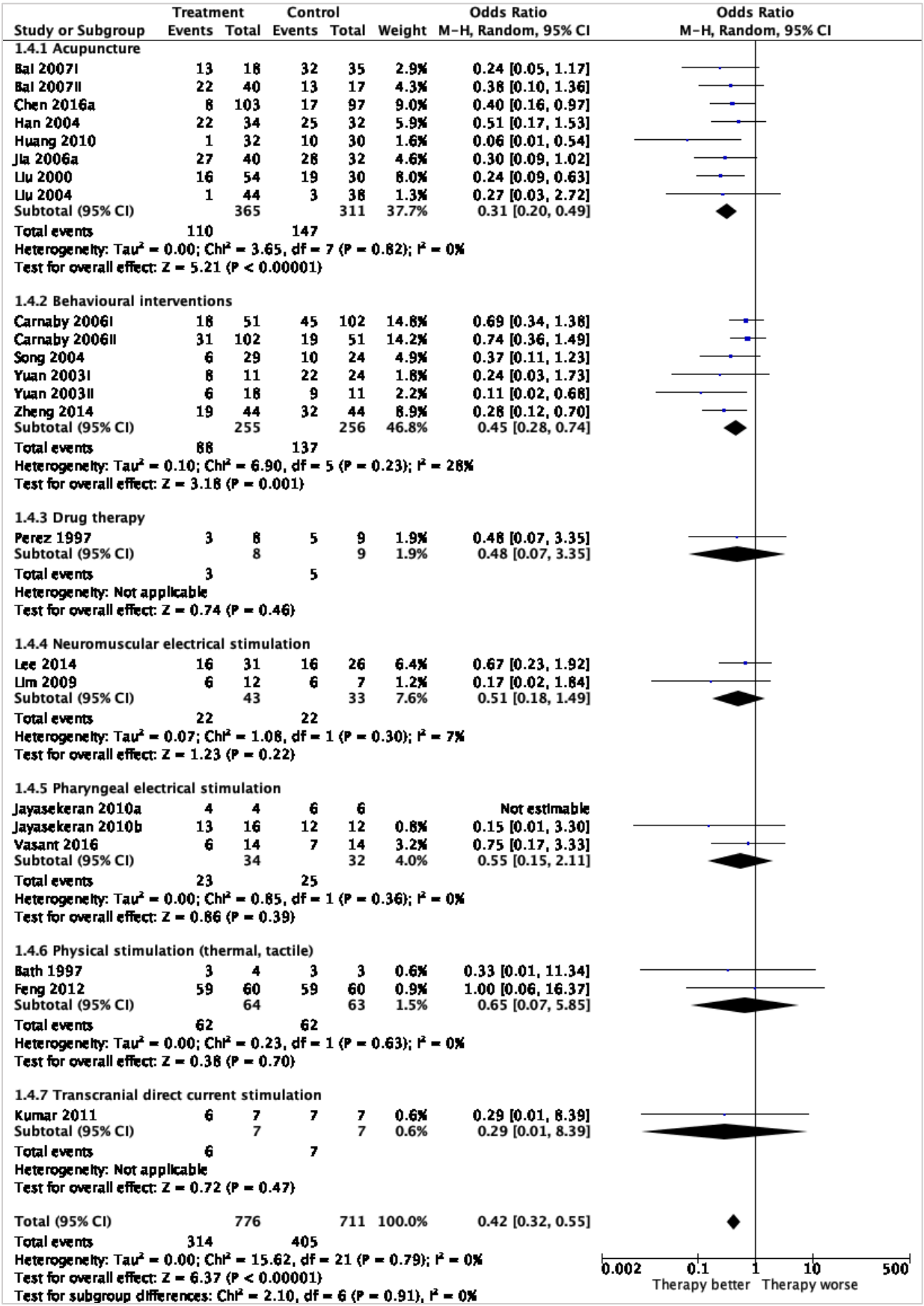
**Figure 2-6** Forest plot of length of inpatient stay




**Proportion of patients with dysphagia at end of trial**

Swallowing therapy probably reduced the proportion of participants with dysphagia at end of trial (OR 0.42, 95% CI 0.32 to 0.55; 1487 participants; 23 studies; I2 = 0%; P = 0.00001: low-quality evidence; Analysis 1.4). Trials of acupuncture, behavioural interventions, drug therapy, NMES, PES, physical stimulation, and tDCS reported on this outcome. Subgroup analysis showed that acupuncture (OR 0.31, 95% CI 0.20 to 0.49; 676 participants; eight studies; I2 = 0%; P < 0.00001) and behavioural interventions (OR 0.45, 95% CI 0.28 to 0.74; 511 participants; six studies; I2 = 28%; P = 0.001) each reduced dysphagia but did not differ from each other (P = 0.91) (Analysis 1.4).

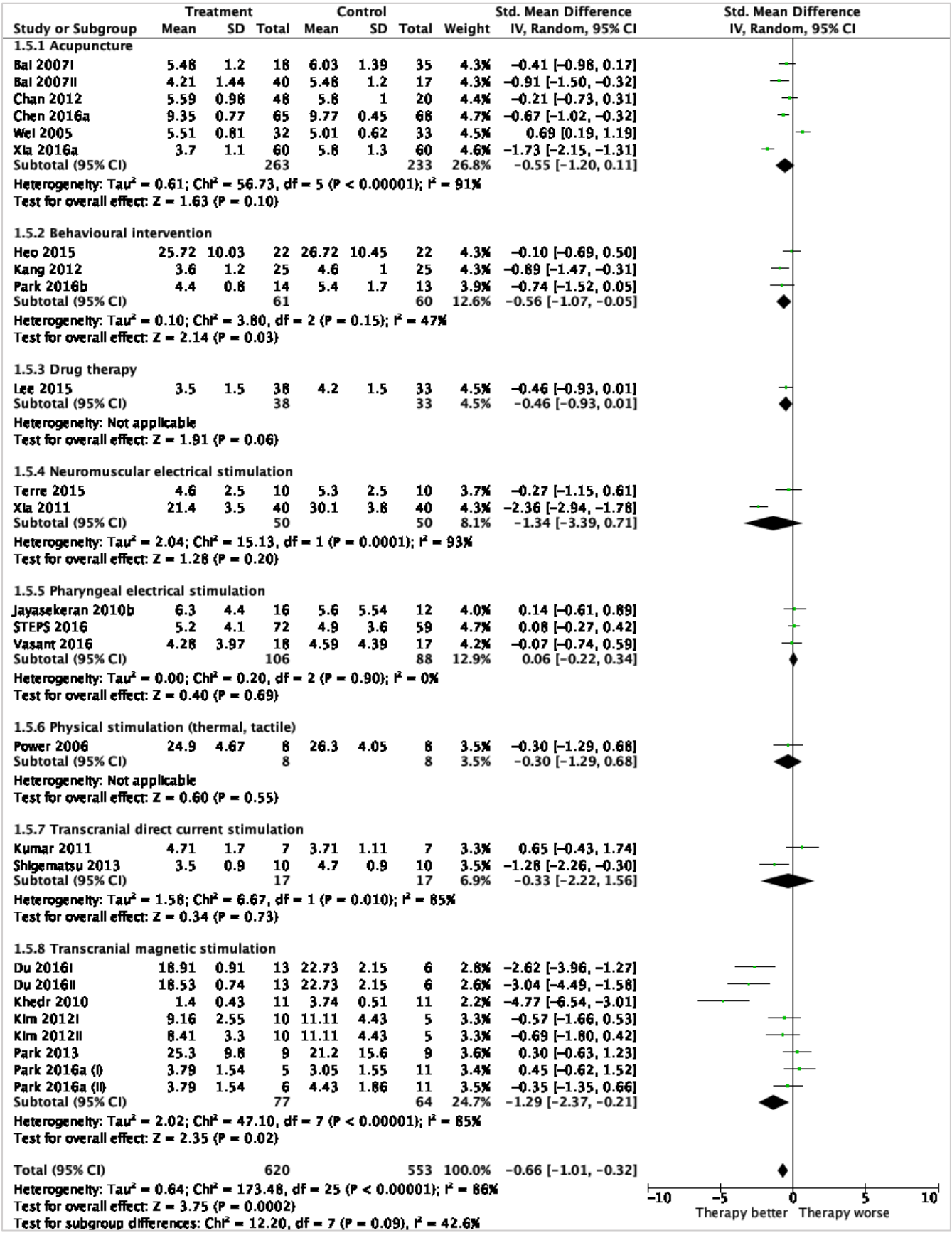
**Figure 2-7** Forest plot of proportion of patients with dysphagia at end of trial



**Swallowing ability**

Swallowing therapy probably improved swallowing ability (SMD -0.66, 95% CI -1.01 to -0.32; 1173 participants; 26 studies; I2 = 86%; P = 0.0002: very low-quality evidence; Analysis 1.5). Trials of acupuncture, behavioural interventions, drug therapy, NMES, PES, physical stimulation, tDCS, and TMS reported on this outcome. Subgroup analysis showed that behavioural interventions (SMD -0.56, 95% CI -1.07 to -0.05; 121 participants; three studies; I2 = 47%; P = 0.03) and TMS (SMD -1.29, 95% CI -2.37 to -0.21; 141 participants; eight studies; I2 = 85%; P = 0.02) each improved swallowing ability but did not differ from each other (P = 0.09). (Analysis 1.5). These studies showed moderate to substantial heterogeneity between trials (Analysis 1.5).

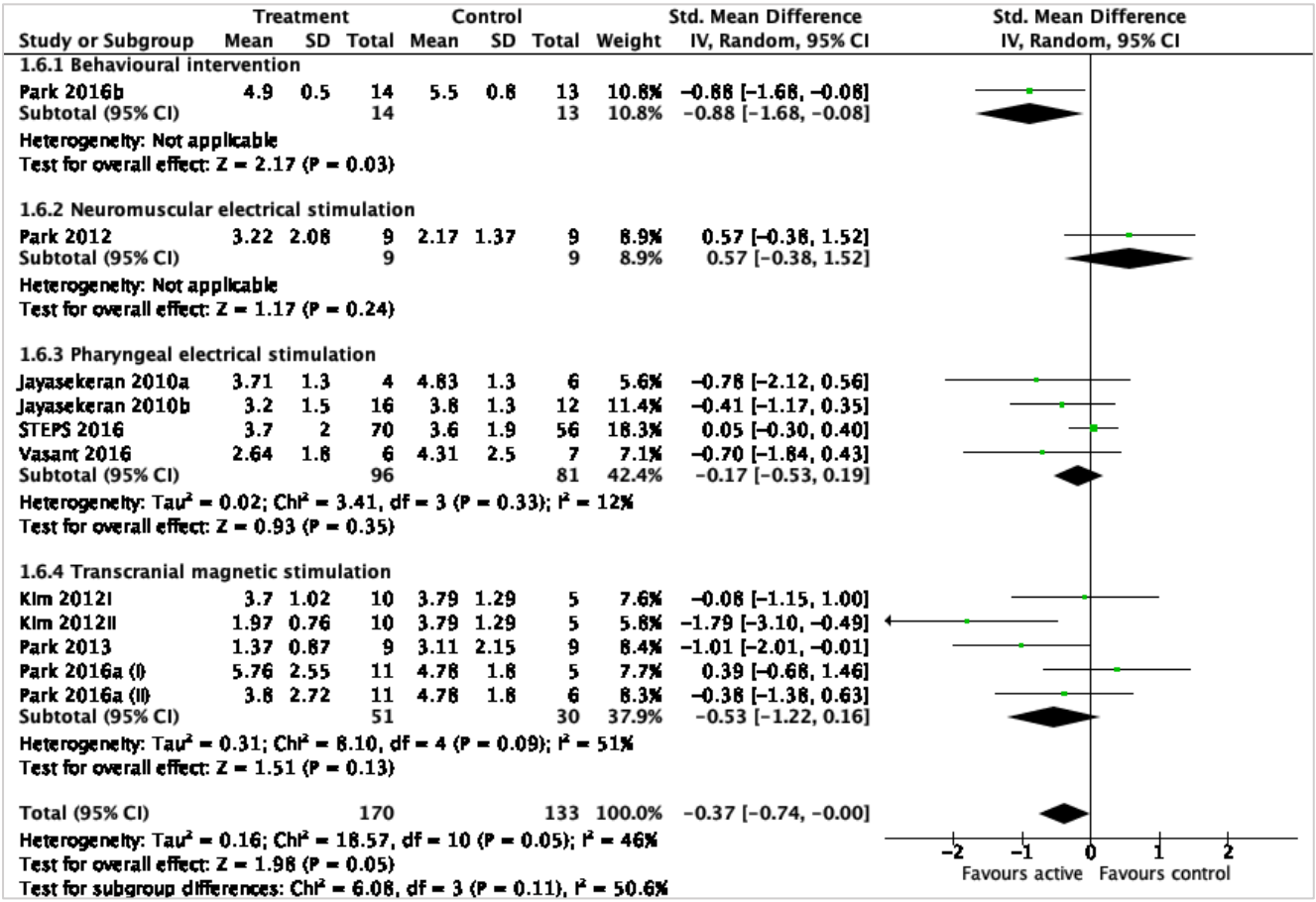
**Figure 2-8** Forest plot of swallowing ability



**Penetration aspiration score**

Aspiration assessed as penetration aspiration score was not significantly reduced by swallowing therapy (SMD -0.37, 95% CI -0.74 to -0.00; 303 participants; 11 studies; I2 = 46%; P = 0.05: low-quality evidence; Analysis 1.6). Trials of behavioural interventions, NMES, PES, and TMS reported on this outcome.

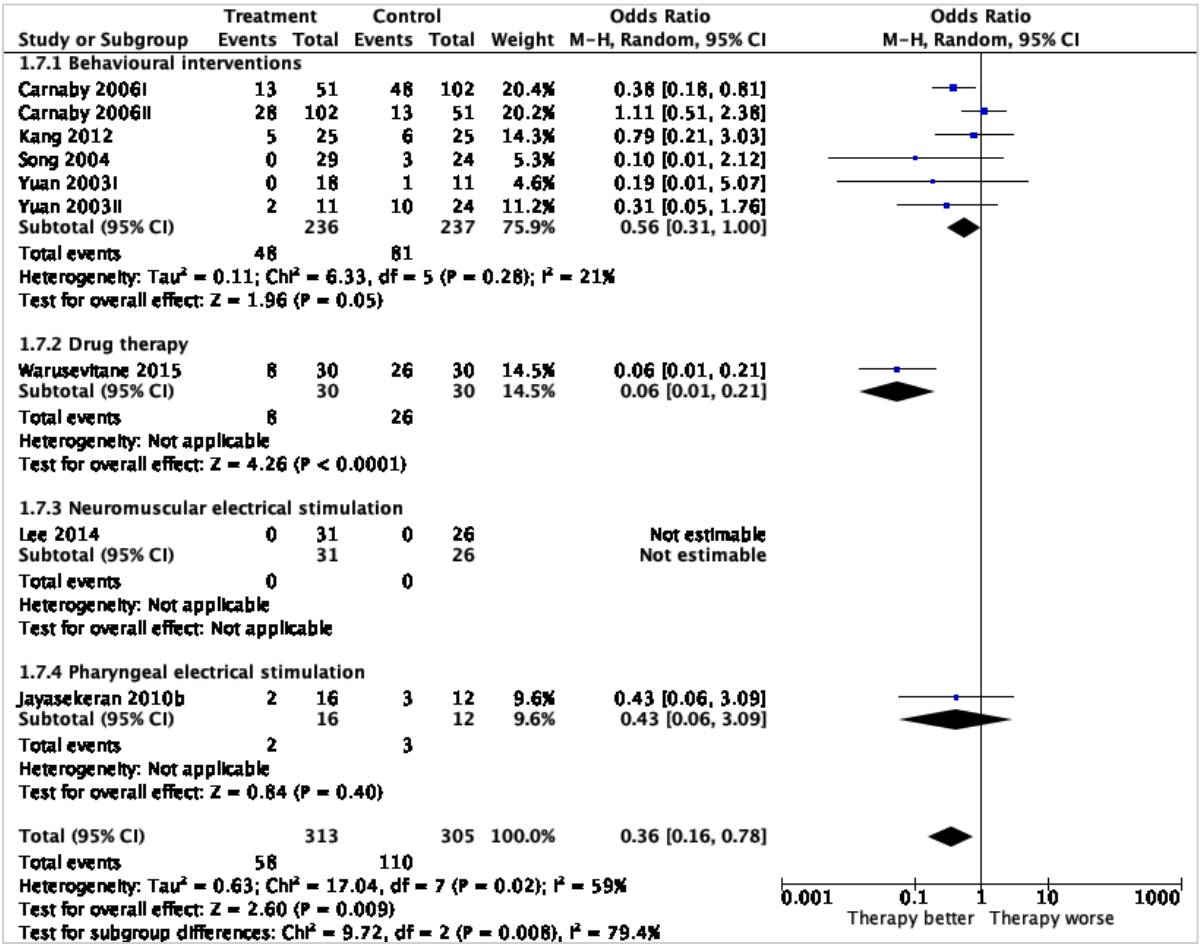
**Figure 2-9** Forest plot of penetration aspiration score



### Chest infection or pneumonia

Swallowing therapy probably reduced the incidence of chest infection or pneumonia (OR 0.36, 95% CI 0.16 to 0.78; 618 participants; nine studies; I2 = 59%; P = 0.009: very low-quality evidence; Analysis 1.7). Trials of behavioural interventions, drug therapy, NMES, and PES reported on this outcome. Subgroup analysis showed that drug therapy (OR 0.06, 95% CI 0.01 to 0.21; 60 participants; one study; I2 not applicable; P < 0.0001) significantly reduced the incidence of chest infection or pneumonia at end of trial, a result that differed significantly from other interventions (P = 0.008) (Analysis 1.7).

**Figure 2-10** Forest plot of chest infection or pneumonia



Three additional outcomes were assessed (pharyngeal transit time, institutionalisation, and nutrition) but they were not included in the Summary of Findings Table (a maximum of seven outcomes are allowed). Therefore, the quality of these studies was not assessed for these outcomes using the GRADE approach; their outcomes are not reported in the main findings.

**Pharyngeal transit time (PTT)**

Swallowing therapy may have reduced PTT (MD -0.23, 95% CI -0.32 to -0.15; 187 participants; six studies; I2 = 29%; P < 0.00001; Analysis 1.8). Trials of drug therapy, NMES, PES, and physical stimulation reported on this outcome. Subgroup analysis showed that NMES (MD -0.23, 95% CI -0.39 to -0.08; 126 participants; three studies; I2 = 63%; P = 0.003; Analysis 1.8) and physical stimulation in one small study (MD -0.19; 95% CI -0.34 to -0.04; 16 participants; one study; I2 not applicable; P = 0.01) each reduced PTT but did not differ from each other (P = 0.98) (Analysis 1.8).

**Institutionalisation**

Swallowing therapy did not reduce incidence of institutionalisation (OR 0.75, 95% CI 0.47 to 1.19; 447 participants; three studies; I2 = 0%; P= 0.22; (Analysis 1.9). Trials of behavioural interventions and pharyngeal electrical stimulation reported on this outcome.

**Nutrition (albumin)**

Swallowing therapy did not reduce nutrition (MD 0.37, 95% CI -1.5 to 2.24; 169 participants; three studies; I2 = 0%; P = 0.70; Analysis 1.10). Trials of

behavioural interventions and pharyngeal electrical stimulation reported on this outcome.

#### 2.3.6.5 Detailed subgroup analysis: Summary of findings for type of intervention

Not all interventions addressed all outcomes as can be seen by the number of outcomes reported in Figure 2.3. Data are reported as available. Table 2.3 provides a summary of interventions and their components.

**Table 2-3** Types of interventions and components of interventions

| Intervention | Number of studies | Number of participants | Author | Components |
|---|---|---|---|---|
| Acupuncture | 11 | 998 | 165 153 166 176 156 148 148 155 150 151 178 | Included routine, sham and no acupuncture. |
| Behavioural interventions | 9 | 632 | 141 172 142-144 157 179 154 169 | Behavioural interventions consisted of swallowing exercises, upright positioning, safe swallowing advice, dietary modification, kinesio-taping, expiratory muscle strength training. |
| Drug therapy | 3 | 148 | 170 180 162 175 | Drug interventions included nifedipine, lisinopril and metoclopramide |
| Neuromuscular electrical stimulation | 6 | 312 | 164 182 167 161 163 173 | NMES was most often compared with traditional dysphagia therapy. One study combined NMES and effortful swallow [167] |
| Pharyngeal electrical stimulation | 4 | 214 | 42 44 174 | All three studies compared PES versus sham at the same parameters. |
| Physical stimulation (thermal, tactile) | 3 | 155 | 149 107 152 | Types of stimulation included tactile stimulation, electrical stimulation, Tongyan spray. |
| Transcranial direct current stimulation | 2 | 34 | 160 171 | Both studies used anodal stimulation versus sham. |
| Transcranial magnetic stimulation | 9 | 167 | 158 159 146 168 145 147 | Studies employed unilateral and bilateral stimulation at a variety of frequencies. |

**Acupuncture**

Acupuncture obtained significant results (i.e., less than 1.0) for reducing the proportion of participants with dysphagia at the end of the trial. However, these findings may be due to chance, given that the test for subgroup differences was not significant. Acupuncture did not reduce swallowing ability. Data on the effect of acupuncture on other outcomes were not available.

Proportion of participants with dysphagia at the end of the trial (OR 0.31, 95% CI 0.20 to 0.49; 676 participants; eight studies; I2 = 0%; P < 0.00001; Analysis 1.4).

Swallowing ability (SMD -0.55, 95% CI -1.20 to 0.11; 496 participants; six studies; I2 = 91%; P = 0.10). Significant heterogeneity was noted. (Analysis 1.5).

**Behavioural interventions**

Behavioural interventions obtained significant results (i.e., less than 1.0) for improving swallowing ability and reducing the proportion of participants with dysphagia at the end of the trial. However, both of these findings may be due to chance, given that the test for subgroup differences in each outcome was not significant. Although behavioural interventions also reduced penetration aspiration score (i.e., less than 1.0), since there was no overall benefit for this outcome, this finding is likely due to chance. Behavioural interventions did not reduce length of inpatient stay, chest infection or pneumonia, case fatality at end of trial, functional outcome, institutionalisation, or nutrition. Behavioural interventions addressed more outcomes than most interventions.

Swallowing ability (SMD -0.56, 95% CI -1.07 to -0.05; 121 participants; three studies; I2 = 47%; P = 0.03; Analysis 1.5).

Proportion of participants with dysphagia at the end of the trial (OR 0.45, 95% CI 0.28 to 0.74; 511 participants; six studies; I2 = 28%; P = 0.001; Analysis 1.4).

Penetration aspiration score (SMD -0.88, 95% CI -1.68 to -0.08; 27 participants; one study; I2 not applicable; P = 0.03; Analysis 1.6).

Length of inpatient stay (MD -2.70, 95% CI -5.68 to 0.28; 370 participants; four studies; I2 = 19%; P = 0.08; Analysis 1.3).

Chest infection or pneumonia (OR 0.56, 95% CI 0.31 to 1.00; 473 participants; six studies; I2 = 21%; P = 0.05; Analysis 1.7).

Case fatality at end of trial (OR 0.83, 95% CI 0.46 to 1.51; 306 participants; two studies; I2 = 0%; P = 0.54; Analysis 1.2).

Functional outcome (OR 1.05, 95% CI 0.63 to 1.75; 306 participants; two studies; I2 = 0%; P = 0.86; Analysis 1.1).

Institutionalisation (OR 0.76, 95% CI 0.39 to 1.48; 306 participants; two studies; I2 = 12%; P = 0.42; Analysis 1.9).

Nutrition (albumen) (MD 0.20, 95% CI -4.77 to 5.17; 64 participants; two studies; I2 = 0%; P = 0.94; Analysis 1.10).

**Drug therapy**

Drug therapy was probably effective at reducing chest infection or pneumonia in one study, a result that differed from the other interventions. Drug therapy did not improve swallowing ability, or reduce case fatality, proportion of participants with dysphagia at the end of the trial, or pharyngeal transit time. Data on the effect of drug therapy on other outcomes were not available.

Chest infection or pneumonia (OR 0.06, 95% CI 0.01 to 0.21; 60 participants; one study; I2 not applicable; P < 0.0001; Analysis 1.7).

Swallowing ability (SMD -0.46, 95% CI -0.93 to 0.01; 71 participants; one study; I2 not applicable; P = 0.06; Analysis 1.5).

Case fatality (OR 1.40, 95% CI 0.31 to 6.28; 148 participants; three studies; I2 = 70%; P = 0.66; Analysis 1.2).

Proportion of participants with dysphagia at the end of the trial (OR 0.48, 95% CI 0.07 to 3.35; 17 participants; one study; I2 not applicable; P = 0.46; Analysis 1.4).

Pharyngeal transit time (MD -0.21, 95% CI -0.91 to 0.49; 17 participants; one study; I2 not applicable; P = 0.56; Analysis 1.8).

**Neuromuscular electrical stimulation (NMES)**

NMES was probably effective at reducing pharyngeal transit time (i.e., less than 1.0). NMES did not reduce the proportion of participants with dysphagia at the

end of the trial or penetration aspiration score and did not improve swallowing ability.

Pharyngeal transit time (MD -0.23, 95% CI -0.39 to -0.08; 126 participants; three studies; I2 = 63%; P = 0.003; Analysis 1.8).

Proportion of participants with dysphagia at the end of the trial (OR 0.51, 95% CI 0.18 to 1.49; 76 participants; two studies; I2 = 7%; P = 0.22; Analysis 1.4).

Penetration aspiration score (SMD 0.57, 95% CI -0.38 to 1.52; 18 participants; one study; I2 not applicable; P = 0.24; Analysis 1.6).

Swallowing ability (SMD -1.34, 95% CI -3.39 to 0.71; 100 participants; two studies; I2 = 93%; P = 0.20; Analysis 1.5).

**Pharyngeal electrical stimulation (PES)**

PES studies addressed many outcomes, but did not show an effect for case fatality, length of inpatient stay, proportion of patients with dysphagia at end of trial, swallowing ability, penetration aspiration score, chest infection or pneumonia, pharyngeal transit time, institutionalisation, or nutrition.

Case fatality (OR 0.92, 95% CI 0.38 to 2.26; 215 participants; four studies; I2 = 0%; P = 0.86; Analysis 1.2).

Length of inpatient stay (MD -6.05, 95% CI -16.40 to 4.31; 207 participants; four studies; I2 = 27%; P = 0.25; Analysis 1.3).

Proportion of participants with dysphagia at the end of the trial (OR 0.55, 95% CI 0.15 to 2.11; 66 participants; three studies; I2 = 0%; P = 0.39; (Analysis 1.4).

Swallowing ability (SMD 0.06, 95% CI -0.22 to 0.34; 194 participants; three studies; I2 = 0%; P = 0.69; Analysis 1.5).

Penetration aspiration score (SMD -0.17, 95% CI -0.53 to 0.19; 177 participants; four studies; I2 = 12%; P = 0.35; Analysis 1.6).

Chest infection (OR 0.43, 95% CI 0.06 to 3.09; 28 participants; one study; I2 not applicable; P = 0.40; Analysis 1.7).

Pharyngeal transit time (MD -0.15, 95% CI -0.67 to 0.37; 28 participants; one study; I2 not applicable; P = 0.56; Analysis 1.8).

Institutionalisation (OR 0.73, 95% CI 0.36 to 1.48; 141 participants; one study; I2 not applicable; P = 0.38; Analysis 1.9).

Nutrition (MD 0.40; 95% CI-1.62 to 2.42; 105 participants; one study; I2 not applicable; P = 0.70; Analysis 1.10).

**Physical stimulation (thermal, tactile)**

Physical stimulation reduced pharyngeal transit time in one small study (i.e., less than 1.0). However, these findings may be due to chance, given that the test for subgroup differences was not significant.

Physical stimulation had no effect on case fatality at the end of the trial or proportion of participants with dysphagia at the end of the trial and did not improve swallowing ability.

Pharyngeal transit time (MD -0.19, 95% CI -0.34 to -0.04; 16 participants; one study; I2 not applicable; P = 0.01; Analysis 1.8).

Case fatality at the end of the trial (OR 1.05, 95% CI 0.16 to 6.92; 19 participants; one study; I2 not applicable; P = 0.96; Analysis 1.2).

Proportion of participants with dysphagia at the end of the trial (OR 0.65, 95% CI 0.07 to 5.85; 127 participants; two studies; I2 = 0%; P = 0.70; Analysis 1.4).

Swallowing ability (SMD -0.30, 95% CI -1.29 to 0.68; 16 participants; one study; I2 not applicable; P = 0.55; Analysis 1.5).

**Transcranial direct current stimulation (tDCS)**

tDCS did not alter the proportion of participants with dysphagia at the end of the trial and did not improve swallowing ability. Data on other outcomes were not available.

Proportion of participants with dysphagia at the end of the trial (OR 0.29, 95% CI 0.01 to 8.39; 14 participants; one study; I2 not applicable; P = 0.47; Analysis 1.4).

Swallowing ability (SMD -0.33, 95% CI -2.22 to 1.56; 34 participants; two studies; I2 = 85%; P = 0.73; Analysis 1.5).

**Transcranial magnetic stimulation (TMS)**

TMS improved swallowing ability at the end of the trial, (i.e., less than 1.0), although this finding may be due to chance, given that the test for subgroup differences was not significant. Considerable heterogeneity was also noted. TMS did not alter case fatality at the end of the trial or penetration aspiration score. Data on other outcomes were not available.

Swallowing ability (SMD -1.29, 95% CI -2.37 to -0.21; 141 participants; eight studies = 8; I2 = 85%; P = 0.02; Analysis 1.5).

Case fatality at the end of the trial (OR 0.28, 95% CI 0.03 to 2.93; 78 participants; four studies; I2 = 0%; P = 0.29; Analysis 1.2).

Penetration aspiration score (SMD -0.53, 95% CI -1.22 to 0.16; 81 participants; five studies; I2 = 51%; P = 0.13; Analysis 1.6).

In summary, acupuncture, behavioural interventions, and TMS appeared to be individually effective at reducing some outcomes. However, as the test for subgroup differences was not significant, none of these interventions are convincingly different from the summary result. Drug therapy was the only intervention significantly less than 1.0 and significantly different for the test of subgroup differences, although this result was based on very low-quality evidence.

## 2.4 Discussion

### 2.4.1 Summary of main results

A total of 41 studies were included in this updated review of swallowing therapy in people with stroke (Table 2.1). A further 22 studies are ongoing, and 86 studies are awaiting classification.

Eight types of stimulatory techniques have been assessed - acupuncture, behavioural therapy, drug therapy, NMES, PES, physical stimulation, tDCS, and TMS. Swallowing therapy had no effect on functional outcome (death or dependency, or death or disability) although this outcome was only reported in one trial (two data sets). Swallowing therapy also had no effect on case fatality at end of trial, or penetration aspiration score. However, swallowing therapy probably reduced length of inpatient stay, the proportion of participants with dysphagia at end of trial, and incidence of chest infection or pneumonia (with significant effects for drug therapy from one study). Swallowing therapy also probably improved swallowing ability. In the absence of significant effects on the primary outcome, statistically significant findings in secondary and explanatory outcomes are hypothesis-generating and might reflect chance, for example due to multiple comparison testing. Hence, further trials are needed to test these observations.

### 2.4.2 Overall completeness and applicability of evidence

The results are incomplete at this time due to the significant number of ongoing studies and those that are awaiting classification. Nevertheless, the addition of

new studies to this version of the review has tightened confidence intervals although the overall conclusion that dysphagia treatment does not alter functional outcome has not changed.

### 2.4.3 Quality of the evidence

The quality of evidence ranged from very low, low through moderate to high, as presented in Summary of Findings Table (Table 2.2) The most common reasons for the quality of evidence being lowered was due to a lack of blinding, moderate to considerable heterogeneity between trials, and a lack of precision (i.e., multiple different interventions) being included.

### 2.4.4 Potential biases in the review process

The results of the present analysis are subject to several caveats. First, different interventions were combined together for analysis, to assess whether there was any effect of swallowing therapy as a whole as opposed to no intervention or usual care. This means that decisions on what specific types of interventions are effective are not able to be made based on this data. Future reviews will focus on assessing effects of specific interventions on main outcomes. Second, 80 studies were excluded from the analysis. One common reason for exclusion was that studies compared two active treatments without having a control or placebo group. Trials were also excluded due to a lack of uniformity in usage of outcome measures and lack of data on clinical outcomes, such as dependency, mortality, institutionalisation, and chest infections or pneumonia. Further, the trials used various swallowing assessment techniques, cortical excitability techniques, and videofluoroscopic measurements. So, trialists are encouraged to design future

trials with a control or placebo group, and to incorporate standard outcome measures. Third, a further 86 studies are awaiting assessment, subject to the availability of full-text articles; such omission of multiple studies will inevitably bias the results. Fourth, regarding acupuncture, data from the three studies may have been confounded owing to the use of 'routine' acupuncture or a different type of acupuncture as control, variation in the delivery of therapy, and the risk of language bias since some of the acupuncture literature is only available in full in Chinese language journals. Similarly, data from a NMES study was included, [167] which considered sensory stimulation as a control, and therefore one cannot be certain that this trial is not confounded. Lastly, the present analysis only included studies up to six months from stroke onset and the effect of later treatments for post-stroke dysphagia remains unclear.

Importantly, there are many ongoing trials and these should add substantially to the existing data once complete.

### 2.4.5 Agreements and disagreements with other studies or reviews

This is the largest, most inclusive and up-to-date review of this topic and it combines all current interventions for dysphagia in the acute and subacute phase of stroke. A number of separate systematic reviews looking at individual interventions in stroke survivors have been published, including, acupuncture in stroke, [39, 40, 183] behavioural interventions in neurogenic dysphagia, [184] TMS in stroke and acquired brain injury [46, 47, 185, 186] tDCS in stroke and acquired brain injury, [46, 47, 185] NMES in stroke and neurological impairment [45, 187] and PES in stroke. [43] However, these reviews have examined the efficacy of individual

interventions, whereas the current review has examined the efficacy of swallowing therapy overall and hence direct comparisons are difficult to make.

### 2.4.6 Authors' CONCLUSIONS

#### 2.4.6.1 Implications for practice

There continues to be insufficient information available on the effect of swallowing therapy on the primary outcome of death or dependency/disability. Although some swallowing therapies appeared to have a beneficial effect on some outcomes these results are based on lower quality evidence. At present, clinical decisions cannot be based on reliable evidence from clinical trials.

#### 2.4.6.2 Implications for research

Based on existing studies and the need to exclude many others, future trials should consider the following design issues.

Participants: include only those who have post-stroke dysphagia, and limit recruitment to a particular temporal phase after stroke. Researchers need to clearly specify the time from stroke onset to randomisation when reporting trials. Trialists should aim for larger numbers of participants, ideally from multiple centres.

Comparator: in the absence of any proven treatment, the control group should only receive standard care, with the treatment group receiving standard care plus the intervention being tested.

Outcomes: studies need to ensure that standardised outcome measures are used to allow for comparison of trials. Functional outcome (death or dependency) should be included in future trials, as should the number of participants who develop chest infections or pneumonia or have signs of aspiration. Outcomes of relevance to health economics, such as length of inpatient stay and discharge to an institution, should be included, as well as quality of life outcomes (e.g., EuroQoL-5D; SWAL-QOL).

Methods: researchers should endeavour to examine common parameters (i.e., use similar methods), so that results can be compared more readily across different studies.

Quality of research: trialists must report full information on randomisation, allocation concealment, blinding and outcome assessment, and attrition.

Future research: further research is needed to discover which components of swallowing therapy are beneficial. A number of studies assessing interventions for dysphagia are ongoing (22 studies) and these will add further information on this (Characteristics of ongoing studies). A number of studies of mixed groups of chronic dysphagia have been done or are ongoing: a systematic review of these studies may further inform the management of acute and subacute dysphagia post-stroke.

### 2.4.7 Future suggested AMENDMENTS

1. Review the outcomes in the next review. Part of this will include changing the primary outcome to a swallowing outcome.

2. Change the primary analysis to intervention type. It has now been established that there are positive effects for swallowing therapy and further analysis is warranted on specific types of swallowing therapy. In addition, there are now enough studies to do separate meta-analyses for most interventions, the results of which will be invaluable to guide stroke survivors, clinicians and healthcare funders to make informed choices about treatment. Nonetheless, this review has also highlighted that there are a great variety of interventions for dysphagia, given at different dosages, to different areas of the brain, and muscles of the oropharynx, using different methods. Hence it may continue to be a challenge to extract what components of each intervention are most beneficial.

3. Review criteria for acupuncture studies and delete routine acupuncture as a comparator – current reviews published on acupuncture in stroke compare acupuncture to sham acupuncture or no acupuncture, whereas this review compared acupuncture to no acupuncture, sham acupuncture *and routine acupuncture* which may have caused some bias.

4. This review did not include quality of life (QOL) as an outcome due to number of outcomes already defined. The next review should include QOL as this outcome is important, especially for stroke survivors who are suffering the dramatic effects on dysphagia. In addition, as more studies are now collecting this information, there is likely to be enough data to provide a meaningful analysis.

5. Consider whether any other outcomes should be included.

# 3. Development of methodology for analysis of videofluoroscopy data from the STEPS trial

# ABSTRACT

## Background

As seen in the Cochrane review, the STEPS dataset used in this research to examine Pharyngeal Electrical Stimulation (PES) comprised one of the largest collections of imaging data from Videofluoroscopic Swallow Studies (VFSS) of acute stroke patients to date. Although a neutral result was found, this study only evaluated safety measures (PAS). As discussed in Chapter One, a comprehensive analysis of swallowing impairment post-stroke should also encompass timing and clearance measures. The main objective of the current chapter, therefore, was to develop a clear standard operating procedure for measuring the components identified from the literature search in Chapter One, that could then be used to analyse the STEPS data for timing and clearance, alongside safety measures.

## Procedures and methods

Pre-processing of data was undertaken to identify file formats of source files and convert these where required, using Video Converter Ultimate (version 5.5.2.). Frame-by-frame analysis (Quick Time 7) was used to quantify frame rates of each file, using Quick Time 7 (Apple Inc, USA). Detailed data analysis was carried out on a random subset of data (frame rates ≥25fps). A custom-built database, using Bento (v4), was then developed to store the data.

# Results

Data analysis resulted in four sets of operational rules which could then be applied to the whole dataset. Firstly, rules pertaining to nomenclature used in the study and classification of swallow types were developed. Next, rules for scoring aspiration during primary and secondary swallows and which bolus to analyse in each participant were established. Subsequent rules for timing measures defined how to calculate the speed of bolus flow during swallow intervals (such as oral transit time) and the duration of swallow events (such as laryngeal closure duration). Finally, rules for clearance measures specified how to score oral and pharyngeal residue and number of swallows to clear.

# Conclusions

This chapter has generated a highly detailed standard operating procedure that researchers in the field can follow in order to process, organise and analyse videofluoroscopic data obtained at source (i.e., raw data) in acute stroke patients. Once validated, (in Chapter Four), these methods allow for investigation into the effects of PES on measures of safety, timings and clearance (Chapter Five).

## 3.1 Introduction

Despite the lack of an effect for PES seen in the Cochrane review in the STEPS trial, for the primary outcome of penetration aspiration score (Figure 2.9), one cannot rule out that a potential treatment effect may have been missed as only safety (as measured by the PAS) was evaluated. The importance of using multiple measures as opposed to single measures, as the most comprehensive manner to evaluate swallowing was discussed in Chapter One and is the second research question proposed in this thesis. In order to answer this question, the STEPS dataset was used to undertake further analysis using timing and clearance measures (in addition to safety measures).

At the outset of the project, there was a vast amount of data to be analysed. STEPS was an international, multi-centre study involving five different countries, comprising a total of 18 different hospital sites. It was not clear how long the analysis would take and what the best methods to analyse the data would be. A significant part of the initial and middle phases of the project was spent establishing which files were appropriate to include in the study, developing methods to analyse the data and acquiring the skills needed to reliably use these methods.

## 3.2 Participants

### 3.2.1 Participants and Videofluoroscopy Swallow Studies

Data came from the STEPS trial, which was sponsored and funded by Phagenesis®, Limited (Manchester, UK), with kind thanks to Chief Executive

Officer of Phagenesis®, Reinhard Krickl. The STEPS trial contained data from acute stroke participants (stroke onset within 42 days) who were given up to 7 boluses (comprising 6 x 5ml boluses and 1 x 50ml bolus) of thin fluids at 40% wt/vol of either Omnipaque™ 300, Visipaque™ 270 or Accupaque™ during a baseline VFSS. If consecutive occurrences of aspiration were seen, 'stop' criteria were applied, hence not all participants received all 7 boluses. Participants meeting the recruitment criteria (any bolus with PAS >2 seen during VFSS) were then randomly assigned to either PES or sham treatment which was given for 3 consecutive days. A follow-up VFSS was conducted at weeks 2 and 12 according to the STEPS protocol. The primary outcome was the reduction in the mean PAS score between baseline and VFSS at 2 weeks. Participants with a VFSS at baseline and two weeks were included in the current research project.

## 3.3 Measures

The literature review of relevant swallowing measures (undertaken in Chapter One) resulted in a framework of measures that were chosen to be included in this current study, as detailed in Table 1.7. These measures will be discussed in more detail as appropriate in the sections below.

## 3.4 Procedures

### 3.4.1 Pre-processing of data

QuickTime 7 (Apple Inc, USA) was deemed the optimal software for carrying out the data analysis as it allowed both forwards and backwards frame-by-frame slow motion tracking and displayed seconds or frame rate number as required.

File formats that were not compatible with Quick Time 7 (wmv.; VOB. and mpg) were converted to a mov. file using Video Converter Ultimate (version 5.5.2.). File formats in mp4., mov. and avi. were compatible with Quick Time 7 and were not converted. Conversion rendered a high-quality image and comparison of converted (output) files to the source (original) files did not yield any data corruption issues or altered frame rates.

Following file conversion, further pre-processing of data revealed that several files were acquired and/ or recorded at different frame rates. Details of the exact breakdown of frame rates are detailed in Chapter Five, Figure 4.2. At this point, the literature regarding frame rates and VFSS was scrutinised and consultation was undertaken with various experts in the field (medical imaging, engineering, expert SLTs and Philips IGT System Specialists). It was concluded that the frame rates could not be altered for those files that were less than 25fps. This was likely due to two main reasons:

Firstly, some files appeared to be *pulsed* at the wrong frame rate and were then *acquired/ recorded* at that (lower) frame rate, for example 15pps. This frame rate cannot be altered because once an image has been pulsed at a specific rate, the temporal resolution of that image cannot be increased. [188] Even if the recording system was set to record at 25fps, the only way to reach 25fps would be to add a duplicate frame to boost the frame rate to 25fps. This means that there would still only be 15 unique images per second of the swallow in question. A recent study into videofluoroscopy practice in the UK reported that 15pps was the most common pulse rate used (31% of respondents) and that some respondents did not know what imaging mode they used. [189] A follow-up study published in the same area, amongst imaging personnel (mostly

radiographers) also revealed a similar lack of knowledge in this area. [190] This may provide an explanation for some of the data obtained in this study, as some of the sites in the STEPS trial were from the UK.

Concerns regarding radiation dose can also be a reason for the deliberate use of lower pulse rates. However, this can be controlled for by limiting imaging time, and following a set protocol, such as the MBSImP, which averages just under 3 minutes and results in a dose of 0.27mS which is viewed as low dose. [189] In addition, other factors can affect radiation dose (not just pulse rate), such as magnification dose and field of view. [188] And finally, reducing radiation time from 30pps to 15pps does not reduce the corresponding dose by 50% because the perceived noise is greater when the pulse rate is lower, resulting in the VF system 'boosting' the dose to compensate. [191] Consequently, the dose reduction is approximately 10% to 30%, depending on the system when reducing the pulse rate from 30pps to 15pps. [191]

A second reason for files at the incorrect frame rate appeared to be because files were included that may have been *pulsed* at the correct frame rate *but recorded* at a lower frame rate, i.e., frames were deleted or compressed when being recorded/ acquired via hospital recording systems. These systems often have size limitations. [188, 189]

Those files that were identified as being at a true frame rate of ≥25fps were separated from those that were <25fps. Data analysis commenced next.

### 3.4.2 Data analysis

A subset of data from the files that were ≥25fps was randomly chosen to analyse in order to develop the operational rules needed to apply to the whole dataset. Analysis was carried out on a wide variety of different patients to ensure methods were established that could be reasonably applied to the variety of swallowing patterns that were observed in the data. Consultation was undertaken with two expert SLTs when developing the methods especially when resolving discrepancies on how to analyse highly abnormal/ atypical swallow patterns. It was first necessary for the author to re-score the safety measures (PAS scores). Next, the data was organised by specifying nomenclature and classification of swallow types and three groups of operational rules were then devised. Hence, overall, four categories were derived:

- Nomenclature and classification of swallow type
- Aspiration measures
- Timing measures
- Clearance measures

### 3.4.3 Nomenclature and classification of swallow type

#### 3.4.3.1 Bolus versus swallow

In this study, a bolus was defined as new material entering the oral cavity each time and referred to either a 5ml or 50ml amount. A swallow was defined as the onset of distinct hyolaryngeal movement associated with the act of swallowing, in addition to opening of the UOS, in response to any material in the oro-

pharynx. Typically, a 5ml *bolus* may be swallowed in one go, or require more than one *swallow* to be cleared. A 50ml *bolus* is frequently cleared with more than one *swallow*.

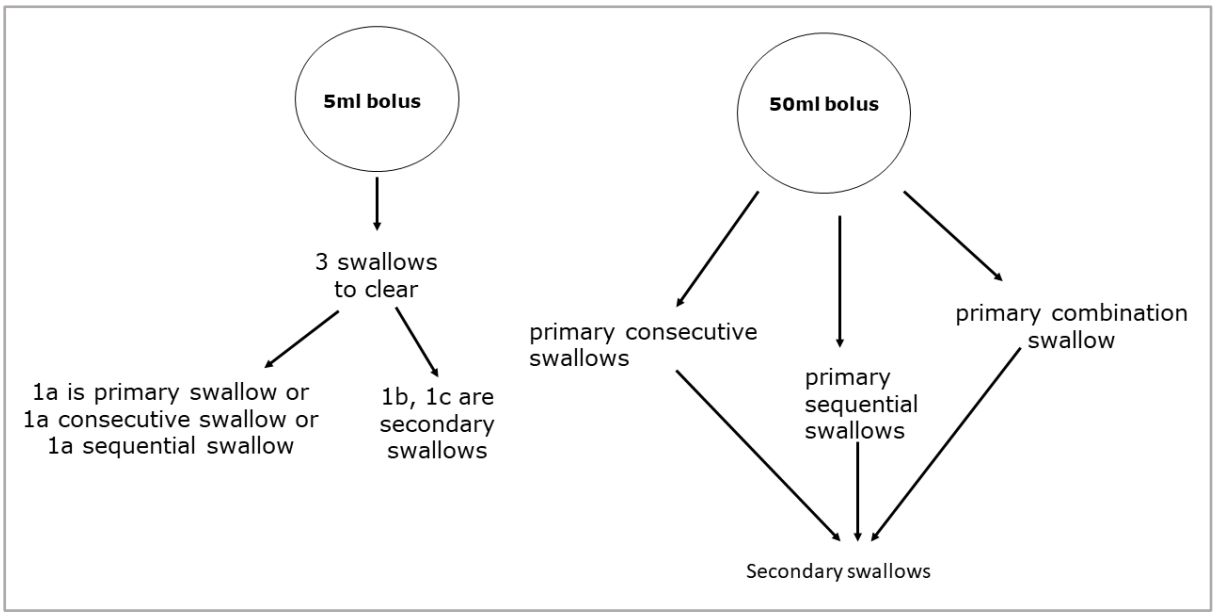
Different types of swallows were observed during ingestion of the 5ml and 50ml boluses which were subsequently coded into different categories. Table 3.1 details the definitions of different swallow types.

**Table 3-1** Definition of swallow type

| **5ml bolus** | |
|---|---|
| Primary swallow | Swallows where the entire 5ml bolus entered the oral cavity in one go. The first swallow initiated in the sequence was coded as the primary swallow. Any subsequent clearing swallows to clear residue in the oral and/or pharyngeal cavity were coded as secondary swallows. Piecemeal versus secondary (clearing) swallows were not distinguished. |
| Consecutive swallow | Swallows where the 5ml bolus entered into the oral cavity using separate, discrete consecutive sips, with lowering of the hyolaryngeal complex and return to upright position of the epiglottis between swallows. [92] Each consecutive swallow was coded as a primary swallow if a separate sip was taken each time. If a secondary swallow occurred (i.e., to clear residue in the oral and/or pharyngeal cavity after each sip), it was coded as such. |
| Sequential swallow | Swallows where the 5ml bolus was ingested in a sequential manner, i.e. whilst maintaining partial hyolaryngeal elevation and inverted epiglottis for the duration of the swallows it took to clear the 5ml bolus. [92] If a secondary swallow occurred (i.e., to clear residue in the oral and/or pharyngeal cavity after a sequential sip), it was coded as such. |
| **50ml bolus** | |
| Consecutive swallow | Swallows occurring one after another, with lowering of the hyolaryngeal complex and return to upright position of the epiglottis between swallows. [92] Swallows were coded as primary or secondary swallows as appropriate. Secondary swallows for the 50ml bolus could still be distinguished from primary swallows according to the sips taken by participants. |
| Sequential swallow | Swallows occurring with swallowing phases overlapping (i.e. maintaining partial hyolaryngeal elevation and continued inversion of the epiglottis between swallows. [92] Swallows were coded as primary or secondary swallows as appropriate. Secondary swallows for the 50ml bolus could still be distinguished from primary swallows according to the sips taken by participants. |
| Mixed swallow | Swallows occurring where at least one occurrence of both swallowing patterns (consecutive or sequential) were observed during the ingestion of the 50ml bolus.<br>Swallows were coded as primary or secondary swallows as appropriate. Secondary swallows for the 50ml bolus could still be distinguished from primary swallows according to the sips taken by participants. |

Figure 3.1 below provides an illustration to further explain the concept of the most common swallow types seen in the 5ml and 50ml boluses.

**Figure 3-1** Depiction of bolus versus swallow and swallow types




* Exception to the above is that there could be more than one primary consecutive swallow. Please see detail below, section 2.4.4.3. under Secondary Aspiration for explanation.

All references to speed of bolus flow during swallowing intervals or duration of swallowing events refer to time in seconds (s). When using examples to describe swallowing scenarios, the use of letter 'a' as in 1a refers to the primary swallow and any letter after that when paired with the same number represents an increasing number of secondary swallows, i.e., 1b, 1c, 1d, represent the next 3 secondary swallows.

### 3.4.4 Rules for aspiration measures

The table below summarises rules for aspiration measures for both 5ml and 50ml boluses, which will then be discussed in detail.

**Table 3-2** Rules for aspiration measures for 5ml and 50ml boluses

| **Measure** | **Component** |
|---|---|
| 5ml | Scoring design: mode-worst- best |
| 50ml | Scoring design: worst only |
| 5ml and 50ml | Within bolus penetration/ aspiration<br>Allocation of PAS scores<br>Definition of before-during-after<br>Timing of before-during-after<br>Secondary aspiration<br>Types of secondary aspiration |
| 5ml and 50ml | Between bolus penetration/ aspiration |
| 5ml and 50ml | Allocating PAS score of 7 and 8 |

#### 3.4.4.1 Scoring Design: 5ml boluses

**Mode-worst-best**

Following trial analysis of the data, it became clear that due to time constraints, it was not feasible to perform timing and clearance measures on every bolus (up to 6) each of which could also have a number of secondary swallows, as well as the 50ml bolus. Following extensive consideration, discussion with expert colleagues, and reading, the following scoring design was decided upon. Every swallow performed to clear each 6 x 5ml bolus (i.e., primary and secondary swallows) was given a PAS score. The highest PAS score from each 5ml bolus was identified, resulting in 6 PAS scores. Of these:

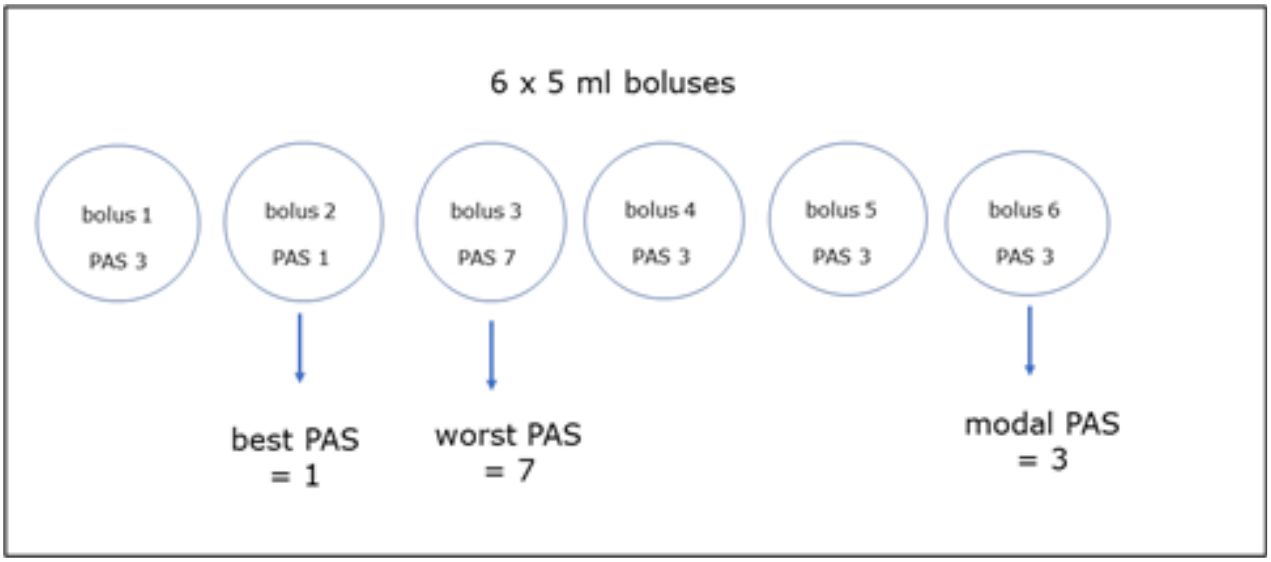
1. The **mode** swallow [103] from 6 boluses (i.e. the PAS score occurring most frequently) was chosen, as it is represents the most frequent swallow pattern for that patient, and
2. The **worst** swallow from 6 boluses was also chosen for analysis. This swallow was chosen as it is important that the swallow causing the most risk and the most severe swallowing impairment is analysed.

Overall, due to the variation in PAS scores that occur across swallows in patients, taking both the worst and mode swallows may be the most instructive way to reflect PAS scores in a dataset. [103]

- The **best** swallow across 6 boluses was also chosen for analysis, to provide a sample of a range of impairment and to see if and how this swallow will change.

This scoring design is illustrated below in Figure 3.2.

**Figure 3-2** Scoring design for each patient at each timepoint (baseline and two weeks)



The order of allocation of PAS scores was as follows:

i). As there will usually be more than one occurrence of the same score for the mode, the *last mode* was chosen. The last mode score was always chosen due to the cumulative effect of penetration and aspiration. For example:
Patient A = 8, 5, 3, **5**, 2, 1: the last mode (i.e., 5, in bold) was chosen.

ii). If there was no mode, the next last worst PAS was chosen to be analysed (not the worst PAS as this will be chosen for the worst PAS): For example:
Patient B = 1, 2, 6, **7**, 8, 3: the mode is 7.

ii). If the mode and the worst PAS were the same, the last worst score was chosen as the worst swallow (i.e., in the sequence below, the sixth digit) and then the next last worst score was chosen as the last mode (in the sequence below, the fourth digit). For example:
Patient C = 2, 2, 1, **2**, 1, **2**

iv). If there are two modes, the **worst** mode was chosen. For example:
Patient D = 3, 5, **5**, 7, 3, 1: the mode is 5

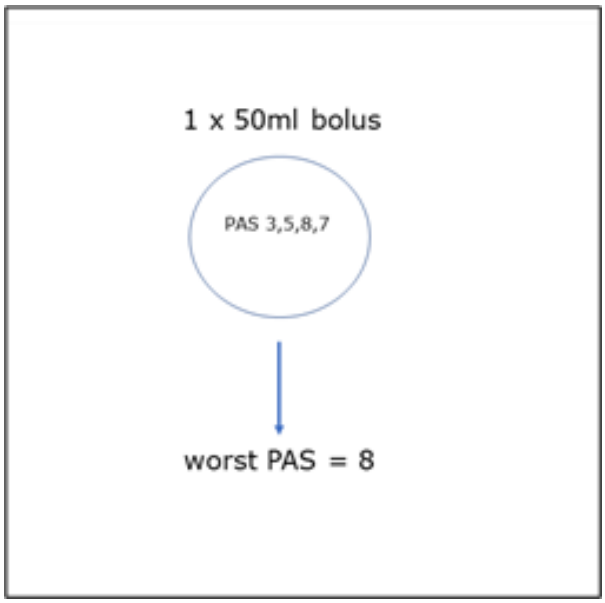
v). If the PAS scores were the same, the order for allocation of swallows in the sequence is best - mode - worst. This may be most obvious when all the scores are the same. That is to say, the best swallow is allocated the fourth score in the sequence (underlined), the modal swallow is allocated the fifth score (in italic) and the worst swallow is allocated the sixth score (in bold).
Patient E = 1, 1, 1, <u>1</u>, *1*, **1**

### 3.4.4.2 Scoring Design: 50ml bolus

**Worst PAS score**

The worst primary swallow (i.e., worst PAS score) that occurred from the 50ml bolus was chosen for analysis.

**Figure 3-3** Scoring design for 50ml bolus




### 3.4.4.3 WITHIN bolus penetration and aspiration

In the STEPS Trial, every swallow was allocated a PAS score. Hence, the same scoring procedure was followed in this research. As a result of the need to score every swallow in a bolus, a set of rules was devised to do this in as methodical manner as possible. This section discusses issues that arose with regards to scoring penetration or aspiration (P/A) or penetration and aspiration (P+A) across swallows *within* a bolus and specifies the method and concomitant rules developed to address this.

To the author's knowledge, in stroke, there are a few published papers which explicitly address this aspect. [128, 135] Most published papers do not comment on how secondary swallows are scored, or if they are scored. The rules devised below are based on the author's experience of analysing the swallows in the dataset, the author's clinical experience and knowledge of swallowing and in consultation with two expert SLT colleagues. Prior to completion of this research, a paper was published that detailed similar guidelines to some of those that had already been decided upon earlier in the course of this research. [128]

**Allocation of PAS scores within swallows across a bolus**

When allocating a PAS score to each swallow occurring across a bolus, one typically allocates a PAS score to each active swallow when hyoid movement occurs. One intuitively determines which swallow the contrast is associated with. However, preliminary data analysis revealed that some patients presented with rapid, overlapping swallows and multiple occasions of P+A. In these patients, it was challenging to determine when one swallow stopped and the next one started and *which swallow* the P+A occurred on. To manage these scenarios in a systematic manner and ensure consistency, the author devised definitions for determining when penetration or aspiration occurred (also known as event sequencing) in the swallow that were also consistent with the literature.

**Event sequencing: definition of penetration or aspiration**

Definition of penetration or aspiration *before* the swallow:

Any intrusion of material into the laryngeal vestibule prior to first hyoid anterior-superior movement.

Definition of penetration or aspiration *during* the swallow:

Entry of material into the laryngeal vestibule at any point during the swallow, i.e., after the onset of anterior-superior movement of the hyoid.

Definition of penetration or aspiration *after* the swallow:

Entry of material into the laryngeal vestibule after the hyoid bone had returned to its rest position, but before any new movement of the hyoid associated with the onset of a subsequent swallow.

**Event sequencing: timing of penetration or aspiration**

It was specified that a primary swallow could show penetration or aspiration at three time points: before, during or after the swallow. However, any secondary swallow by nature of the fact that there had already been a primary swallow of that bolus, could *only* have events of penetration or aspiration *during* and *after* that secondary swallow. The picture is further complicated by the observation that often residue from a primary swallow that begins to move and is subsequently penetrated (or aspirated) frequently causes a secondary swallow to occur. In these cases, it is tempting to want to ascribe penetration (or aspiration) to the secondary swallow when in fact it is due to residue and hence aspiration after the primary swallow. One can also take the view in this instance, that if no secondary swallows occurred, any penetration or aspiration of residue after the first swallow would be viewed as 'belonging' to the primary swallow in any event. It is helpful in these scenarios to also consider the event sequencing from the perspective of how it would look during a FEES assessment, i.e., moving residue after the primary swallow has occurred may be easier to visualise and 'compartmentalise' on a FEES.

**Secondary aspiration**

For most patients, the primary swallow causes the most aspiration and receives the highest aspiration score. However, it became clear from analysing the data, that there were a number of swallows within a bolus, where aspiration only occurred on a secondary swallow, or that the extent of penetration or aspiration was worse on the secondary swallow. These swallows were labelled 'secondary aspirative swallows'. It was decided that the primary swallow would still be chosen for timings analysis when secondary aspiration occurred, with clear coding that the aspiration seen was due to a 'secondary aspirative swallow'. This decision was taken as the resulting secondary aspiration was still ultimately due to the original primary swallow which had resulted in an abnormal swallow response. In addition, the primary swallow would have the bolus head and allow for calculation of OTT and many components that use the bolus head location moving past the angle of the ramus of the mandible as a marker. A secondary swallow could for example, only have residue in the pharynx which would not allow for many calculations to be made as there would be no material in the oral cavity.

The only exception to the above situation was when a patient swallowed the 5ml bolus in a *consecutive* manner, i.e., taking small separate sips each time. In this case, each discrete sip that occurred was in effect, a new primary swallow. Hence, if a patient obtained a worse PAS score on the second consecutive sip, this swallow was chosen to be analysed but was not scored as secondary aspiration and given a different code, i.e., consecutive sip, P/A worse on second sip. This was felt to be important to distinguish as it was unknown for example,

whether repeated consecutive sips could show 'priming effects' and hence faster reaction times.

If secondary P/A or P+A occurred during the 50ml bolus (i.e., the worst PAS score was obtained on residue from a clearing swallow), the primary swallow associated with that bolus was also used for analysis. This was for the same reason as the 5ml bolus, i.e., this is the 'root' swallow responsible for the penetration/ aspiration.

**Types of secondary aspiration**

During the analysis, it was observed that there were 3 different types of scenarios that gave rise to secondary aspirative swallows (i.e., three patterns of penetration or aspiration occurring *during secondary swallows* of the same 5ml bolus). Although it was beyond the scope of this thesis to also code types of secondary aspiration due to time constraints, the three patterns that emerged are briefly mentioned here as they help to provide a clearer understanding of the context of secondary aspiration and helped with scoring P/A or P+A during primary and secondary swallows. These patterns were termed $LV_0$, $LV_1$ and $LV_2$. LV is an abbreviation for laryngeal vestibule and the number refers to whether there has been *new* entry of material into the laryngeal vestibule on the *secondary* swallow. Each swallow type changes the PAS score each time.

**$LV_0$** - In this scenario, there is penetration/ aspiration of material into the laryngeal vestibule during the primary swallow: example swallow 1a = PAS of 5. During the secondary swallow, there is *no new entry* of material into the laryngeal vestibule (hence the use of 0 in $LV_0$), but the material already in the

laryngeal vestibule is 'squeezed'/ moves to a new, lower location which changes the PAS score: example with swallow 1b, contrast passes below the cords with no cough changing the PAS of 5 (swallow 1a) to an 8 (swallow 1b).

**$LV_1$ -** This pattern occurred when no material entered the LV during the primary swallow: example swallow 1a = PAS of 1. However, during the secondary swallow residue from the oral cavity or pharynx entered the laryngeal vestibule for the first time (hence the use of 1 in $LV_1$). Hence in this example, during the clearing swallow, material enters the laryngeal vestibule for the first time and moves to the cords. This changes the PAS score: PAS changes from a 1 (swallow 1a) to a 5 (swallow 1b).

**$LV_2$ -** This pattern occurred when there was already entry of material into the laryngeal vestibule during the primary swallow. On the secondary swallow, there is then further, new entry of material into the laryngeal vestibule from the pharynx, hence the 2 in $LV_2$: example PAS of 3 (swallow 1a). However, during a secondary swallow there is further entry of material into the vestibule which moves to cords, changing the PAS score: PAS changed from a 3 (swallow 1a) to a 5 (swallow 1b).

It is also possible that in severe patients, with each secondary swallow, new material enters the laryngeal vestibule (which could be defined as $LV_3$, $LV_4$, etc.) However, this swallow pattern is felt to collectively be represented by the term $LV_2$.

Based on the above observations, for swallows *within* a bolus, the rule that was specified was to assign a new PAS score was when:

- existing penetrated/ aspirated material moved to a *new location* during a secondary swallow, or
- new material entered the laryngeal vestibule on secondary swallows.

It is important to collect the final location of the contrast as this represents ultimately what the real risk associated with each bolus is.

Correspondingly, a new PAS score should *not* be assigned to secondary swallows when:

- penetrated/ aspirated material does not move further to change the PAS score (i.e., a secondary swallow where no new material enters the laryngeal vestibule, but for example, material remains on the cords from the primary swallow is scored as a PAS of 1 for that secondary swallow, not a PAS of 5 – a PAS of 5 would only be given for the primary swallow).

As the author used this methodology, it may have resulted in a slightly different allocation of PAS scores to those used in the STEPS trial.

#### 3.4.4.4 BETWEEN bolus penetration and aspiration

For new boluses, i.e., the presentation of the next 5ml bolus, a new PAS score was assigned only if there was *new* residue from the *new* bolus entering the laryngeal vestibule. Old residue from the previous swallows was not scored, even if uncleared residue from the previous swallow moved to a new (deeper) location during the primary swallow of the next 5ml bolus. (This would result in this new PAS score being allocated to the previous 5ml bolus, i.e., altering the previous score).

The importance of identifying the **source swallow** of the aspirated material is crucial in accurately determining the correct **source bolus** to be taken for timing measures. Attributing penetration/ aspiration to the wrong swallow and hence wrong bolus will result in potentially the wrong swallow being taken for timings analysis. To complicate matters further, as has been discussed in Chapter One (section 1.10.3), published research has highlighted the variability noted in swallowing performance between stroke patients and this was also observed in this current study. Hence, it is possible that one bolus could score a PAS score of 7 or 8 and the next bolus could score a PAS of 1 in the presence of uncleared residue remaining in the airway from the previous bolus. In this situation careful scrutiny of both boluses is required in order to ensure correct allocation of PAS scores.

#### 3.4.4.5 Allocation of a PAS score of 7 or 8

As this study was a retrospective analysis, on initial scoring, the author scored a PAS score of 7 or 8 according to whether a cough response appeared to be present and whether the cough looked to be spontaneously initiated or not. These scores were then checked against the STEPS original scores at the end of scoring. For the STEPS study, assessors allocated a score of 7 or 8 to a swallow *and* also entered a code according to which prompt, if any was used for that swallow. The STEPS code was as follows:

> Prompt used:
> No, but a spontaneous cough/throat clear was observed (STEPS code of 0).
> No prompt used (STEPS code of 2).
> Yes, a prompt was used to induce a cough/throat clear (STEPS code of 1).

Following discussion with the statistician who had previously worked on the STEPS study, the code specified in the STEPS study was used as the reference, not whether the STEPS assessors had allocated a PAS score of 7 or 8.

### 3.4.5 Rules for timing measures

In developing the rules for timing measures, the MBSImP framework was referred to, alongside a review of the literature, as detailed in Chapter One. The operational *definitions* for the timing measures are detailed in Table 3.3 below. Specific operational *detail* on how to score individual components that comprise each timing measure are then presented. This level of detail is necessary due to how complex the data is to score in a pathological swallow. Additionally, variability is seen in the swallowing literature on timing measures, including diverse naming practices and varying operational definitions adopted by researchers. [117] Specifying an operational definition is really only a starting point and the specific detail needed to accurately adhere to the definition must be stipulated in order to be able to accurately replicate the method. Ordinal measures of bolus transport and initiation of the pharyngeal swallow are not discussed as the operational detail for these measures is detailed in the MBSImP manual. [133]

#### 3.4.5.1 Operational definitions

The operational definitions of the timing measures are listed in Table 3.3 Note that components 4 and 6 of the MBSImP are also listed here, although they are not a continuous, but ordinal measure of swallowing.

**Table 3-3** Operational definitions of timing measures

| Component | Definition |
|---|---|
| Global oral transit time (gOTT, seconds) | The interval between the frame showing onset of manipulation of the bolus by the tongue in the oral cavity and the head of the bolus reaching the angle of the ramus of the mandible |
| Stage transition duration (STD, seconds) | The interval between the frame showing the head of the bolus reaching the angle of the ramus of the mandible and the frame showing onset of anterior-superior hyoid movement, associated with a swallow [192] |
| Initiation of laryngeal closure (ILC, seconds) | The interval between the frame showing the head of the bolus reaching the angle of the ramus of the mandible and the frame showing contact of the arytenoids with base of the epiglottis [110, 192] |
| Laryngeal vestibule closure-reaction time (LVCrt, seconds) | The interval between the frame showing onset of anterior-superior hyoid movement, associated with a swallow and the frame showing contact of the arytenoids with base of the epiglottis [125] |
| Laryngeal closure duration (LCD, seconds) | The interval from the frame showing contact of the arytenoids with base of the epiglottis (airway closure) to the frame showing this contact has discontinued (airway opening) [193] |
| Pharyngeal response time (PRT, seconds) | The interval from the frame showing onset of initiation of laryngeal elevation to the frame showing the tail of the bolus passing into the upper oesophageal sphincter (UOS) [193] |
| Pharyngeal transit time (PTT, seconds) | The interval from the frame showing the head of the bolus reaching the angle of the ramus of the mandible to the frame showing the tail of the bolus passing into the UOS [107] |
| Upper oesophageal sphincter duration (UOSD, seconds) | The interval from first opening of the UOS, as signified by a column of air [194] or head of the bolus entering the narrowest part of the UOS [195] to the frame showing the tail of the bolus passing into the UOS [107] |
| Bolus transport/ Lingual Motion (BT 0-4) | Movement of tongue. 0: brisk tongue motion; 1: delayed initiation of tongue motion; 2: slowed tongue motion; 3: repetitive/ disorganised tongue motion; 4: minimal to no tongue motion [133] |
| Initiation of pharyngeal swallow (IPS, range 0-4) | Location of bolus head when initiation of pharyngeal swallow is triggered. 0: bolus head at posterior angle of ramus; 1: bolus head in valleculae; 2: bolus head at posterior laryngeal surface of epiglottis; 3: bolus head in pyriforms; 4: no visible initiation at any location [133] |

### 3.4.5.2 Operational detail for each component: identification of specific frames

**Frame for onset of manipulation of the bolus by the tongue (component of global oral transit)**

Scoring the first component of oral transit time was difficult due to the wide variety of patterns observed. In view of this, two different types of oral transit patterns were trialled, to assess which measurement was more accurate to score. The first measure was termed gOTT: global oral transit time. Although similar to other terms in the literature which refer to 'onset of bolus movement' [102, 196, 197] this term specifies the first frame is any active manipulation of the bolus in the oral cavity by the tongue. This includes all anticipatory and repetitive movements prior to the swallow, hence the term *global* oral transit time (gOTT) as opposed to only oral transit time. Many stroke patients exhibit a disorganized and uncoordinated swallow at the oral stage and gOTT attempts to capture these features. The second definition trialled was taking the first purposeful posterior movement of the bolus by tongue. gOTT was the more reliable measure and hence this measure was chosen (see Chapter Four, Table 4.6 for further details).

Operational steps on how to score frame for onset of manipulation of the bolus by the tongue:

For this component, it is essential to watch the swallow in real time to gauge what the patient is doing with the bolus. This helps to distinguish between movement associated with receiving the bolus in the mouth, so called 'levelling

out' movements versus movement due to the first active manipulation of the bolus with the tongue.

To help identify the first movement signalling active manipulation of the bolus by the tongue, note that the first movement is generally seen after the bolus is received into the mouth (and the spoon leaves the lips) and in some cases, lip closure occurs.

Tongue movements associated with receiving the bolus in the mouth are not counted as first tongue movement. This includes movements of the tongue body that are in a downwards direction, or 'levelling out' movements, or tongue movements where patients may lick their lips, etc. Although this may be difficult to judge in some patients, the focus is on when the patient looks as if they are consciously starting to manipulate the bolus in preparation for swallowing it, not the action of receiving the bolus in the oral cavity.

Usually, the first movement associated with actively manipulating the bolus is an upward movement of the tongue body or tip in preparation to lift the bolus to the palate for transition through the oral cavity. Upward movements to centralise the head are not counted - focus on the tongue and bolus movement.

Generally, any form of upward movement (of the tongue) tends to signal the first frame. This can be after all of the bolus has entered the oral cavity, or before all the bolus has entered the oral cavity but the patient has started to process it by moving the tongue upwards. For many patients, the whole bolus tends to enter the oral cavity in one go/ at the same time. However, for some patients, active manipulation of the bolus occurs before it is fully in the oral

cavity and one can observe clear tongue movement. This can happen in three instances.

Firstly, when the head is tipped back, the bolus falls in quickly and the patient is forced to start controlling the bolus early to prevent it falling backwards prematurely. Secondly, the patient has general poor oral control/ poor ability to form a bolus (even if their head is not tipped back) and is forced to start manipulating the bolus before all the bolus has been received into the mouth. Thirdly, the patient exhibits a 'sucking' pattern where they continuously strip the bolus along the palate and swallow simultaneously, whilst 'sucking' the bolus backwards in one long continuous sip. For these latter patients, distinguish between movements associated with receiving the bolus in the mouth (sometimes these could be up and down type movements) and the moment there is active movement of the bolus backwards.

An exception to the above rule is: when patients receive most of the bolus in the mouth and it is generally contained (i.e. it is not moving backwards which requires active manipulation), and the patient then lifts the cup back to their mouth to 'fully empty' the sip into the mouth, or it is clear they are still receiving the bolus in the mouth (for these patients, the bolus must still be contained in the mouth), take the first movement after the final attempt to get the liquid in the mouth.

If a patient takes a sip and then goes on to hold the bolus in the mouth and then takes another sip (with original bolus being held in mouth), take tongue movement from the second bolus. This is similar to a patient starting some

volitional movement, then stopping to receive the rest/ all of the bolus into the mouth. Take the last movement after final receiving of fluid in the mouth.

If there is clear premature overspill/ posterior escape, this is not scored as the first frame unless/ until there is some active tongue movement showing that some active processing of the bolus by the patient has started.

If it is very difficult to tell if the first movement is the tongue moving the bolus as opposed to fluid moving around or the head moving, wait for next frame of independent, definite tongue movement.

For dippers,[198] the first movement is still when the tongue first begins to manipulate the bolus, even if this is to elevate the bolus to a horizontal position on the tongue in readiness to swallow.

If the bolus is already in the oral cavity and being moved/ manipulated by the tongue when the fluoroscopy is switched on, one cannot score this component.

If the patient is holding the bolus completely still when the fluoroscopy is switched on, take the first frame as defined above, i.e., first frame showing tongue beginning to manipulate the bolus in preparation to move it through the oral cavity.

**Frame for the head of the bolus passing ramus (component part of gOTT, SRT, ILC and PTT)**

This is defined as the leading edge of the bolus head, which specifically refers to any first leakage of barium passing the angle of the ramus of the mandible. [97] This rule is consistent with the guideline of the MBSImP. [133]

If the bolus has passed the ramus when the fluoroscopy machine is switched on, this component cannot be scored.

In cases where there is premature overspill of the bolus (i.e., the bolus is not neatly contained in the oral cavity), it is important to distinguish between overspill due to the current swallow being viewed and residue that may be present from the previous bolus. For premature overspill associated with the current swallow being viewed, there is likely to be some active movement of the bolus in the pharynx whilst viewing the images, i.e., movement between the valleculae and the pyriform fossae. For old residue, the bolus is more likely to be contained either in the valleculae or pyriform and there will be less change in the thickness of the line of contrast between these two recesses. Looking at the patient's pattern of swallowing can help, for example, viewing previous swallows may help to determine if residue is a feature characteristic of the patient's swallowing pattern. In addition, pay careful attention to the image at the outset of each swallow, noting if there is any residue and where this residue is.

However, if there is residue between the ramus and the valleculae or valleculae and pyriform fossae, it should be noted that sometimes as the patient moves, the old residue can be compressed which can be misinterpreted as premature

bolus spillage. Often, this is not spillage, but thickening of the line of contrast as the patient moves his/ her head sideways. This can sometimes be difficult to differentiate from new moving contrast if the patient moves their head just as the new bolus begins to move. Usually, if the contrast is new, the thickening that is seen heralds the start of *continuous* bolus flow backwards (as opposed to thickening that stops and starts if the patient is moving their head and merely compressing the contrast that is already there.)

Pay careful attention to the possibility of small amounts of subtle premature spillage occurring before the bulk of the bolus has moved, as this would still be taken as the first frame (as per bolus head definition).

For patients who are not seated perpendicular, the superior line of the ramus is used as the marker for the bolus head (as adopted by Molfenter, 2013). [85] There is one exception to this - on the occasion one cannot see the superior ramus very clearly (and it is difficult to choose a frame) or at all (and a frame cannot be chosen), score when the bolus reaches the inferior ramus.

Boluses need to be at least *at* the ramus. This means if the previous frame shows the bolus head close but not at the ramus and the second frame shows it well past, the second frame should be chosen.

Any contrast reaching the ramus will be deemed as appropriate, even if this is 'light' or 'pale' contrast (as opposed to thick black).

If, due to image quality, there is doubt as to whether the bolus is truly at the ramus, take the last frame where the bolus head is clearly visible at the ramus.

At times it is challenging to see the exact point the bolus reaches the ramus - it could easily be a number of frames leading up to the point of the bolus passing the ramus, especially if the movement is slow and typically not considered overt premature overspill or indicative of the beginning of rapid posterior movement of the bolus. In this instance, if it is clear that the bolus is at the ramus the preceding frames, just not clear which one to take, take one frame back from when the bolus goes over the ramus in a continuous motion. This is particularly important for patients who are not seated perpendicular and there is a sizeable gap between the superior and inferior ramus. Although the bolus may appear to reach the superior ramus before the inferior ramus, look at the pattern of bolus movement and ensure that there is continuous backward movement of the bolus indicating continuous posterior movement or overspill. Take the frame when the bolus in the region of the superior ramus is judged to being moving forward *continuously* towards the inferior ramus – this is often recognised as a clear forward projection of contrast continuously downwards. Do not take the frame in instances where the bolus reaches the region of the superior ramus and stays there in an inert position if it is not accompanied by ongoing movement of the bolus towards the hypopharynx or premature spillage. Only take the frame when the bolus starts to move/ be propelled past the ramus in a continuous motion.

**Frame for first hyoid movement (component of SRT)**

This is the first movement signalling the start of the anterior-superior movement of the hyoid and which results in initiation of the pharyngeal swallow.

For some patients, the onset of hyoid movement is obvious and brisk. For other patients, the onset of hyoid movement is more subtle but on close viewing, one

can see a definite anterior-superior movement of the hyoid bone which signals the start of full hyoid movement resulting in a swallow. First onset of hyoid movement may coincide with the frame showing first laryngeal elevation. However, on occasions, there may be movement of the larynx upwards before hyoid movement, or first movement of the larynx may occur after hyoid movement.

Other patterns of hyoid movement were observed:

a). Patients who demonstrate continuous, slow elevation of the hyoid (and at times, larynx) leading up to initiation of the pharyngeal swallow in what seems to be a slow, 'warming up' pattern. Whilst there is definite clear movement superiorly, often there is no anterior hyoid movement and there is no bolus propulsion occurring either until a few frames later, when more brisk anterior movement occurs.

b). Patients who show brisk hyoid movement upwards (as opposed to slower movements) but do not initiate the swallow immediately, i.e., the bolus is not propelled from the oral cavity at the same time as the first brisk movement – often the hyoid continues to move upwards quickly and a second brisk movement, accompanied by overt anterior movement occurs at the same time as the bolus propulsion. It is unknown whether the first brisk (superior only) movement should be scored in these patients, and whether the longer time taken to initiate full anterior hyoid movement is important to record from a diagnostic viewpoint, as this may provide information on slower airway closure. Currently, there is little discussion in the literature on how to score these types of variations in hyoid and laryngeal movement in stroke patients.

These swallows are challenging to score as it is difficult to know what frame to take and where the onset of the swallow truly is. One needs to use their judgement, but:

In this instance, as per the MBSImP, take the first frame or 1-2 frames before (depending on the movement you can see), of obvious brisk anterior-superior movement that occurs close to/ at the same time as propulsion of the bolus and soft palate movement that signifies the swallow occurring. It may be helpful to also look at the larynx for onset of first brisk movement. This may be either the actual frame of obvious, brisk upward movement, or it may be one or two frames before.

**Frame for first laryngeal movement (component of PRT)**

This is the frame showing first upward laryngeal movement leading to the onset of the swallow. This frame is not always a brisk upward movement but can be a subtle movement upwards that coincides with the swallow. Laryngeal elevation can coincide with hyoid movement or occur before or after hyoid movement.

It was noted that sometimes patients demonstrated several frames where continuous, slow upwards movements of the larynx occurred, eventually leading to the initiation of the pharyngeal swallow. As laryngeal movement is more one directional than hyoid movement, it was more challenging to know which first movement to take for the larynx. (For the hyoid, it is easier to discern when there is both an anterior and superior trajectory). The MBSImP states that "Small movements of the hyoid or larynx that occur during chewing, bolus manipulation, anticipation, or tongue stabilisation should not be confused with

the onset of brisk hyoid motion that is a component indicating the onset of the pharyngeal swallow." [133] Hence, in these instances (where there were a number of upward laryngeal movements noted before hyoid movement and swallow onset) the first brisk laryngeal movement occurring close to hyoid initiation or close to the movement of the bolus and soft palate movement was taken. This could be either the actual frame of obvious, brisk upward movement, or it may be 1 or 2 frames before depending on the swallow pattern. It may be helpful to track the brisk movement of the hyoid to help with this component.

It is difficult to know if this is the correct measurement to take in these patients. It is unknown whether there is a clinical importance to patients showing slow continuous upward laryngeal movement and how to measure this component. And indeed, whether small upward laryngeal movements are as clinically significant to measure as more brisk movements. However, this rule was made based on available evidence and tying in the onset of laryngeal elevation with movements most closely associated with the immediate onset of the swallow.

In addition, to the author's knowledge, there appears to be more literature detailing the brisk onset of the hyoid bone, as opposed to onset of laryngeal elevation. However, two studies were found that commented on laryngeal movements being judged in relation to movement of the tracheal air column, where the posterior and superior margins are apparent [199] or movement in the posterior vocal folds and arytenoids. [104]

**Frame for airway closure (component of ILC and LCD)**

This is the first frame showing full contact between the arytenoids and base of the epiglottis, such that closure of the airway has occurred. Typically, the light contrast changes as the airway closes.

Watching the image in real time repeatedly, can help with identifying the patient's pattern of airway opening and closing and tracking backwards frame-by-frame can help to score this.

All the airspace needs to be closed, i.e., if the arytenoids and epiglottis make contact but a gap of air remains, slightly posterior to this point, take the last frame when no air can be seen. This is consistent with the MBSImP rules. [133] For those patients who never quite close the gap (even if the tip/ portal of the epiglottis and arytenoid base is closed), take the last frame before hyoid descent as the frame of airway closure. This is to be consistent with the rule for maximum 'thinning' of contrast before airway opening occurs again (see below).

Note that for patients who have a *slowly* deflecting epiglottis, where there is already full closure of the arytenoids to epiglottis base, usually the deflected epiglottis is not taken as the last frame of airway closure. However, this will depend on the actual pattern of how the patient closes the airway and needs to be judged on an individual basis. If due to abnormal airway movement (for example, reduced anterior-superior arytenoid movement) the deflecting epiglottis may form an essential part of airway closure, then a later frame depicting closure of the airway when epiglottis is complete will be chosen. Also, if there is *very slow* epiglottic deflection such that the gap between the

arytenoids and epiglottis base looks incomplete, a later frame may be chosen. This is a rather rare pattern.

For patients who have penetration into the airway which does not fully reverse, the first frame of full airway closure is taken when the barium is compressed into a thin line and the subsequent frame shows no further 'thinning' of contrast. The thinning action is a result of pressure occurring due to increasing approximation of the base of the epiglottis and arytenoids. Hence, frames where no further 'thinning' is seen denote that there is no remaining gap between the arytenoids and epiglottis for contrast to move and indicates maximum closure.

In patients where there is a lot of penetrated contrast, or the penetrated contrast extends to underneath the epiglottis, the point where no contrast is seen under the epiglottis is taken as the last frame. If this point is not reached before the larynx starts descending, take the last frame before this occurs. (One can see the contrast thicken out/ change direction with relaxation of larynx. It can also help to look at the hyoid bone for first frame of descent).

In instances where the flow of the bolus obscures the point of airway closure this component cannot be scored.

In instances where data quality is poor such that it is very difficult to be certain of frames or thinning of contrast, do not score.

NOTE: If the airway is already fully closed (i.e., arytenoid to base of epiglottis) and there is penetration on the underside of the epiglottis towards the end of the swallow (perhaps in patients where the speed of full epiglottic inversion is slower) this is not included/ not scored for the 'thinning out rule', as the airway

is considered to be closed already (i.e., as PAS of 1). In a similar vein, a PAS of 2 would mean contrast *did* enter the airway and was squeezed out, so this needs to be scored as per the 'thinning' rule.

In cases of old contrast (residue) in the airway and underside of epiglottis, this is not considered for the 'thinning' rule on a subsequent swallow. The penetration in the airway will still thin out, but the pattern of thinning can be used to help score maximum airway closure in these instances.

**Frame for airway opening (component of LCD)**

For most patients, this is usually when the first frame showing contact between the arytenoids and base of epiglottis has ceased, as denoted by a change in light contrast *in the middle of the airway*. This is usually accompanied by epiglottic deflection at the same time or a few frames later. Even if the epiglottis is slow to release and invert, if there has been a ceasing of contact between the arytenoid and epiglottis base first (such that airway opening can be seen), that frame is chosen.

The exception to this is patients who have abnormal airway closure and cannot achieve closure of the arytenoids and epiglottis base. In these cases, the deflecting epiglottis (not the base) compensates and forms an essential part of airway closure. For these patients, the frame of first opening will be when the epiglottis starts to invert, and airway opening is seen.

If in doubt, tracking forwards and backwards can help determine airway closure. In cases where there is a small but definite change in light contrast, it is useful

to ask oneself, if this frame were being taken to score airway closure how one would score it.

Note that some patients demonstrate a prolonged breath hold after the swallow, where airway opening is considerably delayed.

If there is contrast in the airway, do not score when the contrast starts to release/ move with airway opening, only score when light/ opening in airway appears.

For patients with a gap medially in the airway (i.e., patients who do not fully close the airway), there is usually a clear point where further obvious opening of the airway occurs whereby the gap expands, signalling the process of opening the majority of the airway – take this as the first frame of opening.

In patients with unusual airway opening patterns, do not confuse release of the base of tongue from the pharyngeal wall as the release of the epiglottis from the pharyngeal wall - this can be challenging with images of poor quality.

**Frame for opening of the UOS (component of UOS Duration)**

To locate when the UOS has opened (and the bolus is not merely sitting deep in the pyriform fossae), look for entry of the head of the bolus into the narrowest part of the UOS between C4 and C6. [195] As the bolus head enters the top of UOS, there will be a slight indentation or narrowing in the bolus (like an hourglass). Opening may also occur (before any contrast has entered the UOS) when a visible column of air is seen at the top of the UOS. [194]

Frames showing air in the oesophagus as it starts to open that are not at the top of the UOS are not taken as first frame. This is more difficult to appreciate on a still but more easily discernible on a moving VFSS.

If the first frame shows an open column of air with contrast at but not past the UOS, take this as open.

In cases of doubt, track forward one or two frames and look for the UOS opening as the contrast passes through, then place the cursor on UOS opening and track back one frame. If there is any trace of contrast passed the UOS opening as denoted by the cursor, or the contrast is at the cursor, take this as the first frame. If the contrast has not moved passed the cursor or is not at the cursor, take the next frame. In cases of doubt whether it is open or not, take the second frame.

**Frame for closure of the UOS (component of PRT, PTT and UOS)**

This is the last frame showing the tail of the bolus passing into the UOS. The next frame would be when the tail is completely in the oesophagus with no trace of contrast visible at all. To help determine this point, locate the entry of the bolus into the UOS by looking for a narrowing/ indentation in the bolus as described above. This can be seen more clearly in some patients compared to others.

Look along the whole of the space from the pyriform and track the bolus path through to the opening of the UOS. Watch for the point where no trace of contrast is seen along this pathway – i.e., where there is a break in the line of

contrast, which may indicate the UOS has closed (in which case the previous frame would be chosen).

Looking at the bolus flow to determine whether it is still taut or whether it has relaxed may also help to determine at what point the contrast has fully entered the UOS. Also, for these types of patterns, note if the maximum thinning rule (see below) is appropriate.

Note that as the larynx starts to descend, the UOS descends too and it can be challenging to track the exact point of the top of the UOS, i.e., the point at which the tail is passing through and has fully entered the UOS.

For difficult to score patients - as the tail passes through the UOS, usually there is relaxation of structures one or two frames later. Sometimes this coincides with inversion of the epiglottis.

For patients with a continuous trail of contrast extending from the pyriform through the UOS, with no clear break - look for the end of the continuous flow of contrast moving into the UOS. Identify the point at which the trail stops thinning. It can help to track back frame by frame and locate the first frame where obvious contrast moving up past the UOS can be seen – this will be denoted by a slight thickening as the contrast moves up from the UOS to join the continuous trail in the pyriform. Take this frame where the first slight thickening can be seen which denotes the frame where the tail is passing into the UOS and is different to the maximum thinning rule for airway closure.

NOTE: In these patients, a very thin trail of continuous contrast can often still be seen extending from the pyriform into the UOS, even when the bolus has been

seen to pass into the UOS. This may possibly be due to poor clearance, UOS pressure or UOS coordination issues. There may be slight thinning out of the very thin trail as the patient moves or relaxes a few frames later and the coating spreads out or is slightly compressed, but this thinning out is not accompanied by perceptible movement of the bolus tail through the UOS and is not to be taken as the last frame. The decision on the last frame pertains to looking for active, continuous movement of the passage of the bolus through the UOS at the time of swallowing the current bolus.

#### 3.4.5.3 Calculation of timing measures

Once definitions were finalised and data analysis commenced, the correct frames making up each component of a timing measure were identified (two frames per measure) and entered into an excel spreadsheet. Using pre-defined formulas loaded into excel, each measure was calculated by subtracting the relevant frames from each other and multiplied by 0.04s (for a frame rate at 25 (fps)) or 0.033s (for a frame rate at 30fps), to obtain a temporal measurement in seconds.

The order the frames were measured in, according to the sequence they occurred during the swallow was:

1) Frame showing onset of manipulation of bolus by tongue
2) Frame showing bolus head arrival at ramus
3) Frame showing onset of anterior-superior hyoid movement
4) Frame showing onset of laryngeal elevation
5) Frame of first arytenoid contact with epiglottic base
6) Frame showing contact between arytenoids and epiglottic base has ceased
7) Frame showing bolus head entering UOS (or air column at top of UOS)
8) Frame showing bolus tail passing through the UOS

The order of subtraction of frames for each component was:

a) OTT: Frame bolus head ramus – frame showing onset of manipulation of the bolus
b) STD: Frame onset hyoid movement - frame bolus head ramus
c) ILC: Frame of first arytenoid contact - frame bolus head ramus
d) LVCrt: Frame first arytenoid contact – frame onset hyoid movement
e) LCD: Frame ceasing of arytenoid contact – frame of first arytenoid contact
f) PRT: Frame tail passing through the UOS – frame onset laryngeal elevation
g) PTT: Frame tail passing through the UOS - frame bolus head ramus
h) UOS: Frame tail passing through the UOS - frame bolus head opening UOS

### 3.4.6 Rules for clearance measures

Table 3.4 summarises the clearance measures which are based on the MBSImP.

**Table 3-4** Rules for clearance measures for 5ml and 50ml measures

| | |
|---|---|
| 5ml and 50ml | Oral residue (MBSImP) |
| 5ml and 50ml | Pharyngeal residue (MBSImP) |
| 5ml and 50ml | Number of swallows to clear each 5ml and 50ml |

#### 3.4.6.1 Oral residue

For 5ml boluses, oral residue was measured using component 5 of the MBSImP, i.e., immediately after the primary swallow and before any secondary swallows were initiated. Oral residue was not recorded for patients who displayed a sequential swallow- or a consecutive swallow pattern for 5ml if the oral cavity was not clear of material when more material entered the oral cavity.

For 50ml boluses, oral residue was measured at the end of the 50ml swallow sequence but before any secondary swallows were initiated. This is different to

the MBSImP, which scores residue after the entire sequential swallow sequence. However, by scoring residue after primary swallows in the 50ml sequence, the focus is on the efficacy of the swallow, i.e., whether clearance can be achieved without the need for secondary swallows. Measuring residue at the end of the entire sequence focuses on the efficiency of the swallow, i.e., whether using a strategy such as a secondary swallows can achieve clearance. In addition, one cannot rule out that secondary swallows could have been cued by the assessors in the trial.

#### 3.4.6.2 Pharyngeal Residue

For 5ml boluses, pharyngeal residue was measured using the component 16 of the MBSImP, i.e., scored immediately after the primary swallow and before any secondary swallows were initiated.

For 50ml boluses, pharyngeal residue was measured at the end of the 50ml swallow sequence but before any secondary swallows were initiated, as discussed above for scoring oral residue of the 50ml bolus.

#### 3.4.6.3 Number of swallows to clear

The number of primary and secondary swallows required to clear each 5ml bolus and the 50ml bolus were counted.

**As a final step**, the above data regarding swallow types, aspiration, timing and clearance were entered onto a bespoke database that was constructed using Bento Software (v4), a database application (now discontinued) developed by FileMaker Inc. When completed, the information was then exported into an excel

spreadsheet and then loaded into SPSS (version 24, IBM USA) for further evaluation. The standard operating procedure established in this chapter provides clear guidance and detail to researchers in the field on how to conduct investigations in timing, clearance and safety using videofluoroscopic data obtained at source. Prior to implementation however, it is necessary to demonstrate that the methods can be replicated.

## 3.5 Next Steps

The next step in this research project, therefore, was to establish intra- and inter-rater reliability of the methods that had been developed. This work is discussed in the next chapter.

# 4. Reliability of the penetration aspiration scale and timing and clearance measures in post-stroke dysphagia: analysis from the STEPS Trial

# Publications arising from this chapter:

Submission in progress:

Everton LF, Benfield JK, Michou E, Hamdy S and Bath PM. Reliability of the videofluoroscopic penetration aspiration scale and swallowing temporal and clearance measures in post-stroke dysphagia: analysis of measurements from the STEPS Trial. Submitted to the Journal of Speech, Language and Hearing Research, December 2020.

# Presentations arising from this chapter:

Everton LF, Benfield JK, Michou E, Hamdy S and Bath PM. How reliable is the penetration aspiration scale? A retrospective assessment using data from the Swallowing Treatment using Electrical Pharyngeal Stimulation Trial. 8th UK Swallowing Research Group Conference, 6-7 February 2020, London.

# ABSTRACT


## Introduction

This chapter reports on the process of establishing reliability of the methods developed to assess safety, timing, and clearance measures in Chapter Three. It is particularly important to report on reliability estimates. Information on the reliability of outcome measures used to assess the effectiveness of interventions in dysphagia rehabilitation is lacking, particularly when used by different research groups.

## Methods

A subset of data from the STEPS trial in subacute stroke was used. PAS scores (719 swallows from 18 participants) were evaluated and compared to the original PAS scores from the trial. Five conditions were assessed, including reliability for every swallow and overall mean worst PAS score. The methods devised in Chapter Three, for assessing temporal and clearance measures were also assessed for reliability. Inter- and intra rater reliability of component level and derivative level scores were assessed for all measures, using the intraclass correlation coefficient (ICC) and weighted kappa.

## Results

Image quality was variable. Inter-rater reliability for the overall mean worst PAS score was excellent (ICC 0.914, 95% confidence intervals CI 0.853, 0.951) but

moderate for every swallow in the bolus (ICC 0.743, 95% CI 0.708, 0.775). Intra-rater reliability for PAS was excellent (all conditions). Excellent reliability (>0.90) for both inter- and intra-rater conditions, was seen for temporal measures of stage transition duration (ICC 0.998, 95% CI 0.993, 0.999; 0.995, 95% CI 0.987, 0.998 respectively) as well as initiation of laryngeal closure and pharyngeal transit time and all individual swallow events (such as head of bolus arriving at the ramus). Strong scores were obtained for some clearance measures; others were moderate or weak.

# Conclusion

Inter-rater reliability for PAS was acceptable but depends on how the PAS is scored. Inter-rater reliability for most temporal measures was high, although some measures required additional training to reach high scores. No clearance measures had excellent reliability.

## 4.1 Introduction

It is important that methods used in research studies and clinical settings are reliable, i.e., the results obtained by one researcher should be consistent with the results obtained by another researcher using the same methods. Clinical measures without accompanying reliability data can lead to a lack of confidence in the results and rationale concluded. [200]

Evidence for the reliability of both clinical and radiological measures is important, [200] although reporting of the PAS in observational and treatment studies is limited.[201] When reported, reliability has been good or excellent for raters in the same laboratory or who received thorough training; this includes studies involving stroke patients. [60, 129, 202] However, there are fewer studies examining reliability of the PAS with assessors with different experience [201] or from different institutions. These studies overall report a *lower* reliability for reasons such as different levels of experience between institutions [109, 203, 204,] or limited or no specific training in the first place. [108, 203, 204] Furthermore, only one of these studies involved stroke patients. [108]

Given this context, because data from the current study included *different* research groups, i.e., PAS scores from the original STEPS trial and PAS scores that were re-scored by the author using the same data, it was important to establish reliability. In addition, it is evident that there is an increase in multi-centre trials in dysphagia research using the PAS as an outcome measure. Decisions regarding which treatments are effective and should be invested can be determined by the chosen outcome measure. Hence, analysing reliability

between different institutions also informs optimal use of the PAS in these situations.

There are also limited data on inter- and intra-rater reliability of temporal measures in healthy volunteers [117] and a systematic review of VFSS measurements in patients with dysphagia concluded that several studies exhibited difficulties in their methodology.[79] As with the PAS, many research studies using the Intraclass Correlation Coefficient report good or excellent reliability in studies with raters in the same laboratory. [60, 111, 129, 132, 205] However, few studies have explored how raters acquire reliability skills for timing measures.

A final point, is that reliability information is not always reported in adequate detail or less appropriate models are used. [206] An example of this is using Pearson's Correlation Coefficient or choosing the consistency option (instead of absolute agreement) when using the ICC. [206] Both these methods analyse correlation of agreement not identical (absolute) agreement.[206] Clinical measures should almost always be reported using absolute agreement. [206]

The aims of the present study were firstly, to compare reliability of PAS ratings between the STEPS' assessors and the author and secondly, to describe the process for establishing reliable methods for temporal and clearance measures.

## 4.2 Methods

### 4.2.1 STEPS trial and videofluoroscopy swallowing studies

STEPS study information and participants are described in Chapter Three (section 3.2.1.)

### 4.2.2 Reliability assessments

For inter-rater reliability of PAS ratings, data were taken from a randomly selected sample of participants from the STEPS trial. The ratings from that trial (STEPS assessors, rater A, 2012-2014) were compared to new ratings done for the present study carried out by the author (LE, rater B). Data from eighteen participants were measured at three timepoints (weeks 0, 2 and 12), amounting to 50 of 339 available files (15%). Each file contained data up to 7 boluses. Rater B (2017-2020) was blinded to all data except hospital site. Rater B also scored 10 of 50 files (20%) of the inter-rater data on a second occasion (with an interval greater than 3 months), to calculate intra-rater reliability. For the intra-rater condition, Rater B was blinded to all data except hospital site and timepoint.

For temporal and clearance measures, 17 participants were included in the inter-rater reliability condition, amounting to 30 of 306 available files (10%) for temporal measures and 15 of 401 available files (4%) for clearance measures. Ratings were carried out by two expert assessors (raters B and C, JB) who were both experienced in VFSS PAS assessment and trained in the Modified Barium Swallow Impairment Profile (MBSImP), both being MBSImP certified clinicians.[70]

Assessors were blinded to all participant data (except hospital site) and each other's scores. Rater B performed intra-rater reliability (with an interval greater than 3 months) between assessments on 20 of 401 files (5%). The raters and an expert SLT in temporal measurements (EM) agreed and refined rules for each temporal component. Raters B and C then trained on using these rules until raters felt confident. Files were viewed in the sequence in which they were collected. Neither raters B nor C were involved in the original STEPS trial.

### 4.2.3 Penetration aspiration scale

Images for all swallows were viewed using Quick Time 7 (Apple Inc, USA), allowing frame-by-frame analysis. Data were analysed for both 5ml and 50ml boluses together (as in the STEPS study) and individually for 5ml and 50ml scores. Analyses included assessment of intra- and inter-rater reliability of the PAS for five conditions. The first two conditions analysed reliability at the component (individual) scores at the *level of the swallow*: (a) every swallow in each bolus, including secondary (clearing) swallows and (b) the first swallow in each bolus (as in previous published studies). [66, 108, 109, 203, 204] The remaining three conditions analysed reliability for derivative PAS scores (i.e., scores that are *derived* from other PAS scores): (c) the worst score from each bolus of 3-7 boluses (i.e. including 5ml and 50 ml bolus) irrespective of swallow type (primary/first or secondary/clearing) - the score did not need to be from the exact same swallow as reported by the other rater but had to be from the same bolus; (d) the mean of the 3-7 PAS scores identified in condition c, this giving each participant one mean PAS score (replicating the STEPS primary outcome measure);[44] and (e) the mean and worst swallow of the 50ml bolus. PAS scores were assessed in all participants who had timing and clearance measures

completed (≥25fps) and included the 5ml mode swallow, [103] the 5ml best swallow, the 5ml worst swallow, the worst PAS from the 50ml bolus and combined 5ml and 50ml PAS scores.

### 4.2.4 Timing and clearance measures

As with the PAS, reliability was assessed both at the component level (measured in frames for *individual swallow events* such as bolus head passing ramus) as well as *derivative* measures (such as Oral Transit Time, measured in seconds) as detailed in Chapter Three (Table 3.3). These were: oral transit time (OTT), stage transition duration (STD) initiation of laryngeal closure (ILC), laryngeal vestibule closure reaction time (LVCrt), laryngeal closure duration (LCD), pharyngeal response time (PRT), pharyngeal transit time (PTT) and upper oesophageal sphincter duration (UOSD). As discussed in Chapter Three, two different measures were given for OTT in view of the wide variation in oral transit patterns observed. As also discussed in Chapter Three, the Modified Barium Swallowing Impairment Profile (MBSImP) [70] was used to score initiation of the pharyngeal swallow, bolus transport and oral and pharyngeal residue.

### 4.2.5 Ethics

The study underpinning this work had national ethics approvals and patients (or surrogates) had given written informed consent. The trial was registered as ISRCTN25681641.

### 4.2.6 Statistical Analysis

Data are reported as number (%) or mean (standard deviation). PAS reliability assessments were analysed using the intraclass correlation coefficient (ICC). The ICC is widely used to compute the reliability of ordinal data [207] including the PAS. [66 108 135 202 203] The ICC was also used to compute temporal measures. Specifically, ICC 2-way random effects (PAS) and mixed effects (temporal), single measures, absolute agreement and corresponding 95% confidence intervals were calculated using SPSS (version 24, IBM USA). Interpretation was based on Koo [200] (reliability < 0.5 is poor; 0.5 - 0.75 is moderate; 0.75 - 0.9 is good and >0.90 is excellent). Ordinal measures were assessed using the weighted kappa. Interpretation was based on McHugh, [208] (reliability < 0.40 - 0.59 is weak; 0.60-0.79 is moderate, 0.80-0.90 is strong and >0.90 almost perfect).

## 4.3 Results

### 4.3.1 STEPS participants and videofluoroscopy swallowing studies

Of 126 STEPS participants, 28 were included. Eighteen participants were included in the PAS reliability sub study and seventeen in the temporal and clearance measures sub study. Table 4.1 details the baseline characteristics of participants in both studies. Seven participants were common to both sub-studies. Different participants apart from the aforementioned 7 were included in each study due to image quality and because the second study (which focused on precise measurements in seconds) only included participants with a frame rate of 25fps. This contrasts with the PAS study where a random selection of participants was chosen in order to be representative of the STEPS data and all participants received a PAS rating (irrespective of frame rate). In both groups, the mean age of participants was similar (~72 years), as was the distribution of stroke syndrome, with a partial anterior circulation stroke syndrome being most common (~50% of the cohort). Both groups had a similar distribution of oral and non-oral feeding regimens in place and a dysphagia severity rating scale [42] score of between 6 and 7.

**Table 4-1** Baseline characteristics of participants in the penetration aspiration scale (PAS) and timing and clearance reliability studies. Data are number (%) and mean (standard deviation)

| **Participants** | **N** | **PAS** | **N** | **Temporal/clearance** |
|---|---|---|---|---|
| Age, y | 18 | 73.4 (10.2) | 17 | 72.4 (11.4) |
| Sex, female (%) | 18 | 5 (27.8) | 17 | 7 (41.2) |
| Ethnicity, white (%) | 18 | 17 (94.4) | 17 | 15 (88.2) |
| Modified Rankin Scale (/6) | 18 | 3.9 (1.2) | 17 | 3.4 (1.3) |
| Barthel Index (/100) | 18 | 37.8 (36.5) | 17 | 48.8 (38.8) |
| Stroke | 18 | 2 (11.1) | 17 | 4 (23.5) |
| Previous (%) | | | | |
| Type, ischaemic (%) | 16 | 14 (87.5) | 16 | 15 (88.2) |
| Side of CT lesion (%) | 17 | | 16 | |
| Left | | 4 (23.5) | | 8 (50.0) |
| Right | | 10 (58.8) | | 6 (37.5) |
| No lesion | | 3 (17.6) | | 2 (12.5) |
| Syndrome (%) | 18 | | 17 | |
| TACS | | 5 (27.8) | | 5 (29.4) |
| PACS | | 9 (50.0) | | 9 (52.9) |
| LACS | | 4 (22.2) | | 3 (17.6) |
| POCS | | 0 (0.0) | | 0 (0.0) |
| Severity, NIHSS (/42) | 18 | 8.9 (6.6) | 17 | 8.2 (5.2) |
| Dysphasia, NIHSS (%) | 18 | 7 (38.9) | 17 | 4 (23.5) |
| Onset to randomisation (days) | 18 | 17.8 (11.7) | 17 | 18.7 (13.5) |
| DSRS (/12) | 18 | 7.3 (3.8) | 17 | 6.7 (4.3) |
| TOR-BSST, failed (%) | 18 | 18 (100.0) | 17 | 17 (100.0) |
| Feeding route (%) | 18 | | 17 | |
| Oral, normal diet | | 1 (5.6) | | 1 (5.9) |
| Oral, soft diet | | 5 (27.8) | | 7 (41.2) |
| Nasogastric | | 10 (55.6) | | 8 (47.1) |
| PEG | | 1 (5.6) | | 1 (5.9) |
| Other | | 1 (5.6) | | 0 (0.0) |
| Weight (kg) | 18 | 77.5 (15.8) | 17 | 70.4 (16.8) |
| Body Mass Index (kg/m$^2$) | 17 | 26.4 (4.9) | 17 | 24.5 (4.5) |
| Mid-arm circumference (cm) | 18 | 28.4 (3.6) | 17 | 28.5 (4.5) |
| Albumin (g/L) | 17 | 3.8 (0.5) | 17 | 3.8 (0.6) |

CT: computed tomography; TACS: total anterior circulating stroke; PACS: partial anterior circulating stroke; LACS: lacunar stroke; POCS: posterior circulation syndrome; DSRS: dysphagia severity rating scale; NIHSS: National Institutes of Health stroke scale; TOR-BSST: Toronto bedside swallow screening test; PEG: percutaneous endoscopic gastrostomy.

In the PAS reliability study where images were randomly selected, 103 of 822 swallows were excluded due to poor data quality or missing data. Much less data was excluded due to quality in the temporal and clearances measures study. This was because images included in this study were ones that had most if not all temporal and clearances measures conducted by Rater B and by default, were better quality. Point estimates and variability for baseline measures are given in Table 4.2 The mean worst PAS scores in this sub-study are representative of acute patients with post-stroke dysphagia. [43]

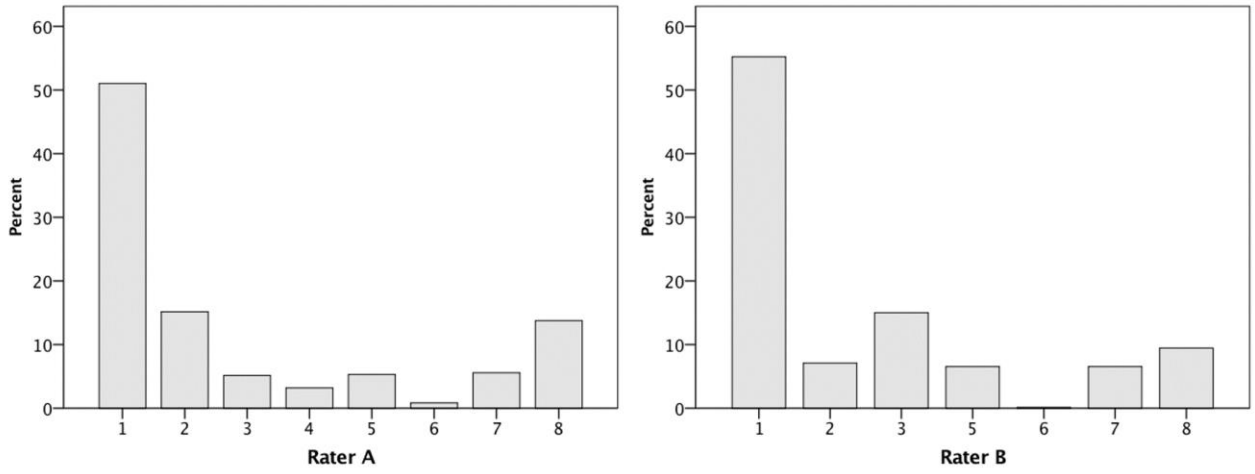
**Table 4-2** Baseline penetration aspiration scores, timing and clearance data from rater B. Data is mean (standard deviation) and median (interquartile range)

| **Outcome** | **N** | **Mean (SD)** | **Median [IQR]** |
|---|---|---|---|
| Every swallow in bolus (7 boluses) | 237 | 3.0 (2.6) | 1.0 [4.0] |
| First swallow in bolus (7 boluses) | 90 | 3.4 (2.6) | 3.0 [4.0] |
| Worst PAS in bolus (7 boluses) | 90 | 4.3 (2.7) | 4.0 [6.0] |
| Mean of worst PAS (7 boluses) | 16 | 4.4 (1.8) | 4.5 [2.7] |
| Mean of 50ml bolus | 10 | 3.9 (2.2) | 2.9 [4.2] |
| Worst PAS from 50ml bolus | 10 | 6.7 (1.8) | 7.5 [3.0] |
| **Temporal measures (seconds)** | | | |
| Global oral transit time (sec) (gOTT) | 12 | 2.71 (1.92) | 2.16 [3.68] |
| Stage transition duration (sec) (STD) | 15 | 1.05 (1.54) | 0.44 [1.56] |
| Initiation of laryngeal closure (sec) ILC) | 15 | 1.38 (1.62) | 0.92 [1.52] |
| Laryngeal vestibule closure-reaction time (sec) (LVCrt) | 16 | 0.39 (0.14) | 0.44 [0.25] |
| Laryngeal closure duration (sec) (LCD) | 16 | 0.46 (0.19) | 0.38 [0.28] |
| Pharyngeal response time (sec) (PRT) | 12 | 0.99 (0.19) | 0.98 [0.32] |
| Pharyngeal transit time (sec) (PTT) | 12 | 1.41 (0.83) | 1.10 [0.72] |
| Upper oesophageal sphincter duration (sec) (UOSD) | 12 | 0.72 (0.22) | 0.70 [0.34] |
| Initiation of pharyngeal swallow (range 0-4) IPS | 15 | 1.53 (1.41) | 2.00 [3.00] |
| **Clearance measures (range 0-4)** | | | |
| Bolus transport (BT) 0-4 | 11 | 1.45 (1.21) | 2.00 [2.00] |
| Oral residue (range 0-4) (OR) | 15 | 1.47 (0.52) | 1.00 [1.00] |
| Pharyngeal residue (range 0-4) (PR) | 15 | 1.60 (0.83) | 2.00 [0.00] |

### 4.3.2 Penetration aspiration scale (PAS)

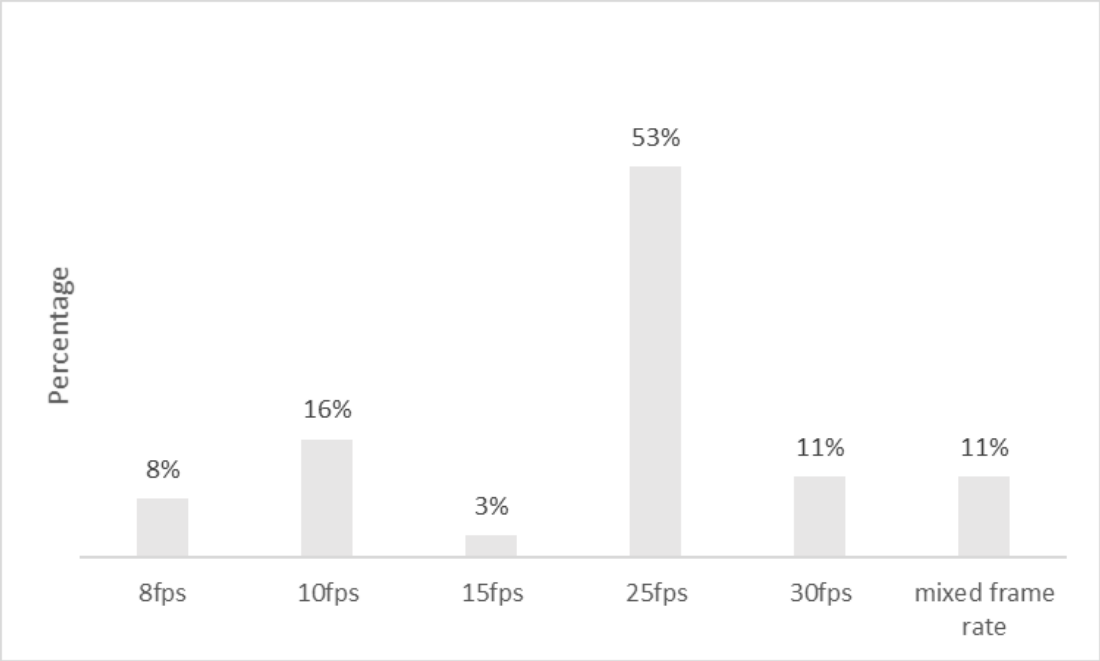
Evidence of both "floor" and "ceiling" effects were apparent with a mode of 1 (frequency slightly greater than 50%) and a further peak at 8 (Figure 4.1). PAS scores of 6 were rarely assigned (<1% of the sample) indicating that aspirated material was seldom cleared (as previously reported). [66 204 103]

**Figure 4-1** Frequency of penetration aspiration scale (PAS) scores for every swallow for raters A and B (N=719)




A variety of frame rates were observed, with the most frequent at ≥25fps, detailed in Figure 4.2 below.

**Figure 4-2** Frequency of frame rates present in videofluoroscopic studies in assessment of penetration aspiration scale (N=18)




Inter-rater reliability varied from being excellent for the mean of the worst PAS score, good for the worst PAS in a bolus and moderate for the first and every swallow in a bolus (Table 4.3). All intra-rater scores were excellent.

When limiting analyses to VFSS $\geq$25 fps, with analysis of the mode, worst and best PAS for 5ml and the worst PAS for 50ml (as per the scoring design chosen in Chapter Three), similar inter-rater reliabilities were observed; i.e., most scores were good, with one moderate score (Table 4.4).

It was noted on occasions that the code given to a swallow (used as the reference point by the author for allocating a PAS of 7 or 8) did not match the PAS score allocated to it by the STEPS assessors, likely due to a transcript error. However, a subset of scores were taken, using both sets of data, comparing the author's scores to the STEPS code and then author's scores to the assessors' allocated scores and there was no significant difference between the two.

**Table 4-3** Inter-rater reliability (raters A and B, 50 files) and intra-rater reliability (rater B, 10 files) as intraclass correlation coefficient (ICC) of penetration aspiration scale (PAS) scores

| Reliability | N | 5/50 ml ICC (CIs) | N | 5 ml ICC (CIs) | N | 50 ml ICC (CIs) |
|---|---|---|---|---|---|---|
| ***Inter-rater*** | | | | | | |
| Every swallow in bolus | 719 | 0.743 (0.708, 0.775) † | 509 | 0.729 (0.686, 0.767) † | 210 | 0.756 (0.689, 0.810) ☐ |
| First swallow in bolus | 293 | 0.747 (0.692, 0.794) † | 258 | 0.730 (0.667, 0.782) † | 35 | 0.869 (0.755, 0.932) ☐ |
| Worst PAS in bolus (7 boluses) | 295 | 0.829 (0.789, 0.861) ☐ | 257 | 0.796 (0.746, 0.837) ☐ | 38 | 0.952 (0.911, 0.975) § |
| Mean of worst PAS (7 boluses) | 49 | 0.914 (0.853, 0.951) § | 49 | 0.907 (0.841, 0.946) § | | - |
| Mean from 50ml bolus | | - | | - | 38 | 0.913 (0.836, 0.955) § |
| Worst PAS from 50ml bolus | | | | | 38 | 0.952 (0.911, 0.975) § |
| ***Intra-rater*** | | | | | | |
| Every swallow in bolus | 174 | 0.944 (0.925, 0.958) § | 121 | 0.930 (0.901, 0.950) § | 53 | 0.949 (0.914, 0.970) § |
| First swallow in bolus | 65 | 0.970 (0.952, 0.982) § | 56 | 0.962 (0.935, 0.977) § | 9 | 1.00 |
| Worst PAS in bolus (7 boluses) | 66 | 0.956 (0.929, 0.973) § | 56 | 0.945 (0.908, 0.967) § | 10 | 0.965 (0.867, 0.991) § |
| Mean of worst PAS (7 boluses) | 10 | 0.965 (0.867, 0.991) § | 10 | 0.945 (0.804, 0.986) § | | - |
| Mean from 50ml bolus | | | | | 10 | 0.961 (0.851, 0.990) § |
| Worst PAS from 50ml bolus | | - | | - | 10 | 0.976 (0.913, 0.994) § |

ICC reliability: < 0.5 = poor; 0.5 - 0.75 = moderate (†); 0.75 - 0.9 = good (☐) and > 0.90 = excellent (§)

**Table 4-4** Inter-rater reliability (raters A and B) as intraclass correlation coefficient (ICC) of penetration-aspiration scores in participants with videoflouroscopic examinations collected at ≥ 25 fps

| Measure | N | ICC (95% CI) |
|---|---|---|
| Mode swallow 5ml at 2 weeks | 79 | 0.772 (0.665, 0.848) # |
| Worst swallow 5ml at 2 weeks | 80 | 0.828 (0.745, 0.886) # |
| Best swallow 5ml at 2 weeks | 79 | 0.643 (0.494, 0.756) † |
| Worst swallow 50ml at 2 weeks | 70 | 0.879 (0.813, 0.923) # |
| Total 5ml and 50ml score at 2 weeks | 80 | 0.878 (0.816, 0.920) # |

ICC reliability: < 0.5 = poor; 0.5 - 0.75 = moderate (†); 0.75 - 0.9 = good (#) and > 0.90 = excellent (§)

### 4.3.3 Timing and clearance measures

At the outset (first round), excellent to perfect reliability was achieved for all individual component measures (Table 4.5) whilst only some derivative temporal measures yielded excellent scores (Table 4.6). Further training was required to reach acceptable inter-rater reliability scores depending on the measure. ICCs for STD, ILC and PTT were achieved readily after the first round, OTT and LCD after two rounds and UOSD and PRT after three rounds. LVC-rt was included later in the analysis as more recent data on LVC-rt was published during the course of the study and a decision was made to include it. Reliability for LVC-rt was moderate (inter-rater) and excellent (intra-rater) respectively. Intra-rater reliability varied from excellent (STD, ILC, LVCrt, LCD, PTT) through good (UOSD) to moderate (OTT, PRT) (Table 4.6).

Bolus transport was discontinued early on in the study due to weak inter-rater scores and hence was not scored for intra-rater reliability. Inter-rater reliability was moderate for IPS and strong for oral- and pharyngeal residue; intra-rater reliability was strong for IPS but weak for oral and pharyngeal residue (Table 4.6).

**Table 4-5** Inter-rater (raters B and C) reliability and intra-rater (rater B) reliability as intraclass correlation coefficient (ICC) for individual component measures of frame reliability as intraclass correlation coefficient (ICC) 5ml bolus

| | Inter-rater | | N | Intra-rater |
|---|---|---|---|---|
| | N | ICC (95% CI) | | ICC (95% CI) |
| **Component measures by frames** | | | | |
| Onset of active manipulation of bolus by tongue (1) | 12 | 0.998 (0.993, 0.999) | 15 | 0.996 (0.988, 0.998) |
| First posterior movement of bolus by tongue (2) | 14 | 0.999 (0.998, 1.000) | | - |
| Bolus head passing angle of ramus | 14 | 1.000 (1.000, 1.000) | 17 | 1.000 (1.000, 1.000) |
| Onset of hyoid movement | 14 | 0.999 (0.998, 1.000) | 15 | 1.000 (1.000, 1.000) |
| Onset of laryngeal elevation | 17 | 1.000 (1.000, 1.000) | 13 | 1.000 (1.000, 1.000) |
| Airway closure | 14 | 0.999 (0.998, 1.000) | 15 | 1.000 (1.000, 1.000) |
| Airway re-opening | 14 | 1.000 (1.000, 1.000) | 15 | 1.000 (1.000, 1.000) |
| Opening of Upper Oesophageal Sphincter | 17 | 1.000 (1.000, 1.000) | 15 | 1.000 (1.000, 1.000) |
| Closure of Upper Oesophageal Sphincter | 14 | 1.000 (1.000, 1.000) | 13 | 1.000 (1.000, 1.000) |

Reliability, ICC: < 0.5 = poor; 0.5 - 0.75 = moderate (†); 0.75 - 0.9 = good (#) and > 0.90 = excellent (§) [200]

The first definition (1) was chosen as one component of oral transit measure due to its higher inter-rater reliability

**Table 4-6** Inter-rater (raters B and C) and intra-rater (rater B) reliability as intraclass coefficient (ICC) for timing measures and weighted kappa for ordinal measures for 5ml bolus

| | Inter-rater | | Intra-rater | |
|---|---|---|---|---|
| | **N** | **ICC (95% CI)** | **N** | **ICC (95% CI)** |
| **Temporal measures** | | | | |
| Global oral transit time 1 ($gOTT_1$) | 12 | 0.955 (0.843, 0.987) § | 15 | 0.686 (0.300, 0.881) † |
| Oral transit time 2 ($OTT_2$) | 14 | 0.897 (0.712, 0.966) # | | - |
| Stage transition duration (STD) | 14 | 0.998 (0.993, 0.999) § | 16 | 0.995 (0.987, 0.998) § |
| Initiation of laryngeal closure (ILC) | 14 | 0.998 (0.994, 0.999) § | 16 | 0.994 (0.984, 0.998) § |
| Laryngeal vestibule closure-reaction time (LVC-rt) | 14 | 0.565 (0.080, 0.836) † | 15 | 0.920 (0.780, 0.972) § |
| Laryngeal closure duration (LCD) | 14 | 0.929 (0.792, 0.977) § | 16 | 0.964 (0.892, 0.988) § |
| Pharyngeal response time (PRT) | 14 | 0.810 (0.510, 0.935) # | 14 | 0.624 (0.099, 0.868) † |
| Pharyngeal transit time (PTT) | 14 | 0.977 (0.931, 0.992) § | 14 | 0.986 (0.958, 0.996) § |
| Upper oesophageal sphincter duration (UOSD) | 14 | 0.932 (0.790, 0.978) § | 15 | 0.757 (0.349, 0.915) # |
| **Ordinal measures** | **N** | **Weighted kappa** | **N** | **Weighted kappa** |
| Bolus transport (BT) | 13 | 0.421 (0.148, 0.694) * | - | - |
| Initiation of pharyngeal swallow (IPS) | 14 | 0.672 (0.372, 0.972) † | 14 | 0.810 (0.533, 1.086) # |
| Oral residue (OR) | 12 | 0.824 (0.498, 1.149) # | 13 | 0.425 (0.146, 0.704) * |
| Pharyngeal residue (PR) | 14 | 0.881 (0.682, 1.080) # | 15 | 0.595 (0.116, 1.073) * |

Reliability, ICC: < 0.5 = poor; 0.5 - 0.75 = moderate (†); 0.75 - 0.9 = good (#) and > 0.90 = excellent (§) [200]

Weighted kappa: 0.40 - 0.59 = weak (*); 0.60-0.79 = moderate (†), 0.80-0.90 = strong (#); >0.90 = almost perfect (§)

$gOTT_1$ was chosen as oral transit measure due to its higher inter-rater reliability

## 4.4 Discussion

This study assessed the reliability of PAS between different research groups in acute stroke patients. The mean worst PAS score per patient had excellent inter-rater reliability, as did all intra-rater scores; other reliable measures included the worst PAS score (inter-rater). This study agrees with the results of the index publication where the mean PAS scores between 4 different judges also achieved excellent ICCs for both inter- and intra-rater reliability (ICC 0.96; 0.95 judge 1 through to 0.97 judge 2 respectively). [66]

Comparing these results directly with other similar studies (between different institutions or assessors with different experience) is more challenging due to different methodology used in those studies. These include: assessment in non-stroke populations [109] [203, 204,] with only one PAS score for each bolus and without comment on secondary swallows or what swallows were scored [66, 108, 109, 204,] with liquid consistencies other than just thin fluids [109, 203] by assessors who were experienced Speech and Language Therapists (SLTs) [108, 203, 204] or who had minimal [109] or no specific training on scoring the PAS [108,203,204] or who come with different experience [109, 203, 204,] using different methodologies such as using only 'good' quality images, [203] image enhancement software [109] or only allowing raters to observe VFSS images twice before assigning a score. [204] The actual reported reliability scores showed a large range : 0.80 for a semi-solid consistency (ICC), [203] between 0.085 and 0.591 for thin fluids (ICC), [108] 0.67 for thin and pureed combined (ICC), [204] and between 69% to 71% (Kendall's Tau) for thin fluids with a chin tuck position. [109]

Both derivations of the PAS scores and the component PAS scores are reported in this study, with the highest reliability scores obtained for derivations. Some researchers may feel that reporting on component PAS scores is preferable as they do not rely on a derived score. However, other researchers suggest that taking an average (derivative) PAS score is more relevant as a summary assessment when a subject performs multiple swallows as part of a swallowing evaluation. [66] Going forwards, studies should provide explicit detail of what PAS scores were used and how they were derived, as currently, many studies lack this detail, although there are some exceptions. [128, 135]

In terms of possible explanations for moderate scores, scoring differences were seen mostly in the mid-range (2-6). This has previously been reported [66, 109] and may provide useful information for future debates on the PA scale. [103] Particularly, Rater B tended to score trace penetration only visible at the height of the swallow as a PAS of 3 or a PAS of 5 as opposed to rater A who scored a PAS of 2 or a PAS of 4 for those respective swallows. Other discrepancies noted were: scoring a PAS of 2, (possibly due to different judgements about laryngeal vestibule closure relative to penetration); a PAS of 6 (depending on how far material coating the inferior border of the true vocal cords was judged to have 'dipped' below) and scoring secondary swallows (especially when residue was present). Published information on scoring secondary swallows is sparse, apart from a few studies. [128] [135]

The results of this study suggest that these scoring disparities between different groups become less important when a derivative PAS score (the overall mean worst PAS score) is used. However, when using component PAS scores, such as every swallow in the bolus and first swallow in the bolus, moderate scores were

obtained. Hence, the importance of having specific training to optimise reliability is recommended, as was also noted in the largest published PAS reliability study to date.[109]

This study additionally created methods for temporal and clearance measures. Published studies using temporal and clearance measures may report on overall reliability but not necessarily on the procedures used to determine reliability. Two studies (healthy participants and stroke patients) reported stage transition duration to be reliable [192] [209] as was also found here. For inexperienced raters, establishing reliable ICCs was an iterative process, requiring development of comprehensive rules, training and practice on various abnormal swallow patterns. The endpoint is to achieve 'acceptable proficiency' for interpreting imaging data. [6] A systematic review into reliability of VFSS measures made similar conclusions. [79] Excellent reliability for component scores did not automatically result in excellent reliability for derivative measures. This may be because two sets of measures are compared in derivative measures (such as first onset active manipulation of the tongue *and* bolus head at ramus for OTT) versus one set of measures for component scores (for example, bolus head at ramus).

Difficulty in establishing reliability was especially present for OTT and UOSD (and PRT by default). A portion of the intra-rater data used was from different patients to the inter-rata data. OTT and UOSD may therefore be less robust reliability measures than STD, ILC, LCD and PTT, which still yielded excellent results for both sets of inter- and intra-rater reliability data.

For OTT, this may be partly due to it being a largely voluntary component, making it difficult to define the beginning and end of the measure. [210] A review (healthy subjects) found no consensus regarding OTT, [115] probably because it is less frequently studied. [210] In the current research study, diverse patterns of bolus containment and transport were observed, making the task of using definitions derived from normal subjects challenging. Hence, a new definition (Global Oral Transit Time) was devised, which although similar to other definitions,[102, 196, 197] captures all anticipatory and repetitive oral behaviours. With regards to reliability of UOSD, the variability seen here with UOSD was also previously reported in one study with lower reliability. [131] This variability may be because when the UOS opens is subject to discussion and may vary between individuals,[195] reduced image quality, or that further practice was required. Clearance measures showed lower reliability (as previously reported), possibly due to the scales per se, which rely on subjective judgements.[79]

## 4.5 Strengths

This research study has several strengths: analysis of VFSS of patients with a wide range of post stroke dysphagia severity; the presence of detailed participant information, a published protocol from a high-fidelity phase III trial and reliability data presented on a wide range of data, including both component and derivative measures.

## 4.6 Limitations

Several limitations are also present. First, this study contained VFSS from 18 hospitals (5 countries). Inevitably, some images were of sub-optimal quality

which may have influenced scoring accuracy. Also, the VFSS frame rate varied within and between sites although it was meant to be collected at 25 fps or higher. Reliability of all VFSS with a frame rate ≥8fps (for PA scores) was assessed and a sensitivity analysis including only VFSS was performed at ≥25 fps (for both PA scores and timings and clearance measures). Image enhancement (for detecting minor contrast in the mid-range) may give higher scores and is recommended.[109] Second, rater A represented the mean scores of 3 different raters who each scored a portion of the STEPS data (as per the trial's protocol reference), whereas rater B (the author) scored all the data, which will have resulted in some variation between rater A and B. Third, some methodological errors were noted, such as occasional discrepancies where PAS scores appeared to be recorded out of sequence. However, in order to ensure ratings were fully blinded to minimise bias, cross-referencing of scores to bolus number with original data was not done. Although several measures were carried out on each participant (particularly in the PAS study), the number of participants is modest. Last, the viewing order of VFSS files was not randomised, which some authors feel can create rater bias.[79]

In conclusion, this study has demonstrated reliability estimates for the safety, timing and clearance measures developed during the course of this research. It should be noted that these observations relate to the methodology reported here and other research groups may score the PAS differently. To optimise reliability, detailed operational definitions and specific training are required for measuring PAS, timings and clearance and it is vital to optimise image quality.

## 4.7 Next Steps

Having demonstrated reliability for these methods, Chapter Five focused on evaluating the effectiveness of using multiple measures of timing and clearance compared to single measures of safety, using retrospective videoflouroscopic data from the STEPS Trial.

# 5. Effects of pharyngeal electrical stimulation on swallow safety, timings and clearance: analysis from the STEPS Trial

# Publications arising from this chapter:

Pending submission:

Everton LF, Benfield JK, Michou E, Hamdy S and Bath PM. Effects of pharyngeal electrical stimulation on swallow timings, clearance and safety: Analysis from the Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS) Trial. Submitted to Stroke Research and Treatment, February 2021.

# Presentations arising from this chapter:

Everton LF, Michou E, Benfield JK, Hamdy S and Bath PM. Effects of pharyngeal electrical stimulation on swallow timings, clearance and safety: adhoc analysis from the Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS) Trial. International Journal of Stroke, 14 (4S), 2019.

# ABSTRACT


## Introduction

Measuring change in swallowing can be complex, ideally requiring a composite outcome measure. In this chapter, Pharyngeal electrical stimulation (PES) was investigated using the multi-dimensional measures that were shown to be reliable in Chapter Four. These measures were: safety (penetration aspiration scale: PAS), speed and duration (timing) and efficiency (clearance), as opposed to the original trial which only measured safety (PAS).

## Methods

Eighty-one randomised participants (PES versus sham) were analysed at baseline and 2 weeks. Participants swallowed up to 6 x 5ml and 1 x 50ml thin fluids at 40% w/v, images at ≥25 frames per second. Safety measures were assessed using the penetration aspiration scale (PAS) on each 5ml and 50ml bolus. The mode, worst and best 5ml boluses were chosen for further analysis, and the worst 50ml bolus, based on PAS scores. Eight timing measures were performed, included oral transit time, stage transition duration and pharyngeal transit time. Clearance measures comprised oral and pharyngeal residue (Modified Barium Impairment Swallowing Profile-MBSImP) and number of swallows to clear. Comparisons of change of scoring outcomes between PES and sham were evaluated at 2 weeks to assess the effect of PES on the above measures. Both groups' combined results were also compared at baseline and two weeks, using descriptive statistics to calculate frequency

distributions and Wilcoxon Signed Ranks Test and McNemar's Test to examine longitudinal changes.

# Results

Between-group analysis showed no statistically significant differences between the PES or sham group for any of the measures at two weeks. However, issues with sub-optimal image quality and frame rate acquisition affected final numbers. When considering longitudinal changes, safety scores showed the most significant improvement. Most measures of speed showed a non-significant trend for improvement, whereas measures of duration showed little change at two weeks. Initiation of the pharyngeal swallow showed a predominance for onset at the level of the pyriform fossae with no significant change at two weeks. A residue collection (MBSImP score of 2) was seen most frequently for oral and pharyngeal residue, with little significant change at two weeks. Number of swallows to clear was not significantly different at two week but there was a trend for few clearer swallows for the 50ml bolus.

# Conclusions

This study, which conducted *additional* measurements of kinematic and residue analysis on the STEPS data did not detect 'missed' improvements in swallowing function that the PAS is not designed to measure. However, one cannot yet conclude from this that only using the PAS as an outcome measure alone is sufficient as more studies are required with greater numbers. Longitudinally, safety and timing measures showed trends for improvements, efficiency measures showed a slight improvement and no change was seen in measures of duration.  Comprehensive analysis of

swallowing using all components (safety, timing and clearance) is important to detect change in swallowing function but can be time consuming.

## 5.1 Introduction

As discussed in Chapter One, dysphagia is associated with poorer outcomes.[18, 19] Despite this, there are few proven treatments for post-stroke (PSD) dysphagia and a need for more evidence to show interventions are effective. [37] Swallowing is a highly complex bodily function comprising multiple components of extremely precise, rapid and often overlapping events, and is frequently assessed using the Penetration Aspiration Scale (PAS).[66] However, the PAS is complicated by high intra-subject variability, [44, 94, 103] a lack of standardised methods on which PAS scores to analyse and variability in statistical methods used to analyse the chosen scores. [201] Furthermore, the PAS only measures one aspect of swallowing, i.e. direction of bolus flow and does not consider collective measures of speed and duration (bolus timing) and efficiency (bolus clearance). [60] As highlighted in Chapter One, using multiple measures of swallowing may provide a more complete measure of swallowing function. [60, 110] Pharyngeal electrical stimulation (PES) is a potential treatment for PSD and has been used in several published studies to date. [41, 42, 44, 174] The largest of these was the STEPS trial. [44] This trial only compared swallowing safety using PAS. The principal aim therefore of this chapter, was to investigate the effect of PES on multiple measures of both speed and duration (timing) and efficiency (clearance) as well as safety (PAS) by conducting a retrospective analysis on the STEPS data. [44]

## 5.2 Methods

### 5.2.1 Participants and videofluoroscopy swallowing studies

Data from the STEPS trial was used to carry out the analysis as detailed in Chapter Three, section 3.2.1. In the original STEPS trial, a follow-up VFS was conducted at weeks 2 and 12. In the STEPS study, the primary outcome was the reduction in the mean PAS score of all boluses between baseline and VFS at 2 weeks. In the current study, participants who were randomised to the active (PES) group or sham group, and who had a baseline and two-week VFSS were included. As highlighted in Chapter Three, only participants with VFSS data recorded at a frame rate of ≥25fps were included in the analysis. Files were viewed in Quick Time 7 (Apple Inc, USA) using frame-by-frame analysis.

### 5.2.2 Safety, timing and clearance measures

The measures detailed in Chapter Three were performed on the data and are summarised in Table 5.1 for ease of reference and then discussed in further detail as appropriate.

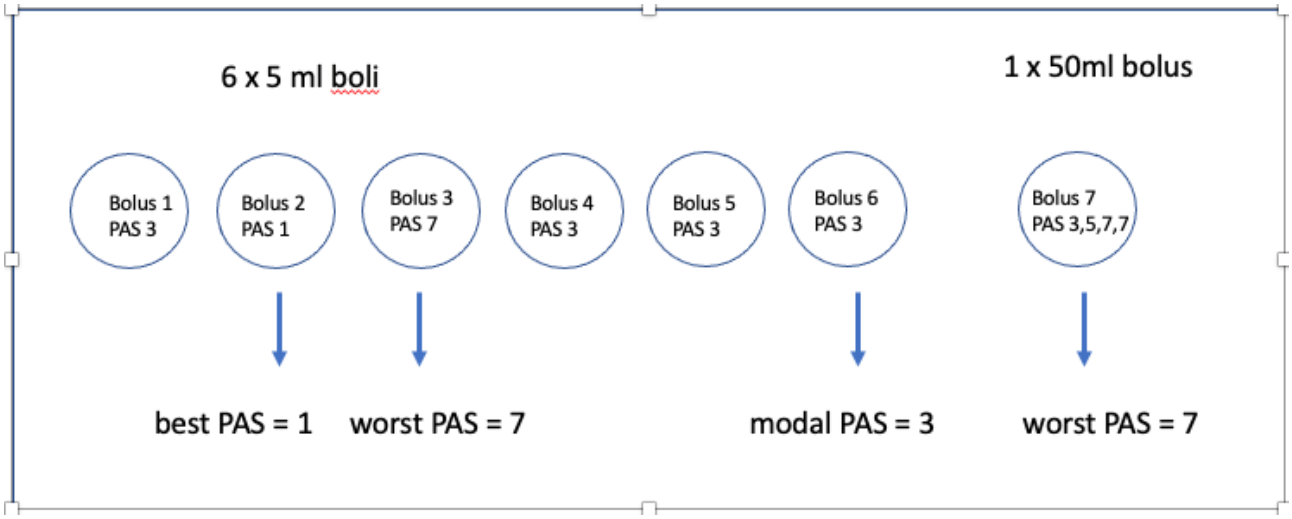
**Table 5-1** Summary of measures carried out on 3 selected 5ml boluses and 50ml bolus

| **Measure** | **Component** |
|---|---|
| 5ml scoring design | Mode bolus, worst bolus, best bolus |
| 5ml timing measures | Global Oral Transit Time (gOTT) |
| | Stage Transition Duration (STD) |
| | Initiation of pharyngeal swallow (IPS) |
| | Initiation of Laryngeal Closure (ILC) |
| | Laryngeal Vestibule Closure- reaction time (LVCrt) |
| | Laryngeal Closure Duration (LCD) |
| | Pharyngeal Response Time (PRT) |
| | Pharyngeal Transit Time (PTT) |
| | Upper Oesophageal Sphincter Duration (UOSD) |
| 5ml clearance measures | Oral residue (OR) |
| | Pharyngeal residue (PR) |
| | Number of swallows to clear 5ml bolus |
| 5ml swallow type | Primary, consecutive or sequential |
| 5ml timing of penetration/ aspiration | Primary or secondary aspiration |
| 50ml scoring design | Worst bolus |
| 50ml timing measures | Initiation of pharyngeal swallow (IPS) |
| 50ml clearance measures | Oral residue (OR) |
| | Pharyngeal residue (PR) |
| | Number of swallows to clear 50ml bolus |
| 50ml swallow type | Consecutive, sequential or mixed |
| 50ml timing of penetration/ aspiration | Primary or secondary aspiration |

### 5.2.2.1 Safety measures

As discussed in Chapter Three, every swallow performed to clear each 6 x 5ml bolus, i.e., primary and secondary (clearing swallows) was given a PAS score. By way of brief recall, the highest PAS score from each 5ml bolus was identified, resulting in 6 PAS scores. Of these, the mode PAS, the worst PAS and the best PAS were chosen for further analysis. The worst PAS score from the 50ml bolus was also chosen for further analysis. The mean PAS score for all 6 x 5ml boluses was calculated for comparison, as was the mean of the 50ml bolus. This scoring design for both 5ml and 50 ml boluses is depicted in Figure 5.1.

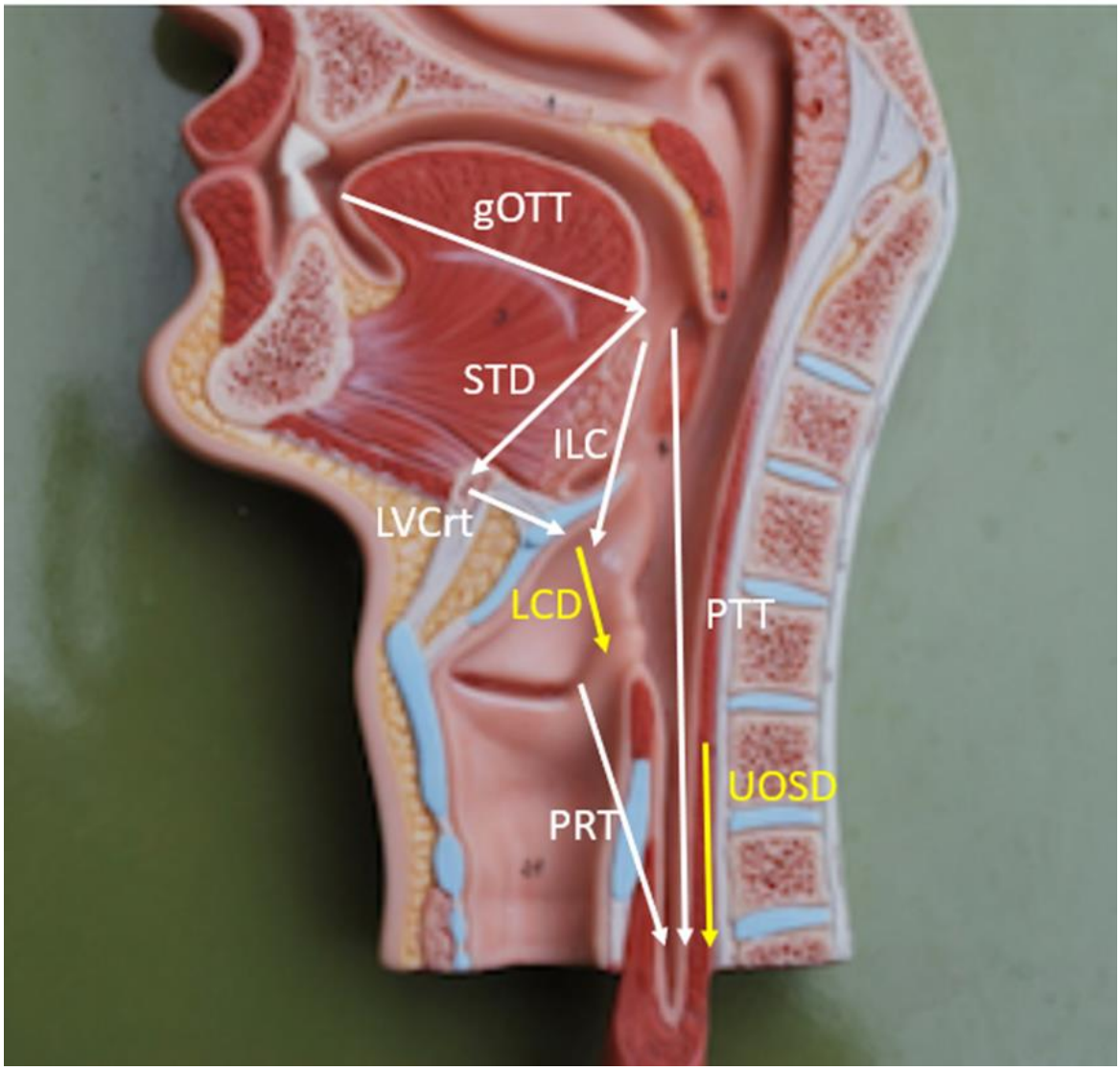
**Figure 5-1** Scoring design for measures of aspiration




### 5.2.2.2 Timing and clearance measures

The timing measures detailed in Chapter Three and listed above in Table 5.1 are shown below in Figure 5.2 in order to provide a context for the range of timings that were measured in the oropharyngeal cavity. Please refer to Chapter Three, Table 3.3 for detailed operational definitions of these timings.

**Figure 5-2** Depiction of timings in oropharyngeal cavity




Taken from flickr.com, John Campbell, public domain, copyright free. White arrows represent measures of speed and yellow arrows represent measures of duration.)

### 5.2.3 Swallow type and allocation of penetration or aspiration (P/A)

As discussed in Chapter Three, each swallow was coded according to the pattern observed. Please refer to Chapter Three, Table 3.1 for details of swallow types and Chapter Three, section 3.4.4 and Table 3.2 for details of how penetration and aspiration were scored.

### 5.2.4 Statistical analysis

Baseline characteristics and baseline VFSS measures of participants were determined using descriptive statistics. The Chi-Square Test and Fisher's Exact Probability Test (binary and ordinal variables) and Welch's T Test (continuous variables) were used to test for significant differences between the groups at baseline. The primary outcome at two weeks was safety, timing and clearance measures of the 5ml mode bolus and secondary outcomes were the same measures for the best and worst 5ml bolus and the worst 50ml bolus. The score changes from baseline to two weeks for each group (PES versus sham) were calculated and compared using the Independent T-Test (unequal variances assumed) for timing (continuous) measures, the Mann-Whitney U Test for clearance (ordinal) measures and Chi-Square Test for nominal measures. Both groups' scores were also combined together at baseline and two weeks. They were then compared using the Wilcoxon Signed Rank Test (as most of the data was not normally distributed) for continuous and ordinal data and McNemar's Test for binary data to look at frequency distributions and longitudinal changes, respectively.

## 5.3 Results

### 5.3.1 Participants and videofluoroscopy swallowing studies

In the original dataset, 162 participants were randomised. Of those, 126 participants received PES or sham and had both a VFSS completed at baseline and 2 weeks. This group comprised the primary outcome population in the STEPS study and were also used as the primary group for the current study. Further analysis revealed that 42 participants in this group had VFSS data recorded at a frame rate <25fps, two files were missing, and one file was unanalysable. These files were excluded from this study (the excluded group). This resulted in a final total of 81 files (64.3%) in the timings and clearance analysis for this study (the included group). In this included group, 71 files (88%) were recorded at a frame rate of 25fps and 10 files (12%) were recorded at 30fps. Figure 5.3 details the breakdown of frame rates for all files (N=126).

**Figure 5-3** Distribution of frame rates (N=126) at 2 weeks

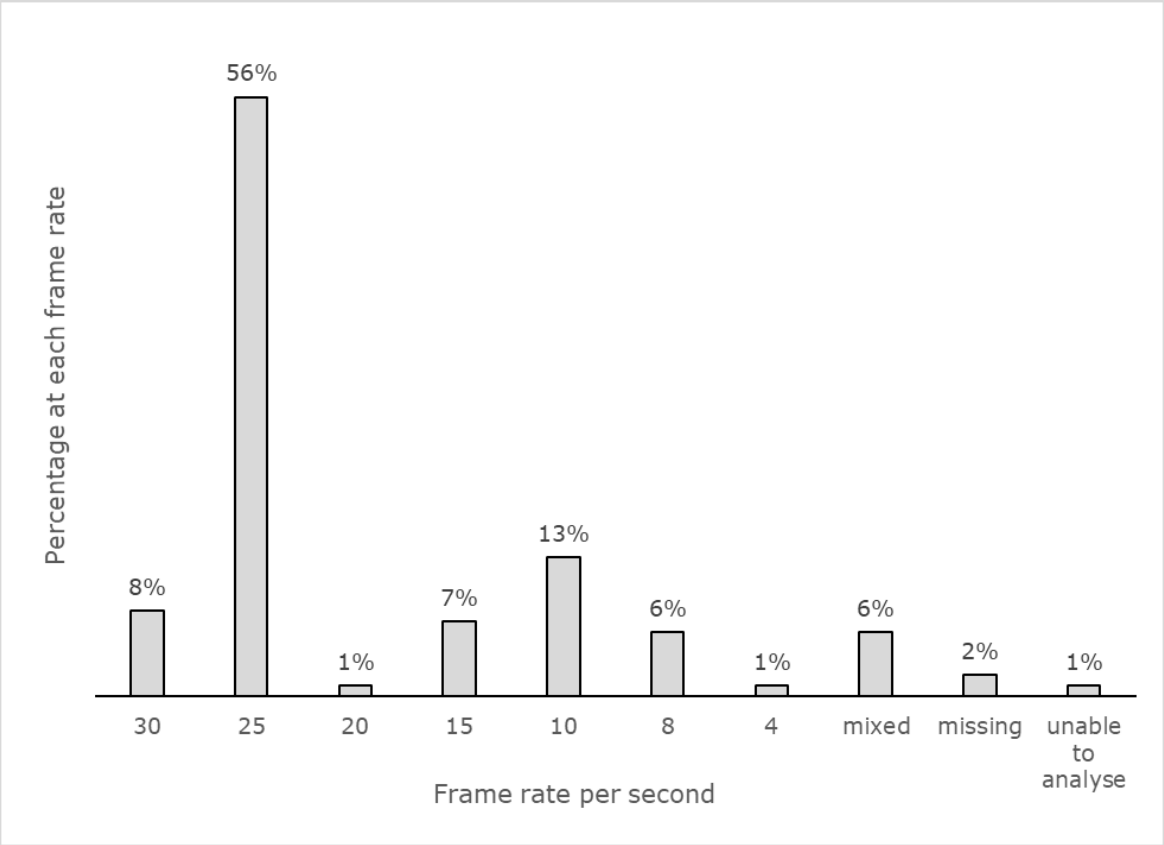



Table 5.2 details the baseline characteristics of the excluded group (N=45) versus the included group (N=81). No significant differences were apparent between these groups at baseline, except for ethnicity. Table 5.2 also details the baseline characteristics of the included group (N=81), according to PES (N=43) and sham (N=38). At baseline, the sham group were more dependant (modified Rankin Score; P=0.032) and more disabled (Barthel Index; P=0.032). However, clinical dysphagia severity (Dysphagia Severity Rating Scale) [42] and feeding route were similar between the groups, i.e. P=0.49 and P=0.06, respectively.

**Table 5-2** Baseline characteristics for participants in STEPS: excluded vs included (N =126); included (N = 81, PES vs sham). Data are number (%), median [interquartile range], or mean (standard deviation). Comparison by Chi-Square (Exact) Test/ Fisher's Exact Test (binary/ ordinal variables) or Welch's T Test (continuous variables)

| | **N** | **All** | **Excluded** | **Included** | **p** | **N** | **PES** | **Sham** |
|---|---|---|---|---|---|---|---|---|
| Patients | 126 | | 45 | 81 | | 81 | 43 | 38 |
| Age, y | 126 | 73.4 (11.4) | 73.3 (11.8) | 73.4 (11.2) | 0.98 | 81 | 72.8 (10.0) | 74.1 (12.5) |
| Sex, female (%) | 126 | 49 (38.9) | 15 (33.3) | 34 (42.0) | 0.45 | 81 | 21 (48.8) | 13 (34.2) |
| Ethnicity, white (%) | 126 | 108 (85.7) | 43 (95.6) | 65 (80.2) | **0.031** | 81 | 39 (90.7) | 36 (94.7) |
| Modified Rankin Scale (/6) | 126 | 4.1 (1.0) | 4.0 (1.1) | 4.1 (1.0) | 0.47 | 81 | 3.9 (1.0) | 4.4 (0.9) |
| Barthel Index (/100) | 126 | 28.9 (29.8) | 31.4 (30.8) | 27.4 (29.4) | 0.48 | 81 | 33.8 (32.7) | 20.1 (23.4) |
| Stroke | | | 3 (6.7) | 12 (14.8) | 0.25 | 81 | 43 | 37 |
| Previous (%) | 126 | 15 (11.9) | | | | | 9 (20.9) | 3 (7.9) |
| Type, ischaemic (%) | 110 | 96 (87.3) | 32 (86.5) | 64 (87.7) | 1.00 | 73 | 33 (86.8) | 31 (88.6) |
| Side of CT lesion (%) | 123 | | | | 0.25 | 80 | 43 | 37 |
| Left | | 55 (44.7) | 20 (46.5) | 35 (43.8) | | | 19 (44.2) | 16 (43.2) |
| Right | | 50 (40.7) | 14 (32.6) | 36 (45.0) | | | 18 (41.9) | 18 (48.6) |
| No lesion | | 18 (14.6) | 9 (20.9) | 9 (11.3) | | | 6 (14.0) | 3 (8.1) |
| Syndrome (%) | 126 | | | | 0.31 | 81 | | |

| | N | All | Excluded | Included | p | N | PES | Sham |
|---|---|---|---|---|---|---|---|---|
| TACS | | 35 (27.8) | 13 (28.9) | 22 (27.2) | | | 11 (25.6) | 11 (28.9) |
| PACS | | 49 (38.9) | 14 (31.1) | 35 (43.2) | | | 21 (48.8) | 14 (36.8) |
| LACS | | 41 (32.5) | 17 (37.8) | 24 (29.6) | | | 11 (25.6) | 13 (34.2) |
| POCS | | 1 (0.8) | 1 (2.2) | 0 (0) | | | 0 (0) | 0 (0) |
| Severity, NIHSS (/42) | 126 | 10.1 (6.5) | 9.5 (7.3) | 10.4 (6.0) | 0.48 | 81 | 10.1 (6.1) | 10.8 (5.9) |
| Dysphasia, NIHSS (%) | 126 | 44 (34.9) | 13 (28.9) | 31 (38.3) | 0.33 | 81 | 17 (39.5) | 14 (36.8) |
| Onset to randomisation (days) mean (SD) | 126 | 16.2 (9.9) | 15.2 (8.3) | 16.8 (10.7) | 0.33 | 81 | 15.4 (10.3) | 18.4 (11.1) |
| Median [IQR] | | 14 [11] | 15.0 [12] | 14.0 [16] | | | 15.5 [15] | 13.0 [13] |
| DSRS (/12) | 126 | 7.4 (3.7) | 7.8 (3.7) | 7.1 (3.7) | 0.35 | 81 | 7.4 (4.0) | 6.8 (3.2) |
| TOR-BSST, failed (%) | 126 | 122 (96.8) | 45 (100) | 77 (95.1) | 0.30 | 81 | 41 (95.3) | 36 (94.7) |
| Feeding Route (%) | 126 | | | | 0.14 | 81 | 43 | 38 |
| Oral, normal diet | | 7 (5.6) | 5 (11.1) | 2 (2.5) | | | 2 (4.7) | 0 (0) |
| Oral, soft diet | | 36 (28.6) | 9 (20.0) | 27 (33.3) | | | 13 (30.2) | 14 (36.8) |
| Nasogastric | | 70 (55.6) | 27 (60.0) | 43 (53.1) | | | 25 (58.1) | 18 (47.4) |
| PEG | | 2 (1.6) | 0 (0) | 2 (2.5) | | | 2 (4.7) | 0 (0) |
| Other | | 11 (8.7) | 4 (8.9) | 7 (8.6) | | | 1 (2.3) | 6 (15.8) |

| | N | All | Excluded | Included | p | N | PES | Sham |
|---|---|---|---|---|---|---|---|---|
| Weight (kg) | 126 | 73.0 (16.1) | 74.1 (16.5) | 72.4 (15.9) | 0.58 | 81 | 71.5 (14.8) | 73.4 (17.2) |
| Body Mass Index ($kg/m^2$) | 122 | 25.6 (4.9) | 25.7 (4.9) | 25.5 (4.9) | 0.88 | 77 | 25.8 (4.3) | 25.3 (5.5) |
| Mid-arm circumference (cm) | 125 | 28.5 (3.6) | 28.2 (3.4) | 28.6 (3.7) | 0.61 | 80 | 28.3 (3.4) | 28.9 (4.0) |
| Albumin (g/L) | 120 | 3.6 (0.6) | 3.6 (0.6) | 3.7 (0.5) | 0.44 | 77 | 3.7 (0.6) | 3.6 (0.5) |
| Chest infection (%) | 126 | 5 (4.0) | 3 (6.7) | 2 (2.5) | 0.35 | 81 | 1 (2.3) | 1 (2.6) |

CT: computed tomography; TACS: total anterior circulation stroke; PACS: partial anterior circulation stroke; LACS: lacunar stroke; POCS: posterior circulation syndrome; NIHSS: National Institutes of Health Stroke Scale; DSRS: dysphagia severity rating scale; TOR-BSST: Toronto Bedside Swallowing Screening Test; PEG: percutaneous endoscopic gastrostomy.

Fifteen hospital sites (Figure 5.4) were included in the study out of a possible eighteen that had VFSS results at both baseline and two weeks. Most sites contributed <10% of the overall data whilst one site contributed 37% of data. A significant number of measures were unable to be calculated due to poor imaging quality and on occasions, reduced field of view. This affected the final numbers for statistical analysis as calculating the change of score required data to be available from both baseline and two-week time-points. In addition, as each component comprised two measures at each time-point (for example, STD comprised measures for bolus head at ramus and hyoid onset), for a dataset to be complete, four measures were required in total for each participant. The breakdown of sites by country is shown in Figure 5.5.

**Figure 5-4** Percentage of included VFSS files (N=81) entered into study at each of 15 hospital sites at 2 weeks

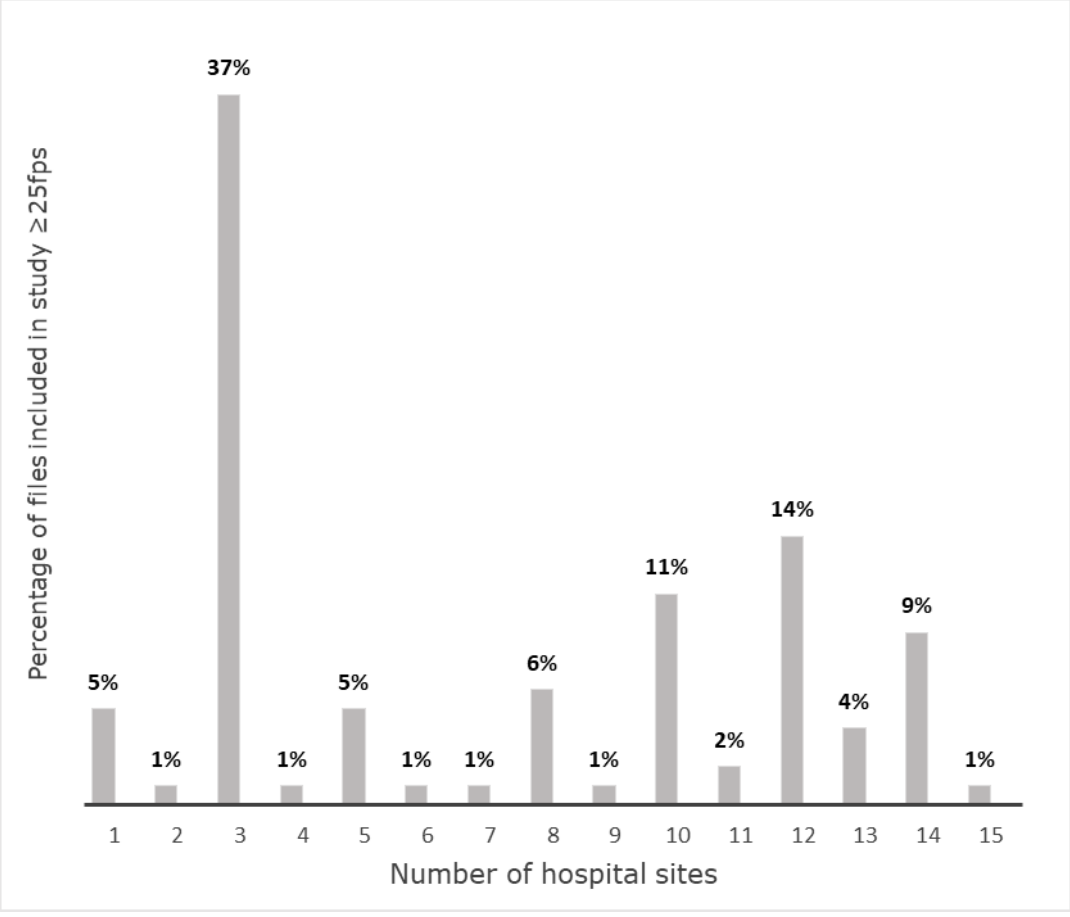
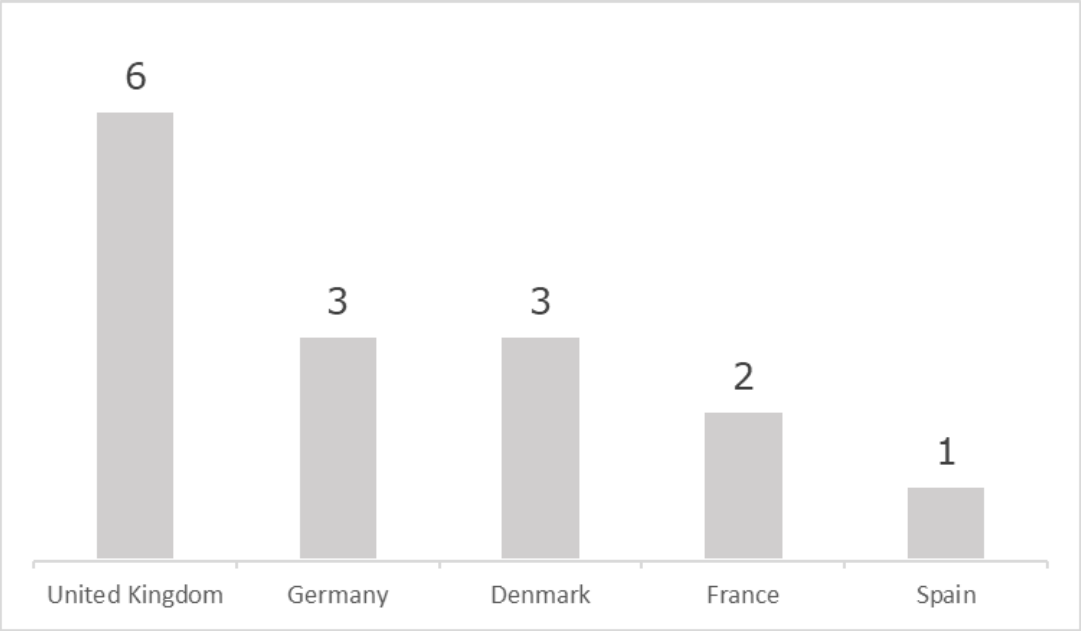


**Figure 5-5** Number of hospital sites per country




## 5.3.2 Safety, timing and clearance measures: Mode bolus: primary outcome measure

### 5.3.2.1 Baseline scores

When comparing outcomes between the PES versus sham group (Table 5.3 below), at baseline, there were no significant differences except for LCD (P=0.039), which was shorter in the sham group and number of swallows to clear 5ml (P=0.048), which were less in the sham group.

**Table 5-3** VFSS measures at baseline for 5ml mode bolus. Data are number (%) or mean (SD); comparison by Chi-Square (Exact) Test/ Fisher's Exact Test or Welch's T Test

| **5ml - mode swallow** | **N** | **All** | **PES** | **Sham** |
|---|---|---|---|---|
| PAS, mode bolus | 72 | 4.4 (2.9) | 4.3 (3.1) [38] | 4.5 (2.6) [34] |
| PAS, mean all boluses /6 | 72 | 4.5 (1.8) | 4.4 (1.9) [38] | 4.7 (1.7) [34] |
| OTT (s) | 40 | 2.14 (3.39) | 2.65 (4.14) [25] | 1.30 (1.16) [15] |
| STD | 62 | 2.07 (6.55) | 2.32 (8.53) [33] | 1.77 (3.20) [29] |
| ILC | 56 | 2.55 (6.87) | 2.91 (9.08) [29] | 2.16 (3.29) [27] |
| LVCrt | 57 | 0.38 (0.15) | 0.39 (0.17) [29] | 0.38 (0.12) [28] |
| LCD | 56 | 0.44 (0.21) | **0.50 (0.25)** [28] | **0.39 (0.13)** [28] |
| PRT | 36 | 0.86 (0.12) | 0.89 (0.13) [20] | 0.82 (0.10) [16] |
| PTT | 37 | 3.73 (8.36) | 4.29 (10.88) [20] | 3.06 (3.96) [17] |
| UOSD | 38 | 0.62 (0.16) | 0.65 (0.17) [20] | 0.59 (0.13) [18] |
| No swallows to clear | 72 | 2.1 (1.1) | **2.3 (1.1)** [38] | **1.8 (1.0)** [34] |
| Initiation of pharyngeal swallow | 69 | | 37 | 32 |
| Ramus | | 10 (14.5) | 5 (13.5) | 5 (15.6) |
| Valleculae | | 12 (17.4) | 10 (27.0) | 2 (6.3) |
| Laryngeal surface | | 8 (11.6) | 2 (5.4) | 6 (18.8) |
| Pyriforms | | 39 (56.5) | 20 (54.1) | 19 (59.4) |
| No visible initiation | | 0 (0) | 0 (0) | 0 (0) |
| Oral residue | 56 | | 28 | 28 |
| Complete clearance | | 0 (0) | 0 (0) | 0 (0) |
| Trace residue | | 12 (21.4) | 9 (32.1) | 3 (10.7) |
| Residue collection | | 42 (75.0) | 18 (64.3) | 24 (85.7) |
| Majority bolus remain | | 1 (1.8) | 1 (3.6) | 0 (0) |
| Minimal/ no clearance | | 1 (1.8) | 0 (0) | 1 (3.6) |
| Pharyngeal residue | 63 | | 34 | 29 |
| Complete clearance | | 4 (6.3) | 3 (8.8) | 1 (3.4) |
| Trace residue | | 19 (30.2) | 11 (32.4) | 8 (27.6) |
| Residue collection | | 39 (61.9) | 19 (55.9) | 20 (69.0) |
| Majority bolus remain | | 0 (0) | 0 (0) | 0 (0) |
| Minimal/ no clearance | | 1 (1.6) | 1 (2.9) | 0 (0) |
| Swallow type | 72 | | 38 | 34 |
| Primary | | 61 (84.7) | 31 (81.6) | 30 (88.2) |
| Consecutive | | 9 (12.5) | 5 (13.2) | 4 (11.8) |
| Sequential sip | | 2 (2.8) | 2 (5.3) | 0 (0.0) |
| Primary aspiration | | 61 (84.7) | 31 (81.6) | 30 (88.2) |
| Secondary aspiration | | 11 (15.3) | 7 (18.4) | 4 (11.8) |

#### 5.3.2.2 Week two scores

One calculates the change score by subtracting the week two score from the baseline score and then running the appropriate statistical test. In Table 5.4 below, a negative score change for timing measures (viewed in the difference column) indicates that a greater change has taken place in the PES group. When comparing the change score at 2 weeks (Table 5.6), statistically, there were no significant differences between the groups for any safety, timing or efficiency measures. Likewise, distribution of swallow type and type of penetration/ aspiration were similar between the groups.

A non-significant trend for greater change in the PAS score in the mode bolus and in most measures of speed were observed in the PES group (except for PRT which showed no change in either group). For duration measures, minimal change was seen. There was also a trend for a prompter IPS in the PES group. There were no obvious trends for residue between the two groups.

**Table 5-4** Comparison of PAS, timing and clearance measures for 5ml mode bolus, by change score from baseline to two weeks, using Independent Samples T Test (continuous variable, seconds), Mann Whitney U Test (ordinal variables, 0-4) and Chi-Squared Test (nominal variables). Timing measures are seconds and ordinal measures are 0-4.

| **5ml– mode swallow (s)** | **N** | **PES mean (SD)** | **N** | **No PES mean (SD)** | **Difference (95% CI)** | ***P* Value** |
|---|---|---|---|---|---|---|
| PAS, mode bolus | 38 | -1.45 (3.06) | 33 | -0.85 (2.54) | -0.60 (-1.93, 0.73) | 0.37 |
| PAS, mean all boluses /6 | 38 | -0.99 (1.66) | 34 | -0.95 (1.58) | -0.04 (-0.80, 0.72) | 0.91 |
| OTT (s) | 20 | -0.64 (1.83) | 9 | -0.51 (1.37) | -0.13 (-1.41, 1.14) | 0.83 |
| STD | 28 | -1.98 (8.94) | 27 | -1.05 (3.39) | -0.92 (-4.60, 2.76) | 0.62 |
| ILC | 24 | -2.04 (9.73) | 24 | -1.17 (3.55) | -0.87 (-5.19, 3.45) | 0.68 |
| LVCrt | 25 | -0.07 (0.15) | 25 | -0.01 (0.19) | -0.07 (-0.17, 0.03) | 0.18 |
| LCD | 22 | 0.04 (0.18)) | 25 | -0.00 (0.19) | 0.04 (-0.07, 0.15) | 0.43 |
| PRT | 15 | 0.01 (0.16) | 9 | 0.01 (0.08) | -0.00 (-0.10, 0.10) | 0.97 |
| PTT | 15 | -3.66 (12.12) | 10 | -1.49 (5.26) | -2.17 (-9.55, 5.21) | 0.55 |
| UOSD | 15 | 0.03 (0.15) | 10 | 0.00 (0.09) | 0.03 (-0.07, 0.13) | 0.58 |
| No swallows to clear | 38 | 0.11 (1.39) | 33 | 0.12 (1.22) | -0.02 (-0.63, 0.60) | 0.96 |
| Initiation of pharyngeal swallow (0-4) | 36 | 0 [2] | 32 | 0 [1] | -0.5 (-1,0) | 0.52 |
| Ramus | | 8 (22.2) | | 5 (15.6) | | |
| Valleculae | | 6 (16.7) | | 2 (6.3) | | |
| Laryngeal surface | | 5 (13.9) | | 3 (9.4) | | |
| Pyriforms | | 17 (47.2) | | 22 (68.8) | | |
| No visible initiation | | 0 (0.0) | | 0 (0.0) | | |
| Oral residue (0-4) | 22 | 0 [0] | 23 | 0 [0] | -0.5 (-1,0) | 0.64 |
| Complete clearance | | 0 (0.0) | | 0 (0.0) | | |
| Trace residue | | 7 (31.8) | | 5 (21.7) | | |
| Residue collection | | 14 (63.6) | | 18 (78.3) | | |
| Majority bolus remain | | 1 (4.5) | | 0 (0.0) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0.(0.0) | | |
| Pharyngeal residue (0-4) | 31 | 0 [0] | 29 | 0 [1] | 0 (-1,0) | 0.53 |
| Complete clearance | | 2 (6.5) | | 0 (0.0) | | |
| Trace residue | | 11 (35.5) | | 14 (48.3) | | |
| Residue collection | | 18 (58.1) | | 15 (51.7) | | |
| Majority bolus remain | | 0 (0.0) | | 0.(0.0) | | |

| 5ml– mode swallow (s) | N | PES mean (SD) | N | No PES mean (SD) | Difference (95% CI) | *P* Value |
|---|---|---|---|---|---|---|
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |
| Swallow type | 38 | | 33 | | 1.0 (1.000, 1.000) | 0.62 |
| Primary | | 34 (89.5) | | 32 (97.0) | | |
| Consecutive | | 3 (7.9) | | 1 (3.0) | | |
| Sequential | | 1 (2.6) | | 0 (0.0) | | |
| Primary aspiration | | 33 (86.8) | | 28 (84.8) | 0.7 (0.713; 0.731) | 0.70 |
| Secondary aspiration | | 5 (13.2) | | 5 (15.2) | | |

### 5.3.3 Worst bolus

#### 5.3.3.1 Baseline scores

For the worst bolus, at baseline (Table 5.5), there were significant differences in PRT (P=0.003) which was quicker in the sham group and UOSD (P= 0.001), which was shorter in the sham group.

**Table 5-5** VFSS measures at baseline for 5ml worst bolus. Data are number (%) or mean (SD); comparison by Chi-square / Fisher's Exact Test or Welch's T Test (unpooled test). Timing measures are seconds and ordinal measures are 0-4.

| 5ml, worst swallow | N | All | PES | Sham |
|---|---|---|---|---|
| PAS, worst swallow | 72 | 6.4 (2.3) | 6.4 (2.4) [38] | 6.4 (2.3) [34] |
| PAS, mean all boluses /6 | 72 | 4.5 (1.8) | 4.4 (1.9) [38] | 4.7 (1.7) [34] |
| OTT (s) | 34 | 1.32 (1.65) | 1.59 (1.97) [20] | 0.93 (0.98) [14] |
| STD | 61 | 1.36 (1.78) | 1.23 (1.61) [33] | 1.52 (1.99) [28] |
| ILC | 55 | 1.81 (1.82) | 1.58 (1.58) [29] | 2.07 (2.06) [26] |
| LVCrt | 59 | 0.45 (0.17) | 0.47 (0.20) [30] | 0.44 (0.13) [29] |
| LCD | 57 | 0.42 (0.3) | 0.50 (0.37) [28] | 0.35 (0.19) [29] |
| PRT | 37 | 0.92 (0.16) | **0.98 (0.17)** [22] | **0.83 (0.10)** [15] |
| PTT | 35 | 2.40 (2.08) | 2.37 (1.91) [21] | 2.46 (2.40) [14] |
| UOSD | 37 | 0.65 (0.14) | **0.71 (0.14)** [22] | **0.57 (0.10)** [15] |
| No swallows to clear | 72 | 2.5 (1.3) | 2.6 (1.4) [38] | 2.3 (1.2) [34] |
| Initiation of pharyngeal swallow (0-4) | 66 | | 34 | 32 |
| Bolus head - ramus | | 14 (21.2) | 8 (23.5) | 6 (18.8) |
| Bolus head - valleculae | | 4 (6.1) | 3 (8.8) | 1 (3.1) |
| Bolus head - laryngeal surface | | 9 (13.6) | 2 (5.9) | 7 (21.9) |
| Bolus head - pyriforms | | 39 (59.1) | 21 (61.8) | 18 (56.3) |
| No visible initiation | | 0 (0.0) | 0 (0.0) | 0 (0) |
| Oral residue (0-4) | 55 | | 30 | 25 |
| Complete clearance | | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Trace residue | | 14 (25.5) | 10 (33.3) | 4 (16.0) |
| Residue collection | | 39 (70.9) | 20 (66.7) | 19 (76.0) |
| Majority bolus remaining | | 1 (1.8) | 0 (0.0) | 1 (4.0) |
| Minimal/ no clearance | | 1 (1.8) | 0 (0.0) | 1 (4.0) |
| Pharyngeal residue (0-4) | 64 | | 34 | 30 |
| Complete clearance | | 3 (4.7) | 3 (8.8) | 0 (0.0) |
| Trace residue | | 20 (31.3) | 10 (29.4) | 10 (33.3) |
| Residue collection | | 39 (60.9) | 20 (58.8) | 19 (63.3) |
| Majority bolus remaining | | 1 (1.6) | 0 (0.0) | 1 (3.3) |
| Minimal/ no clearance | | 1 (1.6) | 1 (2.9) | 0 (0.0) |
| Swallow type | 72 | | 38 | 34 |

| | | | | |
|---|---|---|---|---|
| Primary | | 63 (87.5) | 34 (89.5) | 29 (85.3) |
| Consecutive | | 8 (11.1) | 3 (7.9) | 5 (14.7) |
| Sequential | | 1 (1.4) | 1 (2.6) | 0 (0.0) |
| Primary aspiration | | 63 (87.5) | 34 (89.5) | 29 (85.3) |
| Secondary aspiration | | 9 (12.5) | 4 (10.5) | 5 (14.7) |

#### 5.3.3.2 Week two scores

As with the modal bolus, when comparing the change score at 2 weeks, statistically, there were no significant differences between the groups for any safety, timing or efficiency measures for the worst swallow, as demonstrated in Table 5.6. As with the mode swallow, distribution of swallow type and type of penetration/ aspiration were similar between the groups although a trend for more secondary aspiration was seen in the sham group of the worst bolus.

There was a non-significant greater change in the PES group for the worst PAS score and a trend for greater change in the sham group for OTT, STD, ILC, PTT. Most other changes in timings were minimal. There was a non-significant trend for a prompter IPS in the PES group. There were no trends seen between the groups for residue.

**Table 5-6** Comparison of PAS, timing and clearance measures for 5ml worst bolus, by change score from baseline to two weeks, using Independent Samples T Test (continuous variables, seconds), Mann Whitney U Test (ordinal variables, 0-4) and Chi-Squared Test (nominal variables). Timing measures are seconds and ordinal measures are 0-4.

| 5ml – worst swallow | N | PES mean (SD) | N | No PES mean (SD) | Difference (95% CI) | *P* Value |
|---|---|---|---|---|---|---|
| PAS, worst bolus | 38 | -1.16 (2.87) | 34 | -0.94 (2.27) | -0.22 (-1.43, 0.99) | 0.72 |
| PAS, mean all boluses /6 | 38 | -0.99 (1.66) | 34 | -0.95 (1.58) | -0.04 (-0.80, 0,72) | 0.91 |
| OTT | 16 | -0.23 (1.92) | 10 | -0.44 (2.02) | 0.21 (-1.46, 1.88) | 0.79 |
| STD | 26 | -0.14 (2.36) | 32 | -0.58 (2.23) | 0.44 (-0.77, 1.64) | 0.47 |
| ILC | 24 | -0.05 (2.33) | 28 | -0.56 (2.20) | 0.50 (-0.76, 1.77) | 0.43 |
| LVCrt | 26 | -0.04 (0.18) | 29 | -0.02 (0.18) | -0.03 (-0.12, 0.07) | 0.60 |
| LCD | 25 | -0.05 (0.51) | 24 | -0.03 (0.19) | -0.02 (-0.25, 0.21) | 0.86 |
| PRT | 16 | -0.09 (0.11) | 8 | -0.05 (0.12) | -0.03 (-0.14, 0.08) | 0.52 |
| PTT | 15 | -0.62 (2.99) | 8 | -1.26 (2.63) | 0.64 (-1.92, 3.20) | 0.60 |
| UOSD | 16 | -0.06 (0.12) | 9 | 0.01 (0.11) | -0.06 (-0.16, 0.04) | 0.19 |
| No swallows to clear | 38 | -0.21 (1.28) | 34 | -0.24 (1.52) | 0.02 (-0.64, 0.69) | 0.94 |
| Initiation of pharyngeal swallow | 32 | | 28 | | | 0.37 |
| Bolus head - ramus | | 9 (28.1) | | 6 (21.4) | | |
| Bolus head - valleculae | | 6 (18.8) | | 0 (0.0) | | |
| Bolus head – laryngeal surface | | 2 (6.3) | | 2 (7.1) | | |
| Bolus head – pyriforms | | 15 (46.9) | | 20 (71.4) | | |
| No visible initiation | | 0 (0.0) | | 0 (0.0) | | |
| Oral residue (0-4) | 25 | | 21 | | | 0.35 |
| Complete clearance | | 2 (8.0) | | 1 (4.8) | | |
| Trace residue | | 7 (28.0) | | 6 (28.6) | | |
| Residue collection | | 15 (60.0) | | 13 (61.9) | | |
| Majority bolus remaining | | 1 (4.0) | | 1 (4.8) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |
| Pharyngeal residue | 32 | | 28 | | | 0.68 |
| Complete clearance | | 2 (6.3) | | 1 (3.6) | | |
| Trace residue | | 14 (43.8) | | 11 (39.3) | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Residue collection | | 16 (50.0) | | 15 (53.6) | | |
| Majority bolus remaining | | 0 (0.0) | | 1 (3.6) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |
| Swallow type | 38 | | 33 | | 0.8 (0.839; 0854) | 0.77 |
| Primary | | 34 (89.5) | | 30 (90.9) | | |
| Consecutive | | 3 (7.9) | | 2 (6.1) | | |
| Sequential | | 1 (2.6) | | 1 (3.0) | | |
| Primary aspiration | | 34 (89.5) | | 25 (75.8) | 0.71 (0.704; 0.721) | 0.65 |
| Secondary aspiration | | 4 (10.5) | | 8 (24.2) | | |

## 5.3.4 Best bolus

### 5.3.4.1 Baseline scores

For the best bolus, at baseline (Table 5.7), the groups were matched except for fewer swallows to clear in the sham group (P = 0.034).

**Table 5-7** VFSS measures at baseline for 5ml best bolus. Data are number (%) or mean (SD); comparison by Chi-square/ Fisher's Exact Test or Welch's T Test (unpooled test). Timing measures are seconds and ordinal measures are 0-4.

| 5ml measures – best swallow | N | All | PES | Sham |
|---|---|---|---|---|
| PAS, best swallow | 73 | 2.2 (2.0) | 2.0 (1.9) [39] | 2.4 (2.1) [34] |
| PAS, mean all boluses /6 | 72 | 4.5 (1.8) | 4.4 (1.9) [38] | 4.7 (1.7) [34] |
| OTT (s) | 36 | 1.70 (2.94) | 1.96 (3.23) [23] | 1.23 (2.41) [13] |
| STD | 64 | 2.0 (6.33) | 2.32 (8.42) [34] | 1.64 (2.44) [30] |
| ILC | 53 | 2.55 (6.92) | 2.86 (9.10) [29] | 2.18 (2.66) [24] |
| LVCrt | 57 | 0.31 (0.14) | 0.28 (0.15) [31] | 0.34 (0.13) [26] |
| LCD | 54 | 0.49 (0.21) | 0.53 (0.21) [28] | 0.45 (0.21) [26] |
| PRT | 36 | 0.87 (0.13) | 0.88 (0.14) [22] | 0.86 (0.11) [14] |
| PTT | 37 | 3.56 (8.18) | 3.93 (10.17) [23] | 2.94 (3.07 [14] |
| UOSD | 38 | 0.61 (0.12) | 0.63 (0.13) [23] | 0.57 (0.11) [15] |
| No swallows to clear | 73 | 2.0 (1.0) | **2.3 (1.1)** [39] | **1.8 (0.8)** [34] |
| Initiation of pharyngeal swallow (0-4) | 67 | | 35 | 32 |
| Bolus head – ramus | | 14 (20.9) | 10 (28.6) | 4 (12.5) |
| Bolus head - valleculae | | 13 (19.4) | 7 (20.0) | 6 (18.8) |
| Bolus head - laryngeal surface | | 9 (13.4) | 5 (14.3) | 4 (12.5) |
| Bolus head - pyriforms | | 31 (46.3) | 13 (37.1) | 18 (56.3) |
| No visible initiation | | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Oral residue (0-4) | 55 | | 29 | 26 |
| Complete clearance | | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Trace residue | | 13 (23.6) | 9 (31.0) | 4 (15.4) |
| Residue collection | | 41 (74.5) | 20 (69.0) | 21 (80.8) |
| Majority bolus remaining | | 1 (1.8) | 0 (0.0) | 1 (3.8) |
| Minimal/ no clearance | | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Pharyngeal residue (0-4) | 69 | | 37 | 32 |
| Complete clearance | | 3 (4.3) | 1 (2.7) | 2 (6.3) |
| Trace residue | | 18 (26.1) | 11 (29.7) | 7 (21.9) |
| Residue collection | | 45 (65.2) | 24 (64.9) | 21 (65.6) |
| Majority bolus remaining | | 2 (2.9) | 0 (0) | 2 (6.3) |

| | | | | |
|---|---|---|---|---|
| Minimal/ no clearance | | 1 (1.4) | 1 (2.7) | 0 (0) |
| Swallow type | 73 | | 39 | 34 |
| Primary | | 64 (87.7) | 34 (87.2) | 30 (88.2) |
| Consecutive | | 8 (11.0) | 4 (10.3) | 4 (11.8) |
| Sequential | | 1 (1.4) | 1 (2.6) | 0 (0.0) |
| Primary aspiration | | 70 (95.9) | 38 (97.4) | 32 (94.1) |
| Secondary aspiration | | 3 (4.1) | 1 (2.6) | 2 (5.9) |

#### 5.3.4.2 Week two scores

As with the mode and worst bolus, when comparing the change score at two weeks, statistically, there were no significant differences between the groups for any safety, timing or efficiency measures for the best bolus as demonstrated in Table 5.8. Distribution of swallow type and type of penetration/ aspiration were also similar between the groups.

Non-significant trends were seen for a greater change in the PES group for OTT, STD and ILC, whilst a trend for shorter PTT and improved safety scores were seen in the sham group. Other changes in timings were minimal. For IPS, no trend was seen. There was a trend for less oral residue in the PES group and less pharyngeal residue in the sham group.

**Table 5-8** Comparison of PAS, timing and clearance measures for 5ml best bolus, by change score from baseline to two weeks, using Independent Samples T Test (continuous variables, seconds), Mann Whitney U Test (ordinal variables, 0-4) and Chi-Squared Test (nominal variables). Timing measures are seconds and ordinal measures are 0-4.

| 5ml measures – best | N | PES mean (SD) | N | No PES mean (SD) | Difference (95% CI) | *P* Value |
|---|---|---|---|---|---|---|
| PAS, best bolus | 39 | -0.18 (1.83) | 33 | -0.88 (2.25) | 0.70 (-0.28, 1.68) | 0.16 |
| PAS, mean all boluses /6 | 38 | -0.99 (1.66) | 34 | -0.95 (1.58) | -0.04 (-0.80, 0,72) | 0.91 |
| OTT | 20 | -0.68 (3.24) | 10 | -0.50 (1.56) | -0.18 (-1.98, 1.62) | 0.84 |
| STD | 32 | -1.44 (8.79) | 28 | -0.80 (2.59) | -0.64 (-3.94, 2.66) | 0.70 |
| ILC | 25 | -1.83 (9.91) | 21 | -1.10 (2.51) | -0.73 (-4.94, 3.49) | 0.73 |
| LVCrt | 27 | -0.01 (0.13) | 22 | -0.03 (0.13) | 0.03 (-0.05, 0.10) | 0.45 |
| LCD | 25 | -0.02 (0.13) | 20 | -0.01 (0.17) | -0.01 (-0.11, 0.08) | 0.75 |
| PRT | 12 | 0.00 (0.12) | 9 | -0.03 (0.13) | 0.03 (-0.08, 0.15) | 0.55 |
| PTT | 13 | -0.20 (2.88) | 9 | -2.01 (3.84) | 1.81 (-1.43, 5.04) | 0.25 |
| UOSD | 13 | 0.04 (0.13) | 10 | 0.00 (0.05) | 0.04 (-0.05, 0.12) | 0.37 |
| Number of swallows to clear | 39 | -0.13 (1.28) | 33 | -0.03 (0.92) | -0.10 (-0.62, 0.42) | 0.71 |
| Initiation of pharyngeal swallow | 34 | | 31 | | | 0.19 |
| Bolus head - ramus | | 9 (26.5) | | 9 (29.0) | | |
| Bolus head - valleculae | | 3 (8.8) | | 3 (9.7) | | |
| Bolus head – laryngeal surface | | 4 (11.8) | | 1 (3.2) | | |
| Bolus head – pyriforms | | 18 (52.9) | | 18 (58.1) | | |
| No visible initiation | | 0 (0.0) | | (0.0) | | |
| Oral residue | 23 | | 23 | | | 0.56 |
| Complete clearance | | 2 (8.7) | | 1 (4.3) | | |
| Trace residue | | 8 (34.8) | | 3 (13.0) | | |
| Residue collection | | 13 (56.5) | | 19 (82.6) | | |
| Majority bolus remaining | | 0 (0.0) | | 0 (0.0) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Pharyngeal residue | 34 | | 31 | | | 0.19 |
| Complete clearance | | 4 (11.8) | | 2 (6.5) | | |
| Trace residue | | 7 (20.6) | | 15 (48.4) | | |
| Residue collection | | 23 (67.6) | | 14 (45.2) | | |
| Majority bolus remaining | | 0 (0.0) | | 0 (0.0) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |
| Swallow type | 39 | | 33 | | 0.56 (0.549; 0.568) | 0.42 |
| Primary | | 34 (87.2) | | 32 (97.0) | | |
| Consecutive | | 3 (7.7) | | 1 (3.0) | | |
| Sequential | | 2 (5.1) | | 0 (0.0) | | |
| Primary aspiration | | 38 (97.4) | | 33 (100.0) | -.78 (0.771; 0.787) | 0.50 |
| Secondary aspiration | | 1 (2.6) | | 0 (0.0) | | |

### 5.3.5 Worst 50ml bolus

#### 5.3.5.1 Baseline scores

For the worst 50ml bolus, no significant differences were seen between the groups at baseline (Table 5.9).

**Table 5-9** VFSS measures at baseline for 50ml bolus (comparison by Chi-square/ Fisher's Exact Test or Welch's T Test (unpooled test)

| 50 ml measures at baseline | N | All | PES | Sham |
|---|---|---|---|---|
| PAS, 50ml worst | 49 | 6.7 (1.8) | 6.6 (1.7) [25] | 6.8 (2.0) [24] |
| PAS, 50ml mean | 49 | 3.6 (1.9) | 3.3 (1.8) [25] | 3.9 (1.9) [24] |
| No. swallows to clear | 49 | 7.8 (5.0) | 8.0 (5.5) [25] | 7.5 (4.6) [24] |
| Initiation of pharyngeal swallow (0-4) | 45 | | 22 | 23 |
| Ramus | | 3 (6.7) | 3 (13.6) | 0 (0.0) |
| Valleculae | | 4 (8.9) | 2 (9.1) | 2 (8.7) |
| Laryngeal surface | | 5 (11.1) | 3 (13.6) | 2 (8.7) |
| Pyriforms | | 33 (73.3) | 14 (63.6) | 19 (82.6) |
| No visible initiation | | 0 (0) | 0 (0.0) | 0 (0.0) |
| Oral residue (0-4_ | 40 | | 22 | 18 |
| Complete clearance | | 0 (0) | 0 (0.0) | 0 (0.0) |
| Trace residue | | 1 (2.5) | 1 (4.5) | 0 (0.0) |
| Residue collection | | 37 (92.5) | 20 (90.9) | 17 (94.4) |
| Majority bolus remaining | | 1 (2.5) | 1 (4.5) | 0 (0.0) |
| Minimal/ no clearance | | 1 (2.5) | 0 (0.0) | 1 (5.6) |
| Pharyngeal residue (0-4) | 43 | | 23 | 20 |
| Complete clearance | | 0 (0) | 0 (0.0) | 0 (0.0) |
| Trace residue | | 10 (23.3) | 7 (30.4) | 3 (15.0) |
| Residue collection | | 31 (72.1) | 14 (60.9) | 17 (85.0) |
| Majority bolus remaining | | 1 (2.3) | 1 (4.3) | 0 (0.0) |
| Minimal/ no clearance | | 1 (2.3) | 1 (4.3) | 0 (0.0) |
| Swallow type | 49 | | 25 | 24 |
| Consecutive | | 35 (71.4) | 21 (84.0) | 14 (58.3) |
| Sequential | | 12 (24.5) | 3 (12.0) | 9 (37.5) |
| Mixed | | 2 (4.1) | 1 (4.0) | 1 (4.2) |
| Primary aspiration | 49 | 41 (83.7) | 22 (88.0) | 19 (79.2) |
| Secondary aspiration | | 8 (16.3) | 5 (12.0) | 3 (20.8) |

#### 5.3.5.2 Week two scores

At two weeks, there was no statistically significant change score for any safety or efficiency measures, or for initiation of the pharyngeal swallow (Table 5.10). There was a trend for minor improvement in the mean 50ml safety score in the sham group. Distribution of swallow type and type of penetration/ aspiration were also similar between the groups. There was a slight trend for improved pharyngeal clearance and a slighter prompter swallow in the PES group with slighter improved oral clearance in the sham group.

**Table 5-10** Comparison of PAS, timing and clearance measures for 50ml bolus, by change score from baseline to two weeks, using Independent Samples T Test (continuous variables) and Mann Whitney U Test (ordinal variables)

| 50 ml measures at 2 weeks | N | PES Mean (SD) | N | No PES Mean (SD) | Difference/ 95% (CI) | *P* Value |
|---|---|---|---|---|---|---|
| PAS, 50ml worst | 24 | -1.04 (2.73) | 22 | -0.95 (3.03) | -0.09 (-1.81, 1.63) | 0.92 |
| PAS, 50ml mean | 24 | -0.42 (1.93) | 22 | -0.64 (1.59) | 0.22 (-0.83, 1.27) | 0.68 |
| No. swallows to clear | 24 | -1.17 (4.30) | 22 | -1.27 (4.92) | 0.11 (-2.65, 2.87) | 0.94 |
| Initiation of pharyngeal swallow (0-4) | 21 | | 20 | | | 0.58 |
| Bolus head - ramus | | 4 (19.0) | | 1 (5.0) | | |
| Bolus head - valleculae | | 0 (0.0) | | 0 (0.0) | | |
| Bolus head – laryngeal surface | | 3 (14.3) | | 5 (25.0) | | |
| Bolus head – pyriforms | | 14 (66.7) | | 14 (70.0) | | |
| No visible initiation | | 0 (0.0) | | 0 (0.0) | | |
| Oral residue (0-4) | 19 | | 15 | | | 0.26 |
| Complete clearance | | 0 (0.0) | | 0 (0.0) | | |
| Trace residue | | 0 (0.0) | | 2 (13.3) | | |
| Residue collection | | 18 (94.7) | | 13 (86.7) | | |
| Majority bolus remaining | | 0 (0.0) | | 0 (0.0) | | |
| Minimal/ no clearance | | 1 (5.3) | | 0 (0.0) | | |
| Pharyngeal residue (0-4) | 21 | | 17 | | | 0.35 |
| Complete clearance | | 0 (0.0) | | 0 (0.0) | | |
| Trace residue | | 7 (33.3) | | 2 (11.8) | | |
| Residue collection | | 14 (66.7) | | 15 (88.2) | | |
| Majority bolus remaining | | 0 (0.0) | | 0 (0.0) | | |
| Minimal/ no clearance | | 0 (0.0) | | 0 (0.0) | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Swallow type | 24 | | 22 | | | |
| Consecutive | | 17 (70.8) | | 15 (68.2) | | |
| Sequential | | 3 (12.5) | | 4 (18.2) | | |
| Mixed | | 4 (16.7) | | 3 (13.6) | | |
| Primary aspiration | 24 | 21 (87.5) | 22 | 20 (90.9) | | |
| Secondary aspiration | | 3 (12.5) | | 2 (9.1) | | |

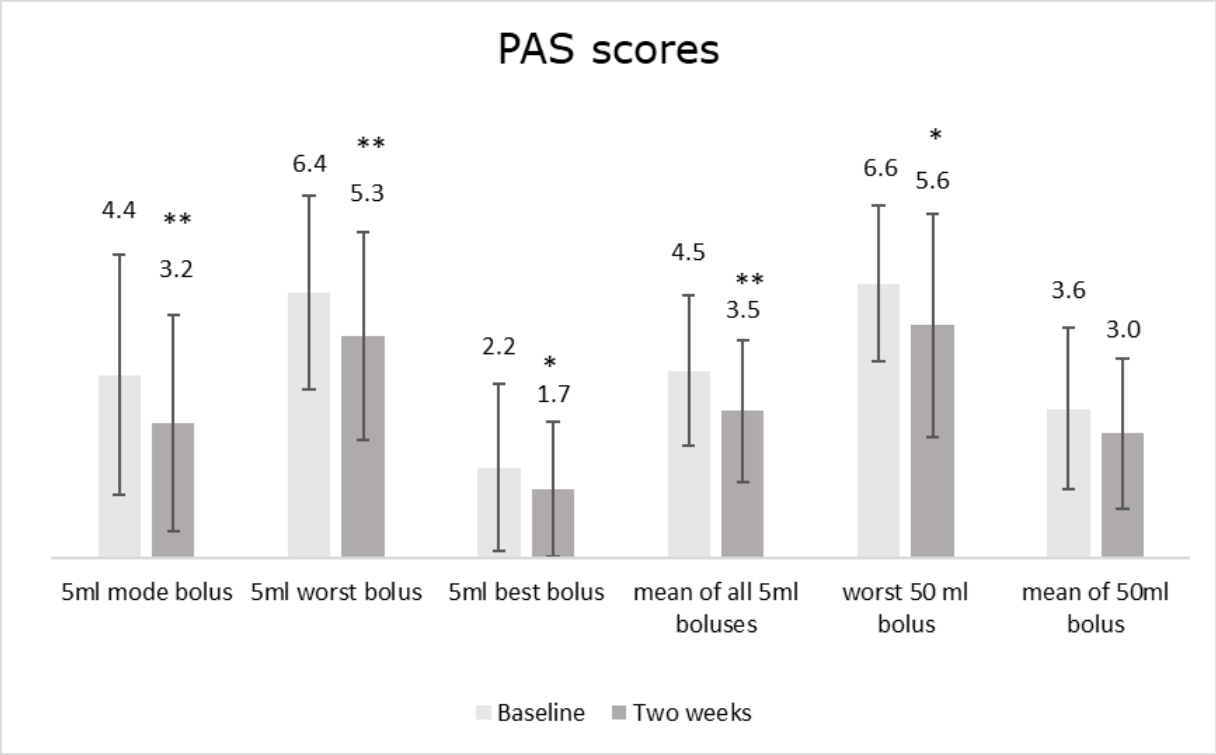
### 5.3.6 General trends in the data

The main objective of this research was to examine the effect of PES on acute stroke patients using multiple measures of safety, timing and efficiency. However, as no significant differences between the two groups was seen at two weeks (between-group difference), the data of both groups was combined and compared at both time points to consider longitudinal changes and look at frequency distribution. Significant results and trends observed in the data are discussed below.

#### 5.3.6.1 Safety measures – PAS scores

As can be seen in the Figure 5.6 below, at two weeks, most scores exhibited a significant improvement (as denoted by *) namely mode bolus ($Z=-3.207$, $p < 0.001$), worst bolus ($Z=-3.255$, $p < 0.001$), best bolus ($Z=-2.049$, $p < 0.040$), mean of 6 boluses ($Z=-4.253$, $p<0.000$) and worst 50ml bolus ($Z=-2.345$, $p < 0.019$). The mean 50ml bolus was not significant ($Z=-1.729$, $p < 0.08$). Of the 5ml boluses, the greatest magnitude of improvement was seen in the mode bolus and the smallest improvement in the best bolus.

**Figure 5-6** Penetration aspiration scores for each condition at baseline and two weeks, data are mean (SD).




* Denotes significant and ** denotes highly significant (P <0.05), mean PAS scores at both timepoints are depicted, PAS score range 1-8

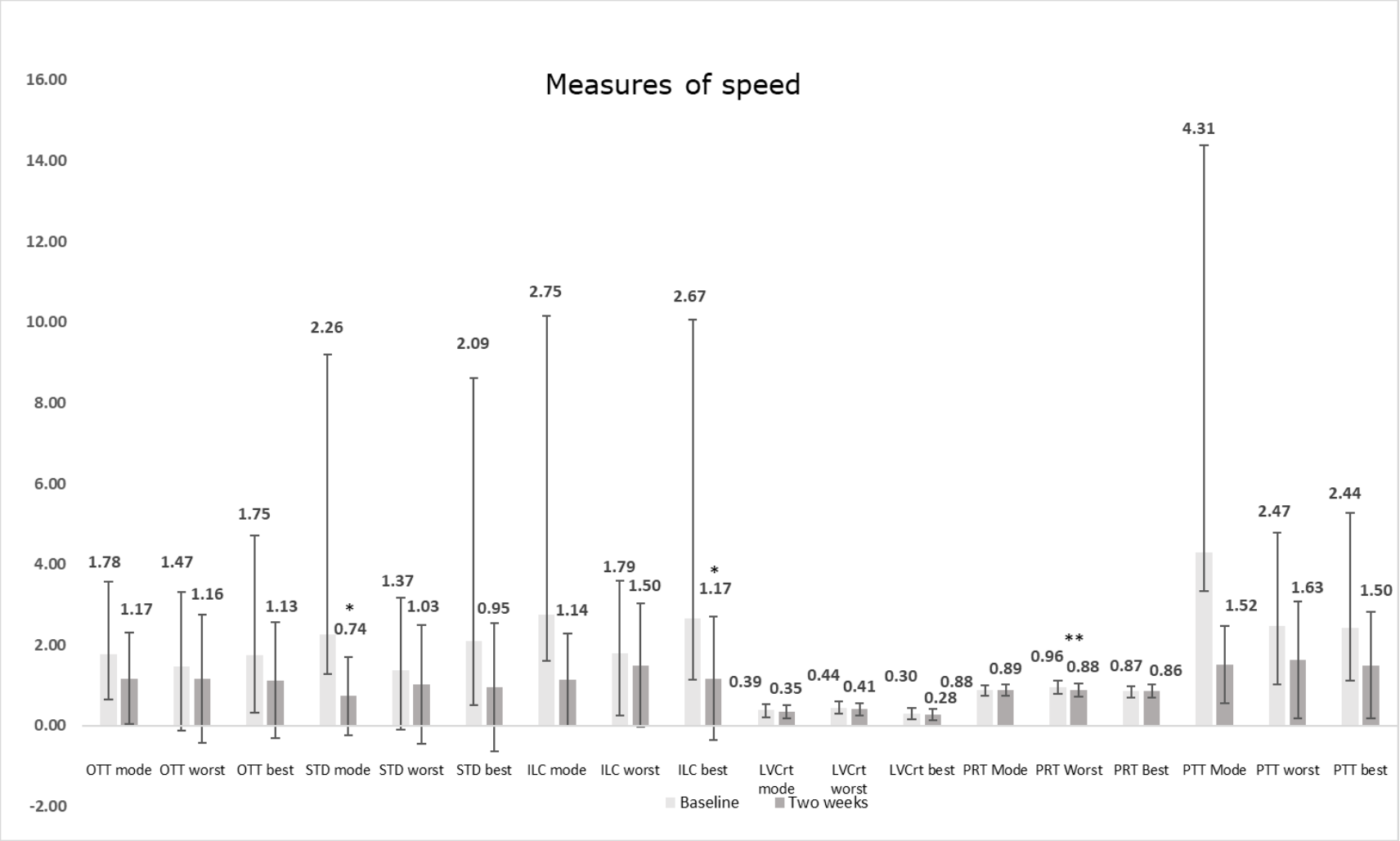
### 5.3.6.2 Measures of speed

Figure 5.7 details timing measures at both timepoints. At two weeks, for OTT, no measures were significant for the mode bolus (Z=-1.46, p< 0.15); worst bolus (Z=-0.53, p<0.59) or best bolus (Z=-1.16, p<0.25). For STD there was a significant improvement at two weeks for the mode bolus (Z=-2.058, p<0.04), but not for the worst bolus (Z=-1.322, p<0.19) or the best bolus (Z=-1.609, p<0.11). For ILC, there were no significant improvements for the mode bolus (Z=1.627, p<0.10) or the worst bolus (Z=-1.269, p<0.20). However, the best bolus was significant (Z=-2.015, p<0.044). For LVCrt, no boluses were significant: mode bolus (Z=-1,589, p<0.11), worst (Z=-0.727, p<0.476) or best

(Z=-1.142, p<0.25) and there was minimal change in scores at both timepoints. PRT was significant for the worst bolus (Z=-2.757, p<0.006) but not significant for the mode bolus (Z=-0.121, p<0.90) or the best bolus (Z=-0.380, p<0.70). For PTT, there were no significant changes for the mode bolus (Z=-1.380, p<0.17), worst bolus (Z=-1.753, p<0.08) or best bolus (Z=-0.800, p<0.42).

Even though most measures were not significant, there was a trend for improvement (i.e., reduced transit times) in OTT, STD, ILC and PTT at two weeks, in contrast to LVCrt and PRT which showed the least amount of change (except for the PRT of the worst bolus).

**Figure 5-7** 5ml timing measures for both groups at baseline and two weeks, data are mean (SD)

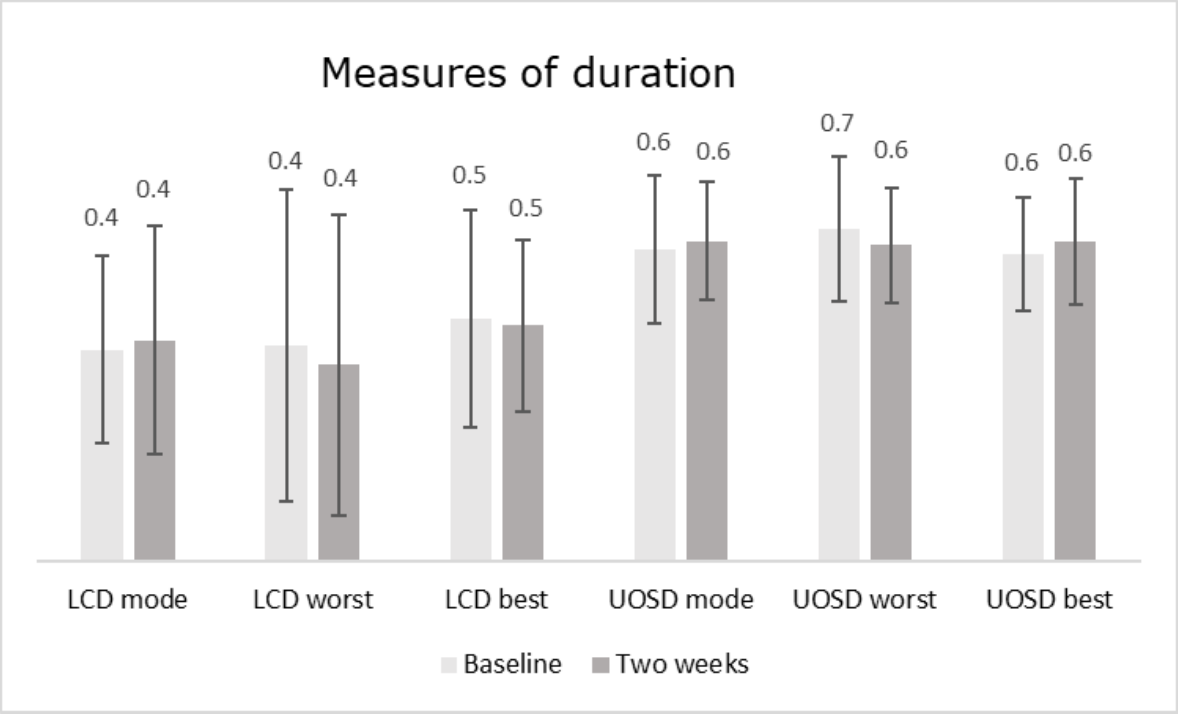



- Denotes significant and ** denotes highly significant (P<0.05); mean timings at both timepoints are in seconds

### 5.3.6.3 Measures of duration

As shown in Figure 5.8, at two weeks, there were no significant changes for LCD for the mode bolus (Z= -0.708, p<0.48), the worst bolus (Z=-0.883, p< 0.38) or the best bolus (Z=-0.200, p<0.84), nor for UOSD for the mode bolus (Z=-0.610, p<0.54), the worst bolus (Z=-1.442, p<0.15) or the best bolus (Z=-1.134, p<0.26). Overall, there was marginal change between these measures with a mixed direction of change (LCD shortened at two weeks in the worst and best boluses and UOSD shortened at two weeks in the worst boluses) although these changes were essentially, very minimal.

**Figure 5-8** 5ml duration measures for both groups at baseline and two weeks, data are mean (SD)

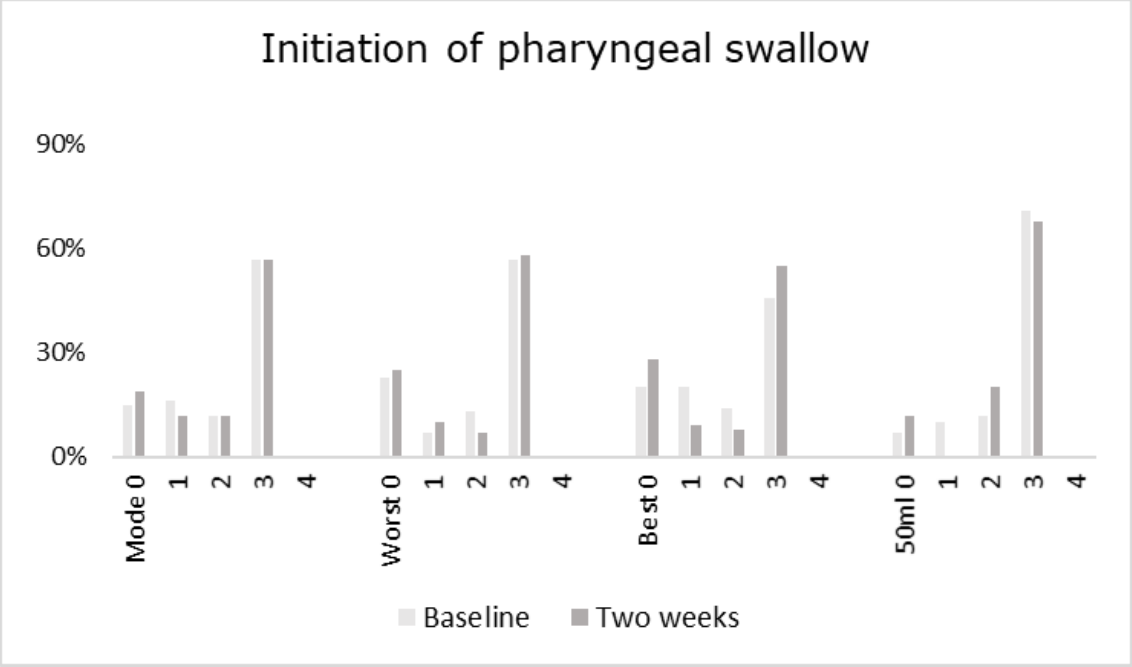



Mean timings at both timepoints are in seconds

### 5.3.6.4 Initiation of pharyngeal swallow

As seen in Figure 5.9, there was no significant change for IPS at two weeks for the mode bolus (Z=-0.353, p<0.72), the worst bolus (Z=-0.388, p<0.70) or the best bolus (Z=-0.191, p<0.85) or for the 50ml bolus (Z=-0.048, p<0.96). The most common location for onset of the pharyngeal swallow was the pyriform fossae, in all boluses, with the 50ml bolus showing the highest frequency for this location. This location of onset did not show a trend for improvement (i.e., become more prompt) at two weeks for any bolus. There were no scores of 4, i.e., no occurrences when the swallow did not trigger.

**Figure 5-9** Initiation of pharyngeal swallow at both timepoints for 5ml and 50ml, data are ordinal 0-4

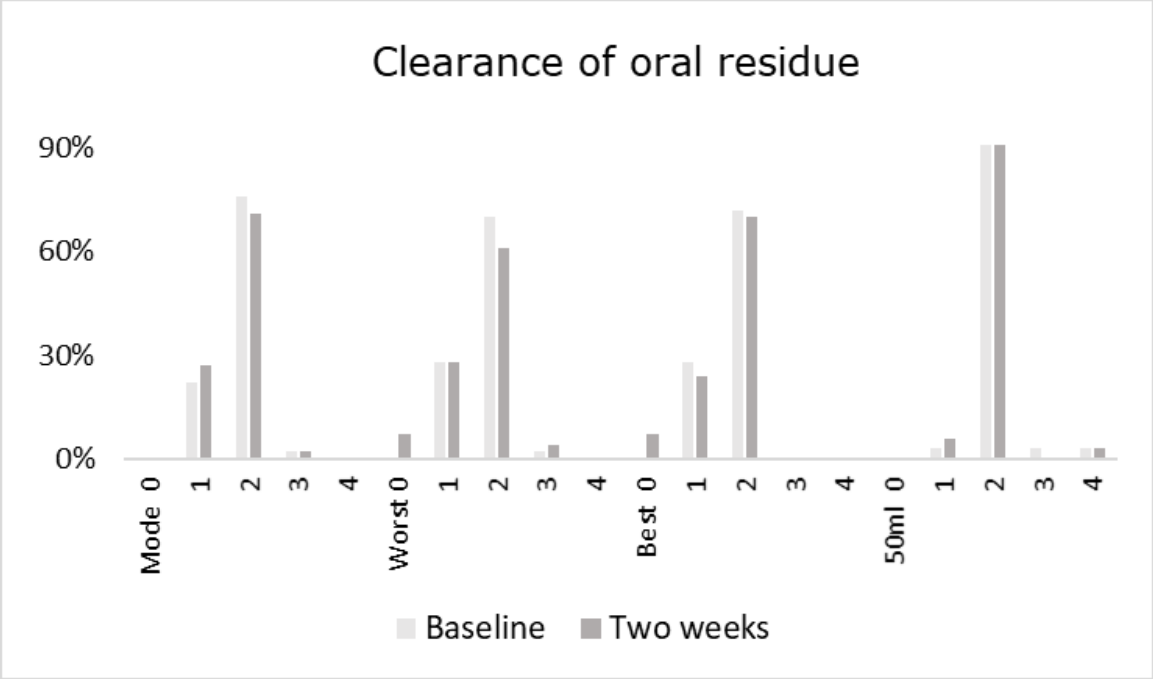



### 5.3.6.5 Clearance measures: Oral residue

As depicted in Figure 5.10, there were no significant changes for oral residue at two weeks for the mode bolus (Z=-0.535, p<0.59), worst bolus (Z=-1.091,

p<0.28) or best bolus (Z=-1.069, p<0.29) or for the 50ml bolus (Z=-0.541, p<0.59). A score of 2 (residue collection) was the most frequent category across the 5ml boluses, followed by a trace collection (the latter is considered within normal limits). The 50ml bolus scored predominantly a score of 2 with fewer instances of trace clearance. There were very few occasions of poor clearance of the bolus. Overall, more residue was seen for oral residue than pharyngeal residue when comparing both locations.

**Figure 5-10** Clearance of oral residue for 5ml and 50ml at both timepoints, data are ordinal 0-4

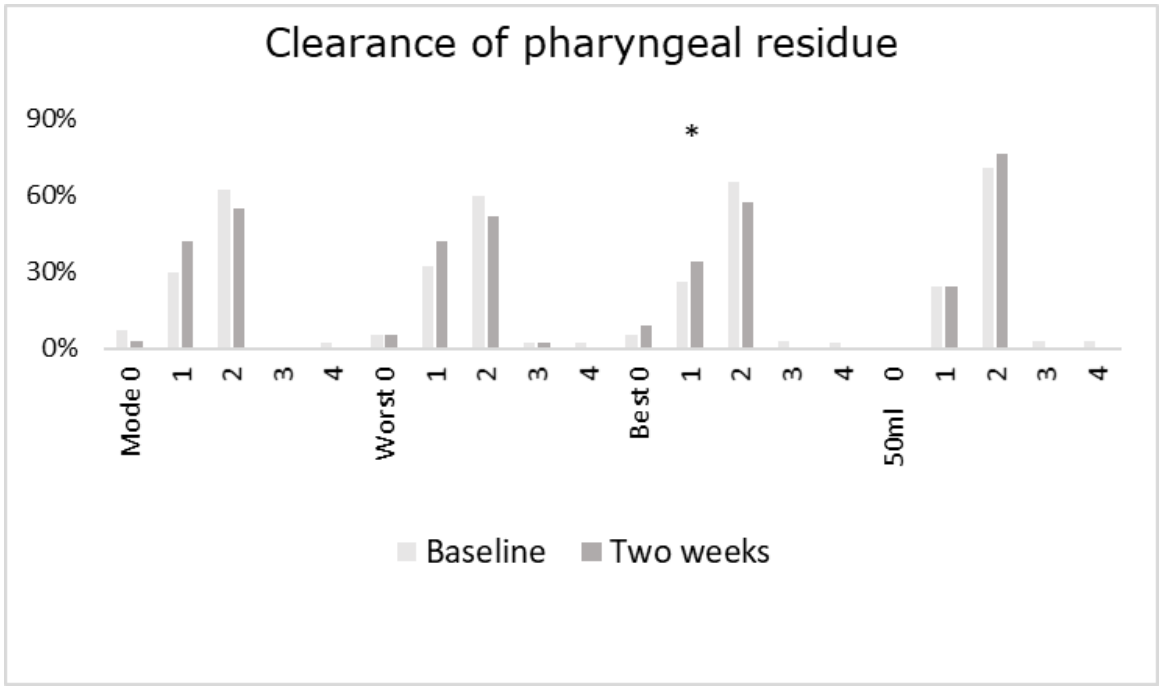



### 5.3.6.6 Clearance measures: Pharyngeal residue

As seen in Figure 5.11, there was no significant change at two weeks for pharyngeal residue for the 5ml mode bolus (Z=-0.893, p<0.37) or the worst bolus (Z= -1.152, p<0.25). However, the best bolus was significant (Z=-2.264, p<0.024). The 50ml bolus was not significant (Z=-0.832, p<0.41) (Figure 5.11).

Although the most common category for pharyngeal residue was also a residue collection (2), this occurred less frequently than oral residue, and more participants scored as having trace residue (1) which is within normal limits. Increasing bolus size to 50ml did result in a trend for more scores of two (residue collection) than one (trace) compared to the 5ml boluses, but this effect was more evident for oral residue than pharyngeal residue.

**Figure 5-11** Clearance of pharyngeal residue for 5ml and 50ml at both timepoints, data are ordinal 0-4



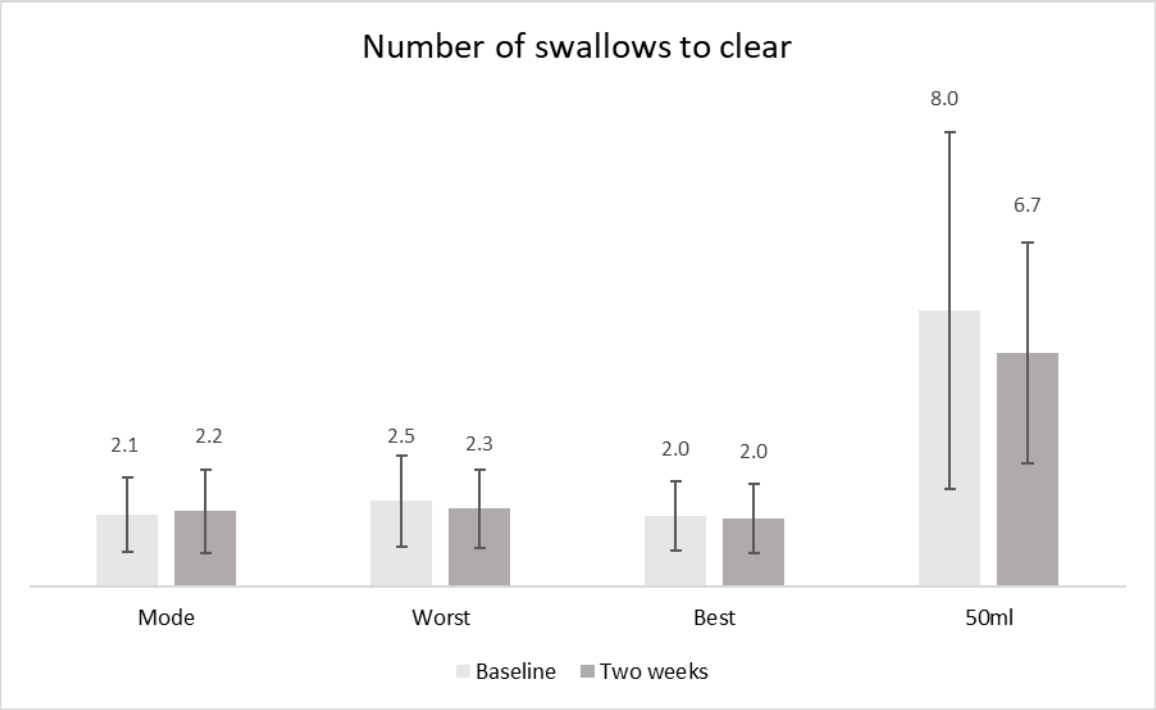

* Denotes significant P<0.05

### 5.3.6.7 Number of swallows to clear

Figure 5.12 shows that at two weeks, there were no significant changes in the number of swallows required to clear 5ml for the mode bolus (Z=-0.974, p<0.33), worst bolus (Z=-1.439, p<0.15) or best bolus (Z=-0.845, p<0.40).

There was no significant change for the 50ml bolus (Z=-1.387, p<0.17) although there was a trend for less clearing swallows at two weeks in this bolus.

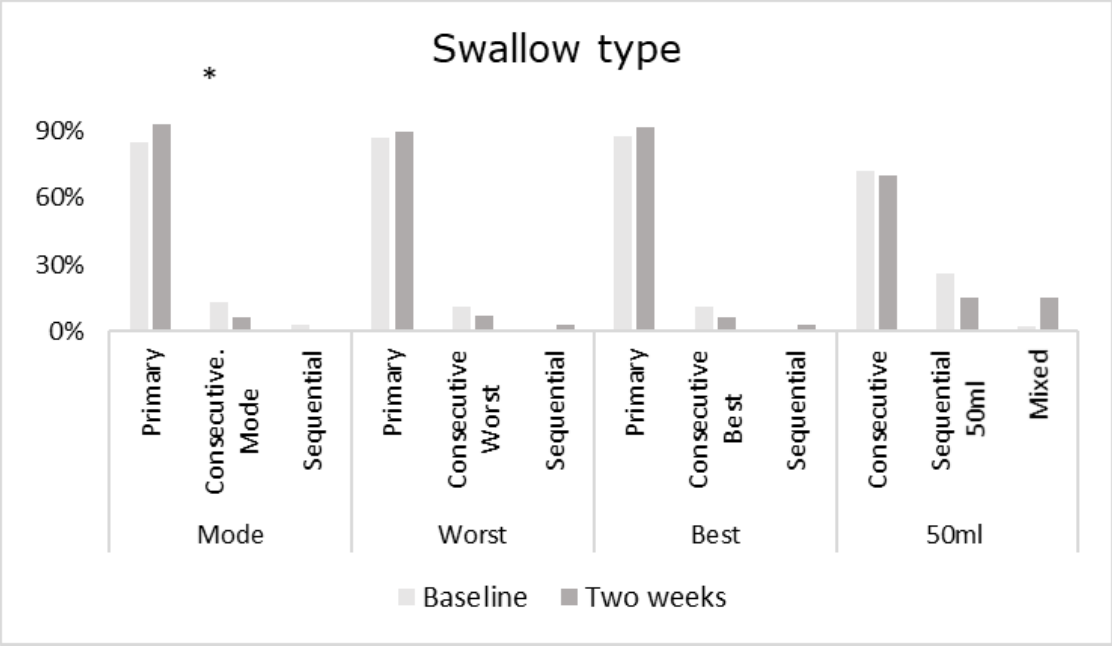
**Figure 5-12** Number of swallows to clear 5ml and 50ml boluses at both time points, data are mean (SD)




### 5.3.6.8 Swallow type

As seen in Figure 5.13, at two weeks, there was a significant difference in swallow type only for the mode bolus (Z=-2.111, p<0.035), but not for the worst bolus (Z=-0.166, p<0.87), best bolus (Z=-0.368, p<0.71) or the 50ml worst bolus (Z=-1.464, p<0.14). For the 5ml boluses, primary swallows were the most frequent swallow type, with few consecutive swallows and very few sequential swallows. For the 50ml bolus, a consecutive swallow was more common than a sequential swallow.

**Figure 5-13** Swallow type for 5ml and 50ml boluses at baseline and two weeks, data are number (%)

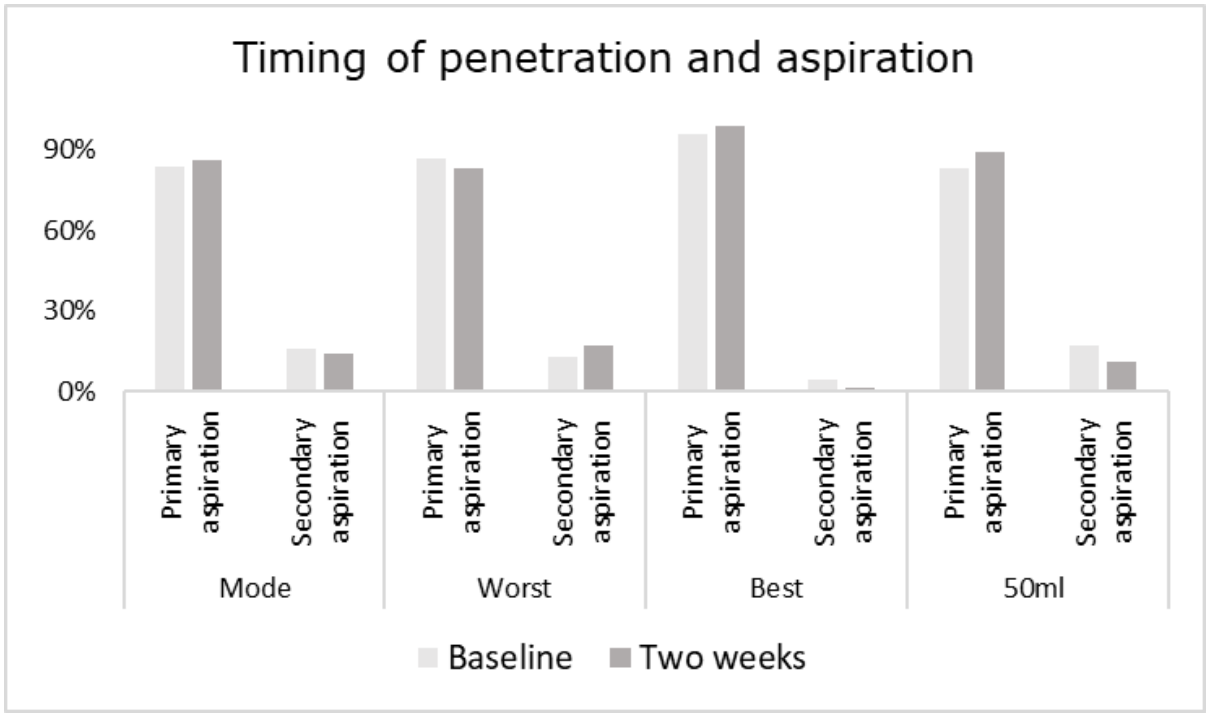



* Denotes significant P<0.05

### 5.3.6.9 Pattern of penetration and aspiration

As depicted in Figure 5.14, there were no significant differences between the mode bolus (P<1.000), worst bolus (P=<0.629), best bolus (p<0.625) or the 50ml bolus (P<0.453) at two weeks for airway invasion patterns. Primary aspiration was most frequent across all boluses. The best swallow showed a lower frequency of secondary aspiration at baseline and almost no incidence at two weeks. There were so few numbers of aspiration occurring on a second consecutive sip (as discussed in secondary aspiration in section 2.4.4.3) that all these swallows were grouped together with consecutive swallows where aspiration occurred on the first sip.

**Figure 5-14** Timing of penetration and aspiration for 5ml and 50ml boluses at both timepoints, data are number (%)



## 5.4 Discussion

### 5.4.1 Main treatment effect

This current study only included imaging data from the STEPS trial at ≥ 25fps. The findings with regards to safety outcomes (PAS) agree with the overall conclusion from the main STEPS study which did not show a significant change between groups. [44] Furthermore, this current study which conducted additional timing and clearance measures on this data has not demonstrated any significant differences between the groups that may have gone undetected by using the PAS alone. These findings therefore *do not support* the hypothesis proposed at the outset of this thesis.

When considering the literature, other acute stroke treatment studies using PES, improvements in safety were seen, although these were smaller studies. [42, 174] In chronic stroke patients, immediate improvements in PAS scores post-PES were seen in one study. [48]

Improvements in timing measures, namely STD and PTT were reported in one previous study in acute stroke patients, using PES, [41] although a further study also using PES in acute stroke patients reported no improvements in these two measures or for OTT, LCD or UOSD. [42] With regards to clearance measures, no studies have reported on the effects of PES using the MBSImP measures used in this study, to the author's knowledge.

### 5.4.2 Mode bolus as primary outcome

The mode bolus was chosen as the primary method of analysis as it represents the most frequently occurring swallow pattern across a series of swallows. It therefore may be a more instructive way to measure PAS scores, being more representative of a patient's unique swallow pattern, as opposed to the mean or median [103] and in the current study, as opposed to using the worst or best bolus. In addition, one may speculate that the mode bolus may be more likely to reflect change in swallow function, as opposed to choosing, for example, the best or worst swallow.

One might expect to see a floor and ceiling effect with these latter swallows respectively, whereby the best bolus may be unlikely to improve much more and the worst bolus may be too severe to improve. As illustrated in Figure 5.6, in this study, when comparing both groups together, the greatest change seen was in the mode swallow from baseline to two weeks: PAS score of 4.4 change to 3.2 (1.2 combined increment change). Perhaps surprisingly, the worst bolus also showed a similar improvement: PAS score of 6.4 change to 5.3 (1.1 combined increment change). In contrast however, the best bolus showed a lower improvement at two weeks: PAS score of 2.2 change to 1.7 (0.5 combined increment change).

The above observations suggest that not only the mode, but also the worst bolus may be more likely to change in acute stroke, following spontaneous recovery and/ or the application of a treatment designed to accelerate recovery of swallowing function, such as PES or usual SLT care. The best bolus can also

show change, but the extent of change may be influenced by how close baseline scores are to normal function.

Choosing different boluses to analyse may help to inform methods in evaluating the PAS. As has been discussed in Chapter One, it is well known that in acute stroke, there is high intra-subject variability of PAS scores, observed both in this study and documented previously. [43, 44, 66, 94, 103] This makes the task of predicting aspiration complicated [105] and presents challenges for researchers when considering which boluses to analyse and how. Future studies with more participants will provide more information either way, both for clinicians and researchers alike.

### 5.4.3 50ml bolus

No significant results were seen between the groups for the worst 50ml bolus or the mean 50ml bolus. Few studies have reported on swallowing larger boluses (≥50ml) in acute stroke patients, perhaps due to concerns regarding safety and one study that did evaluate swallowing of 100ml of thin barium only included milder patients. [123] No studies involving PES have included a 50ml bolus, apart from the STEPS study, as far as is known. In the current study, although the 50ml bolus was swallowed using multiple swallows, it was viewed as one swallowing task (participants were effectively asked to swallow the bolus 'in one go'). Hence, the highest (worst) PAS score from this task was chosen to be analysed. This was different to the 5ml boluses which were six separate, discrete swallowing tasks where a mode, worst and best bolus could be clearly extracted from across the series.

### 5.4.4 Longitudinal changes in PAS scores

The significant improvement in PAS scores observed in all three selected boluses and the worst 50ml bolus in both groups at two weeks (as seen in Figure 5.6) could be due to spontaneous recovery. Longitudinal observational studies at one month post-onset [60] and up to a year [102] as well as treatment studies [43] in acute and subacute stroke have reported improved PAS scores over time. These clinical findings correlate well with physiological evidence from TMS studies demonstrating improved swallow function in many acute stroke patients with dysphagia. [8, 9]

It is also possible that the improvement in PAS scores in both groups was due to a combination of spontaneous recovery and/ or swallowing treatment (PES and/ usual SLT care). This is because, in the original STEPS trial both groups received usual SLT care and in order to preserve blinding as much as possible, both groups also received some PES to obtain threshold and tolerance levels. In addition, levels of PES given to participants in the active group may have been at sub-optimal levels, so called 'under treatment' which may account for why no treatment effect was evident in the STEPS trial [44] and in this research.

Ensuring PES is delivered at the optimal dose (i.e. high enough thresholds) is important when one recalls what is currently known about recovery of swallowing function post-stroke and the principle behind PES and other peripheral and central stimulation treatments. As discussed in Chapter One, TMS studies have demonstrated that recovery of swallowing is associated with uptake of swallowing function in the intact (unlesioned) hemisphere. [9] Current thinking is that PES is thought to accelerate this process. It is hypothesised that PES

provides an enhanced sensory drive in an ascending manner through the cortex and sub-cortex, causing a corresponding increase in activity in motor swallowing areas. A higher dose of PES may therefore activate more sensory thresholds and a larger sensory area, which in turn may drive a stronger motor response, resulting in improved swallowing.

This current study agrees with a previous study examining acute stroke patients (using combined safety, timing and clearance measures) that also reported the greatest degree of change was seen in safety scores. [60] It is not entirely clear why this was if one takes the viewpoint of some researchers, that quantitative timing measures may be more sensitive to improvements than ordinal scales. [81] In the current study, greater numbers were included in the analysis for PAS scores than timing measures, hence reduced power may have influenced the results for the timing measures.

Interestingly, the same study cited above also concluded that *only* using the PAS to define swallowing impairment would have led to patients who were dysphagic on VFSS (compared to normal participants in the same study) being missed. [60] Other researchers have also cited examples of patients with abnormal oral and pharyngeal function scoring normally on the PAS. [70] Although based on limited evidence, this tentatively suggests that using multiple measures is important to detect all abnormalities in swallowing dysfunction, and ideally the PAS (or another standardised measure of aspiration) should always be included as one of these measures as a so-called 'lowest common denominator'.

### 5.4.5 Changes in timing and clearance measures

#### 5.4.5.1 Measures of speed: OTT, STD, ILC and PTT

Longitudinal studies in acute stroke have demonstrated that a reduction in timing measures occurs as patients recover [60, 102, 111] or in response to a swallow treatment such as PES [41] or other swallowing therapy. [205] This was observed in the current study, where most timing measures (OTT, STD, ILC and PTT- Figure 5.7) showed a trend for shorter scores at two weeks although only some scores reached statistical significance. Although there was no clear pattern to this, lower numbers for timings may have contributed to the lack of consistent statistical significance as well as large standard deviations due to outliers.

Observational studies examining patients at baseline have demonstrated the link between longer transit times in acute stroke and higher PAS scores/ aspiration. [94, 95, 119, 113] Although a correlation analysis was not performed on the current data, overall, one can observe that both improved PAS scores and reduced transit times are seen at two weeks suggesting agreement with trends observed in published studies. This is likely because in the main, reduced timing measures reflect quicker transit of the bolus through the oro-pharynx with effectively fewer opportunities for the bolus to enter the airway. The reason for improvement in timings in this study, like PAS scores, may have been due to a combination of both groups receiving some PES, spontaneous recovery and usual SLT care.

Although a small number of extreme outliers were present in the data, which did significantly increase the SD at baseline (particularly affecting measures for PTT

and ILC), they were not omitted. This was because it was felt that these scores represent a minority of severe patients that are seen in acute stroke, who do present with very slow swallowing function. As such, this data contains important information which should not be discarded. [211] In addition, the statistical method used with this data - Wilcoxon Signed Ranks Test, is an appropriate test to use with outliers. With this test, each value is ranked in order and then the sums are ranked and hence extreme values do not heavily influence the sum. [211]

#### 5.4.5.2 Measures of speed: LVCrt

Compared to the other measures of speed, LVCrt had very small magnitude of change and did not show any improvement. LVCrt measures the time taken *to* airway closure once the swallow has been initiated (hyoid onset) and may assist with early airway protection. [126] Limited research has been published on this measure. The mean score for healthy participants (for 5ml thin fluids) was 0.21s on average in one study [126] with slightly shorter scores of 0.095s and 0.179s reported for 10ml and 12ml sips of thin fluids respectively in two further studies. [127, 128]

In contrast, the mean duration for LVCrt in the current study was notable longer for all three 5ml boluses both at baseline for mode-worst-best (0.39s, 0.44s and 0.30s) and at two weeks respectively (0.35s, 0.41s, 0.28s). Although based on modest numbers, (average N=51 across three boluses) this suggests that in this STEPS population of acute stroke patients, once airway closure is initiated, time to full closure took longer than has typically been reported in healthy participants. This is in contrast to one study in acute stroke patients that

appeared to describe a similar event to LVCrt (interval from laryngeal elevation and airway closure). [94] In this study, no difference in scores between stroke patients and healthy participants were reported, although this study included non-aspirating stroke patients not just aspirating patients (unlike in the current research which only included stroke patients who showed penetration and aspiration).

As LVCrt did not show a trend for improvement like other timing measures, one could question whether it has an influence on time to airway closure, because PAS scores improved anyway at two weeks. One may be tempted to hypothesize that other timing measures may be more influential in achieving better airway protection than LVCrt or that other factors not just time to airway closure influence PAS scores.

However, an earlier study consisting of 29 neurogenic patients (majority stroke) and 12 healthy controls, seems to suggest that LVCrt may be influential in airway protection. [112] In this study of 1ml, 3ml and 5ml thin fluids, both delayed onset *and slowed* laryngeal elevation (termed 'slowed enactment' p.1463) was seen in the patient groups. The extent of delay of these two measures accounted proportionally for the extent of airway penetration or aspiration observed and was highest for the 5ml bolus. [112]

Given these findings, [112] it is interesting to note that the best bolus (and lowest PAS score) in the current research study had the shortest LVCrt at both timepoints (0.30s and 0.28s) whilst the worst bolus had the longest LVCrt (0.44s and 0.41s). One wonders if LVCrt had improved more (in combination with swallow onset – STD) whether the PAS scores would have improved further.

Further research is required in this area before any firm conclusions can be drawn.

#### 5.4.5.3 Measures of speed: PRT

Like LVCrt, PRT also showed very little change in the mode and best bolus but in contrast, did show a significant change in the worst bolus, which was significantly longer at baseline (0.96s) than both the other boluses (0.88s and 0.87s). PRT measures how quickly the bolus passes into the UOS once the swallow reflex has triggered. No studies evaluating the effect of PES on PRT in acute stroke have been conducted, although a study with chronic stroke patients showed reduced PRT in groups of patients who received paired associative stimulation and PES. [48]

There are few published studies which include PRT in acute stroke or which reference norms for healthy participants. In observational studies of acute stroke patients and healthy controls, PRT was reported to be longer in the healthy controls (0.93s) compared to stroke patients (0.83s) in one study [129] and the same in both healthy and stroke participants in a second study (0.90s). However, this study reported on very small numbers (N=8) and it was not clear what bolus volume for thin fluids was reported. [110] In contrast, a further study of 31 younger healthy participants reported a shorter PRT of 0.53s (non-cued swallow) and 0.64s (cued swallow) although this was for 10cc (approximately 10ml) amounts.

One could surmise that, like other timing measures, PRT would be prolonged in stroke patients compared to healthy participants. However, PRT is also

influenced by UOSD duration, due to the overlap of the component of the tail of the bolus passing through the UOS being common to both measures. If UOSD duration is reduced, PRT will likely be shorter (and if UOSD is longer, PRT will also be longer). Interestingly, both patterns of UOSD opening have been reported in stroke patients as will be discussed in section 4.4.5.5.

It is interesting that only the worst bolus (which showed the longest PRT at baseline (0.96s) improved at two weeks, to a similar time as the other two boluses (0.88s). Further research is required in this area, along with greater numbers of both healthy participants and acute patients, in longitudinal studies, to understand how PRT presents in normal and abnormal swallowing.

#### 5.4.5.4 Measures of duration: LCD

In contrast to most measures of speed, changes in measures of duration were marginal (Figure 5.7). LCD scores at baseline in this study across the three selected boluses for mode-worst-best, were 0.43s; 0.43s; 0.49s and at two weeks - 0.45s, 0.39s and 0.47s. The aggregate mean range of 0.76s for LCD (of bolus sizes varying from 1ml to 20ml) has been reported in a systematic review of healthy participants, along with the unsurprising observation that LCD duration increases as bolus size increases. [117] When scrutinising the wide range of scores observed in the review (0.31s to 1.07s), it is apparent that most studies that report on LCD for 5ml, report longer durations than the mode, worst and best boluses in this research.

In published studies involving stroke patients swallowing similar 5ml amounts, some studies reported longer LCD for aspirators than seen here: 0.8s [107] and

0.77s [105] as opposed to other research reporting similar baseline durations to those obtained in this research: 0.48-0.52s [42] and 0.48s (although pooled for 2ml and 5ml), [205] 0.44s and approximately 0.52s (although these latter studies did have a more severe definition of aspirators, hence more severe patients). [119] [114]

When considering what this means in context, research has reported mixed results: some studies reported no difference in LCD between aspirators, non-aspirators [105] and/ or controls [114] or different stroke types. [98] In other studies, shorter LCDs have been reported for aspirators [119] and in one study, researchers demonstrated that adding LCD to a predictive model (along with PTT and STD) increased the power to predict aspiration. [105] In addition, other studies suggest if LCD is poor, patients may still aspirate even if STD is timely [113, 119] or was delayed but has since recovered. [111] It is the author's opinion that one would reasonably expect to see shorter LCD in aspirating stroke patients compared to non-aspirators.

It is not clear why LCD did not show a trend for improvement at two weeks. A similar result was reported in a study involving acute stroke patients, where no changes in LCD were seen following a swallowing treatment, unlike ILC which did improve in that study [205] (and was also seen here). The authors of that study suggest that changes in LCD may take longer than one month post-onset to improve. [205]

#### 5.4.5.5 Measures of duration: UOSD

UOSD also showed marginal improvements. UOSD scores at baseline in this study across the three selected boluses for mode-worst-best, at baseline were: 0.63s; 0.67s; 0.62s and 0.64s for all three boluses at two weeks. These scores are significantly longer than the aggregate mean range for normal participants (0.46s) reported in a systematic review, which included boluses up to 30ml. As with measures of LCD, UOSD has been shown to increase as bolus volume increases, hence it may be more appropriate to look at the range of mean values for individual studies for this measure which were between 0.21s – 0.67s. The upper range of these values mostly represent UOS durations for volumes >5ml and hence the scores in this current research study of 5ml boluses are still generally longer than one would expect compared to healthy participants.

Similar studies examining UOSD of stroke patients have reported both similar durations to those seen here (0.64s) [105] but also shorter durations (0.41s). [42] A review paper examining factors related to aspiration risk did not find confirmation of a relationship between UOSD and aspiration. [124] This is reflected in studies in stroke patients that have reported contradictory results. Some studies report reduced duration of UOS opening in aspirators as opposed to non-aspirators, [131] whilst other work reported longer UOS opening in non-aspirators and aspirators compared to controls. [132] In this latter study, the authors suggested that longer UOS times were compensatory, as a result of prolonged pharyngeal transit possibly caused by reduced hyolaryngeal excursion and neuromuscular damage, including to the UOS muscle itself. [132] UOS durations have also been found to increase with age in healthy participants, [117, 130, 212] possibly also as a compensation for slower bolus transit. [130] It is not clear why

UOSD did not show a trend for improvement at two weeks and little research has been published in stroke patients which examines this aspect. It is possible that the combination of slower UOSD naturally occurring in older age requiring compensatory behaviours combined with a stroke further affecting UOSD may mean that recovery (if it is going to occur) will take longer. However, one could use the same argument for STD, which also typically slows down with older age and is frequently disrupted in stroke but which did show a trend for improvement in this study, albeit non-significant.

#### 5.4.5.6 Initiation of the pharyngeal swallow

In the current study, for the 5ml boluses, it is clear most patients triggered in the pyriform fossae. Evidence from studies in healthy participants point towards variability in the location of pharyngeal swallow initiation. [88, 213] In the seminal paper which first introduced the five categories used in component six from the MBSImP, younger participants (<50 years, N=29) were reported to mostly trigger at the ramus for 5ml non-cued thin liquid boluses. [88] However, pointing to the variability between participants, some younger participants triggered as low as the underside of the epiglottis, but interestingly no younger participants triggered as low as the pyriform fossae in this study. This is in contrast to one study which examined cued versus non-cued swallows in 20 healthy younger participants (average age of 31.5 years). [121] In this study, 20% (N=4) of participants were reported to trigger in the pyriform fossae in the non-cued condition (but none in the cued condition), although this study used a bigger bolus of 10ml not 5ml. However, this study may be the exception, not the norm.

Martin-Harris, et al.'s (2007) [88] results have since been confirmed by two recent systematic reviews. These reviews report a trend for younger participants to trigger the swallow more quickly than older participants, relative to the bolus arriving at the ramus of the mandible. [212, 213] Both these reviews reported on research from participants spanning a broad age range. These findings have also been reported in a third recent review in the oldest old (>85 years). [130] In one review, onset of pharyngeal phase swallowing was seen up to the level of the valleculae in asymptomatic individuals less than 60 years. [213] In contrast, the pharyngeal swallow was seen in more distal regions such as the hypopharynx and pyriform fossae in older individuals (in this study >60 years) as well as symptomatic individuals. Similar findings were reported in the second review. [212]

It is feasible then, to perhaps expect that the participants in this study (who have a mean age of 73.4 as detailed in Table 5.2), would have more distal locations for onset of the pharyngeal swallow. Although some studies using the MBSImP in stroke patients are emerging, these papers have focused on the composite Oral Impairment and Pharyngeal Impairment score and have not reported separate results for different components on the MBSImP. [101, 122] As no similar studies on stroke patients (to the author's knowledge) using the MBSImP have been published, these results are not able to be compared directly to another stroke population. However, when examining the evidence more closely from the healthy older participants in the earlier study (>50 years), only 7% were noted to trigger in the pyriform fossae. [88] This is a notably lower frequency than that seen in this current study where the frequency ranged from 46%-57% at baseline and 55-57% at two weeks. It is acknowledged that the number of older participants in the aforementioned study were modest (N=47). [88]

However, based on current available evidence, the results from this research suggest that acute stroke patients with penetration or aspiration may show a higher tendency for pharyngeal swallow initiation in the pyriform fossae than that reported for older healthy participants. Whether this applies to non-aspirating stroke patients is currently unknown.

Another observation from this research is that IPS did not significantly improve at two weeks even though PAS scores did improve (although not to within normal limits for the mode and worst bolus). This is perhaps a surprising finding. As discussed in Chapter One, delays in STD (which fits closely with a more distal swallow trigger for IPS) have been shown to be the most common and disabling feature causing aspiration in cortical and brainstem strokes. [84, 94, 101, 105, 111, 113, 114, 118-120]

Additionally, published evidence from one study suggests that a more distal location for swallow onset in older patients can result in airway invasion or at the very least, represent a greater risk of airway invasion. [92] The authors go on to suggest that for people with diseases that cause dysphagia, a distal pharyngeal swallow trigger could also be a risk factor for airway invasion. The study in question examined sequential straw drinking. Airway invasion was measured for two groups of younger and older healthy participants when the bolus head was inferior to the valleculae (no further definition was provided) at the outset of swallowing for both groups. Despite the bolus head being at the same location for both groups, older healthy participants (especially >70 years) were 5.68 times more likely to show penetration than younger participants when the swallow was triggered.

As mentioned in Chapter One, this could be due to various reasons, including a reduction in reserve and flexibility within the neuromuscular system needed for safe swallowing. [91] Although 'an old swallow is not an impaired swallow' [214] (p. S25), [214] older participants are at greater risk, although this risk appears to mitigated by the fact that older participants can compensate. [119, 214] In fact, one interesting study found that older healthy participants (in their 70s) were more likely to use spontaneous manoeuvres (such as supraglottic swallow) than the younger participants which the authors' suggest could be due to natural compensation. [104] However, the authors do not comment on the oldest group in this study (80 and over) who one would also expect to be using manoeuvres and numbers in each group were also modest (20). In any event, it is entirely possible that older stroke patients with dysphagia and a pattern of distal onset for the swallow, may not be able to compensate as easily which is one reason, they are more likely to aspirate.

Another possible reason for increased penetration risk in older participants was put forward by Martin-Harris et al [88] who reported later onset of apnoea (temporary cessation of breathing as airway closes during swallowing) relative to the trigger of the pharyngeal swallow in older participants in their study. These authors hypothesize that this later closure could result in penetration prior to swallowing although the authors caution against conclusions being drawn, stating that more research is needed due to the small sample size.

If one takes the viewpoint that a distal swallow onset is more likely to be correlated with aspiration in stroke patients, a possible reason for a lack of apparent correlation between improvement in IPS and PAS scores could be because IPS may simply be less sensitive to measuring swallow initiation than

the PAS. Ranging from 0-5, it is a relatively short scale (as opposed to the PAS which has more levels) and a difference of only one frame (i.e., 0.04s or 0.033s) can change a category on the IPS. In addition, as the leading edge of barium was used as a definition in this study, even a *trace* of barium reaching the pyriform just prior to swallow initiation, would mean a swallow is classified as a three on the MBSImP. In the same way, a swallow where the *whole* bolus is seen in the pyriform prior to the swallow trigger would have received the same score. The latter swallow is more likely to result in airway penetration than the former but this would not be reflected by the IPS scale. This opens the debate of how this variable should be scored, such as has been discussed in one study. [97] One suggestion could be to use total swallow duration (i.e., measure from oral transit time through to hyoid return to rest) [97] or taken from beginning of oral transit through to tail of the bolus passing through the UOS, thus negating the need to measure the bolus head location at the ramus.

Whilst the IPS scale may potentially lack sensitivity, another factor needs to be considered. The data from this research and the author's experience suggests that due to the fact that swallowing is such a complex, multifactorial function, improvement in PAS scores are also likely due to improvement in *other* factors occurring *simultaneously*. Hence, the fact that IPS did not improve but PAS scores did, suggests that other factors must have improved too and that IPS alone does not necessarily predict PAS scores.

These potential other factors (some of which are measured by other components from the MBSImP) may include: early control of the bolus in the oral cavity; effective and controlled anterior-posterior bolus propulsion as part of swallow initiation; early airway closure; pharyngeal coordination and relaxation of the

UOS. One study that used timing measures and discriminant modelling to predict aspiration post-stroke showed the optimal model combined SRT, LCD, PTT and age. [105] More recently, possibly one the first studies looking at timing measures and their impact on the Oral and Pharyngeal Components of the MBSImP has recently been published. [122] Unfortunately, the definition of swallowing impairment for inclusion in the study is not well described, no information is provided on whether participants exhibited penetration or aspiration and the definition of a key parameter (laryngeal closure duration) is not clear. A limitation of the current work is that the full MBSImP was not conducted on the data, due to time constraints and the number of time-consuming quantitative measures already employed.

It is key that going forwards, studies measuring IPS (and the rest of the 16 components) on 5ml and 10ml single sips are carried out on age-matched non-aspirating stroke patients together with aspirating stroke patients in order that the observations seen here in stroke patients who do have airway invasion can be placed in context. Studies on older healthy participants using the MBSImP are also required and it may be argued, are needed first.

With regards to IPS of the 50ml bolus, this study agrees with previous research that reports the majority of participants triggered the swallow when the bolus was inferior to the valleculae in both young and older participants [92, 215] and stroke patients with mild dysphagia. [123]

### 5.4.5.7 Clearance measures

Published studies evaluating residue in healthy participants report any amount more than trace is not normal [110, 134] even with thicker consistencies [128] and in older subjects. [90, 97] Studies using the MBSImP in acute stroke reporting on composite Oral and Pharyngeal Impairment scores in dysphagic stroke patients are now emerging. [101, 122] A recent study did measure pharyngeal residue in acute stroke patients although the mean and standard deviation was reported [216] unlike the current research which used number and percentages. Nevertheless, the mean amount of pharyngeal residue (for 5ml and 10ml thin fluids) for 45 acute stroke patients was reported to be 1.80 (SD 0.46) which is similar to the most frequent score of a 2 seen in this research. Other studies in stroke patients have reported on residue, but these vary considerably, making it harder to directly compare the results in this current study. This is because studies use different residue scales, [36, 60, 129] report pooled results on a variety of different bolus sizes, [36] numbers are very small, [36] results are presented for data acquired at low frame rates, [217] or no definition of residue is given and patients were sub-acute. [136]

Hence, apart from the one patient study mentioned above, one also has to consider these results with regards to healthy participants reported above. The results obtained suggest that the amount of residue seen in this study is not within normal limits. That said, most scores fell within the 'residue' collection category of the MBSImP, which can vary between what can be considered as mild residue (enough for a 'scoop' to be collected, p.7) [133] through to moderate residue (under half the original bolus remaining). This suggests that in acute stroke patients, for 5ml amounts of thin fluids, residue post-swallow is common

but is not severe, i.e., participants can clear up to half the original bolus on the primary swallow.

It is unclear why no significant improvement in residue was seen at two weeks, although the author's experience of using the residue scales on the MBSImP is that a score of 1 and 2 can be difficult to distinguish, a finding which has already been noted in the MBSImP guide. [133] This was also seen in the reliability substudy in Chapter Four, when it was observed that every incorrect residue score was always by a margin of 1 point, suggesting there may be some degree of overlap between boundary points for levels on the residue scales. In addition, the category of 2, in the author's opinion is very broad and spans a very mild collection of residue through to just less than half a bolus and thus less obvious improvements in clearance may not have been detected. It is acknowledged that more advanced methods of measuring residue such as computer software are available, although they may be more time consuming.

#### 5.4.5.8 Number of swallows to clear

The number of swallows to clear 5ml in this study appear to be twice that of healthy participants, who have been reported to clear 5ml amounts with one swallow [6. 88. 87] and probably explain why the residue scores above did not fall within normal limits. In a more recent study, even with bigger bolus sizes up to 12ml (an average sip size) the mode and median for healthy participants was one. [128] For the 50ml bolus, the only comparable study in healthy participants (age range 23-91 years) swallowing the same volume reported a mean clearance of 4.35 swallows. [218] This is notably lower than the current study, even after some improvement at two weeks (7.6 at baseline, reducing to 6.6 at two

weeks). These results suggest that stroke patients have a less efficient swallow as they do not clear small or larger volumes of thin fluids as effectively as healthy participants.

This could be due to a number of factors, such as: reduced oral control, resulting in less efficient anterior-posterior transit of the bolus; premature spillage of the bolus (thus interrupting the normal swallow pattern) or reduced strength and coordination of propulsion and clearance of the bolus through the pharynx into the UOS. Further work examining the *nature* of secondary swallows could help to inform this, i.e., examination of whether swallows were piecemeal, could suggest inefficiency in the oral cavity or whether swallows were clearing, could suggest inadequate pharyngeal clearance.

#### 5.4.5.9 Swallow type

Few studies comment on swallow type for 5ml amounts. It is largely assumed that most participants receive the whole 5ml bolus all at once into the mouth, which most participants did. However, a small number of participants slowly ingested the 5ml bolus either in discrete consecutive sips or sequential sips, despite being given the command to pour all of the liquid into their mouth and swallow it. This may be related to habitual premorbid swallowing patterns or poor oral control necessitating adaptive behaviours.

For larger bolus amounts, more research has been published. For 50ml, the distribution of swallow types seen in this study, i.e. consecutive swallow type (with a majority pattern for lowering the hyolaryngeal complex between swallows) was most similar to one study involving only healthy young

participants. [215] Another study also had majority hyolaryngeal lowering as seen in this study, but with significantly more mixed swallow types than seen in this study. [218] However, other studies involving younger and older healthy participants showed a more even distribution between the swallow types. [92] In one study with stroke patients, Murguia et al. (2009) reported a greater proportion of partially elevated (sequential) swallows were seen, unlike in the current study. [123] This is a surprising finding, as a partially elevated swallow is considered to be more challenging than a consecutive swallow. This is due to the need to maintain full *continuous* airway closure over a number of swallows and which was observed in the current study to be problematic for some patients attempting a sequential swallow. However, in Murguia et al.'s (2009) study, patients were described as having a mild dysphagia (unlike the patients in the current cohort) and may have been more likely to be able to perform a sequential swallow.

Some authors suggest the resultant pattern seen when swallowing a large volume bolus is influenced by the instruction given on how to swallow the bolus. [123] This was not borne out in this current research study where the instruction to swallow ('take several mouthfuls one after the other without pausing between swallows, keeping the cup at your lips' p.61) [219] did not result in more sequential swallows. However, this may be influenced by the patient population in this study, some of whom presented with linguistic and cognitive deficits and who may not have fully understood the instruction.

#### 5.4.5.10 Timing of penetration and aspiration

In this study, most aspiration occurred because of airway invasion on the first swallow of each bolus. Although secondary aspiration was not common either in 5ml or 50ml, it did occur in a small number of participants (on average 11% for 5ml and 17% for 50ml). Clinicians and researchers alike should remember not to forget about the risk of airway invasion on secondary swallows. This can provide important diagnostic and clinical information about the nature of the swallowing impairment to help guide clinicians in treatment options, for example, limiting bolus size to reduce aspiration on residue during secondary swallows.

An interesting observation was that secondary aspiration was less frequent in the best 5ml bolus at baseline and almost absent at two weeks. This may suggest that secondary aspiration is more likely to occur with a more severe swallow as evidenced by a more frequent occurrence of this phenomenon in the mode, worst and 50ml bolus all of whom had higher PAS scores. However, this is finding is merely speculative and further research would be required in this area with greater numbers before any firm conclusions can be drawn.

### 5.4.6 Reduced quality and frame rate of Videofluoroscopy Swallow Studies

In this study, reduced imaging quality and sub-optimal frame rate resulted in lower numbers in the final analysis. This has highlighted the importance of acquiring images at the correct frame rate and optimising data quality and field of view as much as possible. Data was meant to be acquired at a minimum frame rate of 25fps, as specified in the STEPS protocol. It is acknowledged that

the data from this study was acquired from many hospital sites and reflected current practice and limitations of recording equipment and/ or facilities at that time. However, the results of two recent UK wide surveys, suggest there is more work to be done. These surveys (of videofluoroscopy practice amongst SLTs [189] and Radiologists) [190] reported that 15fps remains the most common frame rate employed and that reduced knowledge of imaging modes was evident amongst some respondents.

Since the STEPS study, literature specifying optimal parameters for conducting VFSS studies has been published to guide clinicians and researchers, [188] as have studies exploring the effect of reduced frame rates on interpretation of PAS- and MBSImP scores. [220, 221]

In these studies, reducing pulse rates from 30fpps to 15pps resulted in differences in judgements of swallowing impairments [220, 221] and treatment recommendations on the MBSImP. [220] In the first study, PAS scores were also assigned to fifteen stroke patients at a variety of pulse rates: 30pps, 15pps, 7.5pps and 4pps. [220] From these scores, 12/15 (80%) were different between the different pulse rates. When comparing the different pulse rates statistically, all were statistically different except 30pps vs 15pps and 15 vs 7.5pps. In the second study, no statistical differences were seen between PAS scores at 30pps vs 15pps either. However in this latter study, PAS scores were only mild (1 or 2) and stroke patients with and without dysphagia on VFSS were included. [221]

The conclusion from both these studies is that the results currently provide support for using a pulse rate as close to 30pps (and recording it at the same frame rate, i.e., 30fps), although further research is required with larger

numbers and severities of dysphagia. In the UK (as well as Japan, South America, Australia and other parts of Europe) if using video (or DVD) recording equipment, a maximum upper resolution of 25fps is obtained. [188] This frame rate is still routinely used in these countries and many publications from these countries will be based on a frame rate of 25fps, including data from the STEPS trial. However, recent software systems are now available that can record VFSS images at 30fps in the UK. Two studies in the paediatric population have also examined this area but reported contradictory results. However, adult swallowing physiology and paediatric swallowing physiology are different and hence it is felt that it is not appropriate to consider these studies when discussing adult physiology.

### 5.4.7 Single versus multiple measures: analysis and reporting methods for swallowing impairment

The numerous measures performed in this study represented a comprehensive analysis of swallow safety, timings and clearance. As mentioned above, the hypothesis proposed at the outset has not been fulfilled. This is despite the fact that only thin fluids were assessed using the PAS. One could argue as suggested in Chapter One, that it is possible that improvements in timing, reflected for example, in patients moving from being NBM to thickened fluids may not have been detected in this study. However, the fact that the Dysphagia Severity Rating Scale, which was used as a secondary outcome measure, that will have measured patients' improvement on modified diet and fluids and NBM status, was also not significant in the main STEPS trial, suggests this is not the case. Equally, in the numbers studied, it is probable that there was no effect to be detected and hence it is premature to conclude that only using the PAS is

enough to capture all changes in swallowing function following an intervention. Similarly, only using the PAS may miss patients who have a dysphagia but who do not show penetration or aspiration.

Chapter Four of this research project demonstrated that if used, quantitative timing measures are time consuming, rely on good quality images and require substantial training to achieve acceptable reliability. In addition, some researchers point to the variation in timings in stroke, [48] whilst other researchers feel that quantitative measures are reliable and can detect subtle changes that may be missed by rating scales. [81] The merit of using a range of measures to evaluate swallow function should be weighed against the time and resources available to conduct them.

Additionally, consideration should also be given to more ecologically valid, pragmatic outcomes charting progression of oral intake and the effect of interventions on patients' lives. These include cost effective, easy to administer rating scales and patient rated quality of life measures. One can argue that rating scales of oral intake also provide an indirect measure of a patient's risk of aspiration and swallow efficiency, based on the level of modification applied to their diet and fluids.

Finally, standardised protocols (consisting of agreed 'core' components) for analysing and reporting outcomes for post-stroke dysphagia should be considered, like those already in development for patients with aphasia following stroke [222] and that have been recently suggested for swallowing impairments in critical care as part of the Comet Initiative. [223] Standardising protocols would allow for more equitable comparison between trials and hence improve the

quality of the evidence in the acute stroke population. [37] It is important that any protocols are population specific (i.e. specific to stroke), as different pharyngeal swallowing mechanics have been reported within different aetiologies.[110] [224]

## 5.5 Strengths

This study has several strengths. These include analysis of a large dataset with deep phenotypic information from a high-quality phase III trial that followed a published protocol; a comprehensive analysis encompassing all aspects of the swallow (safety, speed, duration and efficiency) and is, to the author's knowledge, the first study to publish results of stroke patients focusing on PAS scores using the distribution of the mode, worst and best PAS scores.

## 5.6 Limitations

However, some limitations are present. As this real-life study included VFSS from 15 different hospitals in 5 countries inevitably, some images were of sub-optimal quality. This resulted in missing data as image quality was not good enough to allow some measurements or were out of field of view, which in turn reduced the power of the study to pick up significant treatment effects. VFSS frame rates also varied both within and between sites which further reduced the number of files available for analysis. The increased time taken to process and organise the data, as well as conduct time consuming quantitative timing measures led to time constraints. However, it is acknowledged that this research did not analyse all six swallows available in the STEPS dataset and this may have had an effect on the final outcomes. In addition, only certain components of the MBSImP were included which may have limited the conclusions which

were able to be drawn from the data. Finally, one site contributed significantly more data than other sites which may represent a bias within the results.

## 5.7 Conclusions

In summary, including measures of timing and clearance (in addition to safety measures) did not detect any further changes in swallowing function, but it would be premature to only use the PAS as an outcome measure. Adequately powered studies assessing the effect of PES in acute stroke where PES is given solely to the PES group and at the optimal dose (preventing 'under treatment'), are required. These studies must be optimised for image quality and be acquired and recorded at a frame rate of at least 25fps, ideally 30fps. When considering longitudinal changes, safety scores showed the most significant improvement. Most measures of speed showed at least a trend for improvement, whereas measures of duration showed little change. The pyriform fossae were the most frequent location for initiation of the pharyngeal swallow on all boluses and this did not change significantly at two weeks. Overall, measures of efficiency showed little change at two weeks, except for the best 5ml bolus for pharyngeal clearance and a trend for fewer clearing swallows in the 50ml bolus. Oral and pharyngeal residue both showed a predominant pattern of a residue collection post-swallow. Comprehensive analysis of swallowing using all components is important to detect change in swallowing function but is also time consuming and should ideally include rating of patients' everyday oral intake and patients' views. Future work on agreeing a standardised protocol for a core set of outcomes to evaluate change in swallowing function post-stroke is required.

# 6. Psychometric assessment and validation of the dysphagia severity rating scale

# Publications arising from this chapter:

Everton LF, Benfield JK, Hedstrom A, Wilkinson G, Michou E, England TJ, Dziewas R, Bath PM and Hamdy S. Validation of the dysphagia severity rating scale in stroke patients. Scientific Reports 2020; 10 :7268.

# Presentations arising from this chapter:

Everton LF, Benfield JK, Hamdy S, Michou E and Bath P. Establishing inter-rater reliability scores for timing measures in videofluoroscopy in stroke. 8th Society of Swallowing Disorders Congress, 2018, 27-29 September, Dublin. Awarded poster of merit. Poster presentation - awarded poster of merit.

Everton LF, Benfield JK, Hamdy S, Michou E and Bath P. Establishing the minimal clinically important difference for the dysphagia severity rating scale and functional oral intake scale. 8th Society of Swallowing Disorders Congress, 2018, 27-29 September, Dublin. Poster presentation

Everton LF, Benfield JK, Michou E, Bath PB and Hamdy S. Is the Dysphagia Severity Rating Scale an effective tool to measure swallowing dysfunction? A retrospective and prospective validation study. International Journal of Stroke,13 13-13; 3 SI Dec 2018. Poster presentation.

Everton LF, Benfield JK, Hedstrom A, England T, Bath PB and Hamdy S. Validating the Dysphagia Severity Rating Scale: a prospective and retrospective study. 9th European Society of Swallowing Disorders, 2019, September, Vienna. Platform presentation

Everton LF, Benfield JK, Hedstrom A, England T, Bath PB and Hamdy S. Validating the Dysphagia Severity Rating Scale. Royal College of Speech and Language Therapist's Conference, 2019, 25-26 September, Nottingham. Platform presentation.

# ABSTRACT

## Introduction

The Dysphagia Severity Rating Scale (DSRS) grades how severe dysphagia is based on fluid and diet modification and supervision requirements for feeding. It is used for clinical research but has limited published validation information. As was mentioned in Chapter Two, using validated outcomes is important in dysphagia rehabilitation to improve the quality of randomised controlled trials and enable easier comparison between studies. This chapter describes validation of the DSRS.

## Method

Multiple approaches were taken to validate the DSRS, including concurrent- and predictive validity, internal consistency, inter- and intra-rater reliability and sensitivity to change. This was done using data from four studies involving pharyngeal electrical stimulation in acute stroke patients with dysphagia, an individual patient data meta-analysis and unpublished studies (NCT03499574 NCT03700853). In addition, consensual- and content validity and the Minimal Clinically Important Difference (MCID) were assessed using anonymous surveys sent to UK-based SLTs.

# Results

Scores for consensual validity were mostly moderate (62.5-78%) to high or excellent (89-100%) for most scenarios. All but two assessments of content validity were excellent. In concurrent validity assessments, the DSRS was most closely associated with measures of radiological aspiration (penetration aspiration scale, Spearman rank $rs=0.49$, $p<0.001$) and swallowing (functional oral intake scale, FOIS, $rs=-0.96$, $p<0.001$); weaker but statistically significant associations were seen with impairment, disability and dependency. A similar pattern of relationships was seen for predictive validity. Internal consistency (Cronbach's alpha) was either "good" or "excellent". Intra and inter-rater reliability were largely "excellent" (intraclass correlation >0.90). The DSRS was sensitive to positive change during recovery (medians: 7, 4 and 1 at baseline and 2 and 13 weeks respectively) and in response to an intervention, pharyngeal electrical stimulation, in a published meta-analysis. The MCID was 1.0 and DSRS and FOIS scores may be estimated from each other.

# Conclusions

The DSRS appears to be a valid tool for grading the severity of swallowing impairment in patients with post-stroke dysphagia and is appropriate for use in clinical research and clinical service delivery.

## 6.1 Introduction

Post stroke dysphagia (PSD) is common affecting upwards of 40% of patients in the first days after ictus, and is associated with poor outcome manifest as increased death or dependency, aspiration and pneumonia, and malnutrition. [225] PSD can be identified by screening and clinical bedside assessments, or diagnosed instrumentally using Videofluoroscopy (VFSS) or fibreoptic endoscopic evaluation of swallowing (FEES); screening devices are also in development. [226] The severity of aspiration may be quantified using VFSS or FEES, and is typically measured using the penetration aspiration scale (PAS). [66] Similarly, a number of scales exist for grading the severity of clinical dysphagia based on oral intake, such as the functional oral intake scale (FOIS), [50] and the dysphagia severity rating scale (DSRS). [42]

The DSRS (Figure 6.1) is a clinician rated scale that was developed from the dysphagia outcome and severity scale (DOSS). [227] It grades how severe clinical dysphagia is, by quantifying how much modification is required to fluids and diet, as well as level of supervision, for safe oral intake. The DSRS comprises three subscales that are totalled to give a score ranging from 0 (best) to 12 (worst). The three subscales comprise five-level ordinal assessments of fluid and dietary intake and supervision; each ranges from normal (score 0) to no intake (4).

**Figure 6-1** Dysphagia Severity Rating Scale

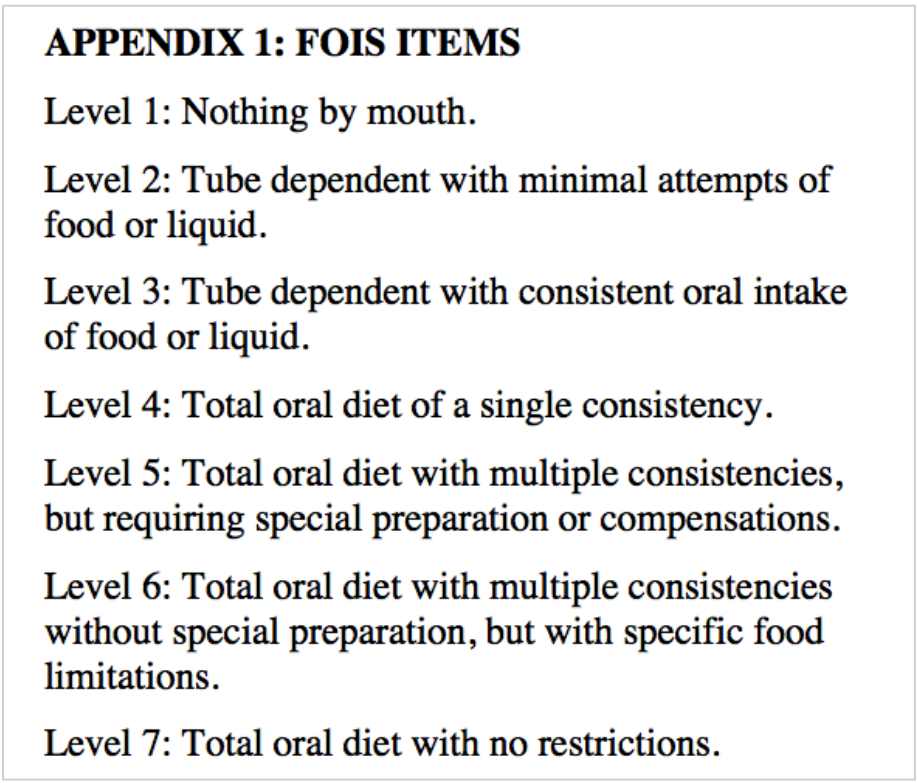
| Score | FLUIDS | Score | DIET | Score | SUPERVISION |
|---|---|---|---|---|---|
| 4 | No oral fluids | 4 | Non oral feeding | 4 | No oral feeding |
| 3 | Pudding consistency | 3 | Puree | 3 | Therapeutic feeding (SALT/trained staff) |
| 2 | Custard consistency | 2 | Soft, moist diet | 2 | Feeding by third party (untrained) |
| 1 | Syrup consistency | 1 | Selected textures | 1 | Eating with supervision |
| 0 | Normal fluids | 0 | Normal | 0 | Eating independently |

NB: Mashed diet texture recommendations will be rated as for 'puree' diet texture.

Taken from: Jayasekeran V, Singh S, Tyrrell P, et al. Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions. Gastroenterology 2010; 138: 1737-1746. 2010/02/09. DOI: 10.1053/j.gastro.2010.01.052.

As with the DOSS, which ranked independence levels according to the Functional Independence Measures (FIM) model and was linked to severity, [228] supervision on the DSRS was also divided into independence levels. However, unlike the DOSS, the DSRS does not require a VFSS to be performed. To date, the DSRS has been used in several published trials of PSD. [42, 44, 174, 229] The DSRS is copyright free and open access for research use. The aim of the present study was to test and describe the validity of the DSRS in patients with a recent stroke. Consensual, content, concurrent, and predictive validity, and internal consistency, inter- and intra-rater reliability, sensitivity to change, and minimal clinically important difference (MCID) were each assessed. Additionally the relationship with the FOIS, a validated dysphagia scale (Figure 6.2) [50] was examined. The MCID of the FOIS was also determined at the same time as the MCID of the DSRS.

**Figure 6-2** Functional Oral Intake Scale



**APPENDIX 1: FOIS ITEMS**

Level 1: Nothing by mouth.

Level 2: Tube dependent with minimal attempts of food or liquid.

Level 3: Tube dependent with consistent oral intake of food or liquid.

Level 4: Total oral diet of a single consistency.

Level 5: Total oral diet with multiple consistencies, but requiring special preparation or compensations.

Level 6: Total oral diet with multiple consistencies without special preparation, but with specific food limitations.

Level 7: Total oral diet with no restrictions.

Taken from: Crary MA, Mann GD and Groher ME. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. Arch Phys Med Rehabil 2005; 86: 1516-1520. DOI: 10.1016/j.apmr.2004.11.049

## 6.2 Methods

This validation study of the DSRS used a mix of retrospectively collected data from completed clinical studies and newly collected prospective data.

### 6.2.1 Approvals, informed consent and ethical approval

In each case, non-attributable anonymised data were analysed. The completed trials each had national ethics approvals and patients (or surrogates) had given written informed consent, this covering subsequent data analyses; an individual patient data meta-analysis has already been published using the three pilot trials. For survey data, the University of Nottingham Faculty of Medicine Research Ethics Committee assessed that a full review by the committee was not indicated as the requests were distributed via professional networks; participation in the surveys was voluntary and anonymous and all data collection was performed in accordance with relevant guidelines and regulations set out by the University. Clinical audit data was collected by members of the clinical team and did not need research ethics approval. Information from a subset of anonymised individual patient trial data will be shared with the international VISTA Collaboration.[230]

### 6.2.2 Validation

Multiple approaches were taken to validate the DSRS including determining content validity, criterion validity (both concurrent and predictive), internal consistency, inter- and intra-rater reliability and sensitivity to change/ responsiveness. These approaches are recommended by COSMIN which provides

taxonomy and definitions of measurement properties for health-related patient-reported outcomes. [231] [232] Additionally, consensual validity and the minimal clinically important difference (MCID) were determined.

### 6.2.3 Data sources

Validation assessments used data from all trials and unpublished studies that are currently known to have used the DSRS as an outcome. These included raw data from published trials of pharyngeal electrical stimulation (PES), [42] [44, 174, 229] an individual patient data meta-analysis of the first three of these PES trials, [43] and unpublished studies (NCT03499574, [233] NCT03700853). [234] All studies involved patients with acute and/or sub-acute stroke.

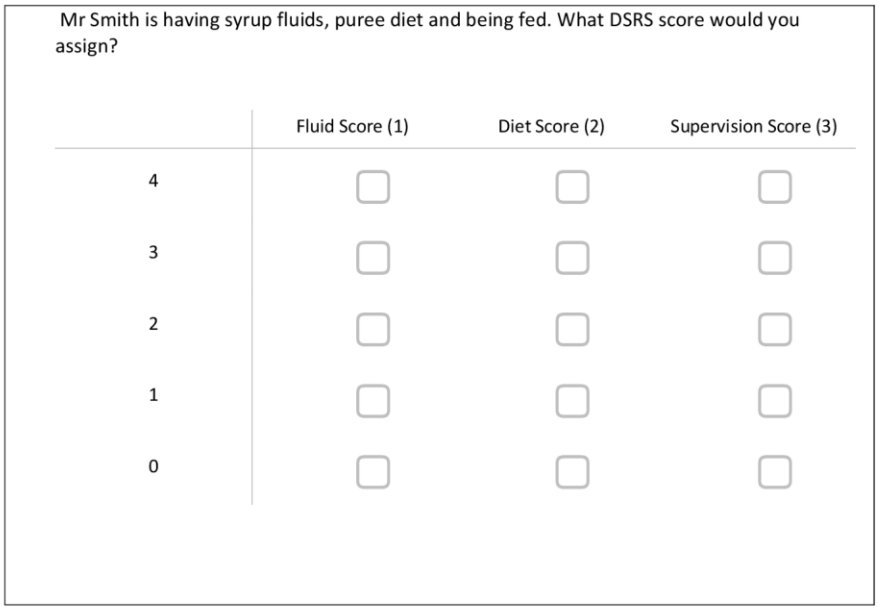
Consensual and content validity were assessed from an anonymous survey sent via Qualtrics$^{XM}$ cloud-based platform on the Internet, to 20 UK-based SLTs experts with experience of working with adults with acquired dysphagia. Similarly, to establish the MCID, an anonymous survey was also used, via SurveyMonkey® cloud-based software, on the internet, which was distributed to a number of UK SLT professional networks.

### 6.2.4 Consensual validity

This is the validity of a test determined by its general acceptance in the community of users, or by the number of users who judge it to be valid. [235] Consensual validity was assessed by asking respondents to rate 5 scenarios using the DSRS, as recently used in validation of the International Dysphagia Diet Standardisation Initiative (IDDSI) Functional Diet Scale. [55] The survey was sent to 20 invited UK-based SLTs as typically, they are the primary clinicians

who treat dysphagia in the UK, although it is acknowledged that some specialist stroke nurses are also dysphagia trained beyond a screening protocol. The responses were collected in September 2018. Scenarios required respondents to rate recommendations of full amounts of oral intake, minimal and consistent oral trials, liquid only diets and accompanying levels of supervision (figure 6.3). The inclusion of oral trials reflected the author's analysis of the use of the DSRS in the STEPS trial, [44] where different scoring patterns were observed for patients on oral trials. Recommendations for a liquid only diet, although a less common occurrence, were also included as this was recently shown to be an area of scoring uncertainty on the IDDSI Functional Diet Scale. [55] It is important to include not only predictable, but also challenging scenarios when evaluating consensual validity. Relevant additional information was provided to the respondents regarding the background and purpose of the scale, and what patient group it was designed for, alongside instructions for completing the survey (Appendix 2). Respondents were asked to provide additional comments at the end of the survey. Excellent or good agreement were considered acceptable. Figure 6.3 provides an example of one scenario.

**Figure 6-3** Sample of scenario from consensual validity




### 6.2.5 Content validity

According to COSMIN, content validity reflects how closely the items (content) of an instrument represent what the instrument aims to measure. [231, 232] The first part of establishing content validity usually includes designing the instrument and the second part assesses it for accuracy of content. [236] When considering content validation of the DSRS, the first part was already undertaken by the researchers who originally designed the scale in 2010. [42] Although the assessment of content validity is usually undertaken before an instrument is finished, [237] it is still important and appropriate to assess content validity in retrospect. In this regard, Polit and Yang (2016) refer to the US Food and Drug Administration's guiding document regarding the use of Patient Reported Outcomes (PRO) in clinical trials. This document recommends undertaking a separate content validation on PRO measures that have been selected to be

used if this process has not already been done when the instrument was drawn up. Although the DSRS is not a patient reported scale per se, it is still used to report on the outcomes of patients in clinical trials and hence should still undergo content validation.

Content validity also refers to the extent that a test includes all aspects of its construct, including relevance and comprehensiveness.[237] Relevance was assessed using the content validity index (CVI).[238] The CVI is an indicator of inter-rater agreement that asks experts to appraise how relevant items are [237, 238] and is particularly appropriate to use on instruments that have scales with multiple items. [237, 238] The CVI specifically focuses on relevance of agreement between raters, not just agreement in and of its own. [238] Although the CVI does not account for chance agreement, Polit et al [238] have developed a method to adjust for chance agreement by converting items into values of a modified kappa statistic. The CVI method as described by Polit et al. [238] and Polit (2016) [237] was used in this survey.

Content validity was assessed at the same time as consensual validity, to the same group of SLTs, with accompanying instructions (Appendix 2.) Experts were provided with a copy of the scale and asked to evaluate each item on the fluid, food and supervision scales respectively, by assigning a score of 1 (not relevant), 2 (somewhat relevant), 3 (quite relevant) or 4 (highly relevant) as depicted below:

**Figure 6-4** Sample of question from content validity survey

**Dysphagia Severity Rating Scale**

| Score | Fluids | Score | Diet | Score | Supervision |
|---|---|---|---|---|---|
| **4** | No oral fluids | **4** | Non-oral feeding | **4** | No oral feeding |
| **3** | Pudding consistency | **3** | Puree | **3** | Therapeutic feeding (SALT/ trained staff) |
| **2** | Custard consistency | **2** | Soft, moist diet | **2** | Feeding by third party (untrained) |
| **1** | Syrup consistency | **1** | Selected textures | **1** | Eating with supervision |
| **0** | Normal fluids | **0** | Normal | **0** | Eating independently |

NB: Mashed diet texture recommendations will be rated as for 'puree' texture.

Q1 Please score each item according to how relevant the item is to the fluid scale. How relevant is **no oral fluids**?

- ○ Not relevant (1)
- ○ Somewhat relevant (2)
- ○ Quite relevant (3)
- ○ Highly relevant (4)

To calculate validity of individual *items*, only scores of 3 and 4, representing quite relevant and highly relevant ratings were summed and divided by the total number of respondents to give an I-CVI score. For a scale to be considered as displaying excellent content validity, items need to have I-CVIs of 0.78 or higher. [238]

Each *scale* was evaluated using the averaging method, referred to as scale-level CVI average (S-CVI/Ave). In this approach, each I-CVI score for every item on the scale is summed and divided by the number of items. For a scale to be considered as displaying excellent content validity, scales need to have S-CVI/Ave of 0.90 or higher, although taking a liberal viewpoint, a minimum of 0.80 would need to be achieved. [238]

In parallel, respondents were asked after each subscale, if that section was comprehensive and whether the wording was clear by commenting yes or no and providing comments.

### 6.2.6 Concurrent validity

This demonstrates how well a measure (in this case, the DSRS) correlates with other measures taken at the *same* timepoint [237] and is part of criterion validity as specified by COSMIN. [232] In this study, the DSRS was correlated with stroke-related clinical and radiological measures. These included radiological aspiration (penetration aspiration score, PAS by VFS); [66] swallowing (Toronto bedside swallowing screening test [TOR-BSST],[239] using the sum of the 14 components rather than just the dichotomous pass/fail score (see detail below); and FOIS; [50] neurological impairment (National Institutes of Health stroke scale, NIHSS); disability (Barthel index, BI) [240]; dependency (modified Rankin scale, mRS) [240] and quality of life (EuroQoL 5-dimension 3-level, EQ-5D-3L; EuroQoL visual analogue scale, EQ-VAS). [241] Associations were performed at all available timepoints, typically at baseline, and on and after treatment, using Spearman's correlation coefficient.

With regards to the TOR-BSST, this is a pass-fail screening tool and as such, would not therefore be informative in this context. However, since the TOR-BSST uses a graded approach of increasing amounts of water to screen swallowing function, a score of 1 was given to normal function for voice quality, tongue movement and normal performance with tsps and sips of water. A score of 0 was given for abnormal voice and tongue movement or coughing/ voice change or drooling with tsps and sips of water. This generated a composite score out of 14 where a higher score was associated with more normal function on the TOR-BSST. This then afforded an opportunity to assess for correlations on the performance on the TOR-BSST with scores on the DSRS.

### 6.2.7 Predictive validity

This demonstrates how well a measure (in this case, the DSRS) correlates at baseline with stroke-related clinical and radiological measures assessed at a *later* timepoint [237] and is part of criterion validity as specified by COSMIN. [232]The measures are those as identified immediately above as for concurrent validity and were analysed using Spearman's correlation coefficient.

### 6.2.8 Internal consistency

This assesses how well the components of the scale relate to each other and is a measure of scale reliability as specified by COSMIN. [231, 232]The interrelation between scores from the three subscales were assessed using Cronbach's alpha. [242] Data sources were from the STEPS, Vasant and PHAST-TRAC trials, and anonymised clinical audit data from a stroke ward as determined by a Speech and Language Therapist (JB) and Research Practitioner (AH).

### 6.2.9 Inter/intra-rater reliability

These are the degree of agreement among raters, and among repeated measurements by one rater, respectively and fall under the domain of reliability in COSMIN. [232] Inter-rater and intra-rater reliability was performed by JB and AH using the same audit data as used for internal consistency. Both measures of reliability were assessed using the inter-class correlation coefficient (ICC).

### 6.2.10 Sensitivity to change

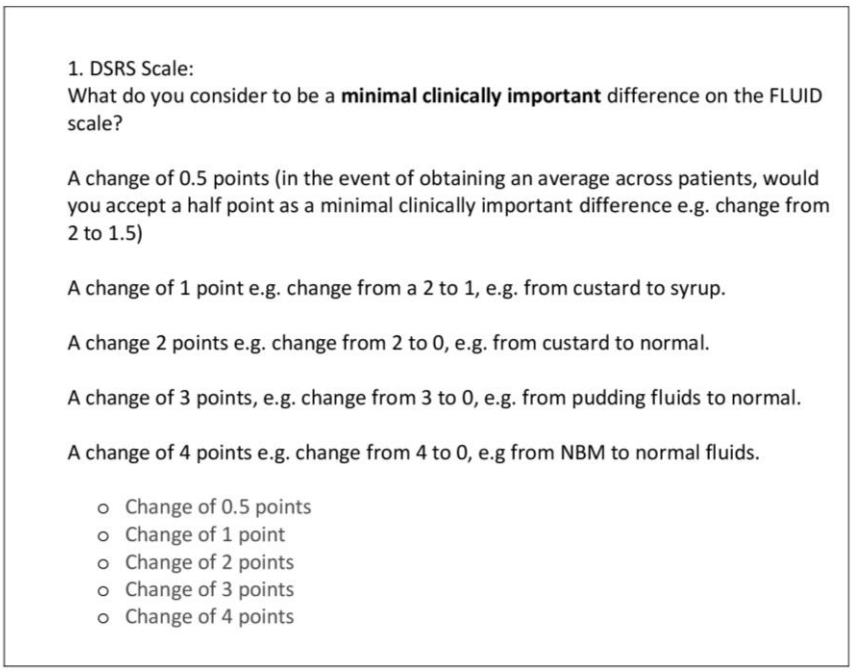
This is also known as responsiveness according to COSMIN [231] [232]and refers to how well an instrument identifies longitudinal changes, in a proportionate manner. [237] Changes in the DSRS during the rehabilitation phase after stroke, i.e., from study baseline to final follow-up, were assessed using data from the STEPS trial.

### 6.2.11 Minimal clinically important difference (MCID)

The MCID is the minimum difference in a score that is considered valuable and changes patient management. [243] The MCID therefore, assesses whether changes seen on the DSRS that may be statistically significant, are also judged to be clinically meaningful. [56] MCID was assessed in three different ways through assessment of statistical distribution (both half standard deviation and standard error of mean), anchor method (change in end point scores of aspiration at two weeks and change in oral- and non-oral feeding at two weeks in STEPS trial and consensus through a survey. [56, 58, 244] Data for analysis of statistical distribution and anchor methods came from the STEPS trial [44] and an individual patient data

meta-analysis of three pilot trials of PES. [43] Data for the MCID came from a survey to UK-based SLTs and sought to establish the MCID for both the DSRS and the FOIS. The survey, as mentioned above, was sent to a number of SLT professional networks via SurveyMonkey®. Consent was sought from the administrator of each network for distribution to its members. It was up to the discretion of the network administrators as to whether the survey was forwarded. A letter with instructions to score the MCID and copies of the DSRS and FOIS (Appendix 3) were provided to network administrators. The survey started in April 2017 and ran until January 2018. A push to send surveys again (in December 2017) to a wider number of networks (after a decline in responses) led to further responses being received. A sample question for each of the DSRS and FOIS are provided below.

**Figure 6-5** Sample of question from MCID survey for DSRS


1. DSRS Scale:
What do you consider to be a **minimal clinically important** difference on the FLUID scale?

A change of 0.5 points (in the event of obtaining an average across patients, would you accept a half point as a minimal clinically important difference e.g. change from 2 to 1.5)

A change of 1 point e.g. change from a 2 to 1, e.g. from custard to syrup.

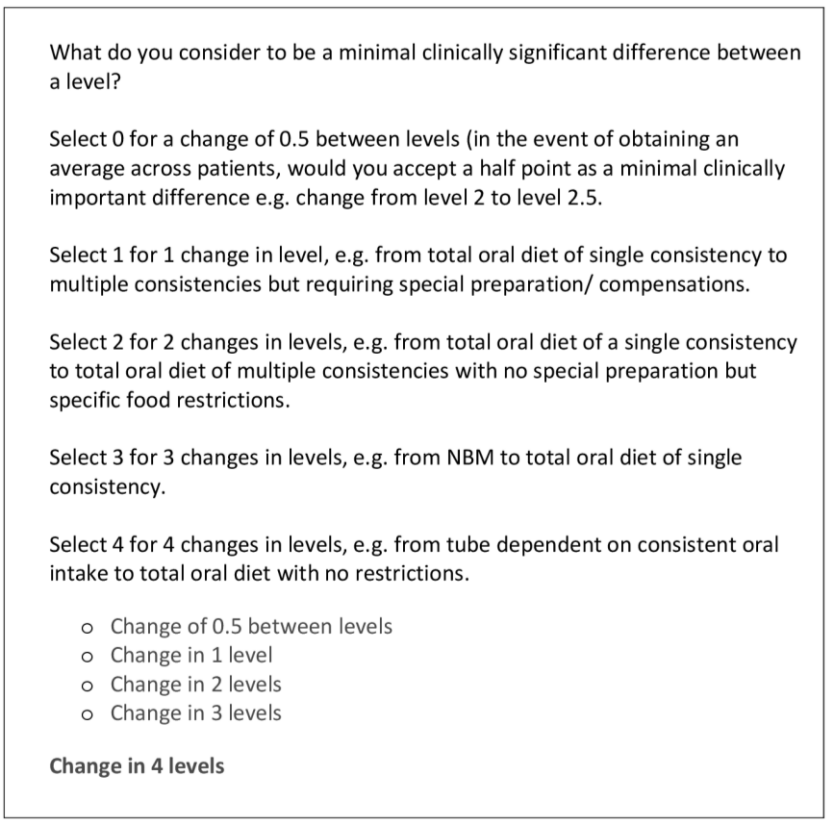
A change 2 points e.g. change from 2 to 0, e.g. from custard to normal.

A change of 3 points, e.g. change from 3 to 0, e.g. from pudding fluids to normal.

A change of 4 points e.g. change from 4 to 0, e.g from NBM to normal fluids.

- Change of 0.5 points
- Change of 1 point
- Change of 2 points
- Change of 3 points
- Change of 4 points

**Figure 6-6** Sample of question from MCID survey for FOIS




### 6.2.12 Relationship between DSRS and FOIS

The DSRS and FOIS measure overlapping aspects of clinical dysphagia although they have an opposite direction of severity. Their relationship and interconversion were determined through mapping equivalent levels and using data from studies that measured both in parallel. Where a range of values was estimated the median of these is given.

### 6.2.13 Statistical analyses

In addition to the specific analyses detailed above, standard approaches were used to present results as number (%), median [interquartile range, IQR] or mean (standard deviation, SD).

## 6.3 Results

### 6.3.1 Trial individual patient data

Four trials of pharyngeal electrical stimulation after stroke have been performed where DSRS was recorded: Jayasekeran, Vasant, STEPS and PHAST-TRAC. [42, 44, 174, 229] Data on DSRS and other clinical and radiological measures were available at baseline and variously at days 2, 14, 30 and 90. The mean age was 71 (SD 12) years with 109 (38%) female, mean onset to randomisation of 21 (SD 17) days; the most common clinical syndrome was partial-anterior circulation, 92 (43%) and just 3 (1%) patients had a posterior syndrome; 211 (85%) participants had an ischaemic stroke and 38 (15%) an intracerebral haemorrhage (Table 6.1). A ceiling effect was noted at baseline with 139 (48%) patients having a maximum DSRS score of 12. Increasing dysphagia impairment, assessed using the DSRS, was significantly associated with time from onset to randomisation, worse neurological deficit (NIHSS), stroke type, dependency (modified Rankin scale), disability (Barthel index), swallow screening (component score on TOR-BSST), radiological aspiration (PAS) and non-oral feeding state (Table 6.1).

**Table 6-1** Baseline clinical characteristics in four trials by baseline dysphagia severity rating scale (DSRS) at baseline

| | N | All | DSRS | | | | | | | | | | | rs | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 287 | 8.5 (3.9) | <3 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | |
| N | | | 22 | 17 | 26 | 20 | 12 | 18 | 10 | 11 | 6 | 6 | 139 | - | - |
| Age (yr) | 287 | 71 (12) | 68 | 71 | 73 | 74 | 73 | 76 | 78 | 74 | 80 | 78 | 69 | -0.093 | 0.12 |
| Female (%) | 287 | 109 (38) | 13.6 | 35.3 | 57.7 | 40 | 50 | 44.4 | 60 | 27.3 | 66.7 | 33.3 | 34.5 | -0.025 | 0.67 |
| OTR (days) | 287 | 21 (17) | 16.5 | 14.1 | 12.4 | 15.2 | 16.6 | 18.4 | 11.10 | 21 | 17 | 19.2 | 26.11 | 0.319 | **<0.001** |
| Syndrome (%) | 215 | | | | | | | | | | | | | -0.007 | 0.92 |
| TACS | | 71 (33) | 22.7 | 47.1 | 24.0 | 45.0 | 8.3 | 16.7 | 70 | 54.5 | 60 | 0 | 33.3 | | |
| PACS | | 92 (43) | 45.5 | 23.5 | 56.0 | 30.0 | 58.3 | 55.6 | 20 | 27.3 | 20.0 | 83.3 | 43.5 | | |
| LACS | | 49 (23) | 31.8 | 29.4 | 20.0 | 25.0 | 33.3 | 27.8 | 10 | 9.1 | 0 | 16.7 | 21.7 | | |
| POCS | | 3 (1) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9.1 | 20.0 | 0 | 1.4 | | |
| NIHSS (/42) | 282 | 12 (7) | 8.64 | 10.7 | 9.3 | 10 | 9.2 | 8.6 | 17.7 | 13.9 | 11.2 | 8.7 | 14 | 0.304 | **<0.001** |
| Type (%) | 249 | | | | | | | | | | | | | 0.147 | **0.020** |
| IS | | 211 (85) | 95.5 | 92.9 | 95 | 100 | 50 | 81.3 | 100 | 88.9 | 66.7 | 100 | 80.3 | | |
| ICH | | 38 (15) | 4.5 | 7.1 | 5 | 0 | 50 | 18.8 | 0 | 1.1 | 33.3 | 0 | 19.7 | | |
| mRS (/6) | 254 | 4.2 (1.1) | 3.54 | 3.9 | 3.5 | 4.0 | 3.9 | 4.3 | 4.6 | 4.4 | 4.0 | 3.0 | 4.5 | 0.390 | **<0.001** |
| Barthel index (/100) | 215 | 25.9 (28.3) | 32.4 | 32.7 | 37.3 | 28.4 | 27.2 | 19.6 | 8.2 | 7.6 | 18.6 | 33.67 | 23.9 | -0.189 | **0.005** |

| | N | All | DSRS | | | | | | | | | | rs | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TOR-BSST failed (%) | 190 | 185 (97) | 92.3 | 93.8 | 100 | 100 | 90.9 | 94.4 | 100 | 100 | 100 | 100 | 98.4 | 0.073 | 0.31 |
| TOR-BSST (/14) [a] | 154 | 2.4 (3.9) | 3.0 | 2.9 | 2.9 | 2.8 | 1.1 | 3.5 | 0.5 | 2.6 | 5.0 | 5.0 | 1.6 | -0.167 | **0.038** |
| PAS (/8) | 200 | 4.7 (2.0) | 3.5 | 3.6 | 3.4 | 4.0 | 4.3 | 5.4 | 4.4 | 4.2 | 5.2 | 4.8 | 5.9 | 0.475 | **<0.001** |
| Feeding, non-oral (%) | 287 | 205 (71) | 18.2 | 11.8 | 30.8 | 40 | 58.3 | 61.1 | 60 | 90.9 | 100 | 83.3 | 99.3 | 0.625 | **<0.001** |

a STEPS only

ICH: intracerebral haemorrhage; IS: ischaemic stroke; OTR: onset to randomisation; NIHSS: National Institute for Stroke Health Scale; mRS: modified Rankin Score; PACS: partial anterior circulation syndrome; LACS: lacunar syndrome; POCS: posterior circulation syndrome; TACS: total anterior circulation syndrome; PAS: penetration aspiration scale; TOR-BSST: Toronto bedside swallowing screening test;

### 6.3.2 Consensual validity

Between eight and ten respondents rated each scenario. Seventy percent of respondents had 10+ years' experience. The areas of expertise of the respondents were: stroke (5), head and neck (2), dementia (1), other (2). Consensus was excellent (100%) for recommendations of full oral intake; moderate (78%) to low (56%) for *minimal* oral trials of liquids (e.g., 5 sips) and solids (e.g., 5 tsps.) respectively, and high (89%) and moderate (78%) for *consistent/ substantial* oral trials of liquids (e.g., 100ml) and solids (e.g., half portions of diet) respectively. Consensus was excellent for scoring the liquid-only diet (100%) but not the accompanying diet component of this scenario (62.5%) which means this component, overall, had a moderate consensus. Supervision scores were high (80-100%) for full oral intake, high (89%) for minimal oral trials and moderate (67%) for consistent/ substantial oral trials. (Table 6.2). Respondents' comments requested clarification on how to score consistent amounts of oral trials and liquid diets (Appendix 2).

**Table 6-2** Consensual validity assessed using consensus for 5 scenarios. Data are number (%) agreeing

| **Agreement (%)** | **Fluids** | **Diet** | **Supervision** |
|---|---|---|---|
| *Full oral intake*<br>1. Mr Smith is having syrup fluids, puree diet and being fed.<br>2. Miss Brown is having normal fluids and managing most normal foods. However, she is still avoiding certain textures but eats independently. | 10 (100)<br>10 (100) | 10 (100)<br>10 (100) | 8 (80)<br>9 (100) |
| *Minimal oral trials*<br>3. Mrs Jackson is having 5 sips of custard consistency fluids and 5 tsps. of chilled smooth puddings 3 x day. She has an NG Tube in. | 7 (78) | 5 (56) | 8 (89) |
| *Consistent oral trials*<br>4. Mr Jones is having half puree meals 3 x day and 100ml syrup fluids 3 x day, he has a nasogastric tube *in situ*, and he is being fed. | 8 (89) | 7 (78) | 6 (67) |
| *Liquid diet*<br>5. Mrs Ward is on a purely liquid diet of syrup consistency (such as smoothies, fortified drinks), does not require tube feeding and eats independently. | 8 (100) | 5 (63) | 10 (100) |

### 6.3.3 Content validity

As part of the same survey, ten of the 20 invited UK-based SLTs responded to the content validity exercise. This is an acceptable number of expert views for undertaking content validation of an instrument.[238] All but two components of the DSRS sub-scales had "excellent" relevance (I-CVI>0.90): "pudding consistency" was good and "selected textures" was fair (Table 6.3). At a scale level, both the fluid and food scale achieved an S-CVI/Ave rating of 0.84 (good) and the supervision scale a rating of 0.96 (excellent) (Table 6.3).

**Table 6-3** Content validity of DSRS sub-scales assessed by 10 UK Speech and Language Therapists

| Item | Rating 3 or 4 (N of 3, 4) | I-CVI | Rating | S-CVI | Rating |
|---|---|---|---|---|---|
| *Fluids sub-scale* | | | | | |
| No oral fluids | 9 (1, 8) | 0.90 | Excellent | 0.84 | Good |
| Pudding consistency | 7 (3, 4) | 0.70 | Good | | |
| Custard consistency | 8 (1, 7) | 0.80 | Excellent | | |
| Syrup consistency | 8 (1, 7) | 0.80 | Excellent | | |
| Normal fluids | 10 (2, 8) | 1.00 | Excellent | | |
| *Diet sub-scale* | | | | | |
| Non oral feeding | 9 (1, 8) | 0.90 | Excellent | 0.84 | Good |
| Puree (mashed) | 10 (0, 10) | 1.00 | Excellent | | |
| Soft, moist diet | 9 (1, 8) | 0.90 | Excellent | | |
| Selected textures | 5 (2, 3) | 0.50 | Fair | | |
| Normal diet | 9 (0, 9) | 0.90 | Excellent | | |
| *Supervision* | | | | | |
| No oral feeding | 9 (2, 7) | 0.90 | Excellent | 0.96 | Excellent |
| Therapeutic feeding | 10 (0, 10) | 1.00 | Excellent | | |
| Feeding by third party | 9 (0, 9) | 0.90 | Excellent | | |
| Eating with supervision | 10 (0, 10) | 1.00 | Excellent | | |
| Eating independently | 10 (0, 10) | 1.00 | Excellent | | |

Interpretation of I-CVI: Excellent >0.78; Good >0.60-0.78; Fair >0.40-<0.60 [238]

Interpretation of S-CVI: Excellent >0.90; Good >0.80-<0.90 [238]

S-CVI is average of I-CVI in sub-scale

Expert feedback regarding wording and comprehensiveness are given in Table 6.4. and can also be viewed in detail in Appendix 2. Many of these related to the lack of mention of IDDSI [245] in the DSRS definitions, a point addressed in the Discussion. Table 6.4 provides a summary of the three main themes that emerged from respondents' comments.

**Table 6-4** Content validity: respondents' comments on comprehensiveness and wording

| % | Response | Fluids | Solids | Supervision |
|---|---|---|---|---|
| Comprehensive | Yes | 30 | 20 | 60 |
| | No | 40 | 40 | 40 |
| | Comment-only given | 30 | 40 | - |
| Wording | Clear | 50 | 30 | 80 |
| | Unclear | 20 | 60 | 20 |
| | Comment-only given | 30 | 10 | - |

**Comments from respondents**

*Terminology* – most respondents noted that the labels were not updated to reflect the terminology used by the International Dysphagia Diet Standardisation Initiative (IDDSI), [25] which has been adopted by the UK (where respondents were based).

*Need for more detailed descriptors* – some respondents felt that more detail was needed to define terms, for example, "selected textures", or that a description of bolus cohesiveness/food consistency should be included. Respondents also noted that some terms were subjective.

*Missing items* – respondents felt that additional levels would be helpful to include, e.g., having a separate group for pre-mashed or mashable foods; sub-dividing supervision into distant versus close supervision; including a category of slightly thick fluids (as present in IDDSI).

### 6.3.4 Concurrent validity

Data were available for all four trials and are detailed in Table 6.5. [42] [174] [44] [229] In the largest trial (STEPS), DSRS at baseline and weeks 2 and 13 was associated significantly and in appropriate directions with measures, at the same time points of aspiration (PAS using VFS), swallowing (TOR-BSST), disability (Barthel index) and dependency (modified Rankin scale). At 2 weeks post randomisation, DSRS was also associated with impairment (NIHSS). DSRS was not related to quality-of-life measures at 13 weeks post randomisation. The three sub-scale components of the DSRS (fluids, diet and supervision) were also each associated significantly with aspiration at all three time points. Similar magnitudes of associations were seen in the smaller studies of Jayasekeran [42] and Vasant [174] although associations did not always reach significance in these studies.[174] Overall, associations were stronger between DSRS and measures of swallowing and aspiration then with global measures of impairment (NIHSS), disability (BI) and dependency (mRS).

DSRS was strongly negatively correlated with FOIS at day 2 and week 13 in the PHAST-TRAC trial. The association could not be performed at baseline since all participants had a DSRS of 12/FOIS of 1 as part of the trial's inclusion criteria. [246]

**Table 6-5** Concurrent validity - Relationships between DSRS and clinical and radiological assessments at a variety of timepoints in trials of pharyngeal electrical stimulation. (Spearman's rank correlation coefficient)

| **DSRS *** | **Measure** | **Outcome** | **Range of Values** | **Timing (weeks)** | **N** | **Median (IQR)** | **rs** | **P** |
|---|---|---|---|---|---|---|---|---|
| STEPS [44] | | | | | | | | |
| Total score | DSRS | Dysphagia | 0 to 12 | 0 | 154 | 7 (8) | - | - |
| | | | | 2 | 131 | 4 (5) | - | - |
| | | | | 13 | 106 | 1 (3) | - | - |
| | VFS-PAS | Aspiration | 1 to 8 | 0 | 154 | 4.71 (3.66) | **0.488** | **<0.001** |
| | | | | 2 | 126 | 3.27 (3) | **0.387** | **<0.001** |
| | | | | 13 | 95 | 2.29 (2.93) | **0.398** | **<0.001** |
| | TOR-BSST | Swallowing | 0 to 14 | 0 | 154 | 1 (3) | **-0.167** | **0.038** |
| | | | | 2 | 127 | 2 (10) | **-0.459** | **<0.001** |
| | | | | 13 | 103 | 6 (13) | **-0.520** | **<0.001** |
| | NIHSS | Impairment | 0 to 42 | 0 | 150 | 9 (10) | 0.020 | 0.81 |
| | | | | 2 | 131 | 8 (10) | **0.301** | **<0.001** |
| | | | | 13 | 106 | 5 (8) | 0.117 | 0.23 |
| | BI | Disability | 0 to 100 | 0 | 151 | 20 (40) | **-0.279** | **0.001** |
| | | | | 2 | 131 | 25 (60) | **-0.517** | **<0.001** |
| | | | | 13 | 106 | 65 (65) | **-0.407** | **<0.001** |
| | mRS | Dependency | 0 to 5 | 0 | 151 | 4 (1) | **0.179** | **0.028** |
| | | | | 2 | 131 | 4 (2) | **0.382** | **<0.001** |
| | | | | 13 | 106 | 4 (2) | **0.279** | **0.004** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | EQ-VAS | QoL | 0 to 100 | 13 | 87 | 58 (35) | -0.149 | 0.17 |
| | EQ-5D-3L | QoL | -0.5 to 1.0 | 13 | 95 | -0.04 (0.489) | -0.109 | 0.29 |
| Fluids | VFS-PAS | Aspiration | 1 to 8 | 0 | 154 | 4.71 (3.66) | **0.498** | **<0.001** |
| | | | | 2 | 126 | 3.27 (3) | **0.374** | **<0.001** |
| | | | | 13 | 95 | 2.29 (2.93) | **0.362** | **<0.001** |
| Diet | | | | 0 | 154 | 4.71 (3.66) | **0.402** | **<0.001** |
| | | | | 2 | 126 | 3.27 (3) | **0.416** | **<0.001** |
| | | | | 13 | 95 | 2.29 (2.93) | **0.371** | **<0.001** |
| Supervision | | | | 0 | 154 | 4.71 (3.66) | **0.417** | **<0.001** |
| | | | | 2 | 126 | 3.27 (3) | **0.236** | **0.008** |
| | | | | 13 | 95 | 2.29 (2.93) | **0.343** | **0.001** |
| Jayasekeran[42] | | | | | | | | |
| Total score | DSRS | Dysphagia | 0 to 12 | 0 | 28 | 5.5 (11) | - | - |
| | | | | 2 | 28 | 2.5 (5) | - | - |
| | VFS-PAS | Aspiration | 1 to 8 | 0 | 28 | 4.5 (3) | 0.345 | 0.073 |
| | | | | 2 | 28 | 4 (3) | 0.146 | 0.46 |
| | BI | Disability | 0 to 20 | 0 | 28 | 6 (4) | -0.340 | 0.077 |
| | | | | 2 | 28 | 14 (7) | -0.273 | 0.16 |
| Vasant [174] | | | | | | | | |
| Total score | DSRS | Dysphagia | 0 to 12 | 0 | 36 | 8 (8) | - | - |
| | | | | 2 | 34 | 3 (8) | - | - |
| | | | | 13 | 32 | 1 (3) | - | - |
| | VFS-PAS | Aspiration | 1 to 8 | 0 | 18 | 3.50 (4) | **0.551** | **0.018** |
| | | | | 2 | 15 | 3 (2) | **0.537** | **0.039** |
| | | | | 13 | 10 | 1 (2) | 0.159 | 0.66 |
| | NIHSS | Impairment | 0 to 42 | 0 | 36 | 11.50 (11) | 0.142 | 0.41 |
| | | | | 2 | 33 | 6 (7) | **0.378** | **0.030** |
| | | | | 13 | 26 | 4 (5) | 0.301 | 0.14 |
| | BI | Disability | 0 to 100 | 0 | 36 | 21.50 (39) | -0.017 | 0.92 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | 2 | 34 | 37.50 (50) | **-0.400** | **0.019** |
| | | | | 13 | 27 | 65 (58) | -0.258 | 0.20 |
| | mRS | Dependency | 0 to 5 | 0 | 35 | 4 (1) | -0.030 | 0.86 |
| | | | | 2 | 33 | 3 (2) | **0.359** | **0.040** |
| | | | | 13 | 27 | 2 (2) | 0.311 | 0.11 |
| PHAST-TRAC[229] | | | | | | | | |
| Total score | DSRS | Dysphagia | 0 to 12 | 0 | 69 | 12 (0) | - | - |
| | | | | 0.3 | 60 | 10.5 (2.5) | - | - |
| | | | | 13 | 52 | 5.1 (5.2) | - | - |
| | FOIS | Dysphagia | 1 to 7 | 0 | 69 | 1 (0) | ND | ND |
| | | | | 0.3 | 60 | 1.8 (1.3) | **-0.955** | **<0.001** |
| | | | | 13 | 52 | 4.3 (2.6) | **-0.978** | **<0.001** |

* DSRS range is 0-12 for total score, and 0-4 for subscales

BI: Barthel index; DSRS: dysphagia severity Rating scale; EQ-5D-3L/HUS: EuroQoL-5 dimension-3 level as health utility scale; EQ-VAS: EuroQoL-visual analogue scale; FOIS: functional oral intake scale; mRS: modified Rankin scale; NIHSS: National Institutes of Health Stroke Scale; PAS: penetration aspiration scale [66]; Richmond agitation and sedation scale (RASS); [247] VFS: videofluoroscopy

ND: Not done - all participants had DSRS=12 and FOIS=1 at baseline [246]

### 6.3.5 Predictive validity

As can be seen in Table 6.6, using data from the STEPS trial, baseline DSRS was associated with radiological aspiration (PAS using VFS) at 2 and 13 weeks; and swallowing (TOR-BSST), disability (BI) and dependency (mRS) at 2 weeks. There was no association with impairment (NIHSS), or quality of life (EQ-5D-3L, EQ-VAS). The three DSRS sub-scale components (fluids, diet and supervision) at baseline were also each associated significantly with radiological aspiration at 2 and 13 weeks.

Associations between baseline DSRS and post-treatment measures in the trials of Jayasekeran and Vasant were not statistically significant. It was not possible to assess the relationship between baseline DSRS and post treatment FOIS in the PHAST-TRAC trial since all participants had a baseline DSRS score of 12. [246]

**Table 6-6** Predictive validity - Relationships between DSRS at baseline with clinical and radiological assessments on or after treatment in trials of pharyngeal electrical stimulation. (Spearman's rank correlation coefficient)

| Trial | DSRS * | Measure | Outcome | Range of values | Timing (weeks) | N | Median (IQR) | rs | P |
|---|---|---|---|---|---|---|---|---|---|
| STEPS [44] | Total score | VFS-PAS | Aspiration | 1 to 8 | 2 | 126 | 3.27 (3) | **0.461** | **<0.001** |
| | | | | | 13 | 95 | 2.29 (2.93) | **0.419** | **<0.001** |
| | | TOR-BSST | Swallowing | 0 to 14 | 2 | 127 | 2 (10) | **-0.252** | **0.004** |
| | | | | | 13 | 103 | 6 (13) | -0.131 | 0.19 |
| | | NIHSS | Impairment | 0 to 42 | 2 | 132 | 8 (10) | 0.094 | 0.28 |
| | | | | | 13 | 106 | 5 (8) | -0.010 | 0.92 |
| | | BI | Disability | 0 to 100 | 2 | 132 | 25 (59) | **-0.281** | **0.001** |
| | | | | | 13 | 107 | 65 (65) | -0.176 | 0.070 |
| | | mRS | Dependency | 0 to 5 | 2 | 132 | 4 (2) | **0.177** | **0.042** |
| | | | | | 13 | 110 | 4 (2) | 0.048 | 0.62 |
| | | EQ-5D-3L | QoL | -0.5 to 1.0 | 13 | 95 | -0.04 (0.489) | -0.075 | 0.47 |
| | | EQ-VAS | QoL | 0 to 100 | 13 | 87 | 58 (35) | 0.070 | 0.52 |
| | Fluids † | VFS-PAS | Aspiration | 1 to 8 | 2 | 126 | 3.27 (3) | **0.445** | **<0.001** |
| | | | | | 13 | 95 | 2.29 (2.93) | **0.394** | **<0.001** |
| | Diet † | | | | 2 | 126 | 3.27 (3) | **0.365** | **<0.001** |
| | | | | | 13 | 95 | 2.29 (2.93) | **0.351** | **<0.001** |
| | Supervision † | | | | 2 | 126 | 3.27 (3) | **0.388** | **0.001** |
| | | | | | 13 | 95 | 2.29 (2.93) | **0.342** | **0.001** |
| Jayasekeran [42] | Total score | VFS-PAS | Aspiration | 1 to 8 | 2 | 28 | 4 (3) | -0.220 | 0.26 |
| | | BI | Disability | 0 to 20 | 2 | 28 | 14 (7) | -0.303 | 0.12 |
| Vasant [174] | Total score | VFS-PAS | Aspiration | 1 to 8 | 2 | 16 | 3 (4) | -0.058 | 0.83 |
| | | | | | 13 | 11 | 1 (2) | -0.169 | 0.62 |
| | | NIHSS | Disability | 0 to 42 | 2 | 33 | 6 (7) | 0.245 | 0.17 |
| | | | | | 13 | 27 | 4 (4) | 0.104 | 0.61 |
| | | BI | Disability | 0 to 100 | 2 | 34 | 38 (50) | -0.242 | 0.17 |
| | | | | | 13 | 28 | 65 (56) | -0.113 | 0.57 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | mRS | Dependency | 0 to 5 | 2 | 33 | 3 (2) | | 0.098 | 0.59 |
| | | | | 13 | 28 | 2 (2) | | 0.099 | 0.62 |

* DSRS range: 0-12 for total score; 0-4 for subscales

† Associations between post-treatment DSRS and outcome measures at subsequent timepoints

BI: Barthel index; DSRS: dysphagia severity Rating scale; EQ-5D-3L/HUS: EuroQoL-5 dimension-3 level as health utility scale; EQ-VAS: EuroQoL-visual analogue scale; FOIS: functional oral intake scale; mRS: modified Rankin scale; NIHSS: National Institutes of Health Stroke Scale; PAS: penetration aspiration scale; VFS: videofluoroscopy

### 6.3.6 Internal consistency

The interrelation between the scores from the three subscales, at various timepoints, were assessed using Cronbach's alpha [248] using data from STEPS, Vasant and PHAST-TRAC trials. [44, 174, 229] Internal consistency was "Good" at baseline, varied between "Good" and "Excellent" over the first two weeks, and "Excellent" at 12 weeks. (Table 6.7). Similarly, audit of clinical data by JB and AH revealed "Excellent" consistency between the subscales (Table 6.8).

**Table 6-7** Internal consistency assessed using Cronbach's alpha for three trials

| **Day** | **0** | **2** | **4** | **6** | **8** | **14** | **90** |
|---|---|---|---|---|---|---|---|
| *STEPS* [44] | | | | | | | |
| N | 154 | ND | ND | ND | ND | 131 | 106 |
| Alpha | 0.89 (0.66, 0.78) | | | | | 0.88 (0.63, 0.77) | 0.92 (0.72, 0.84) |
| Interpretation † | Good | | | | | Good | Excellent |
| *Vasant* [174] | | | | | | | |
| N | 28 | ND | ND | ND | ND | 28 | 27 |
| Alpha | 0.88 (0.54, 0.84) | | | | | 0.87 (0.52, 0.83) | 0.91 (0.61, 0.88) |
| Interpretation † | Good | | | | | Good | Excellent |
| *PHAST-TRAC* [229] | | | | | | | |
| N | ‡ | 60 | 46 | 41 | 31 | ND | 53 |
| Alpha | | 0.88 | 0.80 | 0.92 | 0.91 | | 0.96 |
| Interpretation † | | Good | Good | Excellent | Excellent | | Excellent |

ND = measures not done in this trial at this timepoint

**Table 6-8** Internal consistency assessed using Cronbach's alpha (95% confidence intervals) for audit data

| | **Speech** | **Therapist** | **Research** | **practitioner** |
|---|---|---|---|---|
| Measure | 1 (n=58) | 2 (n=31) | 1 (n=58) | 2 (n=31) |
| Alpha | 0.924 (0.814, 0.982 | 0.919 (0.746, 0.990) | 0.943 (0.846, 0.988) | 0.951 (0.808, 0.996) |
| Interpretation | Excellent | Excellent | Excellent | Excellent |

### 6.3.7 Inter/intra-rater reliability

The DSRS was scored in 31-58 of hospitalised stroke patients by JB and AH, using the updated guidelines following feedback from the consensual activity exercise. The inter-rater reliability was "Excellent" for DSRS with intra-class correlation (ICC) = 0.955 (95% confidence intervals 0.925, 0.973) for rater 1 and 0.929 (0.859, 0.965) for rater 2; similarly, the intra-rater reliability for both raters was perfect ICC= 1.00 (1.00, 1.00) (Table 6.9). Assessments within the subscale were mostly excellent with one good and one moderate result.

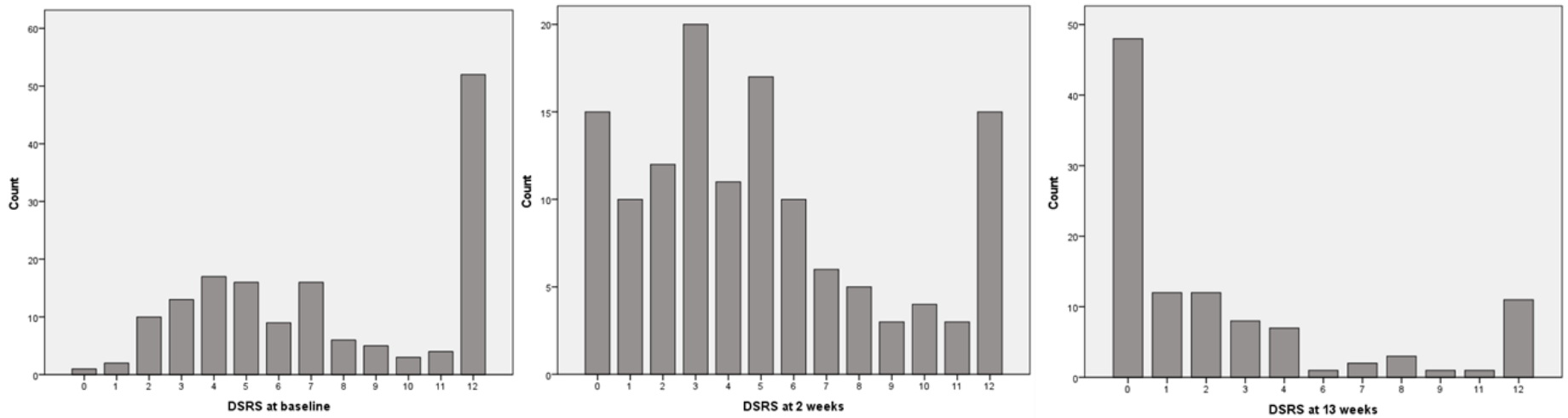
**Table 6-9** Intra- and inter-rater reliability for DSRS and subscales assessed using the intra-class correlation. Each rater scored data on two occasions separated by a month

| | Comparison | Scale | ICC | Interpretation |
|---|---|---|---|---|
| Inter-rater | 1 (n=58) | DSRS | 0.955 (0.925, 0.973) | Excellent |
| | | Fluids | 0.837 (0.740, 0.900) | Good |
| | | Diet | 0.985 (0.974, 0.991) | Excellent |
| | | Supervision | 0.952 (0.921, 0.971) | Excellent |
| Inter-rater | 2 (n=31) | DSRS | 0.929 (0.859, 0.965) | Excellent |
| | | Fluids | 0.721 (0.501, 0.855) | Moderate |
| | | Diet | 0.982 (0.965, 0.992) | Excellent |
| | | Supervision | 0.958 (0.915, 0.979) | Excellent |
| Intra-rater | 1 (n=41) | DSRS | 1.00 (1.00, 1.00) | Excellent |
| | | Fluids | 1.00 (1.00, 1.00) | Excellent |
| | | Diet | 1.00 (1.00, 1.00) | Excellent |
| | | Supervision | 1.00 (1.00, 1.00) | Excellent |
| Intra-rater | 2 (n=31) | DSRS | 1.00 (1.00, 1.00) | Excellent |
| | | Fluids | 1.00 (1.00, 1.00) | Excellent |
| | | Diet | 1.00 (1.00, 1.00) | Excellent |
| | | Supervision | 1.00 (1.00, 1.00) | Excellent |

### 6.3.8 Sensitivity to change

DSRS scores were sensitive to spontaneous recovery for patients with acute/subacute PSD, declining during follow-up in STEPS with modal values of 12, 3 and 0 at weeks 0 (baseline), 2 and 13 respectively (Figure 6.7). Similarly, the median (7, 4, 1) and mean (7.6, 4.9, 2.7) values declined at the same timepoints. As with VFS-PAS, DSRS was sensitive to detecting change following treatment with pharyngeal electrical stimulation in a meta-analysis of three pilot trials being 1.7 points lower (p=0.040) in the PES group as compared with the control group.[43] In contrast, the STEPS trial was neutral for the effect of PES on VFS-PAS and there was no difference in DSRS scores between treatment groups.[44]

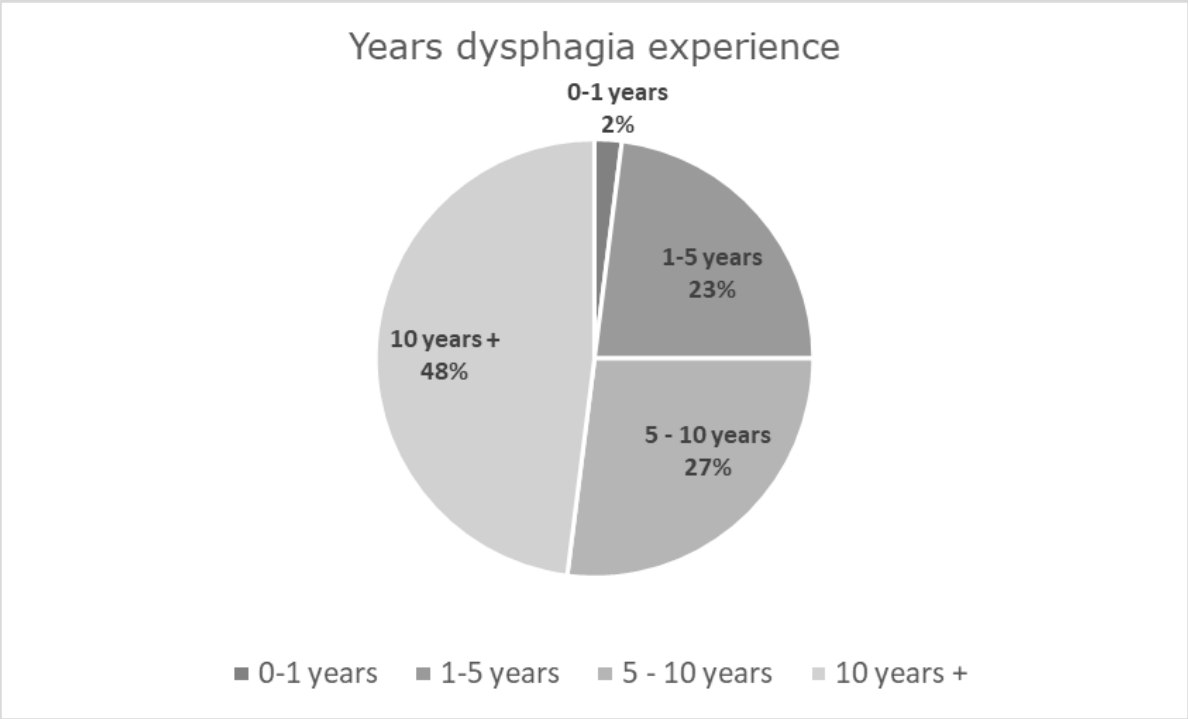
**Figure 6-7** Histograms of distributions of dysphagia severity rating scale from STEPS trial. At baseline (n=154), mean 7.6 (3.8), median 7.0 [8], mode 12; at week 2 (n=131), mean 4.9 (3.7), median 4.0 [5], mode 3; at week 13 (n=106) mean 2.7 (3.9), median 1.0 [3], mode 0.



### 6.3.9 Minimal clinically important difference (MCID)

Eighty-four responses were received from UK based SLTs. As not all administrators (who received the survey) replied to say whether they had forwarded it, it was not possible to estimate the number that received the survey. Therefore, the response rate could not be calculated. Overall, the survey identified an MCID of 1.0 as being important for both the DSRS and the FOIS. The original copy of participants' responses is detailed in Appendix 3. In summary, the results for individual questions are presented below:

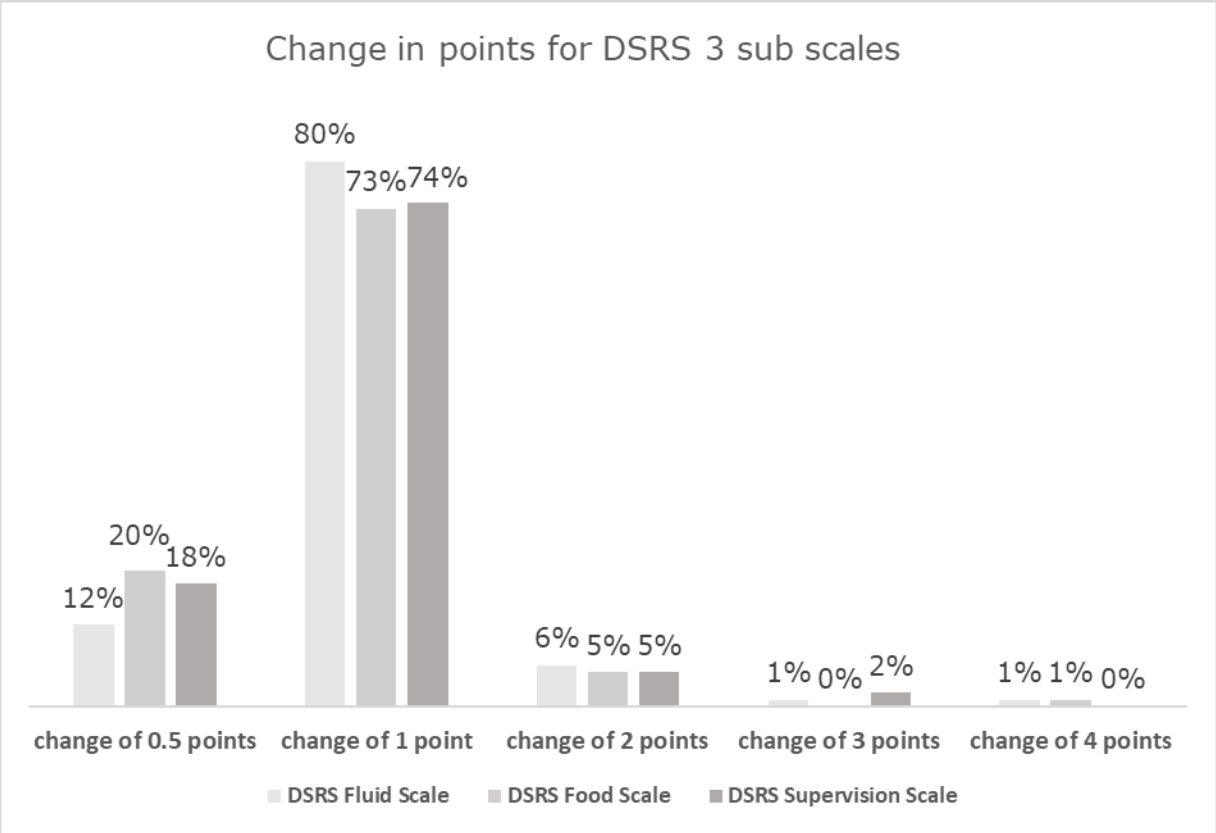
**Figure 6-8** Years' experience of respondents in MCID survey




As can be noted from Figure 6.8, the majority of respondents had more than 10 years' experience working in the field of adult acquired dysphagia.

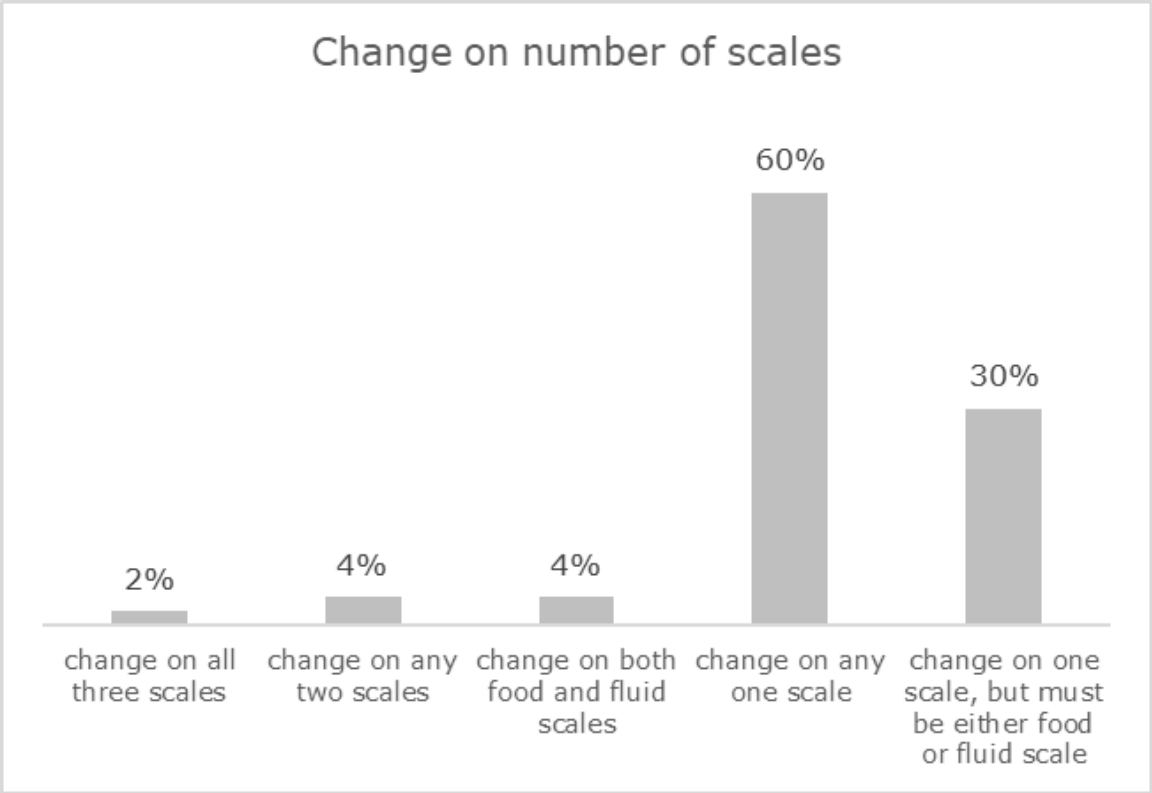
When asked how many points needed to change from *each scale* to be clinically meaningful, as can be seen from the figure below, a clear majority for a 1-point change on each subscale was received. Slightly more respondents expressed a preference for a 1-point change on the fluids scale than the diet or supervision scale, although this is balanced by the fact that more respondents would have accepted a 0.5 change on those latter two scales.

**Figure 6-9** Change in points on each of DSRS three sub scales



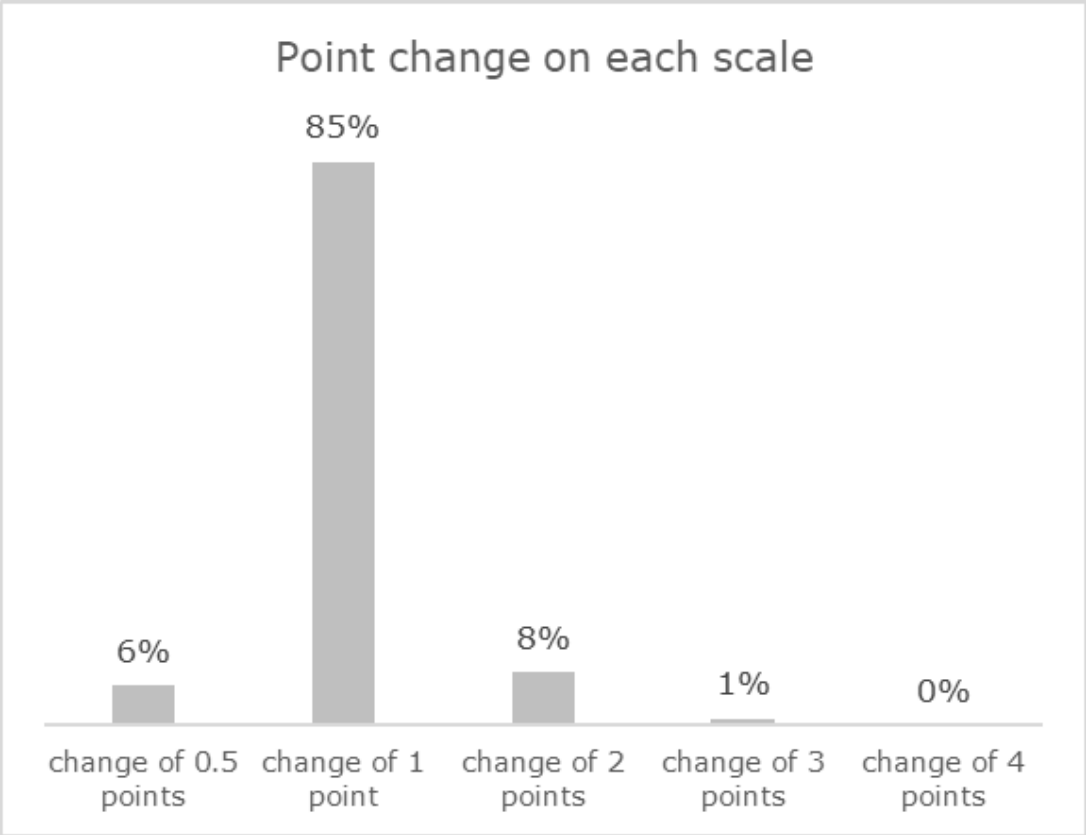

When asked *how many scales* needed to show a change in points overall, 90% of respondents indicated a meaningful difference was needed on one scale only. However, 30% of these respondents chose that the change needed to be on either the food or fluid scale, as illustrated in  Figure 6.10.

**Figure 6-10** Change on number of scales



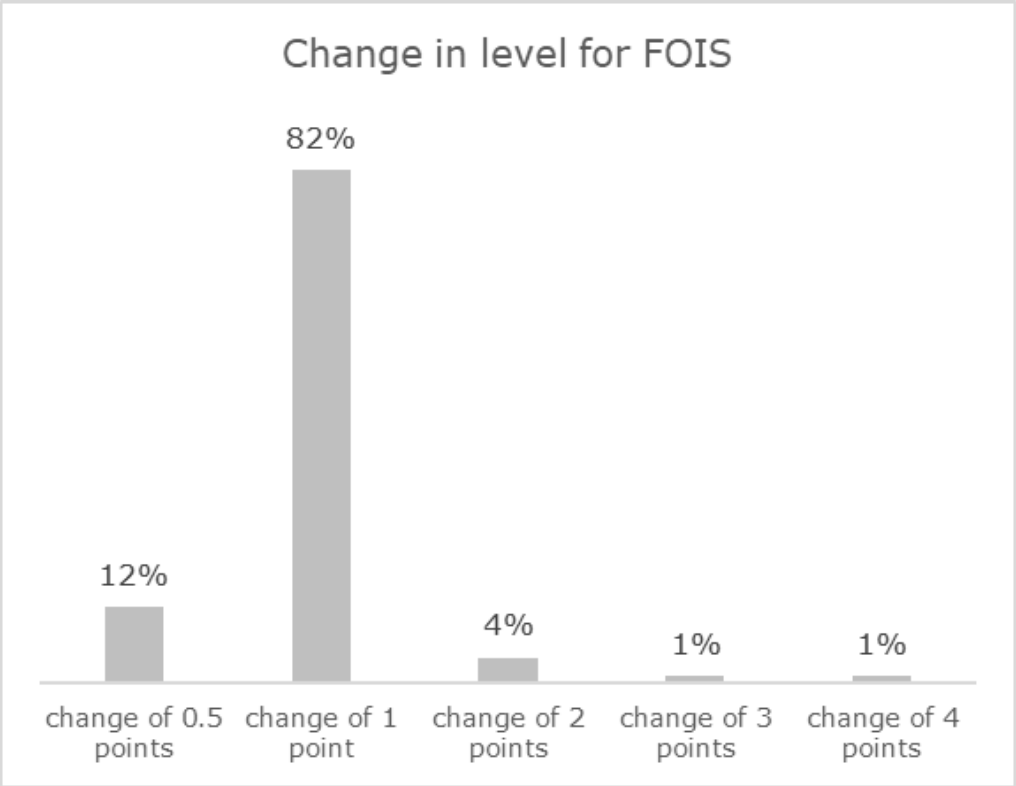

For clarification, respondents were then asked how many points change each scale should change. This question is similar to the question asked in Figure 6.9 but directs respondents to consider how many points the change on the scale would need to be, according to their immediate previous answer. It was felt this was the easiest way to conduct the survey to maximise participants' understanding of what they needed to do. It also helps to confirm participants' responses as the responses seen here (Figure 6.11) are similar to those in Figure 6.9 i.e., most respondents chose a change in one point to be meaningful.

**Figure 6-11** Point change on DSRS scales




Respondents were then asked how many levels needed to change on the FOIS scale to be considered meaningful. In Figure 6.12, one can see that most respondents (82%) indicated a change in one FOIS level would be acceptable and 12% would accept a 0.5 change as being acceptable. This was the same proportion of respondents who accepted a 0.5 change on the DSRS fluid scale.

**Figure 6-12** Point change in FOIS level




When calculating the MCID using the statistical distribution and anchor methods, the MCID varied between 0.3 and 2.5 (Table 6.10)

**Table 6-10** Tabulation of minimal clinically important difference (MCID)

| **Method** | | **Source** | **MCID** |
|---|---|---|---|
| Statistical distribution | Half standard deviation | STEPS [44] | 1.9 |
| | | IPD MA [43] | 2.0 |
| | Standard error of mean | STEPS [44] | 0.3 |
| | | IPD MA [43] | 0.5 |
| Anchor | Aspiration at week 2 | STEPS [44] | 2.5 |
| | | IPD MA [43] | 0.8 |
| | Oral vs non-oral feeding at week 2 | STEPS [44] | 1.0 |
| Delphi | Number of DSRS scales needed to show change | Survey | 1.0 |
| | Number of points change on each scale | Survey | 1.0 |

### 6.3.10 Relationship between DSRS and FOIS

FOIS could be extrapolated from DSRS scores; however, some combinations of the DSRS subscale scores are incongruent from a clinical perspective (e.g., needing to avoid mixed consistencies when still on thickened fluids and when having a regular diet) and so these have no equivalent FOIS value. Appendix 4 gives a detailed breakdown of mapping of the DSRS and FOIS. Conversely, DSRS could be estimated from FOIS although in most cases it was not possible to determine subscale results since the subscales of supervision and fluids above level 3 are not scored on the FOIS (Table 6.11).

**Table 6-11** Conversion of FOIS to median value of total DSRS

| FOIS | DSRS Total | Fluids | Food | Supervision |
|---|---|---|---|---|
| 1 | 12 | 4 | 4 | 4 |
| 2 | 7 | 0-4 | 0-4 | 3 |
| 3 | 7 | 0-4 | 0-4 | 3 |
| 4 | 6 | 0-3 | 3-4 | 0-2 |
| 5 | 5 | 0-3 | 2 | 0-2 |
| 6 | 4 | 0-3 | 1 | 0-2 |
| 7 | 0 | 0 | 0 | 0-2 |

The PHAST-TRAC trial recorded both DSRS and FOIS at multiple post-randomisation timepoints (days 2, 4, 6, 8, 10, 30 and 90).[229] The frequency of paired scorings is shown in Table 6.12. The inverse nature of DSRS and FOIS is noted and percentages match the estimated equivalents in Appendix 4 and Table 6.11.

**Table 6-12** Relationship between post-treatment DSRS and FOIS measures in the PHAST-TRAC trial. Data are percentages for each combination of DSRS and FOIS.

| | | FOIS | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **%** | **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| DSRS | 0 | | | | | 0.5 | | 11.1 |
| | 1 | | | | | 0.5 | 1.6 | |
| | 2 | | | | | 0.5 | 0.5 | |
| | 3 | | | 0.5 | | 1.6 | 1.1 | |
| | 4 | | | | 2.1 | 0.5 | 0.5 | |
| | 5 | | | 0.5 | 1.1 | 1.6 | | |
| | 6 | | 0.5 | | | 1.1 | | |
| | 7 | | 1.1 | 0.5 | 1.6 | 0.5 | | |
| | 8 | | 2.1 | 1.1 | 1.1 | 0.5 | | |
| | 9 | 0.5 | 1.6 | 2.1 | 1.6 | | | |
| | 10 | | 4.2 | 0.5 | | | | |
| | 11 | 2.1 | 2.6 | 0.5 | | | | |
| | 12 | 48.7 | 0.6 | 0.5 | | | | |

## 6.4 Discussion

This comprehensive assessment of the DSRS suggests that it is a valid tool for grading dysphagia severity (based on oral intake and supervision requirements) in patients with post-stroke dysphagia. Using data from four randomised controlled trials and 2 surveys, the DSRS was found to exhibit consensual validity, content validity, concurrent validity, predictive validity and internal consistency. Following feedback from the consensual validity exercise, operationalisation of scoring for certain feeding scenarios was undertaken, resulting in excellent inter- and intra-rater reliability when used in a clinical audit. The minimal clinically important difference approximated to 1 unit irrespective of the method of estimation for the DSRS and was the same for the FOIS. The DSRS was sensitive to change during the natural resolution of dysphagia seen through the sub-acute and rehabilitation phases after stroke, and in response to treatment with pharyngeal electrical stimulation in some trials. The intrinsic relationship between DSRS and FOIS allowed these two dysphagia scales to be mapped to each other.

### 6.4.1 Minimal clinically important difference

The main strength of this study is the large number and variety of detailed validations performed. Data is also provided on the minimal clinical important difference for the DSRS and FOIS and a means for interconverting the two scales is offered. As mentioned in Chapter One, there is a paucity of research into the MCID in dysphagia rehabilitation - to the author's knowledge, there is only one published study [56] that evaluates the MCID in patients with Head and Neck

Cancer and no studies in the field of dysphagia post-stroke. Although the MCID is usually reported by the patient, it can also be established by healthcare professionals [58, 249] as was explored here. The next step would be to conduct research with stroke survivors with dysphagia to establish whether their estimation of MCID is the same on these two scales derived by SLTs. One point to bear in mind is that some researchers feel that asking patients to make judgements about meaningful change is easier when the disease state is stable and has not been the result of an abrupt cause, such as a stroke. [58] In addition, in the stroke population, cognitive impairments (such as insight and memory) may influence the validity of the responses obtained in the acute phase of stroke. Likewise, the presence of aphasia would need to be accounted for and methods adapted to ensure patients with aphasia can be included in any studies.

A clear majority was expressed for a change of one point on one scale for the DSRS and one level for the FOIS scale. On the DSRS, for each of the subscales, roughly equal levels of consensus were obtained (80%, 73% and 74% for food, fluid and supervision respectively) suggesting that respondents did not perceive a major difference between changes in food, fluids and supervision. A systematic review on quality of life in patients on modified diet and fluids reported that patients perceived modified diets to be associated with a worse quality of life than modifying fluids. [31] However, this study postulated that this may have been because more severe conditions require more modification to food. Future research with patients will provide further insightful information.

It was perhaps surprising that 74% of respondents indicated a change of 1 point on the supervision scale was perceived to be as meaningful as a change in food and fluids (Figure 6.9.) However, one could perceive a need for less supervision

as a move to becoming more independent with feeding which can also be viewed to be as meaningful as changes to oral intake. In subsequent questions, when respondents were given the additional option of choosing change only on the food or fluids scale, 60% of respondents still chose a 1-point change on the supervision scale as being meaningful (Figure 6.10). Although this is lower than the 74% in the previous question (Figure 6.9), it still represents a majority score suggesting respondents viewed supervision to be an important part of change alongside dietary and fluid changes.

### 6.4.2 Data quality and amount of data available

Another strength of this study is that much data came from two phase III trials (STEPS, PHAST-TRAC) rather than just a number of smaller studies. Also, patients with a range of post-stroke severity were included in these validations, with mild-to-moderate patients coming from three trials [42, 44, 174] and more severe ones from a fourth.[229] In addition, a large amount of clinical and radiological outcome data was available. This showed that overall, in the PHAST-TRAC trial, the DSRS was highly correlated with another clinical measure of dysphagia severity (FOIS) which confirms that the DSRS has strong criterion validity. Measures of aspiration (VFS-PAS) and swallowing (TOR-BSST) were also correlated with the DSRS, although the correlations were not as strong as the FOIS. This is an expected finding, as these measures, whilst related to swallowing (so some correlation is expected) do not measure exactly the same aspect. Similarly, lower correlations were seen for global measures of impairment, disability, and dependency, although these still showed some significant correlations. Again, this is an anticipated finding, as one would still expect to see some form of correlation in moderate and severe swallowing

impairment with increasing neurological impairment, dependency and disability. Perhaps surprisingly, the DSRS was not correlated with the EQ-VAS and EQ 5D 3L. However, this is a generic health status measure of quality of life and not a swallowing quality of life measure which may account for the lack of a correlation. In addition, as the EQ-VAS was only done at 13 weeks, when many participants had demonstrated recovery of swallowing function (as illustrated in Figure 6.7), this may have also influenced the lack of correlation.

### 6.4.3 DSRS scoring

There are a number of caveats to the study. First, although all trial protocols gave some guidance on how to use the DSRS, it was not the primary outcome measure in any study and was largely done according to local practice. Hence, the DSRS scores, whilst prospectively collected, are potentially less accurate than could be achieved with formal training and this was reflected in the consensual validity exercise and respondents' accompanying comments. In particular, there was less consensus for scoring patients on oral trials and liquid diets, as noted previously. [55] There was also less consensus on assigning supervision scores for patients on consistent amounts of oral trials, i.e., respondents found it easier to score supervision for patients either on full oral intake or limited trials. It is important that raters routinely using the DSRS clearly specify supervision level when making recommendations following the clinical bedside assessment. In the updated version of the DSRS (Table 6.13 below), rules for scoring supervision are provided, including assigning diet, fluid and supervision scores for oral trials.

**Table 6-13** Updated Dysphagia Severity Rating Scale incorporating International Dysphagia Diet Standardisation Initiative (IDDSI) levels

| Score | Fluids | Score | Diet | Score | Supervision |
|---|---|---|---|---|---|
| 4 | No oral fluids | 4 | Non oral feeding | 4 | No oral feeding |
| 3 | IDDSI level 4 – extremely thick | 3 | IDDSI level 4 - pureed diet or level 5 – minced & moist | 3 | Therapeutic feeding (SALT/trained staff) |
| 2 | IDDSI level 3 – moderately thick | 2 | IDDSI level 6 – soft & bite sized | 2 | Feeding by third party (untrained) |
| 1 | IDDSI level 1 – slightly thick or level 2 mildly thick | 1 | IDDSI level 7 - easy to chew | 1 | Eating with supervision |
| 0 | IDDSI level 0 - thin | 0 | IDDSI level 7- regular | 0 | Eating independently |

DSRS supervision score 3 is always chosen when a patient is on limited or consistent oral trials and still requires NG/ PEG tube. Oral trials are scored from the fluid and diet subscales (i.e., 3 onwards) and can be either trials of food *or* fluid or trials of food *and* fluids.

### 6.4.4 DSRS items

Secondly, the two items that scored lower on the CVI have been retained. The lower validation scores for 'pudding consistency' may reflect the fact that this level of fluids is not routinely used by SLTs. This can be seen in the results of a survey of 145 SLTs in America who reported that if this consistency was recommended, it was rare (5% recommendation, compared to 64% for syrup and 31% for custard). [250] In addition, pudding thick fluids are deemed unpalatable. In the same survey, respondents also perceived thicker consistencies such as custard and pudding to be more highly disliked by patients, than syrup consistency. Frequently patients who can manage this consistency are recommended to have more acceptable diet options, such as pureed puddings. Hence it would seem a feasible finding that less SLTs rated this category as highly relevant or quite relevant. Given that it is appropriate to occasionally use this level with stroke patients (for example with patients who dislike chilled pureed puddings), this item was not excluded. It is noteworthy that this level of fluids is still included on the IDDSI Functional Diet Scale and labelled as 'extremely thick, level 4'. [55]

The lower validation scores for 'selected textures' may be reflected by the fact that at the time of the validation, this level was not formally represented on the IDDSI, or previously on the United Kingdom Texture Diet Descriptors. The item has been retained as it is common practice for SLTs to recommend avoidance of certain challenging textures for patients who would otherwise manage a regular diet. In addition, since the content validity exercise was completed, an extra level, namely, level 7 'easy to chew' diet has been introduced by IDDSI which is similar to 'selected textures'. Some respondents indicated that this label was not

clear to them which may also have accounted for the lower score. However, although some respondents noted that the wording was ambiguous, all respondents chose this option to represent avoidance of some food consistencies in the food rating scenario, which suggests they still all interpreted this label in a similar manner. This level is also represented on the Functional Oral Intake Scale (FOIS) at a level 6, which is referred to as 'a total oral diet of multiple consistencies without special preparation but with specific food limitations'.

### 6.4.5 DSRS terminology

Thirdly, the DSRS was devised and first used in 2010 and so antedates the 2017 IDDSI scale for determining levels of fluid thickness and modified food textures.[245] Further, the DSRS measures an extra domain compared to IDDSI as it also measures supervision required for safe feeding. Nevertheless, comments by respondents in the assessment of content validity commented on the fact that the DSRS does not contain IDDSI terminology regarding wording and comprehensiveness. Going forwards, a redefinition of the DSRS has been proposed to reflect IDDSI descriptors (Table 6.13) and plans to validate this updated scale in due course will be drawn up.

### 6.4.6 Sample size and distribution

Fourth, although the associations between DSRS and other radiological and clinical measures in the trials of Jayasekeran and Vasant [42, 174] were similar in magnitude to those seen in the STEPS trial, most were statistically non-significant due to their much smaller sample size and so reduced statistical power. This emphasises the importance of having large data sets when

performing validation studies of clinical scales. Last, the distribution of DSRS will depend on the population of patients being studied and timing after stroke, and ceiling and floor effects are present at different times after stroke; for example in STEPS, one third of participants had a maximum score of 12 at baseline (reflecting the trial's inclusion criteria) and a minimum score of zero 13 weeks later after natural resolution of dysphagia; this situation is analogous with other scales used in stroke, e.g. the Barthel Index.[251]

## 6.5 Conclusions

In summary, this study has shown that the 12-level DSRS is robust in terms of consensual, content, concurrent and predictive validity. Further, it shows "good-to-excellent" internal consistency, "excellent" inter- and intra-rater reliability, is sensitive to natural and therapeutic change, and has a minimal clinically important difference of 1 point. However, distribution of scores will depend on patient population and time post-onset. Specific guidance for accurate use of the DSRS is provided in the updated version, which incorporates the new IDDSI descriptors. Overall, these results suggest the DSRS is a valid tool for grading the severity of dysphagia in stroke; its ease of use make it relevant for use in clinical studies and trials to define baseline dysphagia severity and assess the effect of natural history or therapeutic change. It is also suitable for use in clinical service delivery.

# 7. Discussion

## 7.1 Introduction

This thesis has described a body of work exploring the lack of definitive interventions for dysphagia post-stroke, as well as optimal measurement of swallowing function and the need for validated outcome measures.

In this current chapter, the research questions this thesis has addressed and important findings that arose during the thesis and which have implications for future research directions, will be examined. The author's recommendations for the most promising interventions that should be tested in future trials as well as how those trials should be conducted will also be discussed.

## 7.2 Swallowing therapy in acute and subacute stroke

The updated Cochrane review in Chapter Two, of interventions for dysphagia in acute and subacute stroke undertaken in this thesis, has demonstrated a positive influence of swallowing therapy on a number of swallowing outcomes post-stroke. The need for further evidence on specific swallowing therapies conducted in a high-quality manner has been highlighted from this review. Please see section 7.6 below which provides further details of the author's recommendations for future trials and how they should be conducted.

## 7.3 Multiple measures versus single measures

The work undertaken in Chapters Three, Four and Five resulted in the cumulative finding that using additional measures of timing and clearance to investigate the effects of PES did not identify any additional changes that may

have been missed using only the PAS. However, given that reduced image quality and incorrect frame rate acquisition lowered numbers in the final analysis, it would be premature to conclude that only using the PAS as an outcome measure is sufficient. A number of key themes emerged during these chapters with regard to measurement in post-stroke dysphagia that merit further discussion.

### 7.3.1 Complexity and variability in swallowing impairment

The detailed methodology described in Chapter Three highlighted the complex, multifaceted nature of swallowing impairment post-stroke, including the variability seen in swallowing performance in stroke patients.

The variability of scores when using the PAS and the variety of ways one can score the PAS statistically presents challenges in dysphagia rehabilitation and may hinder comparison between studies. Discussion around different ways of scoring the PAS has recently been highlighted in the swallowing literature [103] [201] some of which this thesis has explored. Ideally, a consensus on how to score the PAS is needed - both on what swallows to sample and score and what statistical approaches to use. However, this may be over ambitious considering how complex the act of deglutition can be and the great number of different professions involved in researching this fascinating function.

Training in using the PAS (and other measures) accurately is also important. Establishing reliability in Chapter Four particularly of quantitative measures, was time consuming and challenging due to reduced image quality, but also due to the great variation and deviation from normal swallow patterns that were

observed. Following training, the results indicated that reliability of the PAS, timing and clearance measures used were acceptable but particularly for the PAS, were influenced by the method used to calculate reliability. The need for adequate training in scoring the PAS, particularly when different institutions and different therapists with various levels of experience are involved was clear. As discussed in Chapter Three, the importance of understanding how to score the PAS between and within a bolus must not be underestimated. This is especially important if it is being used to determine entry to a study. Clinical staff involved in research should receive support and training. Notwithstanding, even clinicians in VFSS clinics not involved in research must ensure they know how to score the PAS correctly in order to understand the pathophysiology of the swallow and make appropriate clinical recommendations.

Notwithstanding these challenges, a comprehensive standard operating procedure was developed in Chapter Three and reliability tested in Chapter Four, thus enabling the analysis in Chapter Five to be undertaken. This procedure represents an original contribution to the field that researchers can use to analyse raw videofluoroscopy data in acute stroke, whilst being aware of the challenges described above.

### 7.3.2 Quantitative methods versus visuoperceptual scales

The work presented in this thesis also highlights predicaments surrounding whether to use quantitative information from instrumental assessments, such as VFSS studies (or FEES) or visuoperceptual scales. This can be a daunting prospect. With regards to using timing measures, great variability has been reported in studies using this method, such as different definitions between

research groups and different parameters used in VFSS studies. [117] Certainly, this was also the author's experience, and for additional reasons besides. Although many studies had been conducted, they were not able to be compared for a plethora of reasons: different times post-onset, different bolus sizes, different viscosities, different definitions of aspiration and mixed patient cohorts (i.e., not just stroke). This considerably reduced the available pool of comparable studies and did not allow for the evidence base to be expanded upon in a robust manner.

However, this must be balanced with the fact that some researchers state that quantitative measures are reliable and can detect subtle changes that may be missed by rating scales such as the PAS, [81] although this finding was not evident in this current research project.

Comprehensive, standardised rating scales, such as those included in the MBSImP can be used as an alternative to quantitative measures, may be less time consuming and more easily understood by clinicians and patients. These measures provide a comprehensive swallowing measure and are standardised. This is in contrast to quantitative measures that not only lack standard definitions and operational rules but comprise a vast number of different measures that researchers are at their discretion to include. Using the MBSImP could work towards the point raised in Chapter Five that researchers should consider a standardised protocol when evaluating dysphagia post-stroke, consisting of a number of core outcomes in order to facilitate comparison of results between studies and hence strengthen the evidence base in this area. It is acknowledged that the MBSImP (or other comprehensive rating scales such as the DOSS) may be prone to lower reliability scores. However, with the MBSImP,

there is a thorough training programme to become certified and one can help to maintain competency and reliability in their own area of expertise by arranging regular training/ reliability scoring sessions with colleagues.

### 7.3.3 Instrumental assessments versus clinical outcomes

Aside from issues pertaining to reliability and time taken to carry out outcomes measures, there are other factors to consider. Some researchers may feel that there is too much reliance on the results of instrumental assessments as the primary outcome in studies, or to determine entry criteria to RCTs. Access to instrumental assessments may not be readily available due to lack of resources (both equipment and staff), changes in patient location over the course of a study, be conducted incorrectly or with variable quality data. In addition, VFSS may be inaccessible for severe patients if specialist seating equipment is not available.

The current Covid-19 pandemic has also highlighted the challenges of conducting instrumental assessments when services and staff are stretched and there are restrictions or time-consuming amendments applied to instrumental examinations due to concern surrounding Aerosol Generating Procedures.

In addition, in real clinical settings, not all patients would receive instrumental assessments as a standard part of care in the UK. It has also been argued that instrumental assessments are a 'snapshot' of a patient's swallowing abilities. An argument for consideration of outcomes based on validated clinical outcomes, such as the DSRS or other scales may be more pragmatic, cost effective and accessible for future research trials. These scales could be used as primary

outcome measures, in much the same way the mRS is often used in medical stroke research.

On the other hand, it is important to acknowledge that swallowing impairment is rather unique because true and accurate assessment of dysphagic symptoms and aspiration risk can really only be correctly assessed using an instrumental assessment. Just like a CT scan confirms the presence of a stroke when clinical symptoms are present, so VFSS and FEES assessments confirm the presence of a swallowing impairment (and aspiration) when dysphagic symptoms are observed by clinicians or reported by the patient. It is also true that having an instrumental assessment does afford a clear baseline which confirms the degree of swallowing impairment and allows for more precise quantification of improvement (or lack thereof) at a later date. Instrumental assessment also provides information on the nature of the swallowing impairment and hence provides accurate information on which to base rehabilitation and provides information on how an intervention has improved the swallow.

There is no ideal solution, but it is important for researchers to consider these issues and undertake careful consideration of what outcomes are most appropriate in each trial, before conducting research. As discussed in Chapter Five, it is important to remember that the number and type of outcome measures chosen must be weighed up against the time, resources and expertise available to conduct them.

### 7.3.4 Multifactorial aspects of swallowing

Longitudinal changes of both groups at baseline and two weeks were also presented in Chapter Five. These results demonstrated that the PAS showed the most significant changes post-stroke, with a trend for shorter timing measures (of speed). It was evident that not all findings exhibited an expected course, such as no trend for improvement in LVCrt or in IPS location at two weeks despite improvement in PAS scores. When considering the results further, it is recommended that due to the multifactorial nature of swallowing, statistical approaches incorporating predictive modelling and regression analysis should be used. Measures such as STD, LVCrt, PTT and LCD could be combined. This may provide the most accurate picture of aspiration risk. Future work on the current dataset exploring predictive modelling would be informative. The large amount of data available from the STEPS trial would also yield valuable results were it to be analysed using the entire MBSImP.

### 7.3.5 Videofluoroscopy image acquisition

A very important finding from Chapter Five drew attention to the issue of sub-optimal frame rates being used in VFSS, resulting in a significant portion of data being omitted from the study. SLTs have a duty of care to ensure optimal quality images are obtained, for best possible clinical and research delivery. If researchers do choose to use VFSS, it is crucial that they are acquired and recorded at the optimal frame rate so that accurate measurements and information can be extracted from the data. As discussed in Chapter Five, this is still not happening routinely, with the results of two recent UK-based surveys highlighting a lack of technical knowledge of clinical SLTs (and Radiographers)

using VFSS and ongoing practice of acquiring and/or recording VFSS at lower than recommended frame rates. [189] [190] There is a clear need for specialist training and improvement in national guidelines for the set up and delivery of VFSS studies. [189]

## 7.4 Validating the dysphagia severity rating scale

The importance of using standardised outcomes was highlighted in Chapter Two. The results of Chapter Six demonstrated (using multiple validations of retrospective and prospective data), that the dysphagia severity rating scale is a valid tool to measure the severity of dysphagia in acute and subacute stroke patients. This scale is now a validated, additional tool to be used in the field of outcome measurement post-stroke. In addition to traditional validation methods, the MCID of the DSRS (and FOIS) was also obtained using the views of experts.

Currently the updated DSRS is already being used in clinical trials and future work will use this data to further validate the scale. It is possible that tighter correlations will be observed, as the updated DSRS is based on more objective measurements of fluid and food modification, now that IDDSI has been introduced.

## 7.5 Limitations

The limitations of each piece of work were discussed individually in the relevant chapters.

## 7.6 Recommendations for future clinical trials

### 7.6.1 Future directions for interventions to be used in trials

#### 7.6.1.1 Research based on individual interventions

The work in this thesis has provided insights and directions into the way forward for clinical trials in dysphagia rehabilitation. As stressed in the Cochrane review, it is the author's opinion that as more data is now available from many more randomised controlled trials, future Cochrane reviews should be conducted based on individual interventions not swallowing therapy collectively. In particular, careful attention should be paid towards behavioural interventions, acupuncture and drug therapies, as these interventions may be promising and some positive effects have already been reported.

A point to bear in mind with regards to behavioural interventions, is that they comprise a diverse area. Ideally, different types of behavioural interventions should be analysed separately, so that decisions on the effectiveness of specific interventions can be made. Those areas which do not have enough studies to conduct separate analyses will be unable to be definitively assessed for a meta-analysis which in itself is important information and will provide guidance for future research priorities.

#### 7.6.1.2 Pharyngeal electrical stimulation

This thesis in particular has also clearly demonstrated two important points regarding future studies using PES: firstly, only participants in the active group should receive PES and secondly, every effort should be made to ensure that

participants receive an optimal dose of PES, aiming for as high a dose as participants can comfortably tolerate.

#### 7.6.1.3 Gaps in the evidence base

Specific gaps identified for future analysis from this thesis also include conducting studies of swallowing therapy in chronic stroke patients, as well as studies where blinding or having a true control group is challenging (such as RCTs involving postural strategies and thickened fluids). Given that currently there is a lack of evidence demonstrating that the use of thickener in stroke reduces aspiration pneumonia, this would also be a future research priority. In terms of methodology, research is needed into optimal ways to analyse the PAS in the presence of intra-subject variability. In addition, future research applying predictive modelling using regression analysis is also indicated when evaluating the multiple components of swallowing.

#### 7.6.1.4 MBSImP

Research using the MBSImP, presenting detailed analysis of all its components on acute stroke patients (both dysphagic and non-dysphagic) is also required, as are studies on age matched healthy participants using the MBSImP. This is important and would help to place the results of studies using the MBSImP on stroke patients in context. Ideally studies on age matched healthy participants are needed first.

#### 7.6.1.5 Establishing MCID

Future work should also aim to establish the MCID of the DSRS and FOIS, involving patients and their carers. Moreover, additional research using the MCID within the broader realm of dysphagia rehabilitation is required with a specific focus on involving patients and their carers when establishing the MCID for interventions. This may also help to inform certain practices which are viewed as less tolerable than others, such as food or fluid modification. In this context, for example, possible drawbacks of interventions can be weighed up against benefits (or lack thereof) reported by patients and carers.

#### 7.6.1.6 Core outcomes

Ideally establishing a standardised protocol of agreed 'core' components (for example through a Delphi consensus method) for analysing and reporting outcomes for post-stroke dysphagia should be considered.

### 7.6.2 Future directions and considerations for implementation of trials

#### 7.6.2.1 Recommendations for improving quality

As demonstrated in the Cochrane review, it is important as far as possible, that trials should not be confounded, i.e., researchers should only compare usual care versus the treatment being evaluated plus usual care. Full details of trials should be provided such as information on bias and randomisation. Standardised outcomes should be used as far as possible. In addition, outcomes that measure key areas of swallowing impairment beyond swallowing ability per se should be

included, such as health economics, mortality, morbidity and chest infections. Given the serious impact of dysphagia on QOL, outcome measures should routinely include patient reported outcomes and quality of life measures. Patients and their carers should also be consulted on what outcomes they feel are important to address.

#### 7.6.2.2 Dosage

Work on dosage intensity is also a future research priority as currently, researchers use different dosages which hinders comparison between trials and the ability to synthesize data effectively.

#### 7.6.2.3 Big data considerations and training

This thesis has also shown that many studies referred to throughout this thesis have consisted of small numbers. Triallists are therefore recommended to aim for larger numbers of participants, ideally from multiple centres. This will boost patient numbers in order to increase the power of studies to detect treatment effects. For multicentre trials, to optimise reliability when using outcome measures, it is important that training to the same criterion is carried out if different institutions are collaborating.

## 7.7 Conclusions

Going forwards, researchers and clinicians should carefully consider which outcomes they want to use, ensure they are trained in the chosen measures (including technical aspects of VFSS), check that the measures sample a range

of meaningful outcomes, are validated and used in interventions which are well designed.

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# 9. Appendices

## 9.1 Appendix 1: Cochrane search strategies

### 9.1.1 CENTRAL search strategy

1.MeSH descriptor: [Cerebrovascular Disorders] this term only

2.MeSH descriptor: [Basal Ganglia Cerebrovascular Disease] this term only

3.MeSH descriptor: [Brain Ischemia] explode all trees

4.MeSH descriptor: [Carotid Artery Diseases] explode all trees

5.MeSH descriptor: [Cerebral Small Vessel Diseases] explode all trees

6.MeSH descriptor: [Intracranial Arterial Diseases] explode all trees

7.MeSH descriptor: [Intracranial Embolism and Thrombosis] explode all trees

8.MeSH descriptor: [Intracranial Hemorrhages] explode all trees

9.MeSH descriptor: [Stroke] explode all trees

10.MeSH descriptor: [Stroke, Lacunar] this term only

11.(stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc* or cva*):ti,ab,kw (Word variations have been searched)

12.((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery) near/5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*)):ti,ab,kw (Word variations have been searched)

13.((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli*

or putaminal or putamen or posterior fossa or hemispher*) near/5 (h?emorrhag* or h?ematoma* or bleed*)):ti,ab,kw (Word variations have been searched)

14.{or #1-#13}

15.MeSH descriptor: [Deglutition] this term only

16.MeSH descriptor: [Deglutition Disorders] explode all trees

17.((swallow* or deglutit* or dysphag*) near/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)):ti,ab,kw (Word variations have been searched)

18.MeSH descriptor: [Pharynx] this term only

19.MeSH descriptor: [Pharyngeal Muscles] this term only

20.((pharyn* or oropharyn*) near/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*)):ti,ab,kw (Word variations have been searched)

21. {or #15-#20}

22.#14 and #21

### 9.1.2 **MEDLINE search strategy**

1.cerebrovascular disorders/ or basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or stroke, lacunar/

2.(stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebrovasc$ or cva$).tw.

3.((brain$ or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw.

4.((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$) adj5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw.

5.or/1-4

6.Deglutition/

7.exp Deglutition Disorders/

8.((swallow$ or deglutit$ or dysphag$) adj5 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

9.Pharynx/ or pharyngeal muscles/

10.((pharyn$ or oropharyn$) adj3 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

11.or/6-10

12.randomized controlled trial.pt.

13.controlled clinical trial.pt.

14.randomized.ab.

15.placebo.ab.

16.random$.ab.

17.trial.ab.

18.groups.ab.

19.or/12-18

20.5 and 11 and 19

Previous version of search strategy

1.stroke.mp.

2.infarction.mp.

3.exp cerebral infarction/

4.exp cerebrovascular disease/

5.cerebrovascular disease.mp.

6.hemorrhage.mp.

7.exp cerebral hemorrhage/

8.cerebral haemorrhage.mp.

9.1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

10.(dysphagia or deglutition or swallowing or deglutition disorders or swallowing disorders or malnutrition or undernutrition).mp.

11.(intervention or supplementation or feeding or nutrition or nutritional supplementation or therapy or swallowing therapy or tube feeding or fluid or fluid supplementation or sip feeding or feeding route or timing or diet or hydration).mp.

12.10 or 11

13.9 and 12

14.(randomized controlled trial.pt. or controlled clinical trial.pt.or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti.) and humans.sh.

15.13 and 14

### 9.1.3 **Embase search strategy**

1.cerebrovascular disease/ or brain disease/ or exp basal ganglion hemorrhage/ or exp brain hematoma/ or exp brain hemorrhage/ or exp brain infarction/ or exp brain ischemia/ or exp carotid artery disease/ or exp cerebral artery disease/ or exp cerebrovascular accident/ or exp intracranial aneurysm/ or exp occlusive cerebrovascular disease/ or exp vertebrobasilar insufficiency/

2.(stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebrovasc$ or cva$).tw.

3.((brain or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw.

4.((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$) adj5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw.

5.or/1-4

6.dysphagia/

7.swallowing/

8.((swallow$ or deglutit$ or dysphag$) adj3 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

9.exp pharynx/

10.((pharyn$ or oropharyn$) adj3 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

11.or/6-10

12.Randomized Controlled Trial/ or "randomized controlled trial (topic)"/

13.Randomization/

14.Controlled clinical trial/ or "controlled clinical trial (topic)"/

15.control group/ or controlled study/

16.clinical trial/ or "clinical trial (topic)"/ or phase 1 clinical trial/ or phase 2 clinical trial/ or phase 3 clinical trial/ or phase 4 clinical trial/

17.Crossover Procedure/

18.Double Blind Procedure/

19.Single Blind Procedure/ or triple blind procedure/

20.placebo/ or placebo effect/

21.(random$ or RCT or RCTs).tw.

22.(controlled adj5 (trial$ or stud$)).tw.

23.(clinical$ adj5 trial$).tw.

24.((control or treatment or experiment$ or intervention) adj5 (group$ or subject$ or patient$)).tw.

25.((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.

26.((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.

27.(cross-over or cross over or crossover).tw.

28.(placebo$ or sham).tw.

29.trial.ti.

30.(assign$ or allocat$).tw.

31.controls.tw.

32.or/12-31

33.5 and 11 and 32

Previous version of search strategy

1.stroke.mp.

2.infarction.mp.

3.exp brain Infarction/

4.cerebrovascular disease.mp.

5.exp cerebrovascular disease/

6.hemorrhage.mp.

7.exp cerebral hemorrhage/

8.cerebral haemorrhage.mp.

9.9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

10.(dysphagia or deglutition or swallowing or deglutition disorders or swallowing disorders or malnutrition or undernutrition).mp.

11.(intervention or supplementation or feeding or nutrition or nutritional supplementation or therapy or swallowing therapy or tube feeding or fluid or fluid supplementation or sip feeding or feeding route or timing or diet or hydration).mp.

12.10 or 11

13.09 and 12

14.((RANDOMIZED-CONTROLLED-TRIAL/ or RANDOMIZATION/ or CONTROLLED-STUDY/ or MULTICENTER-STUDY/ or PHASE-3-CLINICAL-TRIAL/ or PHASE-4-CLINICAL-TRIAL/ or DOUBLE-BLIND-PROCEDURE/ or SINGLE-BLIND-PROCEDURE/) or ((RANDOM* or CROSS?OVER* or FACTORIAL* or PLACEBO* or VOLUNTEER*) or ((SINGL* or DOUBL* or TREBL* or TRIPL*) adj3 (BLIND* or MASK*))).ti,ab) and human*.ec,hw,fs.

15.13 and 14

### 9.1.4 **CINAHL search strategy**

1.S1 (MH "Cerebrovascular Disorders") OR (MH "Basal Ganglia Cerebrovascular Disease+") OR (MH "Carotid Artery Diseases+") OR (MH "Cerebral Ischemia+") OR (MH "Cerebral Vasospasm") OR (MH "Intracranial Arterial Diseases+") OR ( (MH "Intracranial Embolism and Thrombosis") ) OR (MH "Intracranial Hemorrhage+") OR (MH "Stroke") OR (MH "Vertebral Artery Dissections") OR (MH "Stroke Patients") OR (MH "Stroke Units")

2.S2 TI ( stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex ) or AB ( stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex )

3.S3 TI ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery ) N5 ( ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*)) OR AB ((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery ) N5 ( ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*))

4.S4 TI (( brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* ) N5 ( haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed* )) OR AB (( brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* ) N5 ( haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed* ))

5.S5 S1 OR S2 OR S3 OR S4

6.S6 (MH "Deglutition") OR (MH "Gagging")

7.S7 (MH "Deglutition Disorders")

8.S8 TI ( (swallow* or deglutit* or dysphag*) N3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*) ) OR AB ( (swallow* or deglutit* or dysphag*) N3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*) )

9.S9 TI ((swallow* or deglutit* or dysphag*) N3 (scale* or screen* or checklist* or assess* or exam* or identif* or recogni* or evaluat* or diagnos* or detect* or hazard

or risk or test)) OR AB ((swallow* or deglutit* or dysphag*) N3 (scale* or screen* or checklist* or assess* or exam* or identif* or recogni* or evaluat* or diagnos* or detect* or hazard or risk or test))

10.S10 S6 OR S7 OR S8 OR S9

11.S11 MH Random Assignment or MH Single-blind Studies or MH Double-blind Studies or MH Triple-blind Studies or MH Crossover design or MH Factorial Design

12.S12 TI ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or AB ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or SU ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study")

13.S13 TI random* or AB random*

14.S14 AB "latin square" or TI "latin square"

15.S15 TI (crossover or cross-over) or AB (crossover or cross-over) or SU (crossover or cross-over)

16.S16 MH Placebos

17.S17 TI ( ((singl* or doubl* or trebl* or tripl*) N3 (blind* or mask*)) ) OR AB ( ((singl* or doubl* or trebl* or tripl*) N3 (blind* or mask*)) )

18.S18 TI Placebo* or AB Placebo* or SU Placebo*

19.S19 MH Clinical Trials

20.S20 TI (Clinical AND Trial) or AB (Clinical AND Trial) or SU (Clinical AND Trial)

21.S21 S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20

22.S22 S5 AND S10 AND S21

Previous version of review search strategy

1.S1. stroke

2.S2. infarction

3.S3. brain Infarction

4.S4. cerebrovascular disease

5.S5. hemorrhage

6.S6. cerebral hemorrhage

7.S7. cerebral haemorrhage

8.S8. S1 or S2 or S3 or S4 or S5 or S6 or S7

9.S9. dysphagia or deglutition or swallowing or deglutition disorders or swallowing disorders or malnutrition or undernutrition

10.S10. intervention or supplementation or feeding or nutrition or nutritional supplementation or therapy or swallowing therapy or tube feeding or fluid or fluid supplementation or sip feeding or feeding route or timing or diet or hydration

11.S11. S9 or S10

12.S12. S8 and S11

13.S13. randomised controlled trials or controlled clinical trial or randomized or clinical trials

14.S14. S12 and S13

### 9.1.5 **Web of Science search strategy**

1. TS=(stroke* or poststroke or apoplex* or cerebral vasc* or brain vasc* or cerebrovasc* or cva*)

2. TS=((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA* or anterior circulation or posterior circulation or basilar artery or vertebral artery) NEAR/5 (isch?emi* or infarct* or thrombo* or emboli* or occlus*))

3. TS=((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher*) NEAR/5 (h?emorrhag* or h?ematoma* or bleed*))

4. #3 OR #2 OR #1

5. TS=((swallow* or deglutit* or dysphag*) NEAR/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*))

6. TS=((pharyn* or oropharyn*) NEAR/3 (disturbance* or disorder* or difficult* or dysfunction* or impair* or condition* or abnormal* or damage* or injur*))

7. #6 OR #5

8. TS=(random* or RCT or RCTs)

9. TS=(controlled NEAR/5 (trial* or stud*))

10. TS=(clinical* NEAR/5 trial*)

11. TS=((control or treatment or experiment* or intervention) NEAR/5 (group* or subject* or patient*))

12. TS=((control or experiment* or conservative) NEAR/5 (treatment or therapy or procedure or m.anage*))

13. TS=((singl* or doubl* or tripl* or trebl*) NEAR/5 (blind* or mask*))

14. TS=(cross-over or cross over or crossover)

15. TS=(placebo* or sham)

16. TS=trial

17. #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8

18. #17 AND #7 AND #4

Previous version of review search strategy

1.stroke

2.infarction

3.brain infarction

4.cerebrovascular disease

5.hemorrhage

6.cerebral haemorrhage

7.cerebral hemorrhage

8.1 or 2 or 3 or 4 or 5 or 6 or 7

9.dysphagia or deglutition or swallowing or deglutition disorders or swallowing disorders

10.randomized controlled trial or controlled clinical trial randomized or placebo or clinical trials or trial

11.8 and 9 and 10

### 9.1.6 **SpeechBITE search strategy**

1.Speech Pathology Practice Area: Dysphagia

2.Type of intervention: Swallowing/ feeding

3.Within this population: Stroke/CVA

4.Research Design : Randomised Controlled Trial

5.Age group: Adults

1.Speech Pathology Practice Area: Dysphagia

2.Type of intervention: Swallowing/ feeding

3.Within this population: Stroke/CVA

4.Research Design: Non-Randomised Controlled Trial

5.Age group: Adults

### 9.1.7 **US National Institutes of Health Ongoing Trials Register**

### **ClinicalTrials.gov (www.clinicaltrials.gov)**

1.( Dysphagia AND ( Brain Infarction OR Intracranial Hemorrhages OR Carotid Artery Diseases OR Brain Ischemia OR Cerebral Hemorrhage OR Cerebrovascular Disorders OR Stroke ) ) [DISEASE]

### 9.1.8 **World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch)**

1.stroke AND swallowing OR stroke AND dysphagia

### 9.1.9 **Google Scholar**

1.Stroke

2.Dysphagia

3.Interventions

4.Randomised Controlled Trials

## 9.2 Appendix 2: Content and consensual validity survey

### 9.2.1 Information sent to respondents for content- and consensual validity

Copy of written information on e-mail sent to 20 invited Speech and Language Therapists in September 2018.

Dear _____,

Please can I ask you for assistance with my research project.

I would like to ask you to complete a survey. It should be a fairly brief and asks you to rate items on a dysphagia scale and then complete a few scenarios based on the scale.

The link takes you to an on-line survey which is anonymous. Participation is of course, voluntary.

https://qtrial2018q2az1.az1.qualtrics.com/jfe/form/SV_55XNmGNFqjHrJY1

The link will stay open for 3 weeks.

Many thanks,

Lisa

Lisa Everton
PhD Student & Speech and Language Therapist

Room B56
Stroke, Division of Clinical Neurosciences
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### 9.2.2 **Results of content and consensual survey**

# Dysphagia Severity Rating Scale Validation

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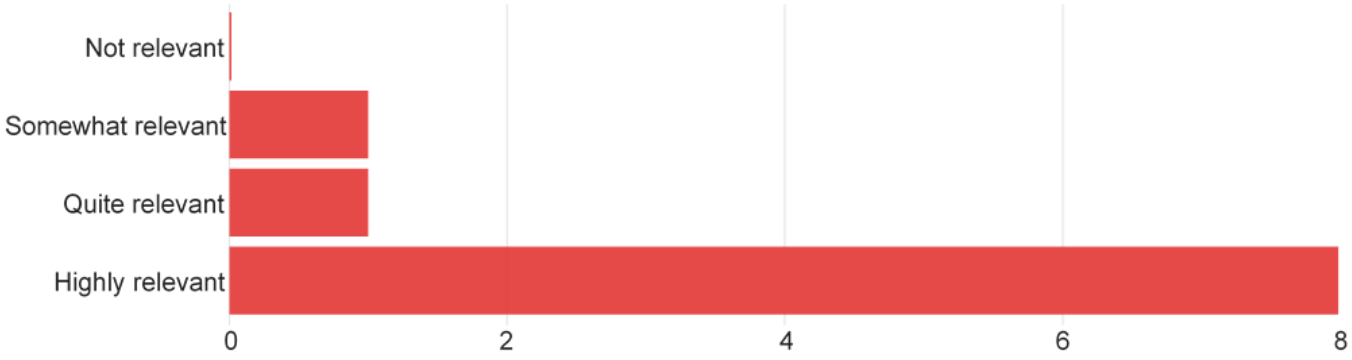
Start of Block: Fluid Scale

**Background Information on the Dysphagia Severity Rating Scale** The Dysphagia Severity Rating Scale (DSRS) is a clinician reported scale that was designed to quantify how much dietary adaptation and feeding supervision patients require (Jayasekeran, 2010). It therefore aims to measure the severity of dysphagia in adult patients with acquired dysphagia. It is a pragmatic scoring system that was modified from the Dysphagia Outcome and Severity Scale (O'Neil, 1999). It has been used in a number of published studies in dysphagia in acute stroke, but has not yet been validated. The scale is reproduced here as it was used in those studies.

This exercise is aimed at developing the content validity of this scale. This is the degree to which this scale is an adequate reflection of what it is supposed to be measuring, i.e., dysphagia severity. The DSRS has three scales – fluids, diet and supervision. Each scale has five levels. It asks you about how relevant you feel each item is and if anything else is needed. You are then asked to rate a few scenarios using the scale. Please score each item according to how relevant the item is.

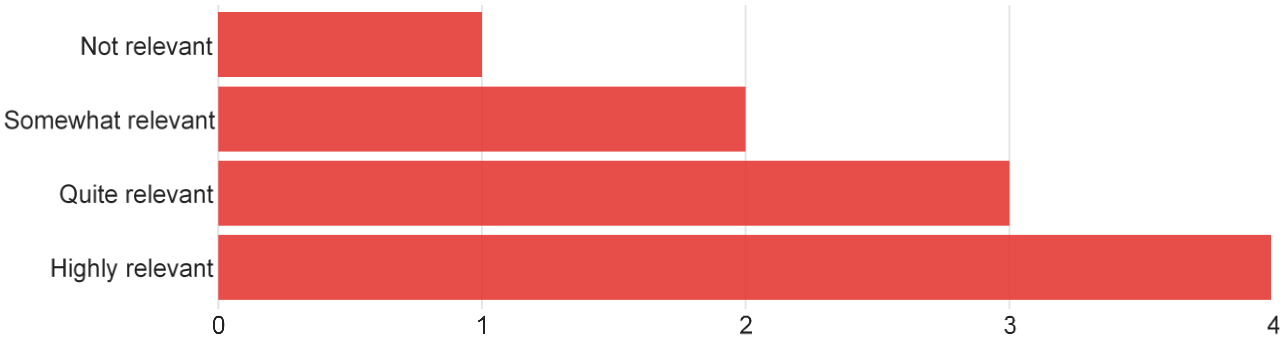
## Q1 - Please score each item according to how relevant the item is to the fluid scale. How relevant is no oral fluids?




Please score each item according to how relevant the item is to the fluid scale. How relevant is no oral fluids?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 1 |
| Quite relevant | 1 |
| Highly relevant | 8 |
| Total | 10 |

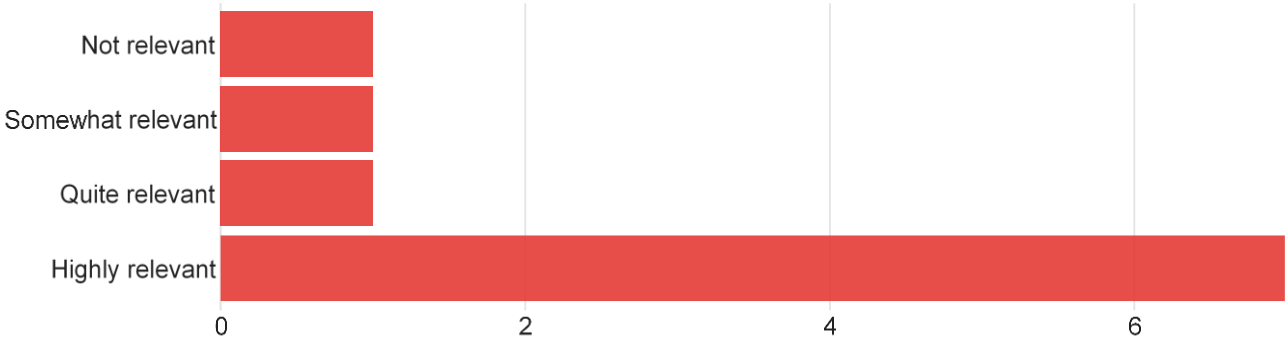
## Q2 - Please score each item according to how relevant the item is to the fluid scale. How relevant is  pudding consistency?




Please score each item according to how relevant the item is to the fluid scale. How relevant is pudding consistency?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 2 |
| Quite relevant | 3 |
| Highly relevant | 4 |
| Total | 10 |

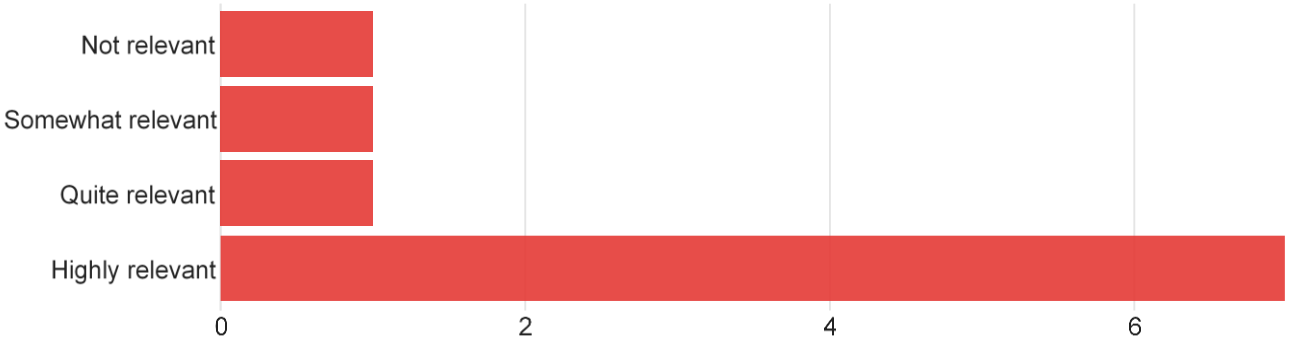
## Q3 - Please score each item according to how relevant the item is to the fluid scale. How relevant is custard consistency?




Please score each item according to how relevant the item is to the fluid scale. How relevant is custard consistency?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 1 |
| Quite relevant | 1 |
| Highly relevant | 7 |
| Total | 10 |

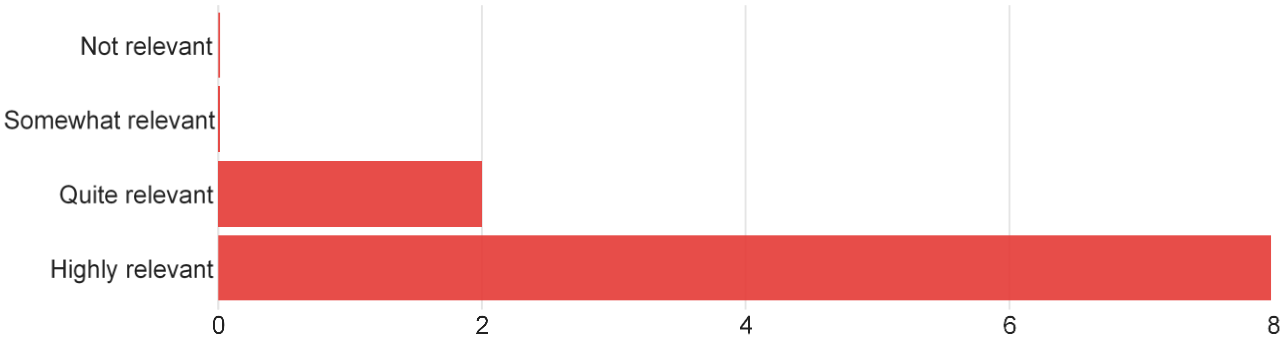
## Q4 - Please score each item according to how relevant the item is to the fluid scale.  How relevant is syrup consistency ?




Please score each item according to how relevant the item is to the fluid scale. How relevant is syrup consistency ?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 1 |
| Quite relevant | 1 |
| Highly relevant | 7 |
| Total | 10 |

## Q5 - Please score each item according to how relevant the item is the fluid scale. How relevant is normal fluids ?




Please score each item according to how relevant the item is the fluid scale. How relevant is normal fluids ?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 0 |
| Quite relevant | 2 |
| Highly relevant | 8 |
| Total | 10 |

# Q6 - Is the Fluid Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

Is the Fluid Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

No - IDDSI terminology would be ideal and the introduction of slight thick drinks would be more comprehensive.

No - it needs to include naturally thick fluids (slightly thickened fluids) as this could make a big difference to patients' quality of life.

Yes- comprehensive for the fluid levels I use.

No. What about bolus size e.g teaspoon vs small sips from an open beaker.

I wasn't sure how to answer this section. If the fluid terminology was all IDDSI compliant I would have rated all the fluid items as "highly relevant". It needs to be updated and comply with IDDSI.

Yes-I think lots of people can manage fluids which are somewhere between normal and syrup i.e. thin syrup or slightly thick (IDDSI). The scale doesn't allow this to be recorded.

No - it is not IDDSI compliant

We are required to use IDDSI descriptors and these do not match, the scale matches our previous system

The IDDS has provided additional fluid consistencies, thin liq, mildly thick etc with a consistency calibration tool

Yes

# Q27 - Is the wording clear? Please answer yes or no with comments.

Is the wording clear? Please answer yes or no with comments.

No but needs to be IDDSI compliant

Yes. However, given move to IDDSI the scale should probably be updated to incorporate this new wording and categories.

Yes it is clear although terminology not IDDSI compliant.

Yes. Needs updating with the IDDSI standardised terminology

Yes, it is clear for the terms used but see above comment re IDDSI.

This terminology only makes sense for those who are familiar with it. Also, the terms are subjective and open to interpretation.

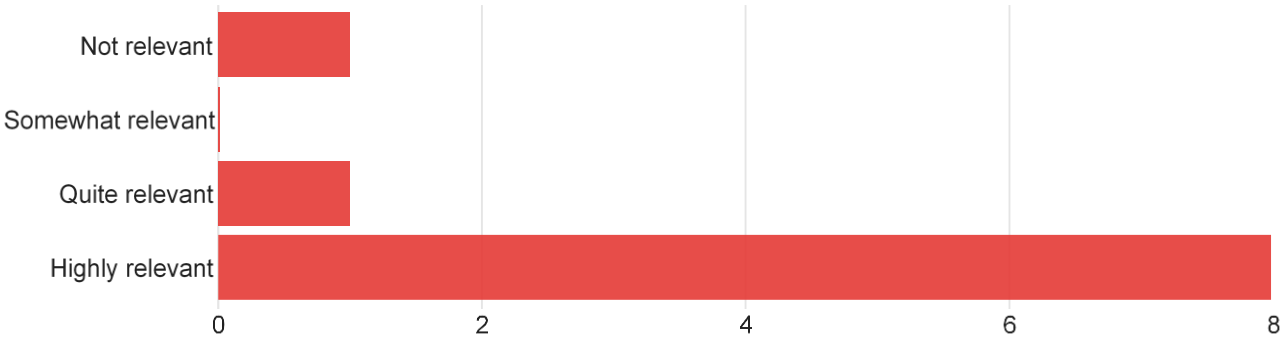
It is not IDDSI compliant

a flow description would enable checking of a prepared consistency

No. Whilst I understand the labels, from my previous training, in the context of the IDDS the wording is less clear.

Yes. The wording is self-explanatory

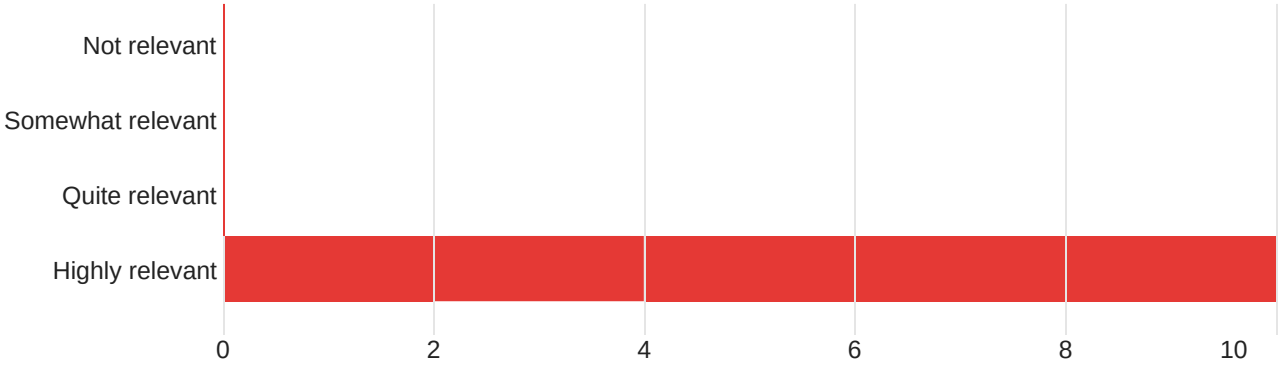
## Q7 - Please score each item according to how relevant the item is to the diet scale. How relevant is non-oral feeding?




Please score each item according to how relevant the item is to the diet scale. How relevant is non-oral feeding?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 0 |
| Quite relevant | 1 |
| Highly relevant | 8 |
| Total | 10 |

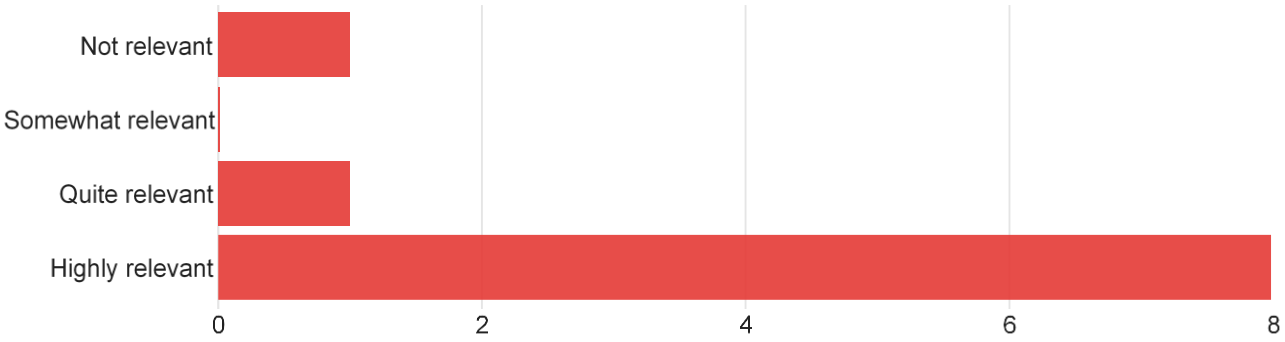
## Q8 - Please score each item according to how relevant the item is to the diet scale.  How relevant is puree?




Please score each item according to how relevant the item is to the diet scale. How relevant is puree?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 0 |
| Quite relevant | 0 |
| Highly relevant | 10 |
| Total | 10 |

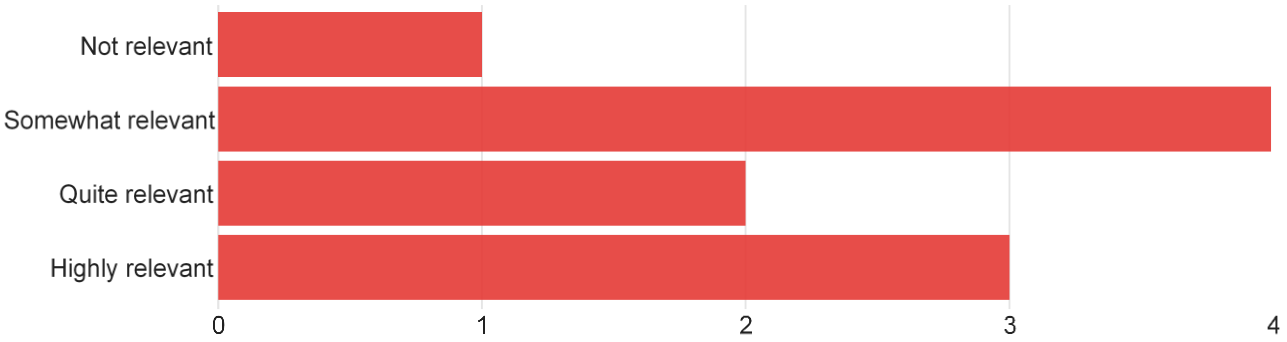
## Q9 - Please score each item according to how relevant the item is to the diet scale. How relevant is soft, moist diet ?




Please score each item according to how relevant the item is to the diet scale. How relevant is soft, moist diet ?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 0 |
| Quite relevant | 1 |
| Highly relevant | 8 |
| Total | 10 |

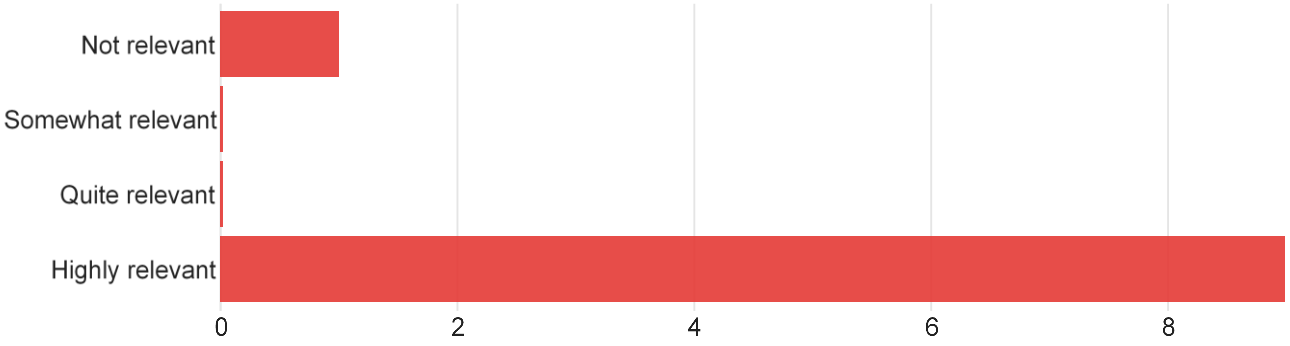
## Q10 - Please score each item according to how relevant the item is to the diet scale. How relevant is selected textures?




Please score each item according to how relevant the item is to the diet scale. How relevant is selected textures?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 4 |
| Quite relevant | 2 |
| Highly relevant | 3 |
| Total | 10 |

## Q11 - Please score each item according to how relevant the item is  to the diet scale. How relevant is normal ?




Please score each item according to how relevant the item is to the diet scale. How relevant is normal ?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 0 |
| Quite relevant | 0 |
| Highly relevant | 9 |
| Total | 10 |

# Q12 - Is the Diet Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

Is the Diet Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

Again needs to be IDDSI terminology going forward

No - I think it would be better to separate it further into the sub-categories and incorporate IDDSI. These small differences make a big difference to a patient's quality of life and need to be captured.

No- would prefer to have a separate mashed option.

No. What about quantity e.g oral trials vs full oral intake.

Again, I feel the diet scale should be IDDSI compliant and I'm not sure what is meant by "selected textures" - this felt ambiguous to me.

Yes-none of the terms allow for people who can manage foods that are fork mashable only or pre-mashed with small pieces that require some minimal chewing.

No - it is not IDDSI compliant. The numbers could be confusing with the numbers used in IDDSI

liquid diet premash diet fork mashable diet

Mixed consistencies, I fond this useful to describe diet that includes for example cereal in milk, soup with vegetables in.

Yes. Just a thought: would adding a description of bolus cohesiveness help better define the items (especially for the selected textures)?

# Q26 - Is the wording clear? Please answer yes or no with comments.

Is the wording clear? Please answer yes or no with comments.

Again needs to be IDDSI terminology going forward

No - I think people still interpret these phrases differently. Incorporating IDDSI terminology would overcome this issue.

Yes although terminology is not IDDSI compliant.

Yes. Needs the new IDDSI terminology

No. I'm not sure what selected textures meant - is this soft options from the regular menu?

Soft and moist diet is open to interpretation. Selected textures is ambiguous-I think it could have lots of different meanings.

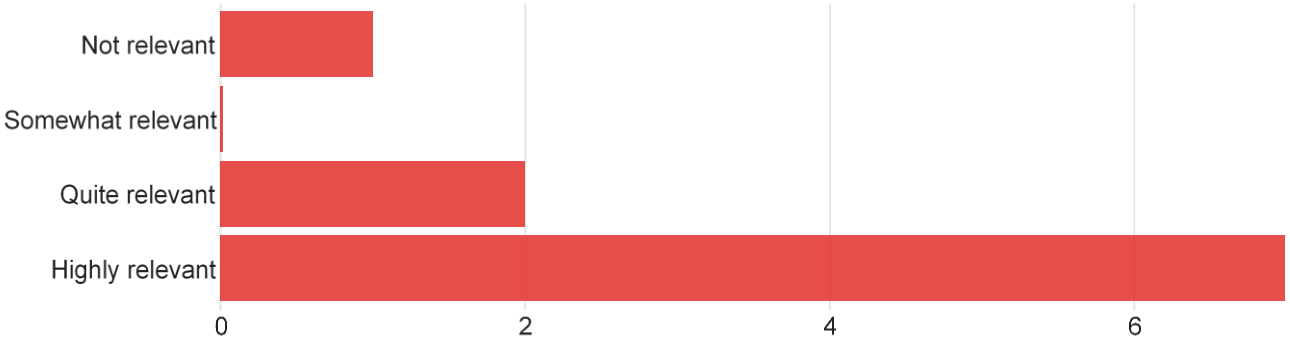
yes

no- needs food consistency description

The wording on selected textures is ambiguous. Normal diet is also ambiguous, but would suggest no restrictions.

The term "selected textures" may need more elaboration. Perhaps examples or definition?

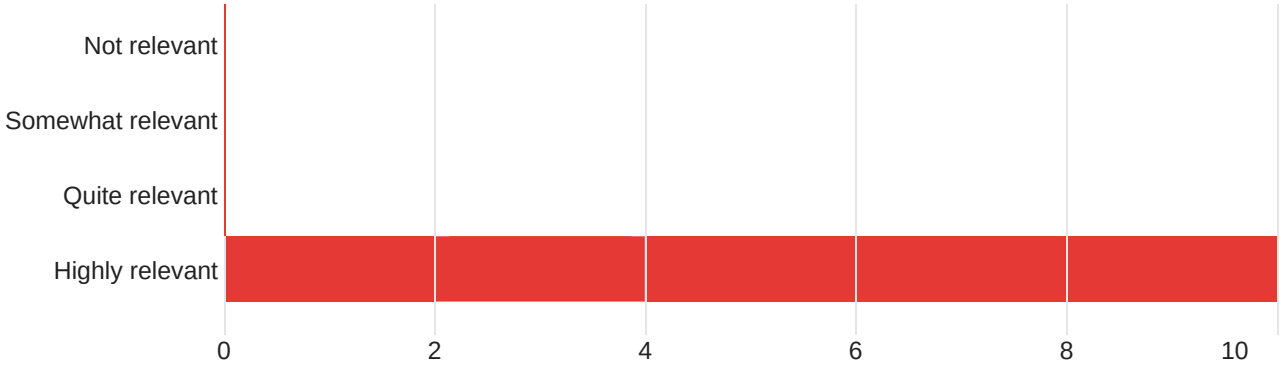
## Q13 - Please score each item according to how relevant the item is to the supervision scale. How relevant is no oral feeding?




Please score each item according to how relevant the item is to the supervision scale. How relevant is no oral feeding?

| Field | Count |
|---|---|
| Not relevant | 1 |
| Somewhat relevant | 0 |
| Quite relevant | 2 |
| Highly relevant | 7 |
| Total | 10 |

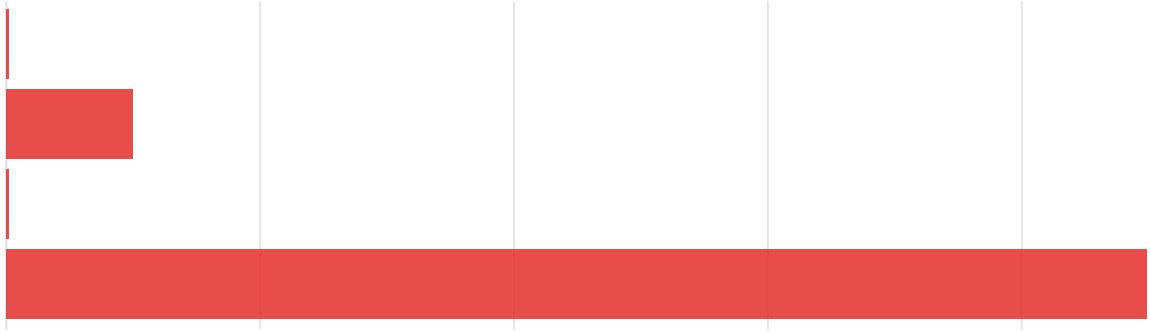
## Q14 - Please score each item according to how relevant the item is to the supervision scale. How relevant is therapeutic feeding (SALT/ trained staff)?




Please score each item according to how relevant the item is to the supervision scale. How relevant is therapeutic feeding (SALT/ trained staff)?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 0 |
| Quite relevant | 0 |
| Highly relevant | 10 |
| Total | 10 |

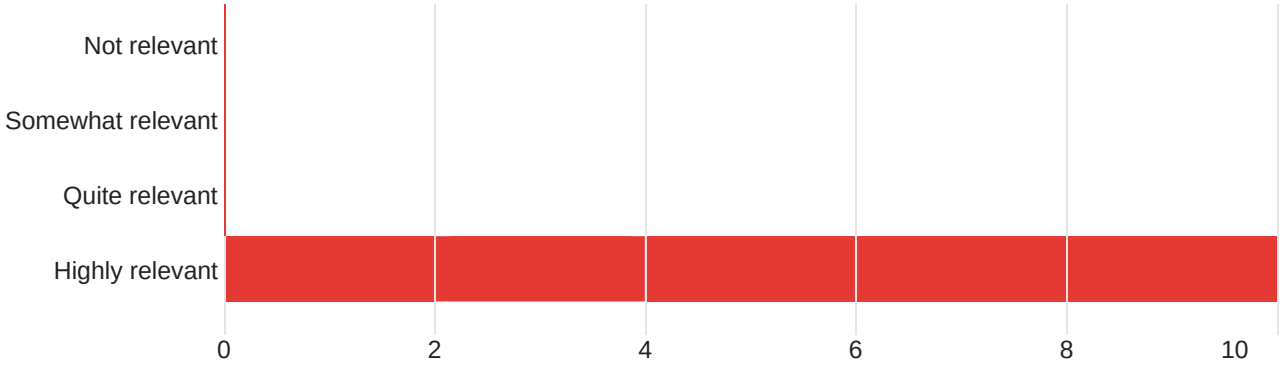
## Q15 - Please score each item according to how relevant the item is to the supervision scale. How relevant is feeding by third party (untrained)?



Please score each item according to how relevant the item is to the supervision scale. How relevant is feeding by third party (untrained)?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 1 |
| Quite relevant | 0 |
| Highly relevant | 9 |
| Total | 10 |

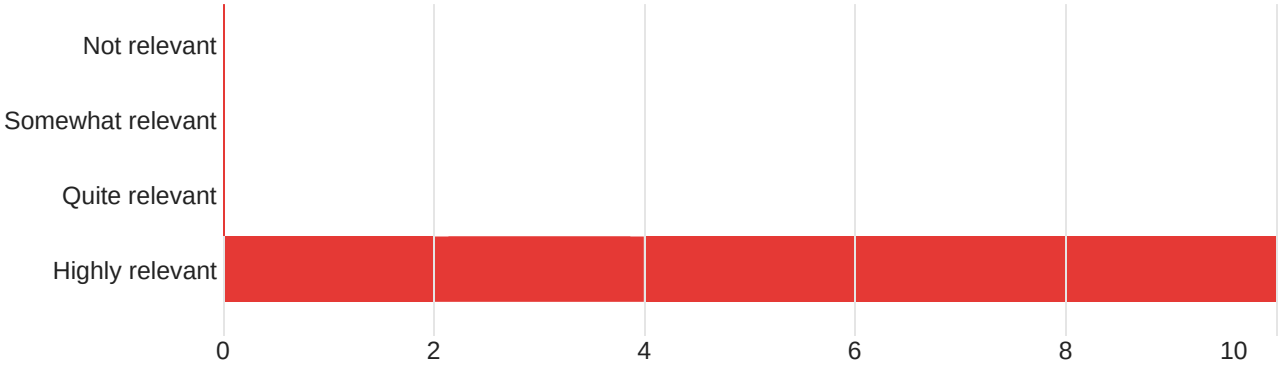
## Q16 - Please score each item according to how relevant the item is to the supervision scale. How relevant is eating with supervision?




Please score each item according to how relevant the item is to the supervision scale. How relevant is eating with supervision?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 0 |
| Quite relevant | 0 |
| Highly relevant | 10 |
| Total | 10 |

## Q17 - Please score each item according to how relevant the item is to the supervision scale. How relevant is eating independently?




Please score each item according to how relevant the item is to the supervision scale. How relevant is eating independently?

| Field | Count |
|---|---|
| Not relevant | 0 |
| Somewhat relevant | 0 |
| Quite relevant | 0 |
| Highly relevant | 10 |
| Total | 10 |

## Q18 - Is the Supervision Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

Is the Supervision Scale comprehensive - do you feel any items are missing? Please answer yes or no with comments.

Yes

No. I think who gives the assistance is less important than the level the assistance is. I don't really feel like any untrained person should be feeding someone really!. I think with a level of assistance system you should also have: - needing assistance in preparing the food e.g. opening packets - needing food loading onto the utensil for them needing adaptive cutlery/plates - needing hand-over-hand support - needing full assistance This may be too much though. This approach is focused on the patient and quality of life. I think the approach above it focused more on cost - so it depends what the focus of the scale is.

Yes

No. Include full supervision vs distant supervision

Yes, it is comprehensive but I wonder if you could distinguish between close and distant supervision?

No

Yes

yes

Not comprehensive, please see below.

Yes

## Q28 - Is the wording clear? Please answer yes or no with comments.

Is the wording clear? Please answer yes or no with comments.

Yes

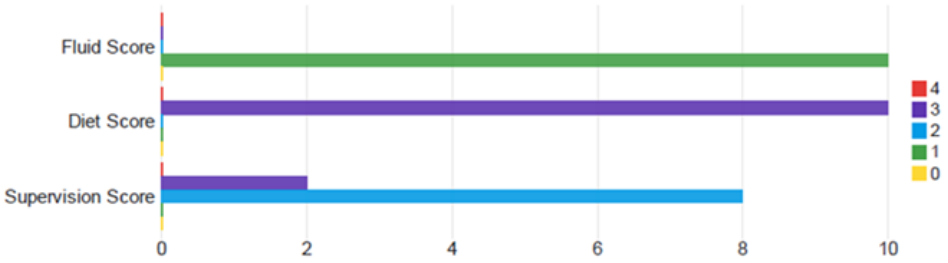
Yes

Yes

Yes

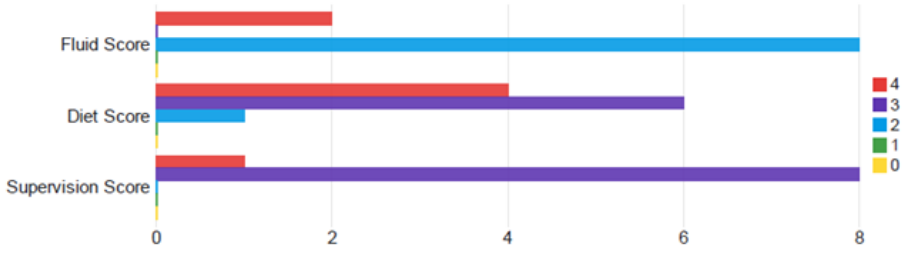
Yes, it is clear.

Q19 - Mr Smith is having syrup fluids, puree diet and being fed. What DSRS score would you assign?



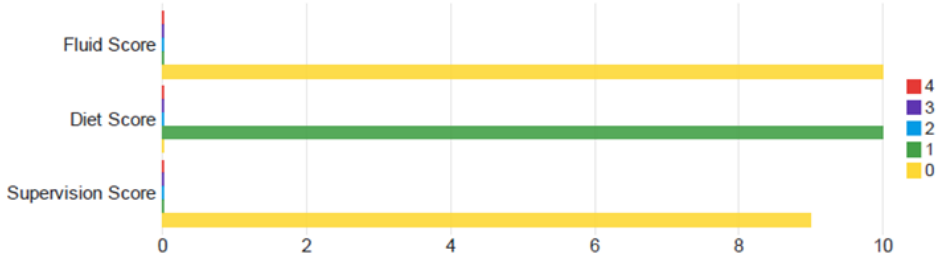

| Field | Fluid Score | Diet Score | Supervision Score |
|---|---|---|---|
| 4 | 0 | 0 | 0 |
| 3 | 0 | 10 | 2 |
| 2 | 0 | 0 | 8 |
| 1 | 10 | 0 | 0 |
| 0 | 0 | 0 | 0 |

Q20 - Mrs Jackson is 5 sips of custard consistency fluids and 5 tsps of chilled smooth puddings 3 x per day. She has an NG Tube in. What DSRS score would you assign?



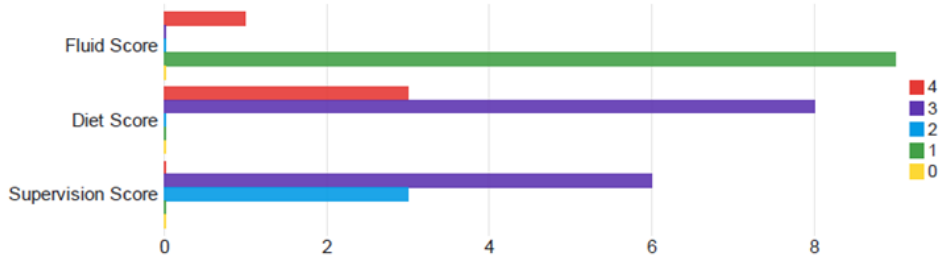

| Field | Fluid Score | Diet Score | Supervision Score | |
|---|---|---|---|---|
| 4 | 2 | 4 | 1 | 7 |
| 3 | 0 | 6 | 8 | 14 |
| 2 | 8 | 1 | 0 | 9 |
| 1 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 |

Q21 - Miss Brown is having normal fluids and managing most normal foods. However she is  still avoiding certain textures but eats independently. What DSRS score would you assign?



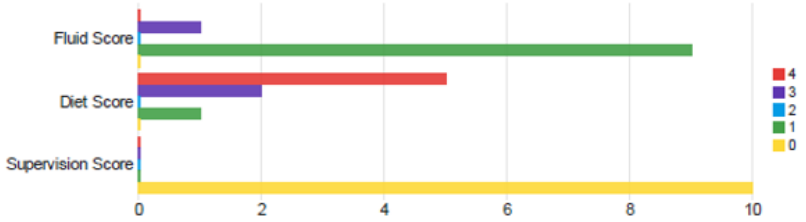

| Field | Fluid Score | Diet Score | Supervision Score | |
|---|---|---|---|---|
| 4 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 |
| 1 | 0 | 10 | 0 | 10 |
| 0 | 10 | 0 | 9 | 19 |

Q23 - Mr Jones is having half puree meals 3 x day and 100ml syrup fluids 3 x day, he has an NG Tube in situ and he is being fed. What DSRS score would you assign?



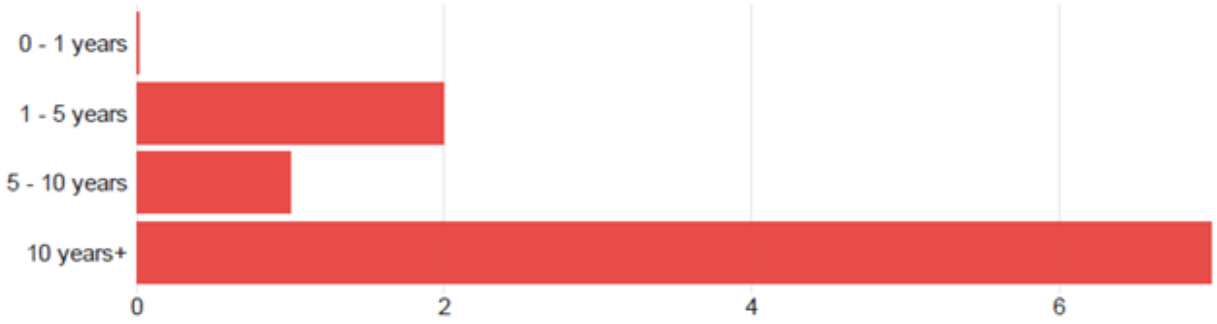

| Field | Fluid Score | Diet Score | Supervision Score |
|---|---|---|---|
| 4 | 1 | 3 | 0 |
| 3 | 0 | 8 | 6 |
| 2 | 0 | 0 | 3 |
| 1 | 9 | 0 | 0 |
| 0 | 0 | 0 | 0 |

Q24 - Mrs Ward is on a purely liquid diet of syrup consistency (such as smoothies, fortified drinks), does not require tube feeding and eats independently. What DSRS score would you assign?




| Field | Fluid Score | Diet Score | Supervision Score | |
|---|---|---|---|---|
| 4 | 0 | 5 | 0 | 5 |
| 3 | 1 | 2 | 0 | 3 |
| 2 | 0 | 0 | 0 | 0 |
| 1 | 9 | 1 | 0 | 10 |
| 0 | 0 | 0 | 10 | 10 |

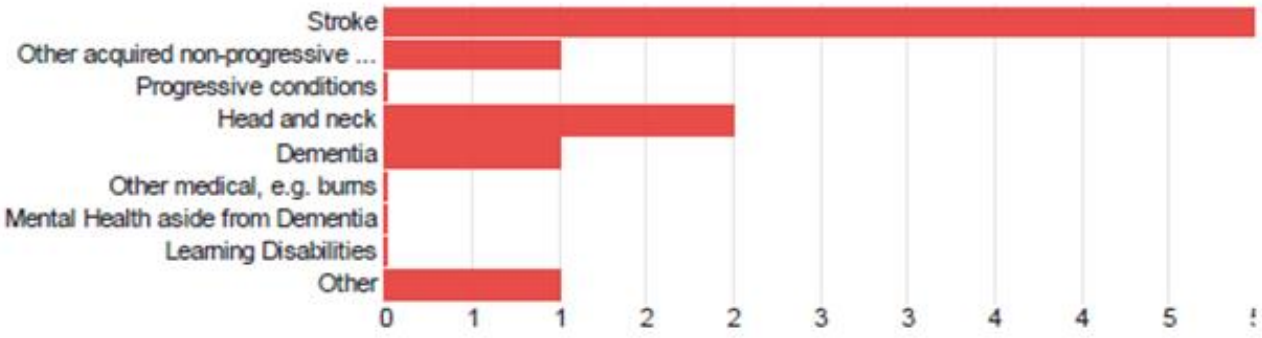
## Q25 - How many years' experience do you have working with dysphagia?




| Field | How many years' experience do you have working with dysphagia? |
|---|---|
| How many years' experience do you have working with dysphagia? | |

| Field | Count |
|---|---|
| 0 - 1 years | 0 |
| 1 - 5 years | 2 |
| 5 - 10 years | 1 |
| 10 years+ | 7 |
| Total | 10 |

## Q27 - What client group do you feel you have the most experience with?




| Field | What client group do you feel you have the most experience with? |
|---|---|

What client group do you feel you have the most experience with?

| Field | Count |
|---|---|
| Stroke | 5 |
| Other acquired non-progressive neurological conditions, e.g. traumatic brain injury | 1 |
| Progressive conditions | 0 |
| Head and neck | 2 |
| Dementia | 1 |
| Other medical, e.g. burns | 0 |
| Mental Health aside from Dementia | 0 |
| Learning Disabilities | 0 |
| Other | 1 |
| Total | 10 |

# 9.3 Appendix 3: MCID Survey

## 9.3.1 Information sent to respondents for MCID survey

UNITED KINGDOM – CHINA – MALAYSIA

Faculty of Medicine and Health Sciences
School of Medicine
Division of Clinical Neuroscience
Stroke
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB
t: +44 (0)115 823 1765
f: +44 (0) 115 823 1767
www/nottingham.ac.uk/medicine/about/clinicalneuroscience
Head of Division/Head of Stroke
Stroke Association Professor of Stroke Medicine:
Professor P M W Bath

Dear Colleague,

Thank-you for taking the time to complete this survey! Just a bit of information to read before you start.

Why do we want this information?

The Dysphagia Severity Dysphagia Scale (DSRS) and the Functional Oral Intake Scale (FOIS) are dysphagia outcome scales. A copy of both questionnaires is provided as an attachment to this e-mail. These scales and most scales do not state what change in score is clinically meaningful, i.e., if a patient scores a 3 at the beginning of treatment and then gets a 5, is this actually clinically meaningful? There are various ways to try and work out what change is considered a meaningful outcome. One way is to conduct a survey and ask a group of experts, i.e., SLTs would be identified as an expert group in this case, as well as patients themselves. As a group of identified experts, I am seeking your views in order to form a consensus.

What do you need to do?

Read the scales below and click on the link in the e-mail. There are 7 questions and no right and wrong answers. If you want to send any extra information, you can e-mail me at:

lisa.everton@nottingham.ac.uk

What exactly do you need to comment on?

I am asking you to decide what change in score on the scales would represent a minimal clinically important difference? That is, the smallest change in score on a dysphagia scale that you and/ or patient would identify as clinically important or the smallest change that you feel means an intervention has had an effect. I realise people may feel the difference between each level is not equal but have a go and let me have any comments. We would hope to do this with patients as well in the future.

Thank-you very much.

Lisa Everton

PhD Student and SLT

Room B56

Stroke, Division of Clinical Neurosciences

Clinical Sciences Building

University of Nottingham

E-mail: lisa.everton@nottingham.ac.uk

Tel. 0115 8231808

# Dysphagia severity rating scale (DSRS)

| **Score Fluids** | **Score Diet** | **Score Supervision** |
|---|---|---|
| 4 No oral fluids | 4 Non oral feeding | 4 No oral feeding |
| 3 Pudding consistency (IDDSI level 4 extremely thick) | 3 Pureed/ pre-mashed (texture C & D/ IDDSI level 4 (pureed) & 5 (minced and moist) | 3 Therapeutic feeding (SLT/ trained staff – oral trials) |
| 2 Custard consistency (IDDSI level 3 moderately thick) | 2 Soft, moist, fork mashable diet (texture E/ IDDSI level 6 - soft & bite sized) | 2 Needs feeding |
| 1 Syrup consistency (IDDSI level 2 mildly thick) | 1 Selected textures (avoiding certain foods) | 1 Eating with supervision |
| 0 Normal fluids (IDDSI level 0) | 0 Normal (IDDSI level 7 regular) | 0 Eating independently |

Jayasekeran, V., et al., Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions. Gastroenterology, 2010. 138 (5): p. 1737-46

# Functional Oral Intake Scale (FOIS)

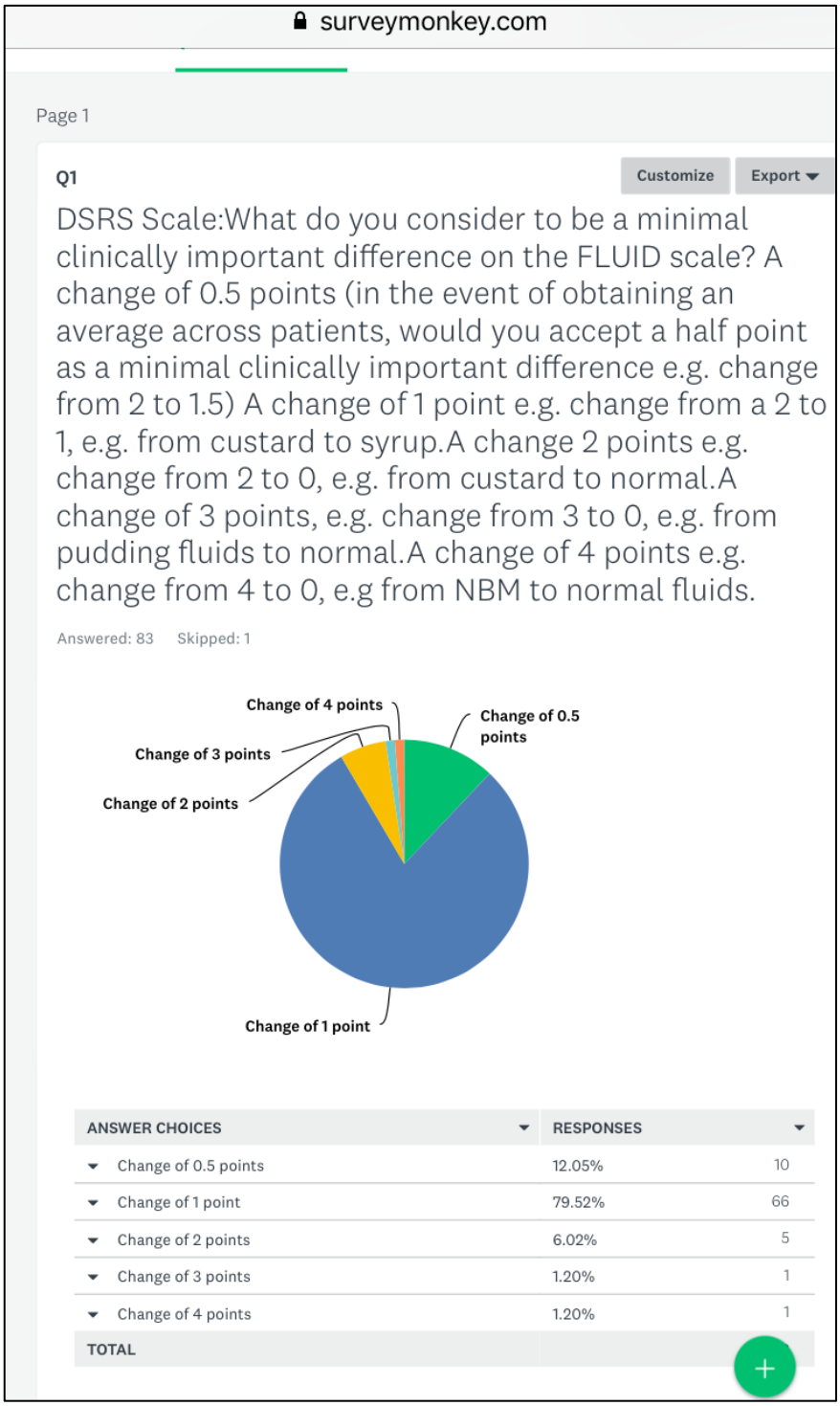
**NOTE:** Levels 4-7 ONLY use food/ diet to score NOT liquids.

| Level | FOIS Description | What this translates into |
|---|---|---|
| **Level 1** | Nothing by mouth | Needs/ relies on/ has non-oral feeding |
| **Level 2** | Tube dependent with minimal attempts of food or liquid | E.G., limited oral trials/ sips water for comfort |
| **Level 3** | Tube dependent with consistent oral intake of food or liquid | E.G., having consistent amounts orally, but not enough/ fatigue issues |
| **Level 4** | Total oral diet of a single consistency | Full pureed diet/ pre-mashed diet (texture C&D/ IDDSI level 4 or 5) (no longer tube dependent) |
| **Level 5** | Total oral diet with multiple consistencies, but requiring special preparation or compensations | Fork mashable diet, soft diet/ normal diet if requiring preparation, e.g., cutting up meat or using strategies e.g., fluids to wash through, etc. |
| **Level 6** | Total oral diet with multiple consistencies without special preparation, but with specific food limitations. | Where patient is only avoiding certain foods, but food taken is not being prepared specially and no strategies being used |
| **Level 7** | Total oral diet with no restrictions. | Normal diet. IDDSI level 7 |

Crary, M.A., Carnaby-Mann, G.D. and Groher, M. E. Initial Psychometric Assessment of a Functional Oral Intake Scale for Dysphagia in Stroke Patients. (2005). *Arch Phys Rehabil*, Vol 86.

### 9.3.2 **Results of MCID survey**

Question 1



Question 2

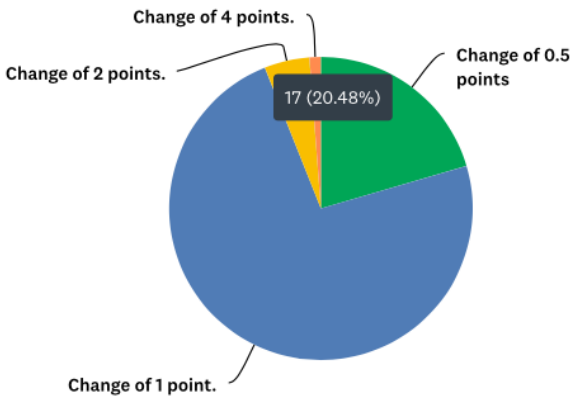
surveymonkey.com

Q2

Customize Export

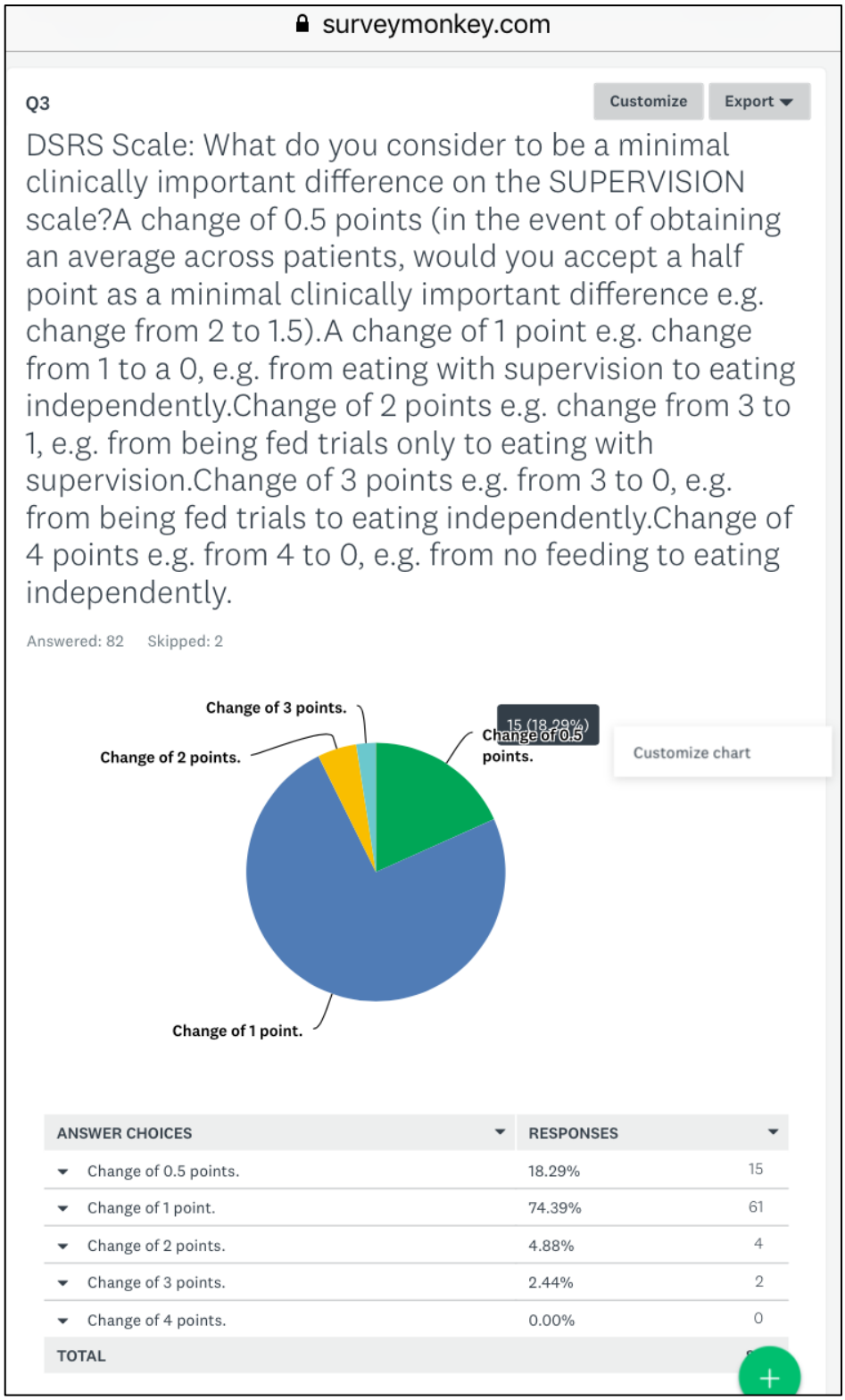
DSRS Scale:What do you consider to be a minimal clinically important difference on the DIET scale?A change of 0.5 points (in the event of obtaining an average across patients, would you accept a half point as a minimal clinically important difference e.g. change from 2 to 1.5).A change of 1 point e.g. change from 1 to a 0, e.g. from soft diet to normal diet.Change of 2 points e.g. change from 3 to 1, e.g. from pureed to soft diet.Change of 3 points e.g. from 3 to 0, e.g. from pureed to normal diet.Change of 4 points e.g. from 4 to 0, e.g. from non-oral feeding to normal diet.

Answered: 83 Skipped: 1




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Change of 0.5 points | 20.48% | 17 |
| Change of 1 point. | 73.49% | 61 |
| Change of 2 points. | 4.82% | 4 |
| Change of 3 points. | 0.00% | 0 |
| Change of 4 points. | 1.20% | 1 |
| TOTAL | | 83 |

Question 3


surveymonkey.com
Q3
Customize
Export
DSRS Scale: What do you consider to be a minimal clinically important difference on the SUPERVISION scale?A change of 0.5 points (in the event of obtaining an average across patients, would you accept a half point as a minimal clinically important difference e.g. change from 2 to 1.5).A change of 1 point e.g. change from 1 to a 0, e.g. from eating with supervision to eating independently.Change of 2 points e.g. change from 3 to 1, e.g. from being fed trials only to eating with supervision.Change of 3 points e.g. from 3 to 0, e.g. from being fed trials to eating independently.Change of 4 points e.g. from 4 to 0, e.g. from no feeding to eating independently.
Answered: 82 Skipped: 2
Change of 3 points.
Change of 2 points.
Change of 0.5 points.
Change of 1 point.
Customize chart
ANSWER CHOICES
RESPONSES
Change of 0.5 points. 18.29% 15
Change of 1 point. 74.39% 61
Change of 2 points. 4.88% 4
Change of 3 points. 2.44% 2
Change of 4 points. 0.00% 0
TOTAL

Question 4

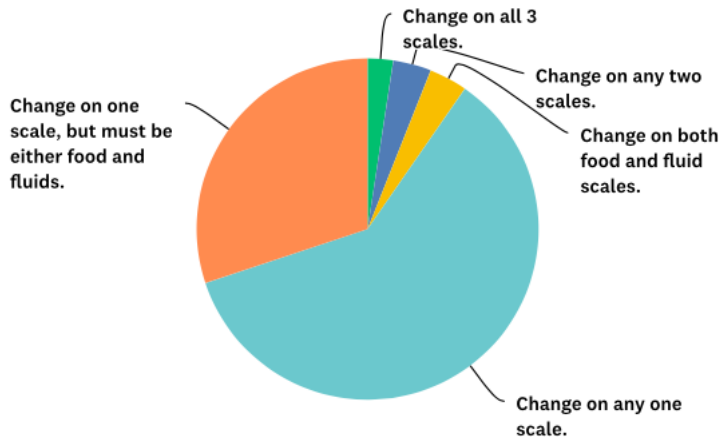
surveymonkey.com

Q4

Customize Export

DSRS Scale: Do you consider a minimal clinically significant difference requires changes on all three scales or both food and fluids scales or on either food or fluid scale only?

Answered: 83 Skipped: 1




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Change on all 3 scales. | 2.41% | 2 |
| Change on any two scales. | 3.61% | 3 |
| Change on both food and fluid scales. | 3.61% | 3 |
| Change on any one scale. | 60.24% | 50 |
| Change on one scale, but must be either food and fluids. | 30.12% | 25 |
| TOTAL | | 83 |

Question 5

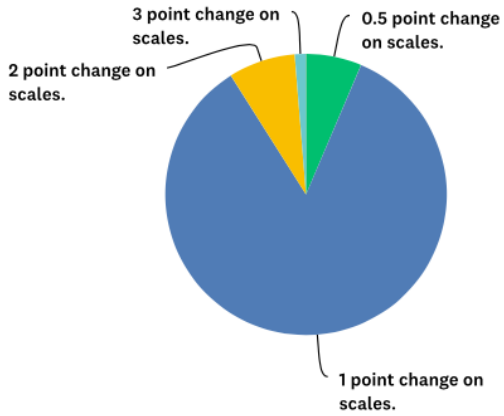
surveymonkey.com

Q5

Customize Export

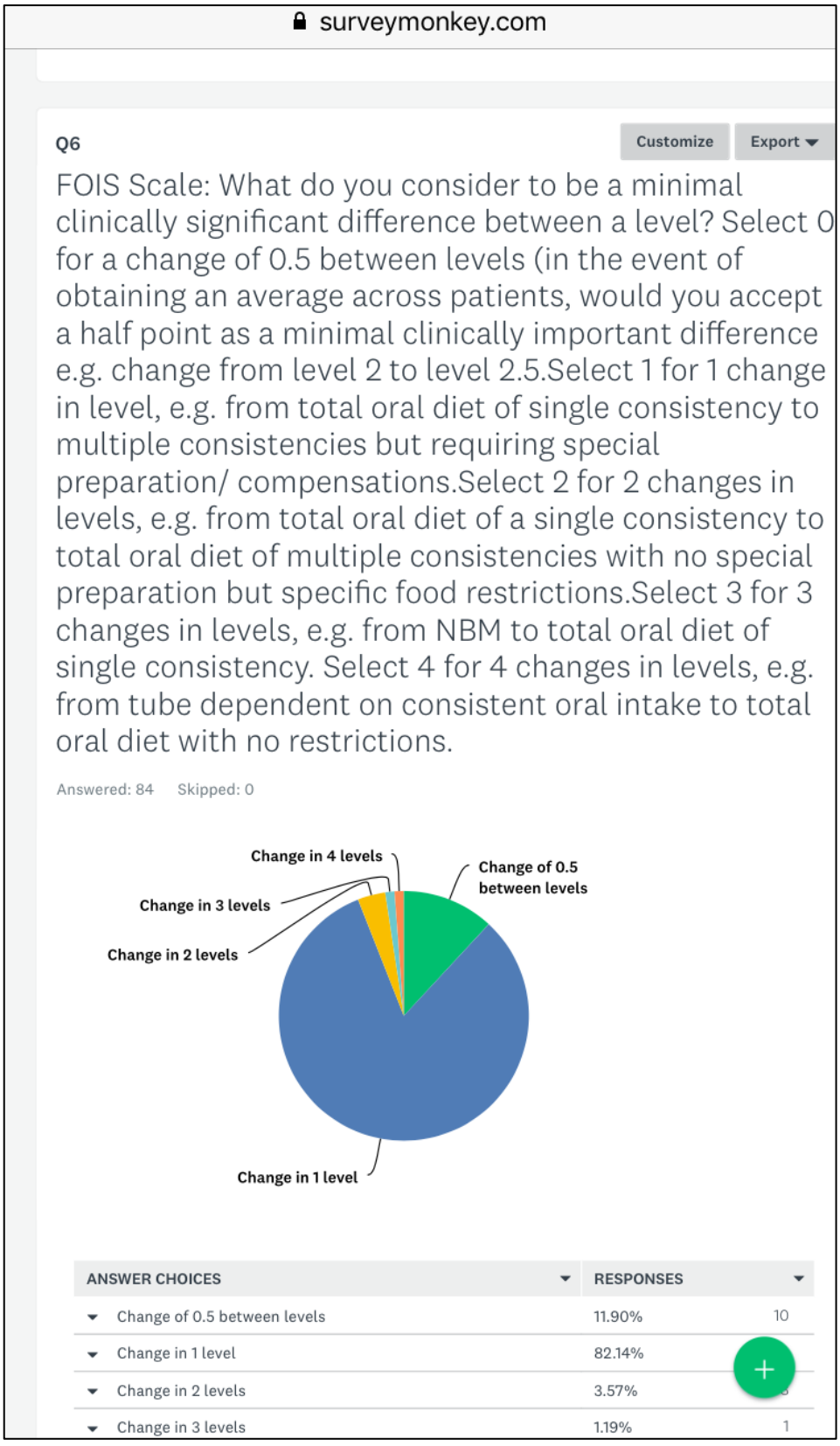
For reference, the options for the previous question are copied here: Change on all 3 scales. Change on any two scales. Change on both food and fluids scales. Change on any one scale. Change on one scale, but must be either food or fluids. According to your chosen answer for the previous question, how many points do you feel EACH scale should change by to be considered a minimal clinically significant change? (Example, if you chose change on all three scales, do you feel there should be a change of 1, 2, 3 or 4 points on all 3 scales; if you chose one scale, do you feel there should be a change of 1, 2, 3 or 4 points on that one scale? Similarly, if you chose two scales, how many points do you feel those two scales should change by (1, 2, 3 or 4 points), to be considered clinically significant?

Answered: 78 Skipped: 6

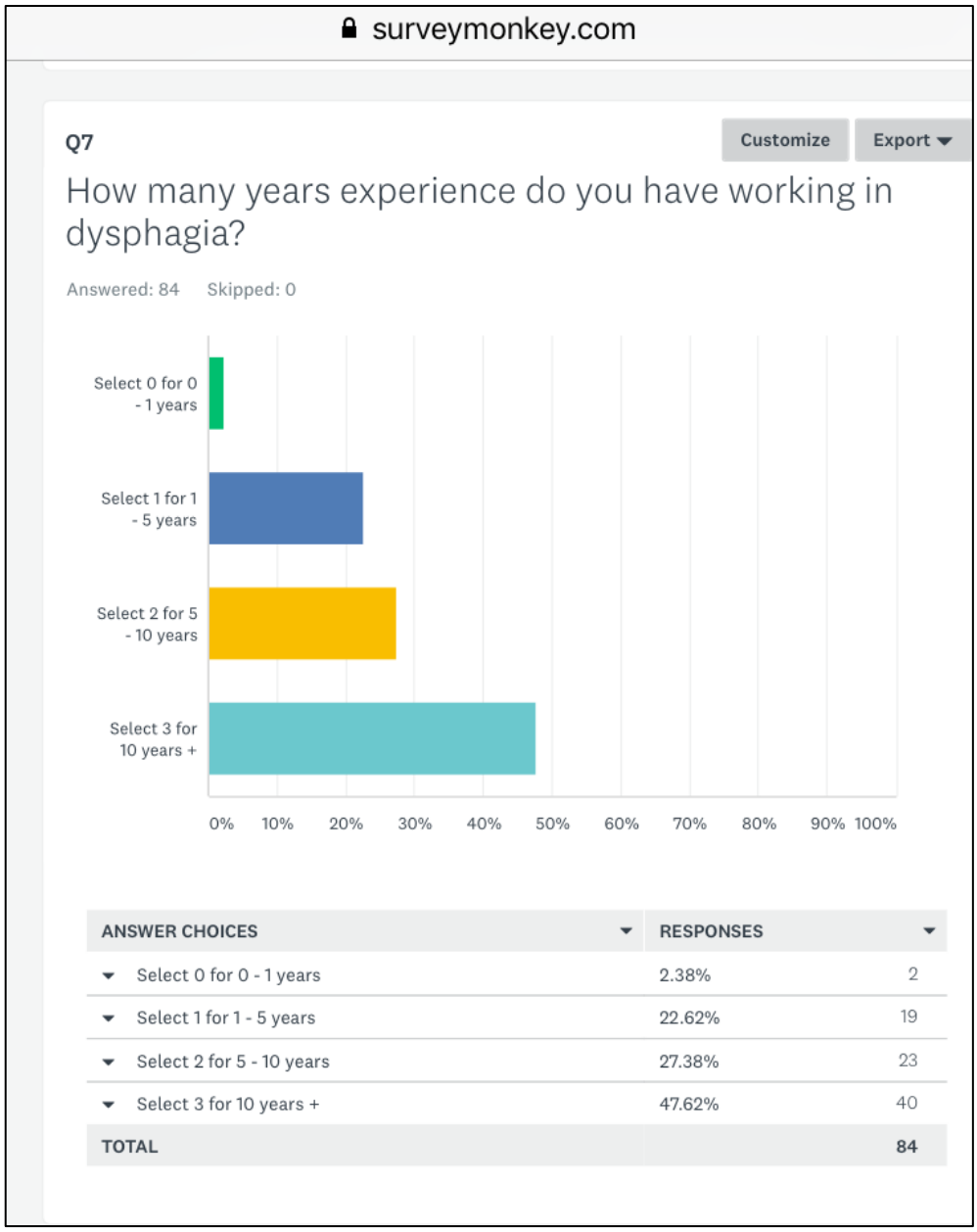



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| 0.5 point change on scales. | 6.41% | 5 |
| 1 point change on scales. | 84.62% | 66 |
| 2 point change on scales. | 7.69% | 6 |
| 3 point change on scales. | 1.28% | 1 |
| 4 point change on scales. | 0.00% | |
| TOTAL | | 78 |

Question 6

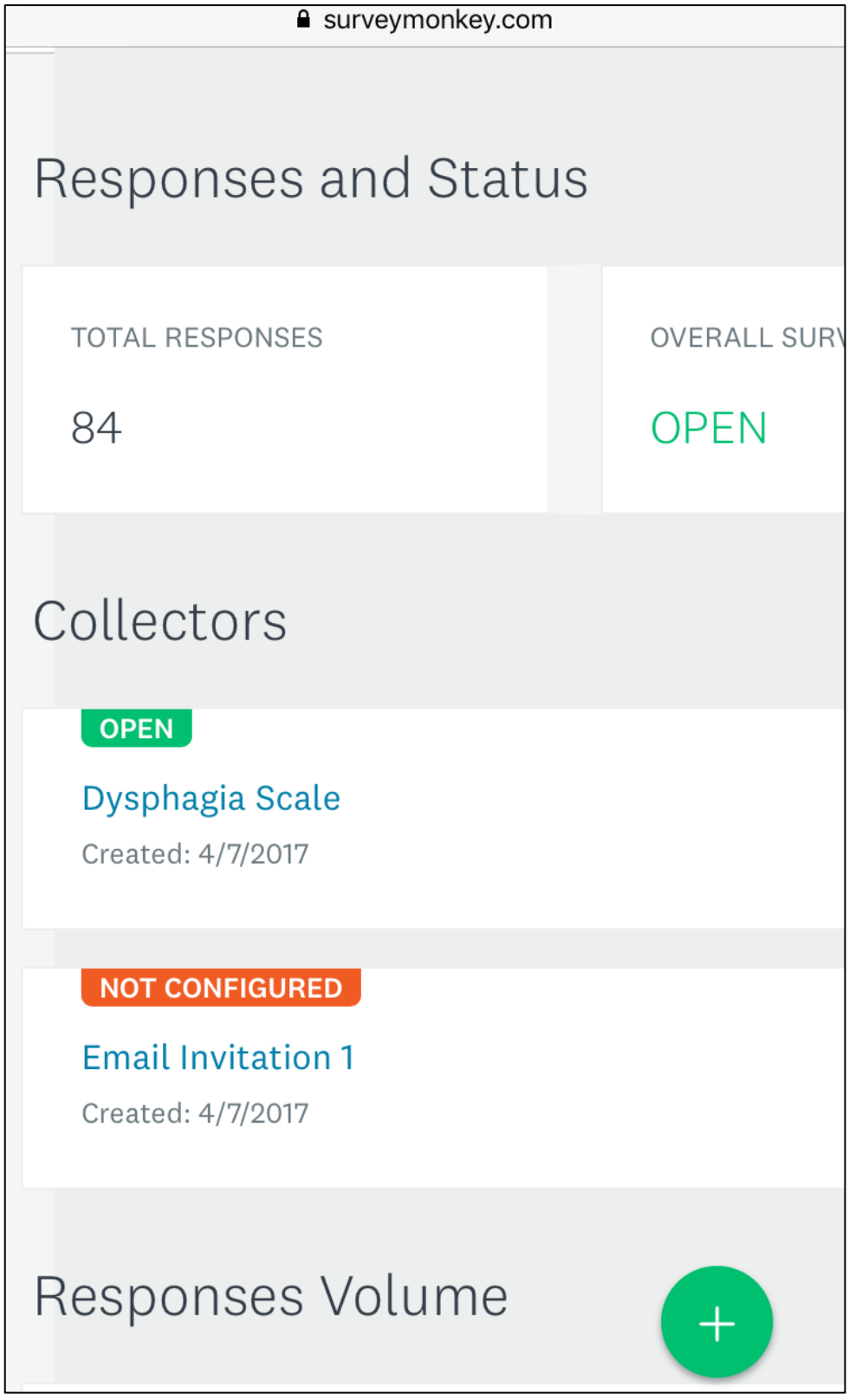

surveymonkey.com
Q6
Customize
Export
FOIS Scale: What do you consider to be a minimal clinically significant difference between a level? Select 0 for a change of 0.5 between levels (in the event of obtaining an average across patients, would you accept a half point as a minimal clinically important difference e.g. change from level 2 to level 2.5.Select 1 for 1 change in level, e.g. from total oral diet of single consistency to multiple consistencies but requiring special preparation/ compensations.Select 2 for 2 changes in levels, e.g. from total oral diet of a single consistency to total oral diet of multiple consistencies with no special preparation but specific food restrictions.Select 3 for 3 changes in levels, e.g. from NBM to total oral diet of single consistency. Select 4 for 4 changes in levels, e.g. from tube dependent on consistent oral intake to total oral diet with no restrictions.
Answered: 84 Skipped: 0
Change in 4 levels
Change of 0.5 between levels
Change in 3 levels
Change in 2 levels
Change in 1 level
ANSWER CHOICES
RESPONSES
Change of 0.5 between levels 11.90% 10
Change in 1 level 82.14%
Change in 2 levels 3.57%
Change in 3 levels 1.19% 1

Question 7




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Select 0 for 0 - 1 years | 2.38% | 2 |
| Select 1 for 1 - 5 years | 22.62% | 19 |
| Select 2 for 5 - 10 years | 27.38% | 23 |
| Select 3 for 10 years + | 47.62% | 40 |
| TOTAL | | 84 |

Total responses



Time period of data collection and response rate

## 9.4 Appendix 4 Conversion of DSRS to FOIS in patients with post-stroke dysphagia

| DSRS fluids | DSRS food | DSRS super-vision | DSRS total | Feasible combination | FOIS | Comments | Number (%) in STEPS |
|---|---|---|---|---|---|---|---|
| 4 | 4 | 4 | 12 | yes | 1 | NBM | 61 (18%) |
| 4 | 4 | 3 | 11 | no | | | 6 (1%) |
| 4 | 4 | 2 | 10 | no | | | 0 |
| 4 | 4 | 1 | 9 | no | | | 0 |
| 4 | 4 | 0 | 8 | no | | | 0 |
| 4 | 3 | 4 | 11 | no | | | 0 |
| 4 | 3 | 3 | 10 | yes | 2 or 3 | Minimal or consistent oral trials (diet only), still requires NG/ PEG | 3 (<1%) |
| 4 | 3 | 2 | 9 | no | | | 3 (<1%) |
| 4 | 3 | 1 | 8 | no | | | 2 (<1%) |
| 4 | 3 | 0 | 7 | no | | | 2 (<1%) |
| 4 | 2 | 4 | 10 | no | | | 0 |
| 4 | 2 | 3 | 9 | yes | 2 or 3 | Minimal or consistent oral trials (diet only), still requires NG/ PEG | 0 |
| 4 | 2 | 2 | 8 | no | | | 1 (<1%) |
| 4 | 2 | 1 | 7 | no | | | 1 (<1%) |
| 4 | 2 | 0 | 6 | no | | | 1 (<1%) |
| 4 | 1 | 4 | 9 | no | | | 0 |
| 4 | 1 | 3 | 8 | yes | 2 or 3 | Minimal or consistent oral trials (diet only), still requires NG/PEG | 0 |
| 4 | 1 | 2 | 7 | no | | | 0 |
| 4 | 1 | 1 | 6 | no | | | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 4 | 1 | 0 | 5 | no | | | 0 |
| 4 | 0 | 4 | 8 | no | | | 0 |
| 4 | 0 | 3 | 7 | no | | | 0 |
| 4 | 0 | 2 | 6 | no | | | 0 |
| 4 | 0 | 1 | 5 | no | | | 0 |
| 4 | 0 | 0 | 4 | no | | | 0 |
| 3 | 4 | 4 | 11 | no | | | 0 |
| 3 | 4 | 3 | 10 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 3 | 4 | 2 | 9 | no | | | 0 |
| 3 | 4 | 1 | 8 | no | | | 0 |
| 3 | 4 | 0 | 7 | no | | | 1 (<1%) |
| 3 | 3 | 4 | 10 | no | | | 0 |
| 3 | 3 | 3 | 9 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 2 (<1%) |
| 3 | 3 | 2 | 8 | yes | 4 | | 4 (1%) |
| 3 | 3 | 1 | 7 | yes | 4 | | 7 (2%) |
| 3 | 3 | 0 | 6 | yes | 4 | | 2 (<1%) |
| 3 | 2 | 4 | 9 | no | | | |
| 3 | 2 | 3 | 8 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 3 | 2 | 2 | 7 | yes | 5 | | 0 |
| 3 | 2 | 1 | 6 | yes | 5 | | 0 |
| 3 | 2 | 0 | 5 | yes | 5 | | 1 (<1%) |
| 3 | 1 | 4 | 8 | no | | | 0 |
| 3 | 1 | 3 | 7 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 3 | 1 | 2 | 6 | yes | 6 | | 0 |
| 3 | 1 | 1 | 5 | yes | 6 | | 1 (<1%) |
| 3 | 1 | 0 | 4 | yes | 6 | | 0 |
| 3 | 0 | 4 | 7 | no | | | 0 |
| 3 | 0 | 3 | 6 | no | | Cannot have thickened fluids and be on a normal diet (which includes mixed consistencies) | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3 | 0 | 2 | 5 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 3 | 0 | 1 | 4 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 3 | 0 | 0 | 3 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 1 (<1%) |
| 2 | 4 | 4 | 10 | no | | | 2 (<1%) |
| 2 | 4 | 3 | 9 | yes | 2 or 3 | Minimal or consistent oral trials (fluids only), still requires NG/ PEG | 2 (<1%) |
| 2 | 4 | 2 | 8 | yes, but exception | 4 | ONLY for patients on a full liquidised diet, managing without NG/ PEG, CF corresponds to IDDSI “liquidised diet”/ moderately thick fluids | 1 (<1%) |
| 2 | 4 | 1 | 7 | yes, but exception | 4 | ONLY for patients on a full liquidised diet, managing without NG/ PEG, CF corresponds to IDDSI liquidised diet/ moderately thick fluids | 3 (<1%) |
| 2 | 4 | 0 | 6 | yes, but exception | 4 | ONLY for patients on a full liquidised diet managing without NG/ PEG, CF corresponds to IDDSI liquidised diet/ moderately thick fluids | 0 |
| 2 | 3 | 4 | 9 | no | | | 0 |
| 2 | 3 | 3 | 8 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 3 (<1%) |
| 2 | 3 | 2 | 7 | | 4 | | 6 (1%) |
| 2 | 3 | 1 | 6 | | 4 | | 4 (1%) |
| 2 | 3 | 0 | 5 | | 4 | | 4 (1%) |
| 2 | 2 | 4 | 8 | no | | | 0 |
| 2 | 2 | 3 | 7 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 2 | 2 | 2 | 6 | | 5 | | 2 (<1%) |
| 2 | 2 | 1 | 5 | | 5 | | 8 (2%) |
| 2 | 2 | 0 | 4 | | 5 | | 1 (<1%) |
| 2 | 1 | 4 | 7 | no | | | 0 |
| 2 | 1 | 3 | 6 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2 | 1 | 2 | 5 | yes | 6 | | 0 |
| 2 | 1 | 1 | 4 | yes | 6 | | 2 (<1%) |
| 2 | 1 | 0 | 3 | yes | 6 | | 0 |
| 2 | 0 | 4 | 6 | no | | | 0 |
| 2 | 0 | 3 | 5 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 2 | 0 | 2 | 4 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 2 | 0 | 1 | 3 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 2 | 0 | 0 | 2 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 1 | 4 | 4 | 9 | no | | | 2 (<1%) |
| 1 | 4 | 3 | 8 | yes | 2 or 3 | Minimal or consistent oral trials (fluids only), still requires NG/ PEG | 0 |
| 1 | 4 | 2 | 7 | no | | | 1 (<1%) |
| 1 | 4 | 1 | 6 | no | | | 0 |
| 1 | 4 | 0 | 5 | no | | | 1 (<1%) |
| 1 | 3 | 4 | 8 | no | | | 0 |
| 1 | 3 | 3 | 7 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 2 (<1%) |
| 1 | 3 | 2 | 6 | | 4 | | 6 (1%) |
| 1 | 3 | 1 | 5 | | 4 | | 10 (2%) |
| 1 | 3 | 0 | 4 | | 4 | | 9 (2%) |
| 1 | 2 | 4 | 7 | no | | | 0 |
| 1 | 2 | 3 | 6 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 1 | 2 | 2 | 5 | | 5 | | 3 (<1%) |
| 1 | 2 | 1 | 4 | | 5 | | 15 (4%) |
| 1 | 2 | 0 | 3 | | 5 | | 19 (5%) |
| 1 | 1 | 4 | 6 | no | | | 0 |
| 1 | 1 | 3 | 5 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 1 (<1%) |
| 1 | 1 | 2 | 4 | | 6 | | 0 |
| 1 | 1 | 1 | 3 | | 6 | | 6 (1%) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | 1 | 0 | 2 | | 6 | | 4 (1%) |
| 1 | 0 | 4 | 5 | no | | | 0 |
| 1 | 0 | 3 | 4 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 1 | 0 | 2 | 3 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 0 |
| 1 | 0 | 1 | 2 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 3 (<1%) |
| 1 | 0 | 0 | 1 | no | | Cannot have thickened fluids on a normal diet (which includes mixed consistencies) | 3 (<1%) |
| 0 | 4 | 4 | 8 | no | | | 2 (<1%) |
| 0 | 4 | 3 | 7 | yes | 2 or 3 | Minimal or consistent oral trials (fluids only), still requires NG/ PEG | 0 |
| 0 | 4 | 2 | 6 | no | | | 0 |
| 0 | 4 | 1 | 5 | no | | | 0 |
| 0 | 4 | 0 | 4 | no | | | 0 |
| 0 | 3 | 4 | 7 | no | | | 0 |
| 0 | 3 | 3 | 6 | | 2 or 3 | Limited or consistent oral trials (both fluids and diet), still requires NG | 0 |
| 0 | 3 | 2 | 5 | | 4 | | 1 (<1%) |
| 0 | 3 | 1 | 4 | | 4 | | 2 (<1%) |
| 0 | 3 | 0 | 3 | | 4 | | 2 (<1%) |
| 0 | 2 | 4 | 6 | no | | | 0 |
| 0 | 2 | 3 | 5 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 0 | 2 | 2 | 4 | | 5 | | 0 |
| 0 | 2 | 1 | 3 | | 5 | | 7 (2%) |
| 0 | 2 | 0 | 2 | | 5 | | 17 (5%) |
| 0 | 1 | 4 | 5 | no | | | 0 |
| 0 | 1 | 3 | 4 | yes | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 0 |
| 0 | 1 | 2 | 3 | yes | 6 | | 0 |
| 0 | 1 | 1 | 2 | | 6 | | 7 (2%) |
| 0 | 1 | 0 | 1 | | 6 | | 13 (3%) |
| 0 | 0 | 4 | 4 | no | | | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 0 | 0 | 3 | 3 | | 2 or 3 | Minimal or consistent oral trials (both fluids and diet), still requires NG/ PEG | 1 (<1%) |
| 0 | 0 | 2 | 2 | yes | 7† | | 1 (<1%) |
| 0 | 0 | 1 | 1 | | 7† | | 4 (1%) |
| 0 | 0 | 0 | 0 | | 7† | | 56 (16%) |

Notes:
1. DSRS supervision score 3 is always chosen when patient is on limited or consistent oral trials and still requires NG/ PEG tube.
2. Oral trials can be either trials of food *or* fluid or trials of food *and* fluids.
3. Note exception of how to score when a patient is having a full liquid diet only and is managing without an NG/ PEG tube.
4. Frequency: This will depend on the population being studied. DSRS=12 is likely to be common at baseline in dysphagia trials, and DSRS=0 reflects an excellent outcome. Example frequencies are shown for STEPS (all timepoints).

† Represents resolution

## 9.5 Appendix 5 Consent to use FEES image

**Type of recording made:**

- Videofluoroscopy recording
- FEES recording
- Video recording of assessment/treatment session
- Audio recording of assessment/treatment session
- Photographs

**I consent to the use of the recordings for the following purposes:**

- For educational purposes within: NCHC NHS (Trust)
- For teaching purposes external to AS ABOVE (Trust)
  *(E.g. national/international teaching/training)**
- For publication use in PhD Thesis

*(e.g. journal articles, intranet, internet, information leaflets and other published media)*

*Any recordings used for assessment/treatment planning are deemed part of the patient's medical records and will be stored in accordance with Trust guidelines and treated at all times as confidential. All other recordings will be available for use as indicated above for a period of .....After such time the recording will be destroyed or consent for continued use will be obtained.*

*This consent can be withdrawn at any time by the signatory*

**By signing this consent it is understood that ... Trust may not be able to control future use of the material once it has been placed in the public domain.*

Signature: ..... Date: 28-7-20

signed on behalf of patient as patient is unable to P T O

Print Name: L. EVERTON

Signature of clinician: ..... Date: 28-7-2020

Print name: L EVERTON